SAMPSON COUNTY
BOARD OF COMMISSIONERS
MEETING AGENDA
March 1, 2021

This meeting is to be held during the unprecedented event of the COVID-19 pandemic; therefore, limitations have been placed on the number of persons allowed in the meeting room at one time. Given the restrictions on persons allowed in the meeting room, the meeting will be broadcast via YouTube. Comments related to public hearings and Public Comment have been welcomed via US Mail and email.

6:00 pm Convene Regular Meeting (County Auditorium)
Invocation and Pledge of Allegiance
Approve Agenda as Published

Item 1 Action Items

Comments will be received orally from those present (waiting in the lobby), following the Board's established Rules of Procedure. In addition, written comments will be accepted until 5 pm on the date of the meeting via mail or email. Comments received by the deadline will be read aloud by the Clerk and included in the official minutes of the meeting (unless they violate the Board's Rules of Procedure).

Closed Session – GS 143-318.11(a)(5), Acquisition of Property

Recess to Reconvene – March 16, 2021 at 2:00 pm (Administration Conference Room)

SAMPSON COUNTY
BOARD OF COMMISSIONERS

ITEM ABSTRACT ITEM NO. **1(a)**

Meeting Date: March 1, 2021

___	Information Only	___	Public Comment
___	Report/Presentation	___	Closed Session
x	Action Item	___	Planning/Zoning
___	Consent Agenda	___	Water District Issue

SUBJECT: Update on Economic Development Matters and Adoption of Resolution Authorizing Execution and Submission of Industrial Development Fund Grant Application Documents

DEPARTMENT: Economic Development

PUBLIC HEARING: No

CONTACT PERSON(S): Stephen Barrington, Director

PURPOSE: To receive an update on economic development matters and consider adoption of resolution

ATTACHMENTS: Resolution

BACKGROUND:

Economic Development Director Stephen Barrington will provide an update on economic development matters, including the recent announcement of the award of an Industrial Development Fund grant of $1,281,995 which will allow us to extend a roadway and existing water and sewer lines to the County's newly acquired 120-acre site at the Sampson Southeast Business Center in Clinton.

This is the first ever IDF grant ever awarded to Sampson County, and it will allow the County to capitalize on the Board's prudent land investment in 122 acres of property to serve as the anchor for our future economic development efforts. The funds are earmarked for property improvements that will render the property shovel-ready and attractive to light manufacturers who create higher-paying job opportunities.

The County must complete a full application, which includes adoption of the enclosed resolution authorizing execution of the grant documents, and the completion of a preliminary engineering report for the project.

RECOMMENDED ACTION OR MOTION:

Adopt the enclosed resolution authorizing execution of the grant application documents

RESOLUTION

WHEREAS, the Sampson County Economic Development Commission has requested approval from the Sampson County Board of Commissioners to submit to the North Carolina Department of Commerce a grant application requesting grant funds in the amount of $1,281,995 to assist Sampson County with the Sampson Southeastern Business Center economic development project; and

WHEREAS, the Sampson County Board of Commissioners wishes to authorize submission of the grant application in said amount, subject to the terms and conditions set forth herein;

NOW, THEREFORE, BE IT RESOLVED as follows:

1. The Sampson County Economic Development Commission is hereby authorized to submit a grant application to the North Carolina Department of Commerce, seeking $1,281,995 in grant funding to assist Sampson County with the Sampson Southeastern Business Center economic development project.

2. The Director of the Sampson County Economic Development Commission as well as the County Manager, Assistant County Manager, Finance Director, and any other Sampson County staff required to execute the grant application and/or related documents are hereby authorized to execute the same.

3. Sampson County shall administer the grant through the Sampson County Economic Development Commission and its staff in accordance with the rules and regulations of the North Carolina Department of Commerce and the policies and procedures of Sampson County,

4. The grant will be monitored at least quarterly to assure compliance with the grant application and proposal and the rules and regulations of the North Carolina Department of Commerce and the policies and procedures of Sampson County, to the extent that said policies and procedures are not inconsistent with the rules and regulations of the North Carolina Department of Commerce.

_____
CLARK H. WOOTEN, Chair,
Sampson County Board of Commissioners

ATTEST:

_____
SUSAN J. HOLDER, Clerk,
Sampson County Board of Commissioners

SAMPSON COUNTY
BOARD OF COMMISSIONERS

ITEM ABSTRACT ITEM NO. **1(b)**

Meeting Date: March 1, 2021

___	Information Only	___	Public Comment
___	Report/Presentation	___	Closed Session
x	Action Item	___	Planning/Zoning
___	Consent Agenda	___	Water District Issue

SUBJECT: Department of Aging Transition Following Department Head Retirement

DEPARTMENT: County Administration

PUBLIC HEARING: No

CONTACT PERSON(S): Edwin W. Causey, County Manager

PURPOSE: To discuss recommendations for transition in the wake of the retirement of the Department of Aging Director

ATTACHMENTS: None

BACKGROUND:

We endeavor to work both methodically and expeditiously to transition after the retirement of any County department head. Mr. Causey will present recommendations for the Department of Aging in the wake of the recent retirement of our Director of Aging.

RECOMMENDED ACTION OR MOTION:

Consider County Manager's recommendations

SAMPSON COUNTY
BOARD OF COMMISSIONERS

ITEM ABSTRACT ITEM NO. **1(c)**

Meeting Date: March 1, 2021

___	Information Only	___	Public Comment
___	Report/Presentation	___	Closed Session
x	Action Item	___	Planning/Zoning
___	Consent Agenda	___	Water District Issue

SUBJECT: Review of the Final Budget for the 911 and Emergency Services Facilities Project and Consideration of Award of Bid for Construction

DEPARTMENT: County Administration

PUBLIC HEARING: No

CONTACT PERSON(S): Edwin W. Causey, County Manager

PURPOSE: To consider approval of next steps in financing and construction of the 911 and Emergency Services facilities project

ATTACHMENTS: Budget and Bid Tabulation

BACKGROUND:

We received bids for the 911 and Emergency Services Facilities project on January 27, 2021 and were pleased with the amount of interest in our project. Our architects have reviewed the bids, and with these bids in hand we have developed a final budget for the project, which the County Manager will review. To maintain our project timeline, our next steps would be:

- Receive updated quotes for bank financing not to exceed $7.7 million to complete the project funding, and schedule a public hearing on this financing for March 16, 2021.
- Authorize staff to formally seek Local Government Commission approval of the financing at their April meeting.
- Receive the certified bid tabulation and authorize staff to issue the Notice of Award to the low bidder, subject to LGC concurrence on financing.
- Authorize County Manager and necessary staff to sign the construction contract after LGC approval (subject to Attorney's review of the contract).

RECOMMENDED ACTION OR MOTION:

Authorize the actions as noted above, including scheduling of a public hearing on March 16th, pursuit of LGC approval, issuance of Notice of Bid Award, and authorization to execute contracts

EXPENSES	
Sitework/Building	$12,325,900.00
Construction Contingency	$688,425.00
Technology Budget	$1,164,113.00
Tower Budget	$74,500.00
Console Budget	$510,000.00
Furniture/Fixtures	$634,625.00
A&E Fees	$1,211,000.00
MCP Fees	$390,632.00
ETSF Eligible Expenses	$722,181.00
15% Reduction in 911 grant funds on construction	$537,000.00
Loan interest & fees	$141,624.00

TOTAL EXPENSES	**$18,400,000.00**

GRANTS/LOAN	
NC Office of State Budget & Management	$3,500,000.00
Golden Leaf	$1,000,000.00
911 Grant	$5,479,453.00
ETSF	$722,181.00
Loan	$7,698,366.00

TOTAL GRANTS/LOANS	**$18,400,000.00**

*****NOTE: If the 911 grant is not reduced, we can reduce the loan further by $537,000.**

Sampson County 911 Emergency Services Facility
Certified Bid Tabulation

Final Bid Tabulation Form - General Construction - Single Prime
Wednesday, January 27, 2021 at 2:00 pm
ADW Project #20003

adwarchitects
environmentsforlife

Bidder	License #	Subcontractors		Bid Form (Y/N)	Bid Bond (Y/N)	MBE Forms (Y/N)	Addenda 1-4 (Y/N)	UP #1	UP #2A	UP #2B	UP #3	UP #4	UP #5	Base Bid Amount	Alt. #1	Alt. #2	Alt. #3	Alt. #4	Alt. #5	Alt. #6	Alt. #7	Alt. #8	Alt. #9	Alt. #10	Total Base Bid and Alternates #1 thru #10
Barnhill Contracting Company	3194	Plumbing	Smith's Refrigeration	X	X	X	X	$18.50	$7.00	$20.00	$150.00	$12.85	$5.25	$12,579,000.00	$6,000.00	$130,000.00	$55,000.00	$65,000.00	$12,500.00	$52,000.00	$42,000.00	$12,000.00	$28,000.00	$95,000.00	$13,076,500.00
		Mechanical	Smith's Refrigeration																						
		Electrical	Triple-R Electric																						
Bobbitt Construction		Plumbing												DID NOT SUBMIT										$0.00
		Mechanical																							
		Electrical																							
CIC Construction Group		Plumbing												DID NOT SUBMIT										$0.00
		Mechanical																							
		Electrical																							
Clancy & Theys	2077	Plumbing	Billy's Plumbing	X	X	X	X	$18.50	$7.00	$20.00	$200.00	$12.85	$9.25	$12,715,000.00	$6,000.00	$160,000.00	$71,000.00	$62,000.00	$9,500.00	$75,000.00	$30,000.00	$11,000.00	$24,000.00	$78,000.00	$13,241,500.00
		Mechanical	Smith's Refrigeration																						
		Electrical	Triple-R Electric																						
Daniels and Daniels Construction Company, Inc.	23697	Plumbing	Smith's Refrigeration	X	X	X	X	$18.50	$7.00	$20.00	$245.00	$12.85	$9.25	$12,760,000.00	$8,715.00	$134,240.00	$42,996.00	$77,315.00	$7,600.00	$91,250.00	$52,180.00	$14,865.00	$24,525.00	$79,850.00	$13,293,536.00
		Mechanical	Smith's Refrigeration																						
		Electrical	Triple-R Electric																						
Driven Contractors, Inc.	73604	Plumbing	Banks Channel Plumbing	X	X	X	X	$21.51	$32.64	$32.64	$222.56	$14.06	$13.71	$12,549,700.00	$6,290.00	$165,281.00	$66,120.00	$99,024.00	$10,448.00	$57,417.00	$33,604.00	$12,813.00	$26,749.00	$87,083.00	$13,114,529.00
		Mechanical	Smith Refrigeration																						
		Electrical	Watson Electrical																						
Engineered Construction Company	30010	Plumbing	Billy's Plumbing	X	X	X	X	$23.50	$7.00	$26.50	$154.00	$24.00	$18.00	$12,250,800.00	$27,357.00	$171,742.00	$80,846.00	$72,500.00	$12,075.00	$55,350.00	$51,589.00	$12,410.00	$56,000.00	$84,250.00	$12,874,919.00
		Mechanical	Smith's Refrigeration																						
		Electrical	Kennedy Electrical Service																						
Garrett Construction Services		Plumbing												DID NOT SUBMIT										$0.00
		Mechanical																							
		Electrical																							
Harrod and Assoc. Constructors, Inc.		Plumbing												DID NOT SUBMIT										$0.00
		Mechanical																							
		Electrical																							

Sampson County 911 Emergency Services Facility
Certified Bid Tabulation

Final Bid Tabulation Form - General Construction - Single Prime
Wednesday, January 27, 2021 at 2:00 pm
ADW Project #20003

adwarchitects environmentsforlife

Jackson Builders, Inc.	7193	Plumbing	Banks Channel Plumbing	X	X	X	X	$18.50	$7.00	$19.50	$123.05	$10.00	$8.36	$12,434,098.00	$5,913.00	$133,590.00	$57,291.00	$64,758.00	$13,077.00	$51,991.00	$27,211.00	$16,612.00	$24,496.00	$98,879.00	$12,927,916.00
		Mechanical	Smith's Refrigeration																						
		Electrical	Triple-R Electric																						
Ke'nergy Construction Group, LLC		Plumbing												DID NOT SUBMIT											$0.00
		Mechanical																							
		Electrical																							
Monteith Construction Corp.	43319	Plumbing	Billy's Plumbing	X	X	X	X	$26.00	$11.00	$22.00	$200.00	$12.00	$8.00	$11,792,000.00	$6,000.00	$133,000.00	$39,000.00	$66,000.00	$8,000.00	$36,000.00	$34,000.00	$12,000.00	$18,000.00	$78,000.00	$12,222,000.00
		Mechanical	Smith's Refrigeration																						
		Electrical	Hewitt Power																						
Muter Construction L.L.C.	73095	Plumbing	Banks Channel Plumbing	X	X	X	X	$16.00	$20.00	$20.00	$250.00	$10.75	$9.40	$12,363,000.00	$26,500.00	$141,000.00	$49,000.00	$81,500.00	$6,800.00	$53,000.00	$36,000.00	$12,000.00	$8,000.00	$98,000.00	$12,874,800.00
		Mechanical	LKN Mechanical																						
		Electrical	Triple-R Electric																						
New Atlantic Contracting Inc.	50851	Plumbing	Billy's Plumbing	X	X	X	X	$18.50	$7.00	$20.00	$200.00	$10.00	$8.65	$11,819,000.00	$125,000.00	$135,000.00	$50,000.00	$44,000.00	$6,400.00	$31,000.00	$33,500.00	$12,000.00	$23,000.00	$92,200.00	$12,371,100.00
		Mechanical	Smith's Refrigeration																						
		Electrical	Triple-R Electric																						
T. A. Loving Company	325	Plumbing	Smithfield Refrigeration	X	X	X	X	$64.75	$20.00	$20.00	$200.00	$10.75	$9.40	$12,638,500.00	$5,800.00	$141,000.00	$49,000.00	$68,000.00	$7,900.00	$94,250.00	$35,000.00	$11,700.00	$24,400.00	$79,500.00	$13,155,050.00
		Mechanical	Smithfield Refrigeration																						
		Electrical	Watson																						
TCC Enterprises Inc	72364	Plumbing	Smith Refrigeration	X	X	X	X	$22.00	$8.00	$22.00	$25.00	$14.50	$10.75	$12,500,000.00	$6,000.00	$137,000.00	$50,000.00	$65,000.00	$5,000.00	$35,000.00	$32,000.00	$12,000.00	$25,000.00	$82,000.00	$12,949,000.00
		Mechanical	Smith's Refrigeration																						
		Electrical	Watson Electric																						
Team Construction, LLC	75093	Plumbing	Banks Channel Plumbing	X	X	X	X	$18.00	$7.00	$23.00	$329.00	$12.00	$11.00	$13,250,000.00	$8,000.00	$141,000.00	$46,000.00	$76,000.00	$10,000.00	$88,000.00	$44,000.00	$17,000.00	$28,600.00	$84,000.00	$13,792,600.00
		Mechanical	Eastbound Mechanical																						
		Electrical	Watson Electric																						
Thomas Construction Group		Plumbing												DID NOT SUBMIT											$0.00
		Mechanical																							
		Electrical																							

1/28/2021

Bid Tabulation Certified by ADW Architects,p.a. Paul D. Bonsall, AIA North Carolina Architectural Registration Number 4069

SAMPSON COUNTY
BOARD OF COMMISSIONERS

ITEM ABSTRACT ITEM NO. **2**

Meeting Date: March 1, 2021

___	Information Only	___	Public Comment
___	Report/Presentation	___	Closed Session
___	Action Item	___	Planning/Zoning
x	Consent Agenda	___	Water District Issue

SUBJECT: Consent Agenda

DEPARTMENT: Administration/Multiple Departments

ITEM DESCRIPTIONS/ATTACHMENTS:

Consent Agenda - General

a. Approve the minutes of the February 1, 2021 meeting

b. Award the cost-per-copy contract to Office Value for a five-year term, as recommended by Finance Office

c. Authorize execution of the contract between Sampson County (Register of Deeds Office) and Logan Systems, Inc.

d. Adopt an amended resolution appointing Review Officers and Zoning Officers/Administrators

e. Approve the tax refunds and releases as submitted

f. Approve budget amendments as submitted

Consent Agenda – Board of Health

g. Approve fee revisions as recommended by the Health Advisory Committee

h. Approve the HIPAA Policy 2021 Annual UpdaMarte

i. Approve the new Telehealth Policy

RECOMMENDED ACTION OR MOTION:

Motion to approve Consent Agenda as presented

SAMPSON COUNTY **February 1, 2021**
NORTH CAROLINA

The Sampson County Board of Commissioners convened for their regular meeting at 6:00 p.m. on Monday, February 1, 2021. Members present: Chairman Clark Wooten, Vice Chairperson Sue Lee, and Commissioners Jerol Kivett, Thaddeus Godwin, and Lethia Lee.

Chairman Wooten called the meeting to order and acknowledged Vice Chairperson Sue Lee who called on Commissioner Godwin to provide the invocation. Chairperson Sue Lee then led the Pledge of Allegiance.

Approval of Agenda

Upon a motion made by Commissioner Kivett and seconded by Commissioner Godwin, the Board voted unanimously to approve the agenda with the following additions: Item 4 (b): Updated Home and Community Care Block Grant Funding Plan and Budget Amendment; Item 4 (g): Memorandum of Understanding between Sampson County and the Sampson County Board of Education Regarding School Resource Officers; and Item 4 (h): Revised Sampson County Purchasing Manual.

Item 1: Reports and Presentations

Discussions of Transitions Following Department Head Retirements County Manager Ed Causey informed the Board that since the retirement of Aging Director Lorie Sutton in December 2020 staff had conducted a series of meetings with Aging staff members to evaluate current programs and services and to develop recommendations on how to continue the programs and services in the future. He noted that the recommendations will be shared in March 2021. He then noted Emergency Management Director Ronald Bass' expected retirement in May 2021 and that staff proposes contracting with Developmental Associates, LLC of Chapel Hill, NC, to conduct a hiring process similar to that conducted for the Economic Development Director position filled in October of 2019. He noted that the proposed cost for the project would be approximately $19,000.00, but is expected to be slightly less, to include any incidental expense which may arise. Upon a motion by Commissioner Lethia Lee and seconded by Commissioner Godwin, the Board voted unanimously to authorize staff to pursue contracted services with Development Associates, LLC to facilitate the hiring process of the soon to be vacant Emergency Management Director position.

Update on the 911 and Emergency Services Facilities Project County Manager Ed Causey informed the Board that the County had received 12 bids during the January 27, 2021 bid opening and that a final estimate would be provided after the

bids were reviewed by the architects and bid tabulations completed. He also noted that any changes would not negatively affect any grants monies received for the project. Mr. Causey continued by informing the Board that more information will be provided, and a required public hearing scheduled for March 2021. Construction is expected to begin in April 2021, requiring loan approval to be done at the April 2021 Board meeting.

Item 2: Planning and Zoning Matters

Approval of Final Plat – Taylors Creek Subdivision Phase I (13 lots) Inspections Director Myron Cashwell introduced Mr. Austin Brinkley as the new Senior Planner. The Chairman then opened the hearing and acknowledged Mr. Brinkley who presented the final plat for Taylor's Creek Subdivision Phase I (13 lots). The Chairman opened the floor of comments and none were received. The hearing was closed. Upon a motion made by Commissioner Kivett and seconded by Commissioner Godwin, the Board voted to approve the final plat of the Taylors Creek Subdivision Phase I (13 lots) contingent upon receipt of the NCDEQ Final Approval Letter, to accompany the NCDOT Basic Letter already received by the Planning Department.

Item 3: Action Items

Public Hearing – Economic Development Budget Adjustments Finance Officer David Clack reminded the Board that during the January meeting the proposed mid-year budget adjustments were reviewed, and that any changes to economic development appropriations require a public hearing. The Chairman opened the hearing and opened the floor for public comment. None were received. The Chairman closed the hearing. Upon a motion made by Vice Chairperson Sue Lee and seconded by Commissioner Kivett, the Board voted unanimously to approve the proposed budget amendment presented at the January 4, 2021 regular scheduled meeting.

EXPENDITURE		Economic Development Department		
Code Number		Description (Object of Expenditure)	Increase	Decrease
11449200	512100	Salaries	$3,396.00	
11449200	512700	Longevity		$1,895.00
11449200	518200	Retirement	$1,481.00	
11449200	518300	Group Insurance	$744.00	
11449200	526200	Dept Supplies	$7,862.00	
11449200	538100	Data Processing Programming	$2,967.00	
11449200	534100	Printing	$2,000.00	
11449200	582096	Economic Development Reserve	$250,000.00	

REVENUE

Code Number		Source of Revenue	Increase	Decrease
11031840	412000	Current Year Tax Revenue	$266,555.00	

Tax Administration – Report of Unpaid Taxes Which Are Liens on Real Property Tax Administrator Jim Johnson reported to the Board the amount of $3,375,252.71 of unpaid taxes for the current fiscal year which are liens on real property. This total is $1,080,917.24 less than the previous fiscal year, however, the overall collection rate was 91.28%, whereas it was 90.59% at the same time in the previous fiscal year. Mr. Johnson requested authorization to advertise the unpaid taxes on April 14, 2021, with a deadline for payment to avoid publication being April 7, 2021 at 5:00 p.m. Upon a motion made by Chairman Wooten and seconded by Vice Chairperson Lee, the Board voted unanimously to approve the request.

Scheduling of 2021 Board of Equalization and Review Hearings Mr. Johnson asked the board to consider setting dates for the 2021 Board of Equalization and Review hearings. Upon a motion made by Commissioner Kivett and seconded by Commissioner Godwin, the board voted unanimously to schedule the Board of Equalization and Review hearings for April 22, 2021 to convene from 1-5 p.m.

Item 4: Consent Agenda

Upon a motion made by Commissioner Kivett and seconded by Commissioner Godwin, the Board voted unanimously to approve the Consent Agenda as follows:

a. Approved the minutes of the January 4, 2021 meeting
b. Approved the Home and Community Care Block Grant Funding Plan, reallocating funds from transportation and personal care services to home repairs (amended as a Walk On Item) (Copy filed in Inc. Minute Book ____ Page ____.)
c. Adopted resolutions permitting EMS Services in Turkey Fire Protection Service District and authorized the County Manager to execute a fire protection, emergency medical and rescue services contract with Turkey Volunteer Fire Department (Copy filed in Inc. Minute Book ____ Page ____.)
d. Adopted a resolution requesting the addition of Mill Ridge Court, in Mill Ridge Subdivision, to the State's secondary roads system (Copy filed in Inc. Minute Book ____ Page ____.)
e. Approved tax refunds and releases as submitted:

#9473	William Best	$299.72

#9474	Leon Millette, Jr.	$102.87
#9460	Betty Bronson	$105.65
#9454	Scottie Barnes	$165.41
#9479	Eusebio Torres	$411.75
#9464	Clinton Truck & Tractor Co. Inc.	$461.35
#9475	White Investment Co., NC Corp	$362.81
#9463	Mary Ann Hill	$1,289.70
Tax Release	Sue Barber	$110.54
Tax Release	Daniel Goodling	$189.27
Tax Release	Nathan Pope	$2,484.46
Tax Release	Colin Stoekel	$411.75

f. Approved budget amendments as submitted:

EXPENDITURE		AA-543 Enhancing Detection-COVID		
Code Number		Description (Object of Expenditure)	Increase	Decrease
12551240	512100	Salaries	$111,000.00	
12551240	518100	FICA	$6,882.00	
12551240	518120	Medicare FICA	$1,610.00	
12551240	518200	Retirement	$8,392.00	
12551240	518300	Group Insurance	$9,660.00	
12551240	518400	Dental Insurance	$350.00	
12551240	518901	401K	$8,235.00	
12551240	525100	Gas, Oil, & Tire	$2,000.00	
12551240	526200	Department Supplies	$6,226.00	
12551240	523100	Medical Supplies	$6,500.00	
12551240	537000	Advertising	$1,500.00	
12551240	532100	Telephone & Postage	$4,000.00	
12551240	543000	Rental Equipment	$3,000.00	
12551240	529702	Lab Services	$3,000.00	
12551240	531100	Travel	$1,000.00	
12551240	544000	Contract Services	$74,017.00	
REVENUE				
Code Number		Source of Revenue	Increase	Decrease
12535124	404000	State Assistance	$247,372.00	

EXPENDITURE		AA-716-COVID Vaccine Funding		
Code Number		Description (Object of Expenditure)	Increase	Decrease
12551230	512100	Salaries	$29,035.00	
12551230	518100	FICA	$1,801.00	
12551230	518120	Medicare FICA	$421.00	
12551230	518200	Retirement	$2,196.00	
12551230	518300	Group Insurance	$805.00	

12551230	518400	Dental Insurance	$30.00	
12551230	518901	401K	$2,178.00	
REVENUE				
Code Number		Source of Revenue	Increase	Decrease
12535123	404000	State Assistance	$36,466.00	
EXPENDITURE		Aging		
Code Number		Description (Object of Expenditure)	Increase	Decrease
02558670	525000	Home Repairs – United Way	$200.00	
REVENUE				
Code Number		Source of Revenue	Increase	Decrease
02035867	408401	Home Repair – Donations	$200.00	
EXPENDITURE		Aging		
Code Number		Description (Object of Expenditure)	Increase	Decrease
82558750	524100	URP - Materials	$39,216.00	
82558750	529901	URP – Soft Costs	$8,800.00	
82558750	544000	URP – Contracted Services	$51,984.00	
REVENUE				
Code Number		Source of Revenue	Increase	Decrease
82035875	403605	URP – NCHFA	$100,000.00	
EXPENDITURE		Aging		
Code Number		Description (Object of Expenditure)	Increase	Decrease
02558810	526200	Family Caregiver – Dept Supplies	$200.00	
REVENUE				
Code Number		Source of Revenue	Increase	Decrease
02035881	408401	Family Caregiver- Donations	$200.00	
EXPENDITURE		Sheriff's Department		
Code Number		Description (Object of Expenditure)	Increase	Decrease
11243200	535200	Maint/repair equipment	$6,490.00	
REVENUE				
Code Number		Source of Revenue	Increase	Decrease
11039999	409800	Fund Balance Approp Encumbrances	$6,490.00	
EXPENDITURE		Detention Center		
Code Number		Description (Object of Expenditure)	Increase	Decrease
11243200	535100	Maint/repair buildings and grounds	$49,500.00	
11998110	596076	Trans to County bldg. maint reserve		$49,500.00
REVENUE				
Code Number		Source of Revenue	Increase	Decrease

EXPENDITURE		Water District Operating Dept.		
Code Number		Description (Object of Expenditure)	Increase	Decrease
61971000	555000	Capital outlay Other	$88,900.00	
REVENUE				
Code Number		Source of Revenue	Increase	Decrease
61937100	409900	Fund Balance Appropriated	$88,900.00	

EXPENDITURE		Water District Operating Dept.		
Code Number		Description (Object of Expenditure)	Increase	Decrease
61971000	555000	Capital outlay Other	$150,000.00	
REVENUE				
Code Number		Source of Revenue	Increase	Decrease
61937100	409900	Fund Balance Appropriated	$150,000.00	

- Approved Clinton City Schools Budget Amendment No. 1 (State); Approved Clinton City Schools Budget Amendment No. 1 (Federal); Approved Clinton City Schools Budget Amendment No. 1 (Special Revenue).

g. (WALK ON) Approved the Memorandum of Understanding between Sampson County, the Sheriff of Sampson County, and the Sampson County Board of Education Regarding School Resource Officers (Copy filed in Inc. Minute Book ____ Page ____.)

h. (WALK ON) Approved the Revised Sampson County Purchasing Manual (Copy filed in Inc. Minute Book ____ Page ____.)

Item 5: County Manager's Report

County Manager Ed Causey informed the Board that staff had delayed the scheduling of planning sessions due to the COVID-19 pandemic. He noted that it is still advised that both school systems and Sampson Community College have planning sessions with the Board in early March 2021, offering the opportunity to provide insight on the expected budget expectations and challenges cause by the pandemic. He then informed Commissioner Lethia Lee with brief synopsis of the budget planning process and foresight of what to expect in the coming weeks and months.

Item 6: Public Comment Period

The Chairman opened the floor for comments and no comments were received.

Adjourn

Upon a motion made by Commissioner Kivett and seconded by Vice Chairperson Sue Lee, the Board voted unanimously to adjourn.

_____ _____

Clark H. Wooten, Chairman Susan J. Holder, Clerk to the Board

Sampson County Finance Department

David K. Clack, Finance Officer

MEMORANDUM

TO: Board of Commissioners

FROM: David K. Clack, Finance Officer

DATE: February 19, 2021

SUBJECT: Cost Per Copy Bid Award

Attached please find the evaluation of the cost per copy program that was implemented in 2017. At that time, we implemented a program that replaced all our leased copiers as the leases expired with copiers that had more capabilities and a lower cost.

As noted in the attached evaluation of the cost per copy program we were paying lease costs of $121,398 annually and now that cost has dropped to $35,044, a savings of $86,454.

We received responses to our RFP from 5 vendors. The black and white cost per copy prices ranged from $.0198 to $.0284, based on a 5-year commitment. We are currently paying $.015 per black and white copy.

We respectfully request that the Board award the cost per copy contract to Office Value for a 5-year term.

406 County Complex Road, Suite 120 Clinton, N.C. 28328
Telephone: 910-592-7181 extension 2256
Fax: 910-592-1945

Sampson County Finance Department

Memo

To: David Clack, Finance Officer

From: Juanita Brewington, Purchasing & Contracting Officer

Date: February 17, 2021

Re: Evaluation of Cost Per Copy Program Proposals

We received five proposals as a result of the RFP sent out for Multi-Function Copier – Cost Per Copy Program.

Four of the five proposals provided the County with a fixed cost per copy which included providing new multi-function copiers. The fifth proposal was for a lease of the equipment at a rate greater than the cost per copy proposals.

The cost per copy program has proved to a great cost savings to the County. In 2015 we had lease copiers with a cost of $121,398.48 annually. At the time the RFP was published, the cost per copy cost was $35,044.05 annually.

The table below reflects the annual cost based on volume used in past 12 months and the proposed cost per copy.

Submitted by	36 months	60 months
Sharp Business Systems	$76,768.43	$60,858.44
Systel	$75,614.73	$50,438.69
Office Value	$63,413.67	$44,245.01
Toshiba Business Solutions	$49,789.29	$49,789.29

RFP Bid Tally

Multi-Function Copier - Cost per Copy

RFP Bid Sheets received by 2:00pm, Tuesday, February 9, 2021

Submitted By	36 Months		60 Months		Proposal Expiration Date (no earlier than Mar. 15, 2021)
	Multi-Function Copier Cost Per Copy				
	Black & White	Color	Black & White	Color	
Sharp Business Systems	.0367	.05	.0284	.05	
Systel	.0365	.044	.0235	.042	
Office Value	.0298	.049	.0198	.049	
Toshiba Business Solutions	.0229	.0459	.0229	.0459	
Digital Document Solutions	— Alternative bid - lease - no cost per copy	—	—	—	

Witness: Juanita Pennington

Date: 2-9-2021

Witness: _____

Date: _____

Sampson County Register of Deeds
126A West Elizabeth Street
Clinton, NC 28328
(910)-592-8026

February 11, 2021

To: Sampson County Board of Commissioners

From: Anita H. Lane, Register of Deeds

RE: Logan Systems Inc. Contract

- Logan Systems, Inc. has provided computer hardware, software and support services to Sampson County Register of Deeds for over 25 years.

- Logan Systems, Inc. has not increased our annual fees since July 1, 2008, while providing our office with the most up to date equipment and the attached contract will show that the fees for calendar year 20/21 will remain the same.

- The signing of this agreement/contract is simply formalizing our agreement with Logan Systems, Inc.

PROFESSIONAL SERVICES AGREEMENT

This service agreement between Logan Systems, Inc. ("Logan Systems") and Sampson County, North Carolina (the "County") will become effective January 1, 2021. The respective parties may execute this agreement at different times.

Pursuant to the terms outlined below, Logan Systems agrees to provide professional services to the Sampson County Register of Deeds ("ROD") for the management of permanent records maintained by the ROD.

I. Common Terms

1. Term of the Agreement: This contract shall cover services provided by Logan Systems to the County described below. The term of the agreement is forty-two months (42) and covers all services described below provided from January 1, 2021 through June 30, 2024.
2. Services Provided: LSI provides a turnkey service that includes all necessary hardware, software, training, and support. The services to be provided are consistent with the services currently provided by Logan Systems.
3. Training: All necessary training for both the ROD's staff and the general public will be provided by Logan Systems at no additional charge to the County.
4. Support: Unlimited support is provided via a toll free number from 8:00AM through 5:00PM. In addition, other contact numbers for support representatives have been provided for after hours support. If the problem or question cannot be adequately answered over the telephone, then a support representative will visit the ROD's office. If equipment needs to be repaired or replaced, the target for such replacement is 24 hours.
5. Consumable Supplies: The cost of consumable supplies such as paper and toner are not included in the prices listed below.
6. Ownership of Hardware and Software: All hardware and software provided as part of the professional services provided by Logan Systems remains the property of Logan Systems. As such, Logan Systems remains responsible for the replacement, repair, and upgrade of such equipment.
7. Changes in Technology: If technology changes require Logan Systems to change either the operating systems on which its software and hardware operate, or the type of hardware or media used in the storage of data, Logan Systems will migrate the data it manages for the ROD to the newer media at no charge to the County.
8. Authorization for past Services: If Logan Systems provides services prior to the signing of this contract by both parties, this contract specifically authorizes payments for all such satisfactorily provided services.
9. Integration Clause: This contract represents the entire agreement between the parties. Any modification or alteration of this agreement must be done so in writing and approved by both parties.
10. Severability: The provisions of this contract are severable, and should any court of competent jurisdiction deem any provision(s) invalid, the remaining provisions

will remain valid, unless such ruling will make further performance under the contract impossible or impose an unconscionable burden upon one of the parties.

11. Assignment: This contract may not be assigned without the approval of both parties. Such approval must be in writing by authorized representatives of each party.
12. Site Preparation: Sampson County shall be responsible for the maintenance of the site, including without limitation, providing adequate electrical power for all computers and peripherals, providing all necessary network cabling and firewalls, and providing adequate cooling for all servers.
13. Non-Appropriation Clause: This agreement is subject to and contingent upon appropriation of funds for fiscal years subsequent to Fiscal Year 2021.
14. Termination for Convenience: The County may terminate this contract by providing Logan Systems with written notice of its intent to terminate the contract. Such notice must be received by Logan Systems at least ninety (90) days prior to the proposed termination date in order to be effective. The notice shall be sent to the same address that payments are sent to under the agreement. If this contract is so terminated, the County will pay Logan Systems for all services provided prior to the termination date. (Logan Systems invoices for its services in arrears, meaning that services provided in January are invoiced in February.) If any projects, including but not limited to conversion projects, are in progress when the termination notice is received, then the parties will negotiate in good faith to either complete the projects or to partially complete the projects. Logan Systems would be paid for the agreed portions of the projects.
15. North Carolina Law: This agreement shall be interpreted using North Carolina law.

II. Services Provided by Logan Systems

1. Traditional Indexing Services: Logan Systems will provide traditional indexing services to the ROD's office. This system and service allows the ROD's staff to input indexing data and print out various verification forms and statistical reports to confirm the accuracy of the information. Paper merges will be provided upon request. Indexing binders are included with this service if needed.
2. Automated Indexing and Public Retrieval: Logan Systems will provide a computer system that allows for searches of each indexing database maintained by the ROD. This system will also allow linking to scanned documents to the extent that those records have been digitized.
3. Receipting: Logan Systems will provide a customized receipting system in the ROD's office.
4. Scanning of Land Records: Logan Systems will provide a scanning system that will allow the ROD to scan all land records and vital records. This system allows form feeding for rapid scanning of the single sided documents mandated by current North Carolina law. In order to aid verification efforts, the system places a tag on the scanned page when stored.
5. Remote Access: Logan Systems will provide remote access to the public of all indexing and imaging data managed by Logan Systems, to the extent that the

County and the ROD desire that remote access is provided. For security reasons, this system will be separate from the in-house indexing and image retrieval units, and will have a separate data server.

6. Passing of data to Other County offices: If requested by the ROD, Logan Systems will work with the County's IT department to accommodate the need for certain types of data created by the ROD to be accessed by other County offices. The exact methods of accessing the data will be decided at a later date.
7. Film Conversion: The state of North Carolina requires that archival microfilm for imaged data be created and sent to the archives. Logan Systems will create archival microfilm from the imaging data sent by the ROD for processing, verification, and back up.
8. Marriage License System: Logan Systems will continue to provide a marriage license application and integrated indexing system for the ROD.
9. Electronic Recording: Logan Systems will continue to provide electronic recording capabilities to the office. The vendors used will be at the discretion of the ROD, but currently include Simplifile and CSC.
10. Other Services: Logan Systems will continue to provide services related to the services discussed above, including data management and disaster recovery services.
11. Shipping Charges: Logan Systems will bill the ROD for shipping charges at cost. This cost will include our volume discount from UPS and Federal Express.

III. Cost for Services

1. Logan Systems will bill for the ongoing services it provides on a monthly basis as follows:
   - A flat rate of $4,650.00 per month for the entire term of the agreement
2. Billing in Arrears: Logan Systems bills in arrears for all of the services that it provides. Therefore, by way of illustration, services provided in July are billed in August. All invoices shall be paid in the manner and timeframe typically used by the County. It is expected that the payment shall be made no later than thirty days after the receipt by the County of an invoice from Logan Systems.

Approved by Sampson County:	**Approved by Logan Systems, Inc.**
By: _____	By: _____
Print Name: _____	Print Name: Craig Sanders
Title: _____	Title: President
Date: _____	Date: _____

RESOLUTION APPOINTING REVIEW OFFICERS AND ZONING OFFICERS/ADMINISTRATORS

WHEREAS, G.S.47-30.2 requires the Board of Commissioners in each County, by resolution, to appoint a person to serve Review Officer to review each plat before it is recorded and certify that it meets the statutory requirements for recording; and

WHEREAS, the Sampson County Board of Commissioners had previously appointed Myron Cashwell, Anita Lane and Cindy Cottle as Review Officers under the appropriate North Carolina General Statutes; and

WHEREAS, in accordance with the Sampson County Zoning Ordinance, the Sampson County Board of Commissioners shall appoint Zoning Officer(s)/Zoning Administrator(s) to enforce the provisions of the Zoning Ordinance; and

WHEREAS, the Sampson County Board of Commissioners had previously appointed Myron Cashwell and Anita Lane as Zoning Officers/Zoning Administrators.

NOW THEREFORE, **BE IT RESOLVED**, that effective January 4, 2021, the following persons are appointed as Review Officers: Myron Cashwell, Austin Brinkley, Cindy Cottle, and Michele Lance.

BE IT FURTHER RESOLVED that effective January 4, 2021, the following persons are appointed as Zoning Officers/Zoning Administrators: Myron Cashwell, Austin Brinkley, and Michele Lance.

BE IT FURTHER RESOLVED, that a copy of this Resolution designating the Review Officers and Zoning Officers/Zoning Administrators be recorded in the Sampson County Register of Deeds Office and indexed in the name of the Review Officers/Zoning Officers/Zoning Administrators.

ADOPTED this 1st day of March, 2021.

_____

Clark H. Wooten, Chairman
Sampson county Board of Commissioners

ATTEST:

_____

Susan J. Holder, Clerk to the Board

OFFICE OF THE SAMPSON COUNTY TAX ADMINISTRATOR

P. O. BOX 1082 - CLINTON, NORTH CAROLINA 28329-1082 09505

JIM JOHNSON
Tax Administrator

Telephone 910-592-8146
910-592-8147

SAMPSON COUNTY BOARD OF COMMISSIONERS
406 COUNTY COMPLEX ROAD, BUILDING C
CLINTON, NORTH CAROLINA 28328

Members:

Pursuant to North Carolina G. S. 105-381, I hereby demand refund and remission of taxes assessed and collected by Sampson County against the property owned by Teresa Player

_____ in _____ Township, Sampson County, for the year(s) and in the amount(s) of:

YEAR	
2020	$ 232.61
	$
	$
	$
	$

TOTAL REFUND $ 232.61

These taxes were assessed through clerical error as follows.

Bill # 0055706870
Plate # HD37835
Plate Turn in - Traded
2019 Chev Blazer 2LT

602 County Tax 208.59
School Tax _____
F21 Fire Tax 24.02
City Tax _____
TOTAL $ 232.61

Yours very truly

Teresa H. Player
Taxpayer

Mailing Address.

PO Box 514
Autryville NC 28318

Social Security # _____

RECOMMEND APPROVAL:

Sampson County Tax Administrator

Board Approved _____ _____
Date Initials

OFFICE OF THE SAMPSON COUNTY TAX ADMINISTRATOR

P. O. BOX 1082 - CLINTON, NORTH CAROLINA 28329-1082 9490

JIM JOHNSON
Tax Administrator

Telephone 910-592-8146
910-592-8147

SAMPSON COUNTY BOARD OF COMMISSIONERS
406 COUNTY COMPLEX ROAD, BUILDING C
CLINTON, NORTH CAROLINA 28328

Members:

Pursuant to North Carolina G. S. 105-381, I hereby demand refund and remission of taxes assessed and collected by Sampson County against the property owned by George Edward Wilson Revocable Trust in _____ Township, Sampson County, for the year(s) and in the amount(s) of:

YEAR	
2019	$ 7.26
2019	$ 199.82
2019	$ 33.56
	$
	$

TOTAL REFUND $ 240.64

Bill # 00378414, 00378414144, 00378414225, 00368412320

Plate # BBT2132, BBT2297, PDE1226

Plate Turn In - Sold
93 Chev TK, 14 WINN HC, 15 Fiat 25

602 County Tax 144.91
501 School Tax 25.47
Fire Tax _____
602 City Tax 70.26
TOTAL $ 240.64

Yours very truly

George E Wilson
Taxpayer

Mailing Address.

125 Village Circle
Clinton N.C. 28328

Social Security # _____

RECOMMEND APPROVAL

Jim Johnson
Sampson County Tax Administrator

Board Approved _____ _____
Date Initials

OFFICE OF THE SAMPSON COUNTY TAX ADMINISTRATOR

P. O. BOX 1082 - CLINTON, NORTH CAROLINA 28329-1082 **09504**

JIM JOHNSON
Tax Administrator

Telephone 910-592-8146
910-592-8147

SAMPSON COUNTY BOARD OF COMMISSIONERS
406 COUNTY COMPLEX ROAD, BUILDING C
CLINTON, NORTH CAROLINA 28328

Members:

Pursuant to North Carolina G. S. 105-381, I hereby demand refund and remission of taxes assessed and collected by Sampson County against the property owned by Blair Straughn _____ in _____ Township, Sampson County, for the year(s) and in the amount(s) of:

YEAR	
2020	$ 263.07
	$
	$
	$
	$
TOTAL REFUND	$ 263.07

These taxes were assessed through clerical error as follows.

Bill # 00491957855
Plate # XZX7931
Vehicle Sold
Tag. Surr.
2019 Toy. Rave 4

C02 County Tax 147.14
School Tax _____
Fire Tax _____
C07 City Tax 115.93
TOTAL $ 263.07

Yours very truly

X Blair E Straughn
Taxpayer

Social Security #/. . -

RECOMMEND APPROVAL:

Jim Johnson
Sampson County Tax Administrator

Mailing Address.

Blair Elizabeth Straughn
P.O. Box 476
Roseboro NC 28382

Board Approved _____ _____
Date Initials

OFFICE OF THE SAMPSON COUNTY TAX ADMINISTRATOR

P. O. BOX 1082 - CLINTON, NORTH CAROLINA 28329-1082 09510

JIM JOHNSON
Tax Administrator

Telephone 910-592-8146
910-592-8147

SAMPSON COUNTY BOARD OF COMMISSIONERS
406 COUNTY COMPLEX ROAD, BUILDING C
CLINTON, NORTH CAROLINA 28328

Members:

Pursuant to North Carolina G. S. 105-381, I hereby demand refund and remission of taxes assessed and collected by Sampson County against the property owned by Johnny Cabbel MCBride _____ in _____ Township, Sampson County, for the year(s) and in the amount(s) of:

YEAR	
2020	$ 149.89
	$
	$
	$
	$
TOTAL REFUND	$ 149.89

These taxes were assessed through clerical error as follows.

Bill # 005888260
Plate# TEP4613
2015 Buick MP
Vehicle Sold
Tag Surr.

GOZ County Tax 149.89
School Tax
Fire Tax
City Tax
TOTAL $ 149.89

Mailing Address.

5440 Old Mintz Hwy
Boseboro NC 28382

Yours very truly

X _____
Taxpayer

X Social Security # _____

RECOMMEND APPROVAL:

_____
Sampson County Tax Administrator

Board Approved _____ _____
Date Initials

OFFICE OF THE SAMPSON COUNTY TAX ADMINISTRATOR

Members:

Pursuant to North Carolina G. S. 105-381, I hereby demand a release and adjustment of taxes assessed by Sampson County against the property owned by Matthew Powell Wrenn in North Clinton Township, Sampson County, for the year(s) and in the amount(s) of:

Year	
2020	$ 366.09
	$
	$
	$
	$
Total Release/Adjustment	$ 366.09

G01	County Tax	$ 220.46
S01	School Tax	$ 38.74
	Fire Tax	$
C02	City Tax	$ 106.89
	Total	$ 366.09

The taxes were assessed through clerical error or an illegal tax as follows:
Regular listed items in Duplin County for year 2020

Taxpayer: Matthew Powell Wrenn

Tax Administrator: Jim Thomas

Board Approved: _____ _____
Date Initials

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO: January 4, 2021
Date

FROM: Sandra Kearns, Interim Director

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-2021

1. It is requested that the budget for the AGING Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
02558670-524100	HR- MATERIALS	$ 200.00	

Revenue Account	Revenue Account Description	Increase	Decrease
02035867-408401	HR - DONATIONS	$ 200.00	

2. Reason(s) for the above request is/are as follows:
To budget donated fund to the Home Repairs Program

Sandra Kearns
(Signature of Department Head)

ENDORSEMENT
1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT
1. Forwarded, recommending approval/disapproval. _____, 20____

Date of approval/disapproval by B.O.C.

(County Manager & Budget Officer)

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO:

FROM: Rosemarie Oates, Director, SAT

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-2021

1. It is requested that the budget for the Transportation Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
16145000-535300	MAINT/REPAIR VEHICLES	53,786.00	

Revenue Account	Revenue Account Description	Increase	Decrease
16134500-403611	DHHS CARES ACT--VACCINE	53,786.00	

2. Reason(s) for the above request is/are as follows:
ALLOCATE FUNDS FOR DHHS CARES ACT--TO BE USED FOR TRANSPORTING TO VACCINE CLINICS

Rosemarie Oates Mobley
(Signature of Department Head)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. _____, 20____

Date of approval/disapproval by B.O.C.

(County Manager & Budget Officer)

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO: 2/16/2021 (Date)

FROM: SAMPSON COUNTY HEALTH DEPARTMENT

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-2021 Health

1. It is requested that the budget for the AA-716 R1 COVID Response & Vaccination Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
12551230-512100	SALARIES	76,000.00	
12551230-518100	FICA	4,712.00	
12551230-518120	MEDICARE FICA	1,102.00	
12551230-518200	RETIREMENT	5,746.00	
12551230-518300	GROUP INSURANCE	3,220.00	
12551230-518400	DENTAL INSURANCE	117.00	
12551230-518901	401k	5,700.00	
12551230-526200	DEPARTMENT SUPPLIES	6,226.00	
12551230-523100	MEDICAL SUPPLIES	6,500.00	
12551230-53700	ADVERTISING	1,500.00	
12551230-532100	TELEPHONE & POSTAGE	4,000.00	
12551230-543000	RENTAL EQUIPMENT	3,000.00	
12551230-529702	LAB SERVICES	3,000.00	
12551230-544000	CONTRACT SERVICES	74,140.00	

Revenue Account	Revenue Account Description	Increase	Decrease
12535123-404000	STATE ASSISTANCE	194,963.00	

2. Reason(s) for the above request is/are as follows:

TO ALLOCATE NEW STATE FUNDING FOR COVID RESPONSE AND VACCINATION ACTIVITIES

(Signature of Department Head)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. _____, 20____

Date of approval/disapproval by B.O.C.

(County Manager & Budget Officer)

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO: 2/16/2021 (Date)

FROM: Sampson County Health Department

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-21

1. It is requested that the budget for the Salary Control/Allocation Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
12551010-512100	SALARIES	76,000.00	
12551010-518100	FICA	4,712.00	
12551010-518120	MEDICARE FICA	1,102.00	
12551010-518200	RETIREMENT	5,746.00	
12551010-518300	GROUP INSURANCE	3,220.00	
12551010-518400	DENTAL INSURANCE	117.00	
12551010-518901	401K	5,700.00	
12551020-512100	SALARIES		76,000.00
12551020-518100	FICA		4,712.00
12551020-518120	MEDICARE FICA		1,102.00
12551020-518200	RETIREMENT		5,746.00
12551020-518300	GROUP INSURANCE		3,220.00
12551020-518400	DENTAL INSURANCE		117.00
12551020-518901	401K		5,700.00

Revenue Account	Revenue Account Description	Increase	Decrease

2. Reason(s) for the above request is/are as follows:
Move funds to salary & fringe - AA 716 R1 Additional COVID Funds

Page 2

(Signature of Department Head)

ENDORSEMENT
1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT
1. Forwarded, recommending approval/disapproval. _____, 20____

Date of approval/disapproval by B.O.C.

(County Manager & Budget Officer)

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO: 1/20/2021 (Date)

FROM: Sampson County Health Department

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-21

1. It is requested that the budget for the Salary Control/Allocation Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
12551010-512100	SALARIES	140,035.00	
12551010-518100	FICA	8,683.00	
12551010-518120	MEDICARE FICA	2,031.00	
12551010-518200	RETIREMENT	10,588.00	
12551010-518300	GROUP INSURANCE	10,465.00	
12551010-518400	DENTAL INSURANCE	380.00	
12551010-518901	401K	10,413.00	
12551020-512100	SALARIES		140,035.00
12551020-518100	FICA		8,683.00
12551020-518120	MEDICARE FICA		2,031.00
12551020-518200	RETIREMENT		10,588.00
12551020-518300	GROUP INSURANCE		10,465.00
12551020-518400	DENTAL INSURANCE		380.00
12551020-518901	401K		10,413.00

Revenue Account	Revenue Account Description	Increase	Decrease

2. Reason(s) for the above request is/are as follows:
Move funds to salary & fringe - AA 716 and 543 - COVID Vaccine Funding and Enhanced Detection

Page 2

(Signature of Department Head)

ENDORSEMENT
1. Forwarded, recommending approval/disapproval.

2/18, 2021
(County Finance Officer)

ENDORSEMENT
1. Forwarded, recommending approval/disapproval.

_____, 20____
(County Manager & Budget Officer)

Date of approval/disapproval by B.O.C.

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO:

FROM: ELECTIONS

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for 2020-2021

1. It is requested that the budget for the ELECTIONS Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
11141700-534300	Election Expense	18,738.48 ~~18,738.48~~ 00	
11141700-537000	Advertising	~~6,214.90~~ 6,215.00	

Revenue Account	Revenue Account Description	Increase	Decrease
11034170-402600	HAVA	24,953.38 ~~24,953.38~~ 00	

2. Reason(s) for the above request is/are as follows:
To budget funds from NCSBOE HAVA Funds for
for the 2020 General Election.

2-1-21
(Signature of Department Head)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. _____, 20____

_____
Date of approval/disapproval by B.O.C.

(County Manager & Budget Officer)

20-21-11

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO:

FROM: Sarah W. Bradshaw — 15-Feb-21

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-2021

1. It is requested that the budget for the Social Services Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
13535480-568413	CIP		45000
13535480-568414	LIEAP	195000	

Revenue Account	Revenue Account Description	Increase	Decrease
13535480-403313	CIP		45000
13535480-403314	LIEAP	195000	

2. **Reason(s) for the above request is/are as follows:** Line items adjusted to reflect more allocation of LIEAP funds (195,000) and reduction on CIP funds (45,000)

(Signature of Department Head)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. _____, 20____

Date of approval/disapproval by B.O.C.

(County Manager & Budget Officer)

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO:

FROM: David K. Clack, Finance Officer

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-2021

1. It is requested that the budget for the Human Resources Department be amended as follows:

Expenditure Account Code	Description (Object of Expenditure)	Increase	Decrease
11141210-544000	Contract services	19,750.00	
11999000-509700	Contingency		19,750.00

Revenue Account Code	Source of Revenue	Increase	Decrease

2. Reason(s) for the above request is/are as follows:
To budget funds to pay for consulting on the hiring of Emergency Management Director.

(Signature of Department Head)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. _____, 20____

Date of approval/disapproval by B.O.C.

(County Manager & Budget Officer)

20-21-10 PG#1

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO:

FROM: Sarah W. Bradshaw 16-Feb-21

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-2021

1. It is requested that the budget for the Social Services Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
13553100-512100	Salaries	255371	
13553100-512300	Shift Differential Pay	3500	
13553100-512400	On-Call Pay	3000	
13553100-518100	FICA	18695	
13553100-518120	Medicare FICA	4373	
13553100-518200	Retirement	116017	
13553100-518300	Group Insurance	7633	
13553100-518400	Dental Insurance		3820
13553100-518901	401K County Contribution	4002	
13553100-519900	Other Professional Services	26093	
13553100-531300	Transportation of Patients	7102	
13553100-531100	Travel/Phone Allowance	1020	
13553100-532100	Telephone and Postage	6700	
13553100-532500	Postage	4400	
13553100-533000	Utilities	30000	
13553100-535300	Main/Repair -Vehicles	7300	
13553100-538100	Data Processing	23861	
13553100-539300	Contract Temporary Help		46000
13553100-552000	Capital Outlay - Data Processing		17318
13553100-554000	Capital Outlay - Vehicles		5227

2. **Reason(s) for the above request is/are as follows:** Line items adjusted to reflect mid year review of budget and allocation of new county funds.

(Signature of Department Head)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. , 20

Date of approval/disapproval by B.O.C.

(County Manager)

COUNTY OF SAMPSON
BUDGET AMENDMENT

MEMO:

FROM: Sarah W. Bradshaw 2/16/2021

TO: Sampson County Board of Commissioners

VIA: County Manager & Finance Officer

SUBJECT: Budget Amendment for fiscal year 2020-2021

1. It is requested that the budget for the **Social Services** Department be amended as follows:

Expenditure Account	Expenditure Account Description	Increase	Decrease
13553770-568405	Foster Care Basic Needs	16000	
13553100-544000	Contracted Services (Food Stamps)		6142
13553840-544000	Work Number Fees		751
13553900-536000	Adoption Assistance	24092	
13554210-5688417	IV-E Foster Care		107509
13554310-568401	AA-AD-AB SAA Rest Home		39168
13554610-568404	State Foster Care	185642	
13554710-536030	Aid to the Blind		407
13554710-536030	Special Childrens Adoption Fund		24041
Revenue Account	**Revenue Account Description**	**Increase**	**Decrease**
13535450-403304	Title XIX Transportation	84896	
13535310-403302	Medicaid Admin Claiming	19927	
13535310-403365	IV-E Foster Care Admin	114514	
13535310-403366	TANF CPS and Foster Care	2159	
13535310-403367	CCDF Admin	5672	
13535310-403368	Medical Transportation Admin	6094	
13535310-403375	Food Stamp Admin	24556	
13535310-403376	Energy Admin	1415	
13535310-403377	Medicaid Admin	54725	
13535310-403378	SA Admin	1394	
13535310-403379	Health Choice	2546	
13535310-403382	IV-D Admin	23016	
13535310-403383	FS Incentive	6933	
13535310-403388	LINKS		10025
13535310-403389	WORK First Block Grant	59546	
13535310-404011	Health Choice Fees (Local)	2150	
13535310-404103	IV-D NON AFDC Fees (Local)	300	
13535310-404104	IV-D Blood Test Fees (Local)		750
13535310-409600	County Contribution	92461	
135535430-403309	State Foster Care	92821	
13535410-403312	IV-E Foster Care		89932

2. **Reason(s) for the above request is/are as follows:** Line items adjusted per mid-year review of budget and allocation of new county funds

(Signature of Department Head)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. 2/19, 2021

(County Finance Officer)

ENDORSEMENT

1. Forwarded, recommending approval/disapproval. , 20__

Date of approval/disapproval by B.O.C.

(County Manager & Budget Officer)

CLINTON CITY SCHOOLS

BUDGET AMENDMENT

Fund: **FEDERAL** Budget Amendment: 2

The Clinton City Board of Education at a meeting on the 4th day of February, 2021, passed the following resolution:

Be it resolved that the following amendments be made to the Budget Resolution for the fiscal year ending June 30, 2021.

SEE ATTACHED LISTING

Total appropriation in current budget	$3,521,541.85
Total increase/decrease of amendment	$154,836.00
Total appropriation in amended budget	$3,676,377.85

Passed by majority vote of the Clinton City Board of Education on the 4th day of February 2021.

Linda S. Brunson
Chairman, Board of Education

Secretary, Board of Education

We, the Board of County Commissioners of Sampson County, hereby approve the changes in the Clinton City School Budget as indicated above and have made entry of changes in the minutes of said Board this _____ day of _____ 2021.

Chairman, Board of County Commissioners

Secretary, Board of County Commissioners

BUDGET AMENDMENT DETAIL

FUND: FEDERAL

CODE	DESCRIPTION	INCREASE	DECREASE
3.5320.169.131.000.000.00	Salary- Social Worker	$23,760.00	
3.5320.169.211.000.000.00	Employer's Social Security	$1,817.64	
3.5840.169.131.000.000.00	Salary – Health Services	$26,730.00	
3.5840.169.146.000.000.00	Salary – Health Services	$42,322.50	
3.5840.169.211.000.000.00	Employer's Social Security	$5,282.52	
3.5840.169.311.000.000.00	Health Services – Contracted Svcs *GEER- Student Health Support*	$5,751.34	
3.5330.170.143.000.000.00	Salary- Tutoring	$19,819.79	
3.5330.170.211.000.000.00	Employer's Social Security	$1,516.21	
3.5350.170.198.000.000.00	Salary- Tutoring	$19,819.79	
3.5350.170.211.000.000.00	Employer's Social Security *GEER- Supplemental Instructional Services*	$1,516.21	
3.5210.118.411.000.000.00	EC- Supplies and Materials *DPI Allotment Adjustment*	$4,500.00	
3.5230.119.312.316.000.00	Pre-K EC- Workshop Expense	$1,000.00	
3.5230.119.162.316.000.00	Pre-K- EC-Substitute Pay *DPI Allotment Adjustment*	$1,000.00	

CLINTON CITY SCHOOLS

BUDGET AMENDMENT

Fund: **STATE** Budget Amendment: 2

The Clinton City Board of Education at a meeting on the 4th day of February, 2021, passed the following resolution:

Be it resolved that the following amendments be made to the Budget Resolution for the fiscal year ending June 30, 2021.

SEE ATTACHED LISTING

Total appropriation in current budget	$21,062,435.66
Total increase/decrease of amendment	$93,094.00
Total appropriation in amended budget	$21,155,529.66

Passed by majority vote of the Clinton City Board of Education on the 4th day of February 2021.

Linda S. Brunson
Chairman, Board of Education

Secretary, Board of Education

We, the Board of County Commissioners of Sampson County, hereby approve the changes in the Clinton City School Budget as indicated above and have made entry of changes in the minutes of said Board this _____ day of _____ 2021.

Chairman, Board of County Commissioners

Secretary, Board of County Commissioners

BUDGET AMENDMENT DETAIL

FUND: STATE

CODE	DESCRIPTION	INCREASE	DECREASE
1.6550.056.171.000.000.00	Salary- Bus Driver	$55,825.00	
1.6550.056.211.000.000.00	Employer's Social Security	$4,271.00	
1.6550.056.221.000.000.00	Employer's Retirement *2nd Installment*	$12,102.00	
1.5860.128.462.000.000.00	Non-Cap Computer Equipment *CRF-Unallotted Balance Allocation*	$11,006.00	
1.6400.073.343.000.000.00	Tech Support- Telecommunications *Telecommunications Allotment*	$9,890.00	
1.5350.121.121.330.000.00	Salary – Teacher		$7,976.97
1.5350.121.211.330.000.00	Employer's Social Security		$1,032.91
1.5350.121.221.330.000.00	Employer's Retirement		$2,926.95
1.5350.121.311.330.000.00	Contracted Services		$2,000.00
1.5350.121.312.330.000.00	Professional Development		$636.00
1.5350.121.462.330.000.00	Non-Capitalized Computer Equip.		$0.33
1.6550.121.171.000.000.00	Salary – Bus Driver		$9,593.44
1.6550.121.211.000.000.00	Employer's Social Security		$794.98
1.6550.121.331.330.000.00	Student Transportation		$417.42
1.5840.137.411.000.000.00	CRF-PPE Supplies	$25,379.00	
1.5840.122.311.000.000.00	Contracted Services		$18,904.00
1.5840.137.411.000.000.00	CRF-PPE Supplies	$18,904.00	
1.5110.123.411.000.000.00	Instructional Supplies		$3,965.00
1.6540.137.411.000.000.00	CRF- Custodial Supplies	$3,965.00	
1.7200.125.462.000.000.00	Non-Capitalized Computer Equip		$256,000.00
1.5860.124.418.000.000.00	Computer Software and Supplies	$21,534.00	
1.5860.124.462.000.000.00	Non-Capitalized Computer Equip	$234,466.00	
1.7200.125.462.000.000.00	Non-Capitalized Computer Equip		$13,579.00
1.6540.137.411.000.000.00	CRF- Custodial Supplies	$13,579.00	
1.5860.126.462.000.000.00	Non-Capitalized Computer Equip		$348.00
1.5840.137.411.000.000.00	CRF-PPE Supplies	$348.00	
1.5860.128.462.000.000.00	Non- Capitalized Computer Equip		$40,592.00
1.5840.137.411.000.000.00	CRF-PPE Supplies	$40,592.00	
1.5210.132.411.000.000.00	EC- Supplies		$24,497.00
1.5840.137.411.000.000.00	CRF- PPE Supplies	$24,497.00	
1.5110.134.462.000.000.00	Non-Capitalized Computer Equip		$7,413.00
1.5840.137.411.000.000.00	CRF- PPE Supplies	$7,413.00	

1.6400.135.418.000.000.00	Computer Software Supplies		$957.00
1.5840.137.411.000.000.00	CRF- PPE Supplies	$957.00	
1.5210.132.411.000.000.00	CRF-EC- Supplies	$1,150.00	
1.5840.137.411.000.000.00	CRF- PPE Supplies		$1,150.00

CRF Transfers to needed PRCs

SAMPSON COUNTY HEALTH DEPARTMENT

Wanda Robinson
Health Director

360 County Complex Road, Suite 200
Clinton, NC 28328

To: Mr. Edwin Causey
County Manager

Susan Holder
Assistant County Manager

From: Wanda Robinson
Health Director

Subject: County Commissioner's Consent Agenda Items

Date: February 15, 2021

Attached are items approved by the Health Advisory Committee on January 25th, 2021 and is being submitted for approval by the county commissioners.

I. Sampson County Health Department Lab Fees with Revisions

II. HIPAA Policy 2021 annual update and adoption

III. Telehealth Policy:
New Policy that will allow the Sampson County Health Department to provide telehealth services to better enable the delivery of remote care to patients.

Attachments

Lab Fee with revisions
HIPAA Policy 2021 annual update and adoption
Telehealth Policy

Sampson County Health Department Lab Fee Revisions

Date Added	Name of Test	LabCorp Order Number	CPT Code	Price
12/2020	Pap w/Reflex HPV	199300	88142	$53.00
12/2020	Pap w/ automatic HPV	199330	OL016	$53.00
01/12/2021	Hepatitis B Surface Antibody	006530	86317	$43.90
01/28/2021	Urine Albumin	140285	82043	$64.06

Sampson County Health Department

HIPAA PRIVACY

(Health Insurance Portability & Accountability Act)

POLICY & PROCEDURE MANUAL

SAMPSON COUNTY HEALTH DEPARTMENT
HIPAA Privacy Policy & Procedure Manual: Year 2020
~~Annual/Review/Policy Update Review Form~~

Manual: SCHD HIPAA Manual	Applicable Signatures/Title:
Title: SCHD HIPAA Policy & Procedures	Program Specialist: Wanda Robinson
Program Policy: Program	Supervisor: *NI* A
Program Procedure: Program	Director of Nursing: Kelly Parrish
X Management/Department-wide Policy	Medical Director: Dr. Tim Smith
workforce Policy	Health Director: Wanda Robinson
Fiscal Policy	Board of Health Chair: Clark Wooten
	Health Advisory Board Chair: Jacqueline Howard
Distributed to: All workforce	Effective Date: ~~01/27/2020~~ 12/7/2020
	Supersedes: ~~04/02/2018~~01/27/2020

Review/Revision Date: 04/2003; 04/2004; 04/2005; 04/2006; 04/2007; 04/2008; 04/2009; 04/2010; 04/2011; 04/2012; 04/2013; 04/2014; 04/2015; 04/2016; 04/2017; 04/2018; 01/27/2020; 12/7/2020

Clark Wooten, Board of Health Chair _____ Date _____

Wanda Robinson, Health Director _____ Date _____

Table of Contents

Sampson County Health Department
HIPAA Privacy Policy & Procedure Manual Review & Revision Form

Annual Review Date	Revision Date	Revision: Name, Location, Page # of Section w/ Revision(s)	Changes Made By	Date Staff Notified
04/02/18	04/02/18	1. Entire Policy Revised, is now SCHD only HIPAA policy to meet state and federal EHR HIPAA guidelines for medical entities. 2. Policy to be completely reviewed by all staff as a "new" policy.	W. Robinson	04/02/18
01/27/2020		Policy Update	W. Robinson	02/19/2020
12/7/2020		Policy Update	W. Robinson	12/7/2020

Sampson County Health Department
HIPAA Policy & Procedures Year: 20~~19~~20

Manual: SCHD HIPAA Manual	Applicable Signatures/Title:
Title: SCHD HIPAA Policy & Procedures	Program Specialist: Wanda Robinson
□ Program Policy:_____Program	Supervisor: N/A
□ Program Procedure:_____Program	Director of Nursing: Kelly Parrish
X Management/Department-wide Policy	Medical Director: Dr. Tim Smith
□ workforce Policy	Health Director: Wanda Robinson
□ Fiscal Policy	Board of Health Chair: Clark Wooten
Distributed to: All workforce	Health Advisory Board Chair: Jacqueline Howard
	Effective Date: ~~01/27/2020~~ 12/07/2020
	Supersedes: ~~04/02/18~~ 01/27/2020

Purpose:

To provide guidance to all Sampson County Health Department (SCHD) workforce regarding the laws, rules and regulations as they relate to the privacy and confidentiality of the protected health information (PHI) for all health department patients.

Policy:

Sampson County Health Department recognizes the importance of all aspects of a patient's right to confidentiality and privacy as it relates to the medical information.
The HIPAA Privacy Rule provides that patients have a right to notice of how we may use and disclose a patient's PHI, as well as the patient's rights and the obligations regarding their PHI. We have developed a Notice of Privacy Practices to meet these requirements and will make the Notice available to the patients as described in this policy. Our Practice will strive to abide by the terms of the Notice as currently in effect.
The Sampson County Health Department (SCHD) will implement policies and procedures as required by and specified in the privacy rule of the Administrative Provision in the Health Insurance Portability and Accountability Act of 1996.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B. Every staff person should review and consult the Glossary when reviewing or consulting this Policy Manual.

Applicable Laws, Rules and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part §160, General Administrative Requirements.
45 CFR, Part § 162, Administrative Requirements.
45 CFR, Part § 164, Security & Privacy.
North Carolina General Statute § 8-53.6.
North Carolina General Statute § 8-53.13.
North Carolina General Statute § 130A-12.
North Carolina General Statute § 130A-143-144.

Responsible Persons:

Sampson County Health Department workforce

Procedures:

1. This policy provides the guidelines for the handling of patient medical protected health information (PHI) as set forth by the federal Public Law 104-191; Health Insurance Portability and Accountability Act (HIPAA) of 1996.
2. The policy follows the rules as explained in the Code of Federal Regulations:

   A. 45 CFR, Part §160, General Administrative Requirements.
   B. 45 CFR, Part §162, Administrative Requirements.
   C. 45 CFR, Part §164, Security & Privacy.

3. Additional clarification regarding PHI per North Carolina legislative guidelines are found in North Carolina General Statutes:

   A. North Carolina General Statute § 8-53.6.
   B. North Carolina General Statute § 8-53.13.
   C. North Carolina General Statute § 130A-12.
   D. North Carolina General Statute § 130A-143-144.

4. All health department workforce will follows the guidelines as stated in each of the sections of this policy. The Sections include:

   Section 1: Introduction to HIPAA
   Section 2: Notice of Privacy Practices
   Section 3: Uses and Disclosures of Protected Health Information Not Requiring Patient Authorization
   Section 4: Uses and Disclosures of Protected Health Information Requiring Patient Authorization
   Section 5: "Minimum Necessary" Use and Disclosure of Protected Health Information (PHI)
   Section 6: Uses and Disclosures of Protected Health Information Where the Patient Has an Opportunity to Agree or Object
   Section 7: Access of Individuals to Protected Health Information
   Section 8: Accounting for Disclosure of Protected Health Information
   Section 9: Amendment of Protected Health Information
   Section 10: Business Associates
   Section 11: Safeguarding Protected Health Information
   Section 12: Training
   Section 13: Complaints to the Practice; Mitigation
   Section 14: No Retaliation for the Exercise of Rights or the Filing of a Complaint; No Waiver of Rights
   Section 15: Sanctions for Violations; Exceptions to Sanctions
   Section 16: Communication by Texting, Appointment Card, Phone Call & Letter

Sampson County Health Department
Section 1: Introduction to HIPAA

Purpose:

To provide guidance to all Sampson County Health Department (SCHD) workforce regarding the Health Insurance Portability & Accountability Act (HIPAA) of 1996 laws, rules and regulations as they relate to the privacy and confidentiality of the protected health information (PHI) for all health department patients.

Policy:

The HIPAA Privacy Rule provides that patients have a right to notice of how we may use and disclose a patient's PHI; the patient's rights; and SCHD's obligations regarding their PHI. SCHD will strive to abide by the terms of the Notice as currently in effect.

The Sampson County Health Department (SCHD) provides policies and procedures as required by and specified in the privacy rule of the Administrative Provision in the Health Insurance Portability and Accountability Act of 1996 and North Carolina General Statutes as they related to patient health information.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part §160, General Administrative Requirements.
45 CFR, Part § 162, Administrative Requirements.
45 CFR, Part § 164, Security & Privacy.
North Carolina General Statute § 8-53.6.
North Carolina General Statute § 8-53.13.
North Carolina General Statute § 130A-12.
North Carolina General Statute § 130A-143-144.

Responsible Persons:

Sampson County Health Department workforce

Procedures:

The following is an overview and introduction to the HIPAA law of 1996 and subsequent rules and regulations to ensure the privacy of patient health information.

What is the HIPAA Privacy Rule?

1. To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") was enacted by Congress. HIPAA included what are called "Administrative Simplification" provisions that required the U.S. Department of Health and Human Services ("HHS") to adopt national standards for electronic health care transactions, such as health care claims that are filed electronically.
2. Because advances in electronic technology could make it difficult to protect the privacy of health information, Congress mandated the adoption of the HIPAA Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule" or "Rule").
3. Congress subsequently enacted the HIPAA Security Rule and, more recently, the Health Information Technology for Economic and Clinical Health (HITECH) Act.
4. In addition, North Carolina has enacted laws regarding identity theft prevention, data security breach notification and protected use and disclosure of Social Security numbers (see the SCHD Data Breach Notification Policy). The Rule does not replace other federal, state or other laws that give individuals even greater privacy protections, and are not preempted by the Privacy Rule.
5. The Privacy Rule establishes national protections for the privacy of protected health information ("PHI"), and applies to three types of HIPAA covered entities: health plans, health care clearinghouses, and health care providers, to include the Sampson County Health Department (SCHD), that conduct certain health care transactions electronically. The Rule requires that Covered Entities implement policies and procedures to protect and guard against the misuse of PHI.
6. The HIPAA Manual reflects the commitment to compliance with the Privacy Rule.

Privacy Officer:

1. The Privacy Rule requires that an agency designate a person who will serve as the "Privacy Officer" and who is responsible for the development and implementation of the privacy policies and procedures.
2. The agency must also designate a person to serve as the contact person responsible for receiving complaints under the Privacy Rule and who can make further information available to patients about matters covered by the Notice of Privacy Practices.
3. The Health Director has been designated as the Privacy Officer for SCHD, to be responsible for the development and implementation of SCHD privacy policies and procedures, and to be the contact person to answer questions and receive complaints related to the privacy practices.

What does the HIPAA Privacy Law mean to the Sampson County Health Department and SCHD workforce?

1. All SCHD workforce need to understand what the basic Privacy Policies and Procedures are and how to request help if further information is needed.
2. This policy will be posted on SharePoints and will be available to all SCHD workforce.
3. Each workforce member will be required to review the policies and the Notice of Privacy Practices and participate in training that will be offered on the Privacy Rule.
4. If the Privacy Rule changes, or new guidance is issued that requires a change in the

Policy Manual, the agency will have each member of the workforce review the changed policies.

5. SCHD is committed to providing quality health care to the patients, while maintaining the privacy of their protected health information (PHI) and complying with the Privacy Rule.

Sampson County Health Department
Section 2: Notice of Privacy Practices

Purpose:

To provide guidance for the HIPAA Privacy Rule that provides patients with the right of notice of how SCHD may use and disclose a patient's protected health information (PHI), as well as the patient's rights and SCHD's obligations regarding their PHI. A Notice of Privacy Practices has been developed to meet the requirements and make the Notice available to SCHD patients as described in this policy. SCHD will abide by the terms of the Notice of Privacy Practices that is currently in effect.

Policy:

The Sampson County Health Department (SCHD) will implement policies and procedures as required by and specified in the privacy rule of the Administrative Provision in the Health Insurance Portability and Accountability Act.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part **§** 164.514.
45 CFR, Part § 164.520.

Responsible Persons:

All Sampson County Health Department workforce.

Procedures:

Content of Notice:

1. The Notice of Privacy Practices ("Notice") is written in plain language to contain all of the elements required by the Privacy Rule, including the following:

    A. A description of how the health department will use and disclose patients' PHI, including:

        1. A description, with at least one example, of the types of uses and disclosures that are permitted to make for treatment, payment, and health care operations.

2. A description of each of the other purposes that are permitted or required by HIPAA to use or disclose PHI without the patient's written authorization.
3. A statement that other uses and disclosures will be made only with the patient's written authorization (see Section 4 of Manual).

B. A description of the individual rights of SCHD patients regarding access and control of their PHI, and how a patient may exercise those rights, including:

1. The right to request restrictions on certain uses and disclosures and whether the health department is required to agree to a requested restriction, including agreeing to the request of a patient to restrict disclosure of PHI about him/her to a health plan if the disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law and the PHI pertains solely to a health care item or service for which the patient, or person other than the health plan, has paid SCHD in full for the item or service.
2. The right to receive certain confidential communications.
3. The right to inspect and obtain a copy of PHI.
4. The right to request an amendment of PHI.
5. The right to receive an accounting of certain disclosures of PHI.
6. The right to revoke an authorization.
7. A description of SCHD's complaint procedure for addressing problems the patient may have with SCHD's privacy practices.
8. The right to obtain a paper copy of the Notice, upon request.

2. If SCHD maintains an electronic health record, patients have the right to:

A. Access to or obtain a copy of PHI in an electronic form and format requested by the patient, if it is readily producible or, if not, in a readable electronic form and format as agreed to between SCHD and the patient.
B. Have SCHD transmit such copy directly to a person or entity the patient designates, provided that choice is clear, conspicuous, and specific.
C. Request that SCHD provide an accounting of the disclosures made of the patient's PHI, including disclosures related to treatment, payment and health care operations contained in an electronic health record for no more than 3 years prior to the date of the request (and depending on when SCHD acquired an electronic health record).
D. Notice of any allowed fees related to the above.

3. Patients have a right to and may request:

A. A description of SCHD's legal duties regarding PHI, including the legal obligation to maintain the privacy of PHI and the obligation to notify affected individuals following a breach of their unsecured PHI.
B. Identification of whom in the health department a patient may contact for more information about SCHD's privacy practices.

C. The effective date of the Notice and any revisions of the Notice, with the effective date of such revisions.

Providing the Notice:

1. The Privacy Notice will be presented to each patient at their first date of service delivery by SCHD.
2. Front Desk/Intake-Eligibility Staff will make a good faith attempt to obtain each patient's acknowledgment of the receipt of the Privacy Notice.
3. SCHD will have a patient acknowledge receipt by signing an acknowledgment form.
4. If the patient refuses to provide such acknowledgment, SCHD will document in the patient's chart the efforts to obtain the patient's acknowledgment and the reason why the acknowledgment was not obtained.
5. If there is an emergency treatment situation, SCHD will provide the Notice to the patient as soon as reasonably practicable after the emergency situation is resolved. No acknowledgment of receipt of the Notice needs be obtained in an emergency situation.
6. SCHD has posted the entire current Notice at the Front Desk Reception area.
7. SCHD will provide a paper copy of the Notice upon a patient's request.
8. If the patient has a personal representative acting on the patient's behalf at the time Notice is provided, SCHD will provide the Notice to the representative and make a good faith effort to obtain the representative's acknowledgment of receipt of the Notice.

Revisions & Reviews to the Privacy Notice:

1. SCHD will advise patients in the Notice that SCHD reserves the right to change the terms of the Notice and to make the new Notice provisions effective for all PHI that is maintained.
2. SCHD will review the Privacy Notice at least annually. If SCHD determines at any time that there is a material change to the agency's privacy practices, or there is a change in law that requires a change in the Privacy Notice, SCHD will:

   A. Revise the Privacy Notice.
   B. Date it with the effective date of the revision.
   C. Post the revised Notice in at the Front Desk, Intake cubicles and exam rooms, then implement the changes (unless a change in law requires that SCHD implement the change sooner).
   D. Provide the revised Notice pursuant to this Policy.
   E. Patients will be notified in the SCHD revision Notice that they can obtain a revised Notice upon request on or after the effective date of any revision.

3. No acknowledgement is necessary for providing a revised/reviewed Privacy Notice to a patient who has received a prior version of the Notice.
4. SCHD may utilize a "layered" Notice that consists of a short notice summarizing the patient's rights, attached to a longer notice that contains all of the elements listed in Parts 1 or 2 of this Policy. The patient will be provided with the two documents stapled together, with the shorter notice on top of the longer notice.

Documentation:

1. The Privacy Officer will maintain a file containing a copy of the SCHD Privacy Notice and each revised Notice that is issued by SCHD.
2. SCHD will place in the patient's medical record a copy of the acknowledgment of receipt (which will also contain a reference to the version of the Notice they received), whether provided by hard copy or electronically, or documentation of workforce's good faith efforts to obtain such written acknowledgment.

Sampson County Health Department
Section 3: Uses and Disclosures of Protected Health Information (PHI)

Purpose:

To establish guidelines for the use and disclosure of Protected Health Information (PHI).

Policy:

The Sampson County Health department (SCHD) may use and disclose PHI in certain situations where it is not necessary to obtain the patient's authorization, as allowed under the HIPAA Law Privacy Rule. SCHD will follow Section 5 of this Manual regarding application of the Minimum Necessary principle when using or disclosing PHI without patient authorization.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part **§** 164.502.
45 CFR, Part § 164.506.
45 CFR, Part **§** 164.514.
45 CFR, Part § 164.521.
North Carolina General Statute § 130A-12.

Responsible Persons:

All Sampson County Health Department workforce

Procedures:

In the following situations, the health department may use or disclose PHI without obtaining the patient's authorization:

For Treatment, Payment or Health Care Operations:

1. A patient's authorization is not required when SCHD uses or discloses the patient's PHI for SCHD purposes in order to treat the patient, obtain payment for the services, or conduct SCHD business operations, including disclosure to the agency's business associates (as further described in this Manual).
2. Sampson County Health Department requires a signature on the authorization from a patient on the first visit to the department. The authorization must:

    A. Inform the individual that PHI may be used and disclosed to carry out treatment,

payment and health care operations (TPO).

B. Refer the individual to the Sampson County Health Department's Notice of Privacy Practices for a more complete description of such uses and disclosures.
C. State that the individual has the right to review the notice prior to signing the consent.
D. State that the individual has the right to revoke the consent in writing, except to the extent that the Sampson County health department has taken action in reliance on the consent.
E. Be signed, and dated by the individual and witness.

3. A patient is permitted to request, in writing, that SCHD restrict the uses or disclosures of his or her PHI for treatment, payment or health care operations, or when disclosing information to persons involved in the patient's care, or for notification purposes. Except as set forth below, SCHD is not required to agree to the patient's request, but are bound by any restrictions to which SCHD agrees unless and until SCHD withdraws from such agreement, where permitted. Such requests will be directed to the SCHD Privacy Officer.
4. If a patient requests that SCHD restrict the disclosure of the patient's PHI to his/her health plan, the health department must comply if:

   A. The disclosure is not for purposes of carrying out treatment (only for purposes of carrying out payment or health care operations); and
   B. The PHI pertains solely to a health care item or service for which the health department has been paid out-of-pocket in full.

5. A patient is permitted to request, in writing, that the patient receive communications of PHI from SCHD by alternative means or at alternative locations (other than the usual way SCHD sends communications to patients). SCHD must accommodate a patient's reasonable request for such confidential communications. Such requests will be directed to the SCHD Privacy Officer.
6. Special rules apply if the patient's file contains psychotherapy notes, such cases will be referred to the SCHD Privacy Officer.
7. SCHD may disclose PHI for the treatment activities of another health care provider. Where PHI is disclosed to, or requested by, other health care providers for treatment purposes, SCHD's Minimum Necessary Policy (Section 5) does not apply.
8. SCHD may disclose PHI to another Covered Entity for the peer review activities of that entity, subject to review and approval by the SCHD Privacy Officer.
9. Any use or disclosure of PHI for Treatment, Payment or Health Care Operations must be consistent with SCHD's current Notice of Privacy Practices.

<u>Required Uses and Disclosures Not Requiring Patient Authorization:</u>

Other than for disclosures to the patient, no disclosure under this Section will be made without the prior review and approval of the SCHD Privacy Officer who may consult with the County's legal counsel.

<u>Disclosures to the Patient</u>:

Under the law, except as provided in Section 7 of this Manual, SCHD must make disclosures *to the patient* who requests such disclosure and no authorization is required. If the patient requests a copy of his or her record, refer to Section 7 of this Manual.

Disclosures to the Secretary of HHS/OCR:

SCHD must make disclosures of PHI when required by the Secretary of HHS or to the Office of Civil Rights (OCR) to investigate or determine SCHD's compliance with the requirements of the Privacy Rule.

Disclosures as Required by Law:

To the extent that the use or disclosure of PHI is required by an applicable law, SCHD may do so without the patient's authorization, in compliance with, and limited to, the relevant requirements of such law.

Disclosures for Public Health Activities:

SCHD may use or disclose a patient's PHI, without the patient's authorization, for the following public health activities and purposes:

A. Public Health Authorities: Disclosure to a public health authority that is legally authorized to receive such information for the purpose of:

    1. Preventing or controlling disease, injury or disability, such as reporting of injury or communicable disease.
    2. Vital events such as birth and death.
    3. Public health surveillance, investigation and/or public health intervention.
    4. If directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

B. Communicable Diseases: In addition to reporting communicable disease information to a public health authority as provided for in Subsection A above, SCHD may disclose a patient's PHI, as authorized by state law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Disclosures for Abuse or Neglect:

A. Children: SCHD may disclose a patient's PHI to a public health/legal authority that is authorized by law to receive reports of child abuse or neglect.
B. Adults: Except for vulnerable adults, if SCHD believe that an adult patient has been a victim of abuse, neglect or domestic violence, SCHD may disclose a patient's PHI to the governmental entity or agency authorized by law to receive such information. No disclosure of information about the victim of domestic violence or abuse may be made to law enforcement without the patient's authorization.
C. Vulnerable Adults: When a vulnerable adult is the subject of abuse, neglect or exploitation, SCHD may disclose the patient's PHI to the appropriate government adult protective

services provider.

Disclosures for Health Oversight:

SCHD may disclose PHI to a health oversight agency for activities authorized by law, such as audits; civil, criminal or administrative investigations, proceedings or actions; inspections; or licensure or disciplinary actions.

Disclosures for Legal Proceedings:

SCHD may disclose PHI in the course of any judicial or administrative proceeding, in response to an order of a court or administrative tribunal (but only that PHI for which disclosure is expressly authorized), and, under certain conditions, in response to a subpoena, discovery request or other lawful process. SCHD workforce will direct all subpoenas, and other requests for disclosures for purposes of legal proceedings, to the SCHD Privacy Officer who may consult the County's legal counsel.

Disclosures for Law Enforcement:

SCHD may disclose PHI for law enforcement purposes, without a patient's authorization, so long as specific legal requirements are met. Some of these law enforcement purposes include: warrants and other legal process; limited information requests for identification and location purposes; and information related to a crime (including a medical emergency where it is likely that a crime has occurred). SCHD workforce will direct all law enforcement requests for disclosures to the SCHD Privacy Officer who may consult the County's legal counsel.

Disclosures for Coroners, Medical Examiners, Funeral Directors, and Organ Donations:

1. SCHD may disclose PHI to a coroner or medical examiner for identification purposes, determining cause of death or for the coroner or medical examiner to perform other official duties.
2. SCHD may disclose PHI to a funeral director, as authorized by state law, in order to permit the funeral director to carry out his or her duties, including disclosure prior to, and in reasonable anticipation of, the death of a patient, if necessary for the funeral director to carry out his or her duties.

Disclosures for Research:

If SCHD is requested to use or disclose PHI for research purposes, such use and disclosure will be under the direction of the SCHD Privacy Officer who will consult with the County's legal counsel.

Disclosures for Serious Threat to Health or Safety:

Under certain circumstances, SCHD may use a patient's PHI, or disclose it to another health care professional or to a law enforcement agency, if SCHD believes, in good faith, that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of the patient or to others or is necessary in certain situations for law enforcement authorities to identify or apprehend an individual who is a serious threat to public safety. If the PHI contains

identifying information about a person who has AIDS or an HIV infection, SCHD will not disclose such information without the patient's authorization, unless authorized by state law, or pursuant to a court order.

Disclosures for Specialized Government Functions:

When the appropriate conditions apply, SCHD may use or disclose a patient's PHI for certain military, national security or intelligence activities, or when needed for correctional institutions and other law enforcement custodial situations.

Disclosures for Workers' Compensation:

A patient's PHI may be disclosed by SCHD as authorized under state law to comply with workers' compensation laws and other similar programs established by law that provide benefits for work-related injuries or illness without regard to fault. For routine disclosures for workers' compensation purposes, SCHD follows the standard protocols for such disclosures as part of the Minimum Necessary Policy – see Section 5.

Disclosures for Schools; Immunization Records:

SCHD may disclose a patient's PHI to a school when the patient is a student or a prospective student of the school if:

1. The PHI that is disclosed is limited to proof of immunization;
2. The school is required by state law (or other law) to have proof of immunization prior to admitting the individual; and
3. SCHD obtains and documents the oral agreement for such disclosure from the parent, guardian or other person acting in loco parentis of an emancipated minor or from the individual, if the individual is an adult or emancipated minor.

Verification of the Identity of an Authorized Person:

1. Prior to any disclosure of PHI under this policy, SCHD will verify the identity of the person requesting the PHI and the authority of any such person to have access to the patient's PHI, if the identity or any such authority of the person is not known to us.
2. SCHD will obtain and/or document any pertinent credentials, documentation, statements or representations, whether oral or written, from the person requesting the PHI.

Sampson County Health Department
Section 4: Uses and Disclosures of Protected Health Information Requiring Patient Authorization

Purpose:

To establish guidelines for the use and disclosure of protected health information (PHI).

Policy:

The Sampson County Health department(SCHD) may use or disclose a patient's PHI for those purposes specified in Section 3 of this Manual without obtaining the patient's authorization. Other uses and disclosures of PHI, as addressed in this policy, will be made only with the patient's written authorization. The health department will not condition treatment on the provision by the patient of a requested authorization except as allowed under this policy.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part **§** 164.508.
45 CFR, Part § 164.514.

Responsible Persons:

All Sampson County Health Department workforce

Procedures:

Overview:

Whenever the health department needs to use or disclose a patient's PHI for purposes unrelated to Treatment, Payment or Health Care Operations (or as otherwise described in Section 3), or if a patient requests disclosure of his or her PHI to a specified third party, we will obtain the patient's written authorization prior to such use or disclosure. SCHD will only release PHI that is consistent with the scope of the authorization.

Authorization Form:

The health department's authorization form will provide for the following:

1. The name of the person or entity, or category of persons/entities authorized to make the requested use or disclosure.

2. The name of the person or entity, or category of persons/entities, to whom the use or disclosure may be made.
3. Specifically describe the information to be used or disclosed, including, but not limited to, specific detail such as date of service, type of service provided, level of detail to be released, origin of information, etc.
4. List the specific purposes for the use or disclosure. If the individual does not, or elects not to, provide a statement of the purpose, the form will state the purpose as "at the request of the individual."
5. Specify that the authorization will be in force and effect until a specified date or event (stated in the authorization) that relates to the patient or to the purpose of the use or disclosure, at which time the authorization will expire.
6. Provide for the patient's right to revoke the authorization as set forth in "Revocation of Authorization" #1 and #2 below.
7. Specify that the health department will not condition treatment upon the patient's execution of an authorization, as set forth in "Revocation of Authorization" #3 below.
8. Specify that the information disclosed pursuant to the authorization may be re-disclosed by the recipient and is no longer subject to the protections of the Privacy Rule.
9. Provide for the patient's signature and date of execution or, if the patient's Personal Representative is signing on behalf of the patient, provide for a description of that person's authority to act and/or that person's relationship to the patient.

Revocation of Authorization:

1. A patient has the right to revoke an authorization at any time, in writing, by mailing such written notification to the attention of the health department's Privacy Officer or by personal delivery to the Privacy Officer.
2. A revocation is not effective to the extent that the health department has taken action in reliance on the patient's authorization.
3. The health department will not condition a patient's treatment on whether the patient provides authorization for the requested use or disclosure if to do so would be prohibited by federal or state law. If a reason exists under law for conditioning the patient's treatment on obtaining an authorization, the patient will be advised of that fact and of the consequences to the patient of refusing to sign the authorization. The Privacy Officer will determine if such reason exists.

Independent Medical Examination:

In accordance with state law, if a third party has requested that the health department examine or evaluate a person ("Examinee") and the Examinee has signed an authorization for the release of the report of such examination or evaluation to the third party:

1. The report will be consistent with the authorization, to avoid unnecessary disclosure of diagnoses or personal information which is not pertinent to the evaluation.
2. The report will be forwarded only to the third party who requested the evaluation, in accordance with the Examinee's authorization and, if no specific individual is identified, the report will be marked "Confidential"; and
3. SCHD will not provide the Examinee with a copy of the report unless the third party requesting the examination consents to its release, except that should the

examination disclose abnormalities or conditions not known to the Examinee, SCHD will advise the Examinee to consult another health care professional for treatment.

4. SCHD will refer the following requests to the Privacy Officer for complying with such requests in accordance with law.

   A. PHI that contains psychotherapy notes.
   B. PHI for marketing purposes.
   C. PHI for research purposes.
   D. A request for a use or disclosure that may be considered a sale of PHI.

5. SCHD will not directly or indirectly receive remuneration in exchange for any PHI of a patient unless the agency has obtained a valid authorization that includes a specification of whether the PHI can be further exchanged for remuneration by the entity receiving the patient's PHI. This requirement will not apply if the purpose of the exchange is:

   A. For public health activities;
   B. For research and the price charged reflects the costs of preparation and transmittal of the data for such purposes;
   C. For treatment and payment purposes;
   D. For the sale, transfer, merger or consolidation of all or part of the health department with another Covered Entity, and due diligence related to such activity;
   E. For remuneration that is provided by the health department to a Business Associate for activities involving the exchange of PHI that the Business Associate undertakes on SCHD's behalf and at the agency's specific request pursuant to a Business Associate Agreement;
   F. To provide a patient with a copy of the patient's PHI pursuant to Section 7 of this Manual;
   G. As required by law; or
   H. For any other purpose permitted by or in accordance with the Privacy Rule where the only remuneration received by SCHD is a reasonable, cost-based fee to cover the cost to prepare and transmit the PHI for such purpose or a fee otherwise expressly permitted by other law.

6. Any offer of remuneration in exchange for PHI will be directed to the SCHD Privacy Officer.
7. Prior to any disclosure of PHI under this policy, SCHD will verify the identity of the person requesting the PHI and the authority of any such person to have access to the patient's PHI, if the identity or any such authority of the person is not known to SCHD; the agency will obtain any documentation, statements or representations, oral or written, from the entity requesting the PHI when such documentation, statement or representation is pertinent to the disclosure.
8. SCHD can accept a government agency's authorization form as long as it meets the requirements of "Authorization Form" #1-9 above.
9. The patient may receive a copy of the authorization, upon request.
10. SCHD workforce will document in the patient's medical record that the patient's authorization was obtained for the specific use or disclosure and will retain the signed authorization in the patient's medical chart, in either written or electronic form, for at least six years from the date when it last was in effect. If the patient revokes the

authorization, SCHD will document such revocation in the patient's medical record and retain the signed revocation in the same manner as an authorization.

Sampson County Health Department
Section 5: Minimum Necessary Use & Disclosure of PHI

Purpose:

To set forth the requirements for making reasonable efforts to limit the use and disclosure of individually identifiable health information (IIHI) and/or protected health information (PHI) to that which is minimally necessary.

Policy:

Except as otherwise stated in this policy, when Sampson County Health Department (SCHD) uses or discloses PHI, or when SCHD requests PHI from another Covered Entity or Business Associate, the SCHD will make reasonable efforts to limit the information to the extent practicable, to the Limited Data Set or, if needed by the health department, to the minimum necessary to accomplish the intended purpose of the use, disclosure or request, respectively.
The minimum necessary requirement applies to: 1) Uses or disclosures for payment or health care operations; 2) Uses or disclosures requiring the patient to have an opportunity to agree or object; 3) Uses or disclosures that are permitted without the patient's permission (except for those required by law or specified otherwise in the Sampson County Health Department HIPAA Privacy Rule Policy Manual; and 4) Uses or disclosures by External Business Associates.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part § 164.502(b).
45 CFR, Part § 164.514(d).

Responsible Persons:

All Sampson County Health Department workforce

Procedures:

Exceptions to the Policy:

SCHD uses and disclosures of PHI, and requests for PHI, that are not subject to this policy requiring that the minimum necessary information be used or disclosed, are as follows:

1. Disclosures to or requests by a health care provider for treatment purposes, including SCHD's requests for disclosure of PHI for Treatment purposes.
2. Disclosures made to the patient, including but not limited to disclosures made to the patient pursuant to the patient's request to access his or her record or for an accounting of

disclosures made by SCHD of the patient's PHI;

3. Uses or disclosures made pursuant to a patient's authorization that meets the requirements of Section 4 of this Manual.
4. Disclosures made to the Secretary of HHS related to enforcement of the requirements of the HIPAA privacy standard.
5. Uses or disclosures required by other law as described in Section 3 of this Manual.
6. Uses or disclosures that are required for compliance with the requirements of the HIPAA privacy standard.
7. PHI that has been de-identified, as specified in the Privacy Rule.

Situations Where the Policy Applies:

1. Uses of PHI:

    A. SCHD has established which persons or categories of persons in the agency need access to PHI to carry out their duties.
    B. For each such person or category, SCHD has determined the types of PHI to which access is needed, including identification of those persons or classes of persons in the health department who need to see the entire medical record, and any conditions that exist for access (job role-based access).
    C. SCHD will make reasonable efforts to limit the access only to the amount of information needed by the person in order to carry out the duties of that position or to accomplish the required use.

2. Disclosures of PHI:

    A. For disclosures of PHI that SCHD makes on a routine and recurring basis, SCHD has established a standard protocol for limiting the PHI disclosed to the minimum amount reasonably necessary to achieve the purpose of the disclosure.
    B. For non-routine disclosures, SCHD has developed criteria designed to limit the PHI disclosed to the minimum information reasonably necessary to accomplish the purpose of the disclosure. SCHD will review requests for such non-routine disclosures on an individual, case-by-case basis for conformance with these criteria.
    C. The criteria for non-routine disclosures do not need to be applied when a request for disclosure is received in the following situations and the request appears to reasonably limit the disclosure to the minimum necessary under the particular circumstances of the request:

        1. Requests for disclosures received from a health care provider, health plan or health care clearinghouse.
        2. Requests for disclosures received from public officials in those situations identified in Section 3 of this Manual (No Authorization Required) and the public official represents that the information requested is the minimum necessary.
        3. Requests for disclosures received from a professional member of the health department, or from one of SCHD's business associates for the purpose of providing professional services to the agency, if the professional represents that the information requested is the minimum necessary for the stated

purpose.

4. Requests for disclosures received from a researcher with appropriate documentation from an Institutional Review Board or Privacy Board.

3. Requests for PHI:

   A. SCHD will limit any request for PHI made to another health care provider, a health plan, or a health care clearinghouse to that which is reasonably necessary to accomplish the needed purposes.
   B. For requests made on a routine and recurring basis, SCHD has a protocol that limits the PHI requested to the amount reasonably necessary to accomplish the needed purposes.
   C. For requests on a non-routine or non-recurring basis, SCHD have developed criteria designed to limit the request for PHI to the information reasonably necessary to accomplish the needed purposes. SCHD will review such non-routine requests on an individual basis for conformance with these criteria.

4. For both routine and non-routine disclosures and requests, SCHD has identified the circumstances under which the entire medical record is reasonably necessary for particular purposes.
5. SCHD will reasonably rely on requests from the business associate of another health care provider, health plan or health care clearinghouse for the disclosure of PHI as meeting the minimum necessary requirement for the intended purpose.
6. SCHD will make reasonable expenditures to implement technologically feasible approaches in complying with this Minimum Necessary Policy – see Section 11 of this Manual: Safeguarding PHI.

Sampson County Health Department
Section 6: Uses and Disclosures of Protected Health Information- Opportunity to Agree or Object

Purpose:

To establish guidelines for the use and disclosure of protected health information (PHI).

Policy:

The Sampson County Health Department (SCHD) may use and disclose PHI in certain situations where it is necessary or beneficial to involve others in the patient's health care or to notify others of the patient's status or condition. In these situations, the patient has the opportunity to agree or object to the use or disclosure of all or part of the patient's PHI for these purposes.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part **§** 164.510.
45 CFR, Part § 164.514.

Responsible Persons:

All Sampson County Health Department workforce

Procedures:

Uses and Disclosures:

1. SCHD will make the following disclosures for involvement in the patient's care and notification purposes:

    A. Disclosing to a family member, other relative, close personal friend of the patient, or any other person identified by the patient, PHI that is directly relevant to that person's involvement in the patient's health care or payment related to the patient's health care.
    B. Using or disclosing PHI to notify, or assist in the notification of, a family member, a personal representative of the patient or another person who is responsible for the patient's care, of the patient's location, general condition or death.
    C. Disclosing PHI to any person identified in 1.A and .B above, who was involved in the patient's care or payment for the patient's health care prior to the patient's death, PHI of the patient that is relevant to such person's involvement, unless doing so is

inconsistent with any prior expressed preference of the individual that is known to SCHD.

2. If the patient is present or otherwise available prior to using or disclosing their PHI in this way, and the patient has the capacity to make health care decisions, SCHD will only disclose the information if SCHD:

   A. Provides the patient with the opportunity to agree or object to the disclosure, and the individual does not express an objection (SCHD can inform the patient orally and accept the patient's oral agreement or objection and will document such agreement or objection in the patient's medical record); or
   B. Can reasonably infer from the circumstances, based on professional judgment, the patient does not object to the disclosure.

3. If the patient is not present, or it is impractical to offer the patient the opportunity to agree or object to a use or disclosure of their PHI in these situations, because the individual is incapacitated or an emergency exists:

   A. SCHD will use professional judgment to determine whether the disclosure is in the best interests of the patient; and
   B. If SCHD determine disclosure is appropriate, SCHD will disclose only that PHI which is directly relevant to the person's involvement in the patient's care or payment related to the patient's health care or needed for notification purposes.

4. If the patient is not present, SCHD will use professional judgment and experience with common practice to allow another person acting on the patient's behalf to pick up medical supplies, or other similar forms of PHI because it is in the patient's best interest.
5. SCHD may use or may disclose a patient's PHI to a public or private entity authorized to assist in disaster relief efforts for coordinating with them in notifying family members or other individuals involved in the patient's health care. In such situations, SCHD will still follow the procedures of Subsections 1 through 4 of this Policy if, in SCHD's professional judgment, to do so will not interfere with the ability to respond to the emergency circumstances.

<u>Patient Request for Special Restrictions on Disclosures to Others:</u>

A patient may request that SCHD restrict disclosures otherwise allowed under this Policy. Any such requests will be directed to the Privacy Officer who may consult with the County's legal counsel.

Sampson County Health Department
Section 7: Access of Individuals to Protected Health Information (PHI)

Purpose:

To outline the steps when an individual makes a request to inspect and obtain a copy of the Protected Health Information (PHI)

Policy:

The Sampson County Health Department (SCHD), in accordance with this policy, will provide a patient the right to inspect and obtain a copy of the patient's PHI for as long as the agency maintains the information.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part § 164.524.

Responsible Persons:

All Sampson County Health Department workforce

Procedures:

General Procedures:

1. A patient of SCHD can request to inspect and/or obtain a copy of their PHI that is maintained in a Designated Record Set and SCHD will provide such access, unless access is to be limited as required in this Policy.
2. A Personal Representative of a patient may also be permitted to access the patient's PHI, in accordance with this Policy.
3. If SCHD does not maintain the PHI that is the subject of the request and SCHD is aware of where the requested information is maintained, SCHD will inform the patient where to direct the request for access.

Requests for Access and Responding to Requests:

1. All requests for inspection of a patient's PHI must be in writing.
2. Patients will be advised of the requirement in the Notice of Privacy Practices. The requests will be directed to the Privacy Officer.
3. SCHD may choose to provide a summary of the requested information. Patients will be advised in the Notice of Privacy Practices of this alternative. SCHD may only provide a

summary if the patient agrees in advance to receive a summary of their PHI.

4. The health department will respond to a request for inspection or copying within thirty (30) days of receipt of the written request.
5. If the patient requests, SCHD will mail the copy of the PHI or the summary of the PHI, as agreed upon, to another person specified by the patient if the patient's request is in a writing signed by the patient and clearly identifying the designated person and where to send the copy of the PHI.
6. If SCHD maintains an electronic health record that contains the PHI requested by the patient, the patient has the right to obtain a copy of that information in an electronic form and format they request, if it is readily producible; if not, a readable electronic form and format as agreed between SCHD and the patient will be provided.
7. The patient may choose to direct SCHD to transmit such copy directly to an entity or person designated by the patient, provided that any such choice is clear, conspicuous, and specific.
8. SCHD will charge a fee for the copy of the patient's PHI or for a summary of the PHI that is reasonable and cost-based, including in all cases any charge limits imposed by federal and/or state law.
9. Any fee imposed for providing an electronic copy or summary of PHI will not be greater than the labor costs accrued in responding to the request and the supplies for creating the electronic media if the individual requests that the electronic copy be provided on portable media, again as limited by federal or state law.
10. Patients will be notified in the SCHD Notice of Privacy Practices that a fee will be charged and patients will be advised of the fee.
11. SCHD will not refuse to provide a patient with a copy of his or her medical record due solely to the fact that the patient has an outstanding balance with the agency, when it is known to us that the record is needed by another health care professional for the purpose of rendering care to the patient. In all other cases, the copying fee must be paid prior to or at the time the copy is provided to the patient or personal representative. This includes clients calling in/walking in a requesting copies and clients that are in the building receiving services. The only exception will be clients in the building requesting a copy of their records for the services provided that day.
12. If the patient requests only to inspect his or her PHI, SCHD will arrange with the patient for a convenient time, no later than 30 days from the request, and place, if the inspection will not occur at SCHD.
13. All inspections of PHI by patients or personal representatives will be under the personal supervision of a designated SCHD staff member.
14. For any state or federal agency or official request, by subpoena or by demand for statement in writing under oath or otherwise, requests a patient's PHI, the SCHD Privacy Officer will contact the County legal counsel immediately.

<u>Denying or Limiting Access:</u>

1. SCHD may deny or limit access to a patient's PHI, ***<u>without any right to a review of</u>*** SCHD's decision, if the information:

    A. Is psychotherapy notes.
    B. Has been compiled in reasonable anticipation of, or for use in, a civil, criminal or administrative action or proceeding.
    C. Is that of an inmate in a correctional institution and SCHD's Medical Providers

were acting under the direction of the correctional institution, and certain circumstances exist which prohibit providing a copy of PHI to the inmate (to be determined by the SCHD Privacy Officer).

D. Was obtained by SCHD in the course of research that includes treatment of the research participant, while the research is in progress, under certain circumstances (to be determined by the SCHD Privacy Officer).

E. Is subject to the Privacy Act, as required by that Act.

F. Was obtained by SCHD from someone other than a health care provider, under a promise of confidentiality, and the requested access would be reasonably likely to reveal the source of the information.

2. SCHD may deny or limit access to a patient's PHI, ***with the right to a review of SCHD's decision, in the following situations:***

A. A licensed health care professional in the health department has determined that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person.

B. The information references another person (unless such other person is a health care provider) and a licensed health care professional has determined that the access requested is reasonably likely to cause substantial harm to that other person.

C. Access is requested by a personal representative of the patient and a licensed health care professional has determined that access by that person is reasonably likely to cause substantial harm to the patient or another person.

D. A licensed health care professional has reason to believe that the patient's mental or physical condition will be adversely affected upon being made aware of the subjective information contained in the PHI (or a summary of the PHI); in this case, the PHI can be provided, if requested by the patient (with an accompanying notice setting forth the reasons for the original refusal) directly to the patient's attorney, another licensed health care professional, the patient's health insurance carrier (through an employee of the carrier), or to a governmental reimbursement program or to an agent of such program who has responsibility to review utilization and/or quality of care.

3. The determination of whether to deny or limit access will be made by a licensed medical provider of SCHD in conjunction with the Privacy Officer.

4. SCHD will provide a patient with a written notice of denial or limitation of access which will contain: the reason for such denial or limitation; a statement of the patient's right to a review of the denial, if such right exists; how to exercise the review rights; and a description of SCHD's complaint procedures (see Section 13 of this Policy Manual), including the name or title and telephone number of the SCHD Privacy Officer as the contact person.

5. If SCHD denies the patient access to some of his/her PHI, SCHD will, to the extent possible, give the patient access to any other of the patient's PHI requested by the patient, where no grounds exist to deny such access.

Appeal of a Decision to Deny Access:

1. A patient may request a review of a denial of access that was made based on one of the reasons under the "Denying or Limiting Access" section above.
2. Requests for review of a denial of access must be in writing and will be directed to the Privacy Officer who will promptly refer the request for review by the person designated pursuant to #3 below.
3. Review of the denial of access will, within a reasonable period of time, be performed by a physician or other licensed health care professional designated by the SCHD Privacy Officer and who did not participate in the original decision to deny access.
4. Where no other physician or licensed health care professional of SCHD Practice exists or is available, the review will be conducted by another health care professional designated by the SCHD Privacy Officer.
5. The health department will conduct the review within a reasonable period of time and will attempt to conduct the review within 30 days of the request for review. Once the review is complete, SCHD will promptly provide a written response to the patient setting forth the decision of the reviewing professional and will provide access or deny access based on that decision.
6. SCHD will maintain a copy of the inspection/copying request form in the patient's medical record, including documentation on the form of the response, and the results of any appeal and review that may have occurred.

Sampson County Health Department
Section 8: Accounting for Disclosures of Protected Health Information (PHI)

Purpose:

To outline the procedure to be followed when an individual requests an accounting of disclosures of his or her Protected Health Information (PHI) made by a covered entity as defined in this section.

Policy:

The Sampson County Health Department (SCHD) will provide patients with an accounting of disclosures of their PHI as required under federal and state law and regulations.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules and Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part § 164.528.

Responsible Persons:

Health Department workforce

Procedures:

1. A patient of the SCHD may request and has a right to receive an accounting of disclosures the health department has made of the patient's PHI, except as limited by this Policy.
2. A patient may request an accounting for a time period of up to six (6) years prior to the date of his or her request. The accounting will include disclosures made to or by the business associates.
3. All requests must be in writing and will be directed to the SCHD Privacy Officer.
4. Accounting does not need to disclosures made:

    A. To carry out Treatment, Payment or Health Care Operations ("TPO") of SCHD, except as set forth in #8 below.
    B. To patients about their own PHI.
    C. Pursuant to an authorization made by the patient or the patient's personal representative regarding the patient's PHI.
    D. To individuals involved in the patient's care or for other allowed notification purposes.
    E. Incident to a use or disclosure otherwise permitted or required by the Privacy Rule and this Policy Manual.

F. For national security or intelligence purposes.
G. To correctional institutions or law enforcement officials.
H. As part of a Limited Data Set

5. In order to provide this accounting to the patients, SCHD will maintain a log or record of all disclosures, other than those excluded under #4 above, of a patient's PHI, for a six (6) year period along with a copy of every accounting made to a patient.
6. A request for an accounting of disclosures will be acted upon within sixty (60) days of receipt of the request.
7. A one-time thirty (30) day extension may be allowed if the patient has been notified, within the initial 60-day period, of the reasons for the delay and the date by which SCHD will provide the accounting.
8. SCHD may choose to provide an accounting of all disclosures made by the health department and by any Business Associate acting on SCHD's behalf; or an accounting of all disclosures made by SCHD and provide to the patient a list of all Business Associates acting on the behalf, including contact information for such Business Associates (such as mailing address, phone, and email address), in which case such Business Associates will provide an accounting of their disclosures upon a request made by SCHD's patient directly to the Business Associate. The SCHD Privacy Officer will determine which option is chosen.
9. For each disclosure for which SCHD is required to provide an accounting under this Policy, SCHD will maintain the following information and will provide the information in the accounting to the patient:

   A. The date of the disclosure.
   B. The name of the entity or person who received the PHI and, if known, the address of such entity or person.
   C. A brief description of the PHI disclosed.
   D. A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request by the DHHS Secretary for a disclosure to investigate or determine SCHD's compliance with the HIPAA privacy standard or a written request received for a disclosure made under "Section 3: Uses and Disclosures of Protected Health Information Not Requiring Patient Authorization."

10. If, during the period covered by the accounting, SCHD have made multiple disclosures of PHI to the same person or entity for a single purpose, the accounting may provide:

    A. The information required in this Policy for the first disclosure during the accounting period.
    B. The frequency, periodicity, or number of the disclosures made during the accounting period.
    C. The date of the last such disclosure during the accounting period.

11. If any disclosures of a patient's PHI involved a particular research purpose, the SCHD Privacy Officer will determine the manner of the agency log of disclosures and the manner of disclosing the accounting to the particular patient.
12. Accounting disclosure summaries will be provided to the client at no cost.

13. SCHD will temporarily suspend a patient's right to receive an accounting of disclosures that the Health Department has made to a health oversight agency or law enforcement official (see Section 3 of this Policy Manual), for the time specified by such agency or official, if such agency or official has provided SCHD with a written statement that such an accounting to the patient would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required. If the agency or official statement is made orally, SCHD will:

    A. Document the statement, including the identity of the agency or official making the statement.
    B. Temporarily suspend the patient's right to an accounting of disclosures subject to the statement.
    C. Limit the temporary suspension to no longer than thirty (30) days from the date of the oral statement, unless the appropriate written statement is submitted to us by the agency or official during that time.

Sampson County Health Department
Section 9: Amendment of Protected Health Information (PHI)

Purpose:

To comply with HIPAA requirements, which provides that individuals may seek to amend their Protected Health Information (PHI) maintained in a designated record set.

Policy:

The health department in accordance with this policy, will provide the patients the opportunity to request amendment of their PHI that we maintain and, where appropriate under this policy, the right to have their PHI amended.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations:
USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part § 164.526.

Responsible Persons:

Health Department workforce

Procedures:

Receiving and Acting Upon a Request for Amendment:

1. A SCHD patient can request to have his/her PHI amended. The SCHD Notice of Privacy Practices will advise all patients that such a request must be in writing and must state a specific reason supporting the requested amendment.
2. All requests for amendment of PHI will be directed to the SCHD Privacy Officer.
3. Action upon the request for amendment will occur within sixty (60) days of receipt.
4. A one-time extension of not more than thirty (30) days may be allowed if the health department, before the end of the initial sixty-day period, provides a written notice to the requestor of the reason for the delay and the date by which SCHD intends to complete its action on the request.
5. The Privacy Officer will track the progress of each request for amendment to attempt to ensure compliance with these timeframes.
6. The Privacy Officer will review the amendment request for the following elements:

    A. The reason for the requested amendment, such as how the information is

incorrect or incomplete.

B. Whether the requested amendment is for:

1. Administrative information; and/or
2. Medical information, including the source, if known, the date(s) of service, and the specific provider of service;

C. Whether the health department was the originator of the information.
D. The specific wording requested to correct the alleged inaccuracy or incompleteness.

7. The Privacy Officer will make a preliminary determination regarding whether an amendment request should be honored, and will then consult with the physician, other health care professional, or administrative staff person of SCHD who provided the care and/or made the entry that is the subject of the amendment.
8. If that physician, health care professional or administrative staff person agrees with the Privacy Officer's preliminary determination, the Privacy Officer will obtain final approval from a Medical Provider.
9. If such final approval is obtained, the Privacy Officer will proceed with the amendment or denial of amendment, pursuant to this policy.
10. If a determination as to whether to accept or deny the amendment cannot be made internally, the Privacy Officer will notify the County legal counsel and request a resolution of the disagreement.

<u>Denying a Request for Amendment:</u>

1. SCHD may deny a request for an amendment in the following situations:

A. SCHD did not create the information, unless the patient provides a reasonable basis to believe that the originator of the PHI is no longer available to act on the requested amendment.
B. The information is not part of the records for a patient.
C. The information would not otherwise be available for inspection (see Section 7 regarding Access to PHI).
D. The health department determines that the information in dispute is neither inaccurate nor incomplete.

2. If SCHD determines that it will deny a request for amendment, in whole or in part, the Privacy Officer will provide written notice to the requestor, within the timeframe stated in "Receiving and Acting Upon a Request for Amendment" #4 , advising of the decision to deny amendment, stating the reason for the denial, and advising of the complaint procedures – see Section 13 of this Policy Manual.
3. The written notice will also advise the requestor that the individual may submit to the Privacy Officer a written statement of disagreement with the denial, stating the basis for such disagreement.
4. In most cases, the length of the statement of disagreement will be limited to one (1) page, unless it is unreasonable in the particular circumstance to impose such a limit.
5. If the patient does not submit a statement of disagreement, the patient may request that

SCHD provide the patient's request for amendment, and the denial, with any future disclosures of the PHI that is the subject of the requested amendment.

6. If a statement of disagreement is received from a requestor, the Privacy Officer, in consultation with the pertinent physician, health care professional or administrative staff person, will determine whether to prepare a rebuttal statement. If a rebuttal statement is prepared, SCHD will provide a copy to the requestor.
7. The denial and the disagreement and rebuttal statement, if any--will be linked to the PHI in dispute by scanning and attaching these documents to the disputed information in the patient's record.
8. Whenever the disputed information is disclosed to another person or entity, the information will include the denial and, if any exists, the statement of disagreement and the rebuttal.
9. Alternatively, SCHD can provide a summary of any of the foregoing information.
10. If the patient has not submitted a statement of disagreement, SCHD will include the patient's request for amendment and the denial, or a summary of the information, with any future disclosure of the patient's PHI only if the patient has requested such action.
11. If such a subsequent disclosure is made using a standard transaction under the HIPAA Transaction Rule that cannot accommodate the denial, disagreement and rebuttal, SCHD will separately disclose the denial, disagreement, and rebuttal to the recipient of the transaction.

<u>Accepting the Request for Amendment:</u>

1. If a determination is made to make the requested amendment, the Privacy Officer will provide written notification to the requestor that the requested amendment has been approved and the exact wording of the amendment.
2. The SCHD Privacy Officer will seek the requestor's identification of, and agreement to, the relevant persons identified by the Privacy Officer as persons or entities with whom the amendment needs to be shared.
3. The requestor will have ten (10) days to object to the form of amendment or to the persons with whom the amendment will be shared. If no objection is received within that time period, the amendment will be made in the PHI and the identified parties notified.
4. The Privacy Officer will identify the records in the designated record set for the patient that are affected by the amendment and append or otherwise provide a link to the location of the amendment.
5. The Privacy Officer will, within a reasonable period of time (but no longer than thirty [30] days), take reasonable efforts, such as send written notification by certified mail with return receipt requested, to provide the exact wording of the amendment to:

    A. Such persons or entities that the patient has identified as having received the relevant portion of the patient's PHI from the health department; and
    B. Such persons, including SCHD business associate that SCHD has identified as having received the relevant portion of the patient's PHI from the health department and who may have relied, or could foreseeably rely, on such information to the detriment of the patient.

Making the Amendment:

1. The SCHD Privacy Officer, or his/her designee, will identify all media forms in which SCHD maintains the information to be amended, i.e., paper, microfiche, microfilm, automated data processing or other electronic medium, and will cross check across all systems and applications maintained by the agency to ensure that the amendment is made, stored (as necessary), and susceptible to audit trails.
2. In no case will the Privacy Officer, a physician or any other person of the SCHD delete, erase, and/or "white out" or otherwise obliterate medical information in a patient's record. Any correction or addition to a patient's PHI will be clearly identified as a correction or addition to the original and will be dated and initialed by the physician or other person who made the entry.

Requests for Amendment where SCHD was not the Originator of the Information:

1. If a request for amendment applies to information for which the health department was not the originator, the Privacy Officer will contact the requestor and advise the requestor to seek amendment from the originator of the information.
2. If the requestor notifies us of a reasonable basis to believe that the originator is no longer available to act on a requested amendment, the Privacy Officer will make a reasonable attempt to confirm the unavailability. If the originator's unavailability is confirmed, the health department will act on the request for amendment as though the health department created the information.

Amendments Received from Other Covered Entities:

1. If SCHD is informed by another health care provider, a health care plan or a health care clearinghouse of an amendment to a patient's PHI, SCHD will amend the patient's PHI that the agency maintains accordingly.
2. The Privacy Officer will:

    A. Document in the patient's record that the approved amendment has been received from another source and the identity of the source providing the amendment;
    B. Ensure that the amendment is properly made in the PHI that is held by the health department; and
    C. If the patient whose PHI is amended is a current patient of the health department, alert the treating provider(s) for that patient of the amendment that has been made.

Sampson County Health Department
Section 10: Business Associates

Purpose:

To establish guidelines and provide assurances from Sampson County Health Department (SCHD) business associates that the business associates will appropriately safeguard the protected health information (PHI) it receives or creates on behalf of SCHD.

Policy:

Before the Sampson County Health Department (SCHD) can disclose PHI to a Business Associate, or allow a Business Associate to create, receive, maintain or transmit PHI on the behalf, the health department will obtain satisfactory assurances that the Business Associate will use or disclose the PHI only as permitted or required by the Business Associate Agreement, will safeguard the PHI from misuse, will help the health department comply with its duties under HIPAA and the Data Breach Notification Rule, and will secure these same assurances from any Subcontractor of the Business Associate. The Business Associate cannot use or disclose PHI provided by us in any manner that would not be a permissible use or disclosure by the health department under the Privacy Rule.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations:
USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part § 164.103.
45 CFR, Part § 164.502(e).
45 CFR, Part § 164.504(e).
45 CFR, Part § 164.532 (d) & (e).

Responsible Persons:

Health Department workforce

Procedures:

Business Associates; Business Associate Agreements:

1. For each new arrangement in which SCHD plans to retain a person or entity to perform a function, activity or service on behalf of the agency, the Privacy Officer will first consult the definition of Business Associate in the Glossary of Terms to determine whether the person or entity is to be treated as a Business Associate of the health department.
2. The health department will enter into a written Business Associate Agreement with

every person or entity who meets the definition of a Business Associate as set forth in the Glossary. The Privacy Officer will consult the SCHD Business Associate Agreement and contact the the County legal counsel as necessary to assist in negotiation and/or preparation of the necessary agreement.

3. Any Business Associate Agreement the health department enters into will meet the requirements of 45 C.F.R. §164.504(e) (1).
4. If a Business Associate presents to the health department the Business Associate's own proposed Business Associate Agreement, the Privacy Officer will compare the proposed agreement to the SCHD Business Associate Agreement and contact the County legal counsel as necessary to assist in negotiation of necessary revisions to the proposed agreement(s).
5. If SCHD has a Business Associate Agreement with an existing Business Associate Agreement that does not address requirements under the Data Breach Notification Rule or is not in compliance with the HITECH Act, SCHD will enter into an Amended and Restated Business Associate Agreement and contact the County legal counsel as necessary for assistance.

Confidentiality Agreements:

If the Privacy Officer identifies a person or entity that is not a Business Associate and who may have more than incidental or inadvertent access or exposure to PHI held by the SCHD, the Privacy Officer will seek to enter into a confidentiality agreement with that person or entity and will obtain the advice of the County legal counsel as necessary.

Responding to Violations by a Business Associate:

1. If any SCHD workforce receives any information leading him/her to believe that a SCHD Business Associate (or an employee or agent of one of the Business Associates) is violating a provision of the Business Associate Agreement or is engaged in some activity that could result in a violation of SCHD privacy policies and procedures, that person will immediately notify and provide that information to the Privacy Officer.
2. The Privacy Officer will keep a record of information provided to him/her pursuant to #1 above. If the information provided appears credible, the Privacy Officer:

    A. Will contact the Business Associate to discuss the problem; or
    B. May contact the County legal counsel prior to contacting the Business Associate.

3. If the information received by the Privacy Officer reflects a pattern of activity or practice of the Business Associate that constitutes a material breach or violation of the Business Associate's obligations under the agreement with that entity or person, the Privacy Officer will notify the County legal counsel for further action as required by the HIPAA Privacy Rule.

Sampson County Health Department
Section 11: Safeguarding Protected Health Information (PHI)

Purpose:

To establish guidelines for safeguarding protected health information (PHI).

Policy:

The health department will provide appropriate administrative, technical, and physical safeguards to try to reasonably safeguard the patients' PHI.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations:

USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part § 164.530 (c).

Responsible Persons:

Health Department workforce

Procedures:

Safeguard Implementation:

1. The health department will implement safeguards to reasonably:

    A. Protect SCHD patients' PHI from intentional or unintentional use or disclosure in violation of the Privacy Rule and the policies and procedures; and
    B. Limit incidental uses or disclosures that may occur as a result of an otherwise permitted or required use or disclosure of PHI.

2. In determining what type of safeguards to implement, SCHD will take into consideration agency needs and circumstances, such as:

    A. The nature of the PHI held.
    B. The potential risks to patients' privacy
    C. The potential effects on patient care.
    D. The financial and administrative burden of implementing particular safeguards.

Types of Safeguards:

Types of safeguards include:

1. Development, implementation, and periodic review and revision of the policies and procedures in HIPAA Policy Manual.
2. The designation of the Privacy Officer as the person responsible for implementing policies and procedures, receiving complaints, and, along with his/her designee, providing information regarding SCHD's Notice of Privacy Practices.
3. Examples of types of safeguards may include:

    A. Proper storage and disposal of documents and records
    B. Speaking quietly when discussing a client's condition with family members in the lobby or other public area.
    C. Avoiding use of clients' name in public hallways and other public areas of the agency.
    D. Refer to the SCHD Information Security Policy for further details.

4. In areas where multiple patient-staff communications routinely occur, use of private offices with doors, cubicles, dividers, shields, curtains, or similar barriers as is reasonable for the agency.
5. Posting signs to remind employees to protect patient confidentiality.
6. Utilizing a patient sign-in sheet that does not include any of a patient's health information and, when calling out patient names or addressing patients in the waiting area, limiting the information disclosed, such as referring the patients to an area in the agency where they can receive further instructions in a more confidential manner.
7. Eliminating the posting of PHI in public areas where unauthorized persons can view the information.
8. Isolating or locking file cabinets or records rooms, or otherwise restricting medical records from access by unauthorized persons, such as maintaining reasonable supervision of these areas.
9. Computer Use:

    A. When maintaining computers outside of exam rooms, using such measures as reasonably limit access to these areas, such as ensuring that the area is supervised, escorting non-SCHD workforce in the area, and/or placing patient records in their holders with identifying information facing the door or wall or otherwise covered to ensure health information about the patient is not visible to others.
    B. Imposing security measures on computers and other systems containing PHI, such as restrictions on workstation use, unique user ID's and strong passwords to access such computers, and firewalls.
    C. Limiting visual access to computer monitors to avoid incidental disclosure of information to unauthorized persons by utilizing screen protectors, automatic screen-savers with password re-entry, inactive screen time limits and automatic log-off.

10. Determining which SCHD workforce has access to keys and/or combinations to gain access to offices and/or to areas housing PHI and limiting such access to those whose duties require this level of access.

11. Establishing a disaster recovery plan, both for paper and electronic records.
12. Establishing a reporting and response system for security violations, in conjunction with SCHD's Data Breach Notification Policy.
13. Providing periodic security awareness training to SCHD workforce – see Section 12: Training.

References:

SCHD Information Security Policy

Sampson County Health Department
Section 12: Training

Purpose:

To establish and provide training for the Sampson County Health Department (SCHD) workforce.

Policy:

The Sampson County Health Department will provide training to all SCHD workforce on the policies and procedures of the HIPAA Policy Manual, as necessary and appropriate for them to carry out their function and duties within the department.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations:
USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part **§** 164.530 (b).

Responsible Persons:

Sampson County Health Department workforce

Procedures:

1. The Privacy Officer will develop and implement a training program for SCHD workforce to include the following:

    A. Making a copy of the HIPAA Policy Manual available to all Members of SCHD workforce for:

        1. Reviewing each section of the Manual prior to training.
        2. Individual review of the Manual
        3. Consulting the Manual on an as-needed basis.

    B. Informal awareness training regarding privacy and security of PHI, including application of the minimum necessary principle for disclosure of PHI see Section 5.
    C. Periodic reminders about the need to make good faith efforts to maintain the privacy and security of SCHD patients' PHI.
    D. Education concerning computer virus protection, detection, and response to a virus infection.
    E. Education about the importance of a computer use requirements, secure login and SCHD's policy regarding creating, changing, and protecting the confidentiality of

computer passwords and other security measures.

2. The health department will provide HIPAA training as follows:

   A. To each new employee within thirty (30) days of hire.
   B. Annually to all SCHD workforce.
   C. To SCHD workforce whose job functions are affected by:

      1. A material change in SCHD's HIPAA policies and/or procedures; or
      2. A material change in the HIPAA Privacy Rule, with such training to occur within a reasonable period of time after the material change becomes effective.

   D. SCHD workforce will sign a log indicating the date and content of training received.

3. All new workforce will sign a confidentiality agreement stating that:

   1. The person has reviewed and understands SCHD's HIPAA privacy policies and procedures.
   2. The person will comply with the HIPAA policies and procedures.
   3. The person understands it is his/her responsibility to protect and maintain the privacy and security of SCHD patients' PHI.

4. The Privacy Officer will maintain records documenting that the training required by this policy is provided.

Sampson County Health Department
Section 13: Privacy Rule Complaints to the Agency -Mitigation

Purpose:

To address the patient's right to file a complaint if a person believes Sampson County Health Department (SCHD) is: not complying with the requirements of the HIPAA Privacy Rule or SCHD's privacy policies and procedures; or has complaints concerning the health department's own privacy policies and procedures.

Policy:

The Health Department will assure a patient's right to file a complaint with the Sampson County Health Department (SCHD) and the Secretary of the Department of Health and Human Services if the patient believes privacy rights were violated and will assure that complaint investigations meet the requirements of the privacy rule. This policy will establish the procedure for the reception, investigation and resolution of privacy complaints at the SCHD.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations:
USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part **§** 164.530 (d) & (f).

Responsible Persons:

Sampson County Health Department workforce

Procedures:

General Procedures:

1. A SCHD patient who has a complaint about HIPAA policies and procedures regarding the handling of PHI, about SCHD's compliance with such policies and procedures or with the Privacy Rule, may file a complaint with the Privacy Officer.
2. A complaint must be filed within 180 days in writing of when the person filing knew, or should have known, that the act of omission occurred, and must state the specific nature of the problem with SCHD policies and procedures or the specific area of alleged non-compliance.
3. The Privacy Officer will acknowledge to the patient, in writing, that SCHD received the complaint and that it will be addressed appropriately and a response provided to the patient.
4. As specified in Section 2: Notice of Privacy Practices, a patient may also file a complaint directly with the Office for Civil Rights (OCR) - see the Glossary.

5. The address for filing a complaint with the OCR will be provided to any person, upon request:

   Timothy Noonan, Regional Manager
   Office for Civil Rights
   U.S. Department of Health and Human Services Sam Nun Atlanta Federal Center,
   Suite 16T70
   61 Forsythe Street, S.W.
   Atlanta, GA 30303-8909
   Customer Response Center: (800) 368-1019
   Fax: (202) 619-3818
   TDD: (800) 537-7697
   Email: ocrmail@dhhs.gov

6. A complaint to SCHD will be acted upon as soon as reasonably possible and at least within thirty (30) days of receipt of the complaint.
7. Upon receipt of a complaint, the Privacy Officer will review the complaint and may notify the County legal counsel for retention in reviewing, investigating, and formulating a response to the complaint.
8. Once the investigation into the complaint has been concluded, the Privacy Officer, in conjunction with legal counsel, will formulate an appropriate response to the complainant.
9. If the investigation of the complaint revealed a problem with SCHD policies and procedures, or a failure to comply with such policies and procedures or with applicable law or regulations, the Privacy Officer, in conjunction with the County legal counsel, will formulate corrective action intended to remedy the problem or non-compliance including, as appropriate, imposing sanctions pursuant to Section 15 of this Manual.
10. If the violation is found to involve a Business Associate of the department, SCHD will take the steps required by Section 10 of this Policy Manual, regarding the health department's Business Associates.
11. The SCHD Privacy Officer will document all complaints received and their disposition.
12. Any correspondence or communication SCHD receives from the OCR--whether regarding the investigation of a complaint, a compliance review, or otherwise--will be immediately provided to the Privacy Officer who will notify the County legal counsel to assist in responding to the OCR. Our Practice will cooperate with the OCR and provide access as required by the HIPAA Privacy Rule.

<u>Mitigation:</u>

1. The Privacy Officer will take reasonable efforts to mitigate, to the extent practicable, any harmful effect that is actually known to the department of a use or disclosure of PHI by SCHD or by one of the agency's Business Associates, in violation of SCHD's HIPAA policies and procedures or the requirements of law.
2. The Privacy Officer will implement SCHD's Data Breach Notification Section of the SCHD Information Security Policy, to determine if any notice is required and what mitigation efforts should be undertaken

Sampson County Health Department
Section 14: No retaliation for the Exercise of Rights/Filing Complaints/No Waiver of Rights

Purpose:

To assure that Sampson County Health Department (SCHD) patients have the right to file a complaint regarding privacy rules and not fear retaliation.

Policy:

The health department will not intimidate, threaten, coerce, discriminate against or take other retaliatory action against any individual who exercises, or attempts to exercise, his or her rights under the HIPAA Privacy Rule or who files a complaint or otherwise participates in HIPAA compliance efforts as described in this policy. Our Practice will not require an individual to waive his or her rights under the HIPAA Privacy Rule as a condition of receiving treatment from the Practice.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations:
USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part § 164.530 (g) & (h).

Responsible Persons:

Sampson County Health Department workforce

Procedures:

1. All requests for access, amendment, copying, authorizations, acknowledgments, and accountings related to the PHI of a patient of the health department will be handled in accordance with HIPAA laws and the SCHD HIPAA Policy Manual.
2. All complaints regarding privacy policies and procedures, or about SCHD compliance with the HIPAA Policy Manual, will be handled in accordance with this Policy Manual and no patient, personal representative, or workforce member will be retaliated against in any way for:

    A. Filing a complaint with the Privacy Officer or with the Secretary of Health and Human Services (Office for Civil Rights) pursuant to Section 13 of this Policy Manual.
    B. Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing related to the Privacy Rule.
    C. Opposing any act or practice that is unlawful under the HIPAA Privacy Rule,

provided the person has a good faith belief that the practice opposed is unlawful, and the manner of the opposition is reasonable and does not involve a disclosure of PHI made in violation of the HIPAA Privacy Rule.

2. Workforce members are encouraged to contact the Privacy Officer for clarification in the event of confusion or questions concerning any part of this Policy Manual.
3. workforce members are encouraged to and will immediately report, in good faith, to the SCHD Privacy Officer any knowledge of a violation of this Policy Manual by a member of the SCHD workforce or by a Business Associate, or a violation of this policy of non-retaliation and non-waiver of rights.
4. If SCHD receives information that this policy may have been violated, the Privacy Officer will promptly investigate the report of retaliation and will consult with the County legal counsel regarding the matter as necessary.
5. Any workforce member found to have violated this policy will be sanctioned according to the provisions of Section 15 of this Manual and consistent with the workforce policies.

Sampson County Health Department
Section 15: Sanctions for Violations of Privacy; Exceptions to Sanctions

Purpose:

To ensure all Sampson County Health Department (SCHD) workforce members read and understand HIPAA policies and procedures and the associated consequences of any violations whether intentional or unintentional.

To ensure SCHD patients' protected health information (PHI) is kept confidential.

To provide guidance or immediate mitigation of any breach of privacy.

Policy:

Sampson County Health Department (SCHD) will apply appropriate sanctions against any member of the workforce who fails to comply with the policies and procedures in this Policy Manual or the requirements of the Privacy Rule. Sanctions will not be imposed, however, under certain circumstances described in this Policy.

Definitions:

This Manual has a Glossary of Terms that explains terms used in the Manual – refer to the Appendix, Attachment B.

Applicable Laws, Rules & Regulations:
USC Public Law 104-191: Health Insurance Portability & Accountability Act (HIPAA) of 1996.
45 CFR, Part § 164.502 (j).
45 CFR, Part § 164.530 (e) & (g) (2).

Responsible Persons:

Sampson County Health Department workforce

Procedures:

General Sanctions Policy:

1. SCHD will receive patient complaints regarding the agency's compliance with the Privacy Policies and Procedures or with the Privacy Rule; SCHD may learn of non-compliance issues through allegations of violations received internally from workforce members.
2. Such complaints will be handled in accordance with Section 13 of this Manual.
3. Workforce members are encouraged to make the Privacy Officer aware of any concerns regarding compliance with SCHD's Privacy Policies or with the Privacy Rule. Any allegations of noncompliance are to be made in good faith, and in accordance with this

Manual.

4. All allegations of a violation by a workforce member of a provision of this Policy Manual will be investigated.
5. Appropriate disciplinary action will be taken whenever it is determined that a workforce member committed a significant violation of this Policy Manual or the Privacy Rule.
6. The established disciplinary procedures and processes are applicable to all workforce members as defined in the glossary of terms.
7. The determination of the disciplinary measures to be imposed will be made on a case-specific basis, appropriate to the nature of the violation, and in accordance with workforce policies. The factors to consider may include:

    A. The severity of the violation.
    B. Whether the violation was intentional or unintentional.
    C. Whether there has been a pattern of noncompliance by the workforce member.

8. Disciplinary actions may include:

    A. Counseling
    B. Written warning
    C. Suspension without pay
    D. Dismissal

9. Per Section 12 of this HIPAA Manual, SCHD has procedures in place requiring the workforce members to:

    A. Receive HIPAA training upon hire and annually to ensure and understanding of federal and state HIPAA laws, rules and regulations.
    B. Review and become familiar with this Manual's privacy policies and procedures to ensure an understanding of expectations regarding PHI, privacy and that noncompliance could result in sanctions.
    C. Such training will include the specific requirements regarding impermissible disclosures.

10. The Privacy Officer will be responsible for documenting all sanctions and disciplinary action resulting from a violation.

<u>Exceptions to Sanctions:</u>

1. Sanctions will not apply to a member of the workforce with respect to activities, where the specific requirements for each type of activity or disclosure is met.
2. Actions taken in pursuit of compliance with the Privacy Rule
3. SCHD will not intimidate, threaten, coerce, discriminate against or take other retaliatory action against workforce members or others who:

    A. File a complaint with the Secretary of Health & Human Services, or the Office for Civil Rights.
    B. Testify, assist or participate in an investigation or a compliance review, proceeding or hearing related to OCR's enforcement of the Privacy Rule.

C. Oppose any act or practice made unlawful by the Privacy Rule, provided the person has a good faith belief that the act or Practice is unlawful, and the manner of the opposition is reasonable and does not involve disclosures of PHI in violation of the Privacy Rule.

Implementation of Policy:

1. Violations of the HIPAA Privacy and Security Policy include, but are not limited to:

   A. Accessing PHI date that you do not need in order to perform the work functions.
   B. Discussing confidential information with an unauthorized individual.
   C. Failing/refuse to cooperate with an investigation by the division/facility Privacy and Security officer.
   D. Copying PHI with authorization.
   E. Unauthorized disclosure or use of PHI.
   F. Unpermitted use of another person's computer access in order to obtain PHI.
   G. Obtaining PHI under false pretenses.
   H. Using and/or disclosing PHI for commercial gain, advantage or malicious harm.
   I. Retaining PHI for commercial gain, advantage or malicious harm.

2. Violations of the HIPAA privacy and security policy may be considered unacceptable personal conduct as defined in the county resolutions and may result in disciplinary action up to and including immediate dismissal.
3. Violations my also carry federal civil and/or criminal penalties, and state criminal penalties.

Whistleblowers:

SCHD will not impose sanctions or otherwise retaliate against a member of the workforce or a Business Associate of SCHD who discloses PHI in the following circumstances:

1. The individual believes that the conduct at issue (which requires the disclosure of PHI in order for the individual to report the conduct) is unlawful or otherwise violates professional or clinical standards, or that the care, services or conditions provided by SCHD potentially endangers one or more patients, workers or the public
2. AND if the disclosure is made to one of the following:

   A. A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the Practice.
   B. An appropriate health care accreditation organization for the purpose of reporting the allegation of misconduct or failure to meet professional standards or misconduct by the Practice.
   C. An attorney retained by or on behalf of the member of the workforce or Business Associate for the purpose of determining the person's legal options and/or obligations with regard to the agency's conduct.

Victims of Crime:

SCHD will not impose sanctions or otherwise retaliate against a member of the workforce who is the victim of a criminal act and discloses PHI related to the crime, provided that:

1. The disclosure is to a law enforcement official;
2. The PHI disclosed is about the suspected perpetrator of the criminal act; **and**
3. The PHI disclosed is limited to the following information:

    A. Name and address;
    B. Date and place of birth;
    C. Social security number;
    D. ABO blood type and Rh factor;
    E. Type of injury;
    F. Date and time of treatment;
    G. Date and time of death, if applicable; and
    H. A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair, scars, and tattoos.

Sampson County Health Department
Section 16: Communication by Texting, Appointment Card, Phone Call & Letter

Purpose:

To provide guidance regarding the use of text messaging between health department staff and clients

To provide guidance regarding the use of appointment cards during correspondence with health department clients

To provide guidance regarding the use of telephone calls and/or messages during correspondence with health department clients

To provide guidance regarding the use of letters for correspondence with health department clients

Policy:

It is the policy of the Sampson County Health Department (SCHD) to ensure compliance with the Health Information Portability and Accountability Act (HIPAA) of 1996 to include appropriate use of correspondence between SCHD staff and clients. This policy is intended to provide guidance to staff to ensure correspondence meets all HIPAA guidance and expectations regarding the use of test messaging, appointment cards and return addresses.

Definitions:

HIPAA: The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, that includes Administrative Simplification provisions requiring HHS to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security; provides mandated protections for individually identifiable health information.

HHS published a final Privacy Rule in December 2000, which was later modified in August 2002. This Rule set national standards for the protection of individually identifiable health information by three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct the standard health care transactions electronically. Compliance with the Privacy Rule was required as of April 14, 2003 (April 14, 2004, for small health plans).

HHS published a final Security Rule in February 2003. This Rule sets national standards for protecting the confidentiality, integrity, and availability of electronic protected health information. Compliance with the Security Rule was required as of April 20, 2005 (April 20, 2006 for small health plans). Source: www.hhs.gov.

Applicable Law, Rules & Regulations:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Responsible Person(s):

All staff

Procedures:

Texting:

1. Texting between staff and clients is not recommended and should only be used on an as needed basis. This may include communication between outreach staff and clients.
2. Texting communication can NOT contain any personal identifying information regarding the client. This includes, but is not limited to:

    A. Date of Birth
    B. Social Security Number
    C. Medical Record Number
    D. Any other personal medical information that is unique to the individual

3. Client confidentiality is to be protected at all times.
4. Staff is to confirm with the client that they wish to communicate via texting and document in the client's record.
5. Texting may ONLY be done on work cell phones, never on personal phones.
6. The message will be deleted from the phone after it is sent.
7. Work cell phones used for texting must have a password and/or PIN and be used when the phone is not in use.
8. Any lost/stolen work phone is to be reported to the health director immediately.
9. Communication can NOT include specific information. Specific organization names, program names or the reason for the contact are not to be used during communication.
10. Communication must be general and contain general information, such as the name of the person texting/calling, a number to call back, the date/time of an appointment. See Appendix: Attachment H.
11. All staff is to be aware that cell phone conversations and text messages are kept in servers for unknown lengths of time. Cell phone companies are NOT subject to HIPAA.
12. Information may also be accessed by law enforcement without cooperation from SCHD.

Appointment Cards:

1. Appointment cards must meet HIPAA information requirements and should only include the minimal information necessary to ensure correct communication. This may include:

    A. Name of the Agency/Phone Number
    B. Name of the Client

C. Date of Appointment
D. Time of Appointment

2. Appointment cards may NOT contain the reason for the appointment, such as STD Clinic or FP Clinic.
3. Mailed appointment cards should be fold-over or in envelopes rather than post cards to help ensure confidentiality.

Phone Calls/Phone Messages:

1. Phone calls/messages must meet HIPAA information requirements and should only include the minimal information necessary to ensure correct communication. This may include:

   A. Name of the Agency/Phone Number
   B. Date of Appointment
   C. Time of Appointment
      OR
   D. Message to contact provider

2. A message may be left with a family member or other person who answers the phone when the patient is not home. The Privacy Rule allows the disclosure of limited information. This may include:

   A. Name of Agency/Phone Number
   B. Message to contact provider

Letters:

1. All letters MUST be sealed to ensure privacy.
2. Return addresses on SCHD business envelopes are permissible under HIPAA.
3. Minimum information is to be used on the return address. This includes:

   A. Name of the agency
   B. Street/Mailing Address
   C. City
   D. State
   E. Zip Code
   F. The Number Code of the program/clinic for mail billing purposes – see Appendix Attachment H.

3. The specific name of the program/clinic can NOT be listed on the envelope.

Confidential Communications:

If a patient has requested communication in a confidential manner, such as by alternative means (i.e., another phone number or address) or at an alternative location, the agency must accommodate the request.

References:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA).
Sampson County Health Department Administrative Manual
Attachment H: Guidance from Frances Q. Taylor, NC DHHS HIPAA Liaison

APPENDIX

GLOSSARY OF TERMS

Authorization - The permission granted by a patient, or the patient's Personal Representative, to use Protected Health Information for specified purposes or to disclose Protected Health Information to a third party specified by the individual. An *Authorization Form* is the document that reflects this permission.

Breach - With certain exceptions, the acquisition, access, use or disclosure of PHI in a manner not permitted under the Privacy Rule which compromises the security or privacy of the PHI.

Business Associate - With certain exceptions, a person or entity that: (1) creates, receives, maintains, or transmits PHI for a function or activity regulated by the Privacy Rule or (2) provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for the practice, or to or for an Organized Health Care Arrangement in which the practice participates, where the provision of the service involves the disclosure of protected health information from the practice or OCHA, or from the Business Associate, to the person. A Business Associate does not include a member of the Covered Entity's workforce nor a health care provider with respect to disclosures by the Covered Entity to the health care provider concerning the treatment of a patient. A Business Associate includes: a personal health record vendor, Health Information Organization, and an E-prescribing Gateway or other organization that provides data transmission of PHI to a Covered Entity and requires access to such PHI on a routine basis but not organizations that are mere conduits for the transport of PHI and do not access the information other than on a random or infrequent basis. A Business Associate is also a subcontractor that creates, receives, maintains or transmits PHI on behalf of a Business Associate.

Business Associate Agreement - A Covered Entity's written agreement with its Business Associate, setting forth the Business Associate's obligations related to the Covered Entity's PHI.

Correctional Institution - Any penal or correctional facility, jail, reformatory, detention Practice, work farm, halfway house, or residential community program Practice operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons* held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses or others awaiting charges or trial. *Inmate* is a person incarcerated in or otherwise confined to a correctional institution. *Covered Entity* - A health care provider who conducts certain financial and administrative transactions electronically for which standards have been adopted under HIPAA, such as electronic billing. Health Plans and Healthcare Clearinghouses are also Covered Entities.

Data Breach – See the Practice's Data Breach Notification Policy.

Designated Record Set - Basically a group of records which a Covered Entity uses to make decisions about individuals, and includes a health care provider's medical records and billing

records, and a health plan's enrollment, payment, claims adjudication, and case or medical management record systems. A *record,* for purposes of a Designated Record Set, means any item, collection or grouping of information that includes PHI and is maintained, collected, used or disseminated by or for a Covered Entity.

Direct Treatment Relationship - A treatment relationship between an individual and a health care provider that is not an Indirect Treatment Relationship.

Disclosure - The release, transfer, provision of access to, or divulging in any other manner, of information outside the entity holding the information.

Electronic Health Record – An electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.

Electronic Media - (1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet or intranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form immediately before the transmission.
Electronic Protected Health Information (EPHI) -

Family Member - An individual's: (1) dependent; or (2) any other person who is a first-degree, second-degree, third-degree, or ftheth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents). First-degree relatives include parents, spouses, siblings, and children. Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces. Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins. Ftheth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

Health Care – Health care includes, but is not limited to, the following: Preventive, diagnostic, therapeutic, rehabilitative maintenance, or palliative care, and counseling service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health Care Clearinghouse - A public or private entity that either: (1) processes or facilitates the processing of health information received from another entity in a nonstandard format or

containing nonstandard data content into standard data elements or a standard transaction; or (2) receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health Care Operations - Certain administrative, financial, legal, and quality improvement activities of a Covered Entity that are necessary to run its business and to support the core functions of treatment and payment. These activities are limited to the activities listed in the definition of "health care operations" at 45 CFR 164.501, such as : conducting quality assessment and improvement activities and case management and care coordination; reviewing the competence or qualifications of health care professionals, training health care and non-health care professionals, accreditation, certification, licensing, or credentialing activities; conducting or arranging for medical review, legal, and auditing services, including fraud and abuse detection and compliance programs; business planning and development; and business management and general administrative activities, including those related to implementing and complying with the Privacy Rule and other HIPAA rules, customer service, resolution of internal grievances, sale or transfer of assets, and creating de-identified health information or a Limited Data Set.

Health Information - Any information, including genetic information, whether oral or recorded in any form or medium, created or received by a provider that relates to the past, present, or future physical or mental health condition of a patient; the provision of healthcare to a patient; or the past, present or future payment for the provision of healthcare to a patient.

Health Oversight Agency - An agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Health Plan - An individual or group plan that provides for, or pays the cost of, medical care.

HHS - The U.S. Department of Health & Senior Services (see *Secretary*). *HIPAA* - The Health Insurance Portability and Accountability Act of 1996.

HITECH – The Health Information Technology for Economic and Clinical Health Act.

Incidental use or disclosure - A secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and that occurs as a result of a use or disclosure permitted by the Privacy Rule.

Indirect Treatment Relationship - A relationship between an individual and a health care provider in which: (1) the health care provider delivers health care to the individual based on the orders of another health care provider; and (2) the health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Individual - The person who is the subject of Protected Health Information.

Institutional Review Board or *IRB* or *Privacy Board* - Within the provisions of the institutional review board (IRB) rules (21 CFR, Part 56) are requirements that the IRB ensure that there are adequate provisions to protect the privacy of research subjects and to maintain the confidentiality of research data.

Law Enforcement Official - An officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to: (1) investigate or conduct an official inquiry into a potential violation of law; or (2) prosecute or otherwise conduct a criminal, civil or administrative proceeding arising from an alleged violation of law.

Limited Data Set – A Limited Data Set is PHI that excludes the following direct identifiers of the individual or of relatives, employers or household members of the individual:

Names;
Postal address information, other than town or city, State, and zip code;
Telephone numbers;
Fax numbers;
Electronic mail addresses;
Social security numbers;
Medical record numbers;
Health plan beneficiary numbers;
Account numbers;
Certificate/license numbers;
Vehicle identifiers and serial numbers, including license plate numbers;
Device identifiers and serial numbers;
Web Universal Resthece Locators (URLs);
Internet Protocol (IP) address numbers;
Biometric identifiers, including finger and voice prints; and
Full face photographic images and any comparable images.

Marketing - Marketing means:

(Except as provided in (2) below) to make a communication about a product or service that enctheages recipients of the communication to purchase or use the product or service.

Marketing <u>does not</u> include a communication made:
to provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the Covered Entity in exchange for making the communication is reasonably related to the Covered Entity's cost of making the communication;
for the following treatment and health care operations purposes, except where the Covered Entity receives financial remuneration in exchange for making the communication:

(A) for treatment of an individual by a health care provider including: case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or setting of care to the individual;

(B) to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the Covered Entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health0related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; or

(C) for case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment.

Financial remuneration means direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.

Minimum Necessary - The principle that a Covered Entity, when using or disclosing PHI, or when requesting PHI from another Covered Entity, must make reasonable efforts to limit such PHI, to the extent practicable, to the *Limited Data Set* or, if needed by the Covered Entity, to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. The Secretary of HHS will issue guidance on what constitutes "minimum necessary."

OCR - The Office for Civil Rights of the U.S. Department of Health & Human Services. OCR is the federal agency charged with enforcing the Privacy Rule and receives complaints regarding same. The OCR address for filing complaints related to SCHD is the Southeast Region – Atlanta OCR Office:
Timothy Noonan, Regional Manager
Office for Civil Rights
U.S. Department of Health and Human Services Sam Nun Atlanta Federal Center,
Suite 16T70
61 Forsythe Street, S.W.
Atlanta, GA 30303-8909
Customer Response Center: (800) 368-1019
Fax: (202) 619-3818
TDD: (800) 537-7697
Email: ocrmail@dhhs.gov

Organized Health Care Arrangement (OHCA) - An Organized Health Care Arrangement is: (1) a clinically integrated care setting in which individuals typically receive health care from more than one health care provider; or (2) an organized system of health care in which more than one Covered Entity participates, and in which the participating Covered Entities: (i) hold themselves out to the public as participating in a joint arrangement; and (ii) participate in joint activities that include at least one of the following: (A) utilization review, in which health care decisions by

participating Covered Entities are reviewed by other participating Covered Entities or by a third party on their behalf; (B) quality assessment and improvement activities, in which treatment provided by participating Covered Entities is assessed by other participating Covered Entities or by a third party on their behalf; or (C) payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating Covered Entities through the joint arrangement and if PHI created or received by a Covered Entity is reviewed by other participating Covered Entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

Payment - The various activities of health care providers to obtain payment or be reimbursed for their services and of a Health Plan to obtain premiums, to fulfill their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care. It includes billing and collection activities, determining eligibility or coverage under a plan and adjudicating claims, reviewing health care services for medical necessity, coverage, justification of charges, etc., utilization review activities (including precertification and preauthorization of services, concurrent and retrospective review of services), and disclosures to consumer reporting agencies of any of the following PHI relating to collection of premiums or reimbursement: name and address; date of birth; social security number; payment history; account number; and name and address of the health care provider and/or Health Plan.

Personal Representative - Under the Privacy Rule, a person authorized under State or other applicable law to act on behalf of the individual in making health care related decisions is the individual's personal representative. Except in certain limited situations specified in the Privacy Rule, a Covered Entity is required to treat an individual's Personal Representative as the individual with respect to uses and disclosures of the individual's PHI, as well as with respect to the individual's rights under the Privacy Rule. *PHI* - Protected Health Information. Protected Health Information is individually identifiable health information that is: (i) transmitted by electronic media; (ii) maintained in any electronic medium; or (iii) transmitted or maintained in any other form or medium, but does not include certain education records covered by the Family Educational Rights and Privacy Act or employment records held by a Covered Entity in its role as an employer. A Covered Entity need only comply with the requirements of the Privacy Rule with respect to the PHI of a deceased individual for a period of 50 years following the death of the individual.

Privacy Act means the Privacy Act of 1974 (5 U.S.C., section 552A).

Privacy Contact - The person or persons designated by the Practice to answer questions and provide information to patients and others about the Notice of Privacy Practices and the policies and procedures, if this role is not filled by the Privacy Officer.

Privacy Rule - The Standards for Privacy of Individually Identifiable Health Information, 45 CFR Parts 160 and 164.

Privacy Officer - The person designated by the Practice to oversee the development and implementation of the Practice's privacy policies and procedures and, where not delegated to a Privacy Contact(s), the person who receives complaints about the privacy practices and answers

questions about the Notice of Privacy Practices.

Psychotherapy Notes - Notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. It excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnoses, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public Health Authority - An agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. Examples of a public health authority include State and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Occupational Safety and Health Administration (OSHA).

Required by Law - A mandate contained in law that compels a Covered Entity to make a use or disclosure of PHI and that is enforceable in a cthet of law, e.g., cthet orders, cthet-ordered warrants, subpoenas, and summons; a civil investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

Research - A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Sale of PHI – With certain exceptions set forth at 45 CFR §164.502(a)(5)(ii)(B)(2), a disclosure of PHI by a Covered Entity or Business Associate, if applicable, where the Covered Entity or Business Associate directly or indirectly receives remuneration from or on behalf of the recipient of the PHI in exchange for the PHI.

Sampson County Health Department (SCHD) workforce: any person who provides any type of services for SCHD; this includes SCHD paid employees, (including contract workforce), volunteers, trainees, students, and other persons whose actions, in the performance of work for SCHD are under direct control of SCHD.

Secretary - The Secretary of the U.S. Department of Health & Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Subcontractor – A person to whom a Business Associate delegates a function, activity or service, other than in the capacity of a member of the workforce of such Business Associate.

Treatment - The provision, coordination or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient, from one health care provider to another, for health care.

Use - With respect to Individually Identifiable Health Information, is the sharing, employment, application, utilization, examination or analysis of such information within an entity that maintains such information.

Workforce - Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a Covered Entity or Business Associate, is under the direct control of such Covered Entity or Business Associate, whether or not they are paid by the Covered Entity or Business Associate.

U.S. Department of Health and Human Services
Office for Civil Rights

HIPAA Administrative Simplification

Regulation Text

45 CFR Parts 160, 162, and 164
(Unofficial Version, as amended through March 26, 2013)

HIPAA Administrative Simplification

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PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

Contents

AUTHORITY: 42 U.S.C. 1302(a); 42 U.S.C. 1320d-1320d-9; sec. 264, Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2 (note)); 5 U.S.C. 552; secs. 13400-13424, Pub. L. 111-5, 123 Stat. 258-279; and sec. 1104 of Pub. L. 111-148, 124 Stat. 146-154.

SOURCE: 65 FR 82798, Dec. 28, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171-1180 of the Social Security Act (the Act), sections 262 and 264 of Public Law 104-191, section 105 of Public Law 110-233, sections 13400-13424 of Public Law 111-5, and section 1104 of Public Law 111-148.

[78 FR 5687, Jan. 25, 2013]

§ 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) Where provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to a business associate.

(c) To the extent required under the Social Security Act, 42 U.S.C. 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 78 FR 5687, Jan. 25, 2013]

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

Administrative simplification provision means any requirement or prohibition established by:

(1) 42 U.S.C. 1320d-1320d-4, 1320d-7, 1320d-8, and 1320d-9;

(2) Section 264 of Pub. L. 104-191;

(3) Sections 13400-13424 of Public Law 111-5; or

(4) This subchapter.

ALJ means Administrative Law Judge.

ANSI stands for the American National Standards Institute.

Business associate: (1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) *Business associate* includes:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(4) *Business associate* does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance

issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of § 164.504(f) of this subchapter apply and are met.

(iii) A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the extent such activities are authorized by law.

(iv) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement by virtue of such activities or services.

Civil money penalty or *penalty* means the amount determined under § 160.404 of this part and includes the plural of these terms.

CMS stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

Compliance date means the date by which a covered entity or business associate must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Disclosure means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.

EIN stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents.

Electronic media means:

(1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card;

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet or intranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form immediately before the transmission.

Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of *protected health information* as specified in this section.

Employer is defined as it is in 26 U.S.C. 3401(d).

Family member means, with respect to an individual:

(1) A dependent (as such term is defined in 45 CFR 144.103), of the individual; or

(2) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one

parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).

(i) First-degree relatives include parents, spouses, siblings, and children.

(ii) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(iii) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(iv) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

Genetic information means:

(1) Subject to paragraphs (2) and (3) of this definition, with respect to an individual, information about:

(i) The individual's genetic tests;

(ii) The genetic tests of family members of the individual;

(iii) The manifestation of a disease or disorder in family members of such individual; or

(iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(2) Any reference in this subchapter to genetic information concerning an individual or family member of an individual shall include the genetic information of:

(i) A fetus carried by the individual or family member who is a pregnant woman; and

(ii) Any embryo legally held by an individual or family member utilizing an assisted reproductive technology.

(3) Genetic information excludes information about the sex or age of any individual.

Genetic services means:

(1) A genetic test;

(2) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(3) Genetic education.

Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. Genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition.

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data

elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, including genetic information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg-91(b)(2) and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg-91(b)(3) and used in the definition of *health plan* in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(1) *Health plan* includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, *et seq*.

(vi) The Voluntary Prescription Drug Benefit Program under Part D of title XVIII of the Act, 42 U.S.C. 1395w-101 through 1395w-152.

(vii) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(viii) An issuer of a long-term care policy, excluding a nursing home fixed indemnity policy.

(ix) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(x) The health care program for uniformed services under title 10 of the United States Code.

(xi) The veterans health care program under 38 U.S.C. chapter 17.

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, *et seq.*

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, *et seq*.

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, *et seq*.

(xv) The Medicare Advantage program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(2) *Health plan* excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Manifestation or *manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this subchapter, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.

Modify or *modification* refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Person means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information:

(i) In education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) In records described at 20 U.S.C. 1232g(a)(4)(B)(iv);

(iii) In employment records held by a covered entity in its role as employer; and

(iv) Regarding a person who has been deceased for more than 50 years.

Respondent means a covered entity or business associate upon which the Secretary has imposed, or proposes to impose, a civil money penalty.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services, or practices:

(i) Classification of components;

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of protected health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Subcontractor means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Health care electronic funds transfers (EFT) and remittance advice.

(12) Other transactions that the Secretary may prescribe by regulation.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Violation or *violate* means, as the context may require, failure to comply with an administrative simplification provision.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002; 67 FR 53266, Aug. 14, 2002; 68 FR 8374, Feb. 20, 2003; 71 FR 8424, Feb. 16, 2006; 76 FR 40495, July 8, 2011; 77 FR 1589, Jan. 10, 2012; 78 FR 5687, Jan. 25, 2013]

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002]

§ 160.105 Compliance dates for implementation of new or modified standards and implementation specifications.

Except as otherwise provided, with respect to rules that adopt new standards and implementation specifications or modifications to standards and implementation specifications in this subchapter in accordance with § 160.104 that become effective after January 25, 2013, covered entities and business associates must comply with the applicable new standards and implementation specifications, or modifications to standards and implementation specifications, no later than 180 days from the effective date of any such standards or implementation specifications.

[78 FR 5689, Jan. 25, 2013]

Subpart B—Preemption of State Law

§ 160.201 Statutory basis.

The provisions of this subpart implement section 1178 of the Act, section 262 of Public Law 104-191, section 264(c) of Public Law 104-191, and section 13421(a) of Public Law 111-5.

[78 FR 5689, Jan. 25, 2013]

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity or business associate would find it impossible to comply with both the State and Federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act, section 264 of Public Law 104-191, or sections 13400-13424 of Public Law 111-5, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:

(i) Required by the Secretary in connection with determining whether a covered entity or business associate is in compliance with this subchapter; or

(ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 74 FR 42767, Aug. 24, 2009; 78 FR 5689, Jan. 25, 2013]

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

(1) The State law for which the exception is requested;

(2) The particular standard, requirement, or implementation specification for which the exception is requested;

(3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;

(4) How health care providers, health plans, and other entities would be affected by the exception;

(5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and

(6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the FEDERAL REGISTER. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met.

§ 160.205 Duration of effectiveness of exception determinations.

An exception granted under this subpart remains in effect until:

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Subpart C—Compliance and Investigations

SOURCE: 71 FR 8424, Feb. 16, 2006, unless otherwise noted.

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, business associates, and others with respect to ascertaining the compliance by covered entities and business associates with, and the enforcement of, the applicable provisions of this part 160 and parts 162 and 164 of this subchapter.

[78 FR 5690, Jan. 25, 2013]

§ 160.302 [Reserved]

§ 160.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable and consistent with the provisions of this subpart, seek the cooperation of covered entities and business associates in obtaining compliance with the applicable administrative simplification provisions.

(b) *Assistance.* The Secretary may provide technical assistance to covered entities and business associates to help them comply voluntarily with the applicable administrative simplification provisions.

[78 FR 5690, Jan. 25, 2013]

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity or business associate is not complying with the administrative simplification provisions may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the person that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable administrative simplification provision(s).

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the FEDERAL REGISTER.

(c) *Investigation.* (1) The Secretary will investigate any complaint filed under this section when a preliminary review of the facts indicates a possible violation due to willful neglect.

(2) The Secretary may investigate any other complaint filed under this section.

(3) An investigation under this section may include a review of the pertinent policies, procedures, or practices of the covered entity or business associate and of the circumstances regarding any alleged violation.

(4) At the time of the initial written communication with the covered entity or business associate about the complaint, the Secretary will describe the acts and/or omissions that are the basis of the complaint.

[71 FR 8424, Feb. 16, 2006, as amended at 78 FR 5690, Jan. 25, 2013]

§ 160.308 Compliance reviews.

(a) The Secretary will conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions when a preliminary review of the facts indicates a possible violation due to willful neglect.

(b) The Secretary may conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions in any other circumstance.

[78 FR 5690, Jan. 25, 2013]

§ 160.310 Responsibilities of covered entities and business associates.

(a) *Provide records and compliance reports.* A covered entity or business associate must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity or business associate has complied or is complying with the applicable administrative simplification provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity or business associate must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the covered entity or business associate to determine whether it is complying with the applicable administrative simplification provisions.

(c) *Permit access to information.* (1) A covered entity or business associate must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable administrative simplification provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity or business associate must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity or business associate under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity or business associate must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable administrative simplification provisions, if otherwise required by law, or if permitted under 5 U.S.C. 552a(b)(7).

[78 FR 5690, Jan. 25, 2013]

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to § 160.306 or a compliance review pursuant to § 160.308 indicates noncompliance, the Secretary may attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the covered entity or business associate and provide the covered entity or business associate an opportunity to submit written evidence of any mitigating factors or affirmative defenses for consideration under §§ 160.408 and 160.410 of this part. The covered entity or business associate must submit any such evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 160.526 of this part) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary finds that a civil money penalty should be imposed, inform the covered entity or business associate of such finding in a notice of proposed determination in accordance with § 160.420 of this part.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to § 160.306 or a compliance review pursuant to § 160.308, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

[78 FR 5690, Jan. 25, 2013]

§ 160.314 Investigational subpoenas and inquiries.

(a) The Secretary may issue subpoenas in accordance with 42 U.S.C. 405(d) and (e), 1320a-7a(j), and 1320d-5 to require the attendance and testimony of witnesses and the production of any other evidence during an investigation or compliance review pursuant to this part. For purposes of this paragraph, a person other than a natural person is termed an "entity."

(1) A subpoena issued under this paragraph must—

(i) State the name of the person (including the entity, if applicable) to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any

documents or items required to be produced; and

(v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the entity must designate one or more natural persons who will testify on its behalf, and must state as to each such person that person's name and address and the matters on which he or she will testify. The designated person must testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by—

(i) Delivering a copy to the natural person named in the subpoena or to the entity named in the subpoena at its last principal place of business; or

(ii) Registered or certified mail addressed to the natural person at his or her last known dwelling place or to the entity at its last known principal place of business.

(3) A verified return by the natural person serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, constitutes proof of service.

(4) Witnesses are entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Fees need not be paid at the time the subpoena is served.

(5) A subpoena under this section is enforceable through the district court of the United States for the district where the subpoenaed natural person resides or is found or where the entity transacts business.

(b) Investigational inquiries are non-public investigational proceedings conducted by the Secretary.

(1) Testimony at investigational inquiries will be taken under oath or affirmation.

(2) Attendance of non-witnesses is discretionary with the Secretary, except that a witness is entitled to be accompanied, represented, and advised by an attorney.

(3) Representatives of the Secretary are entitled to attend and ask questions.

(4) A witness will have the opportunity to clarify his or her answers on the record following questioning by the Secretary.

(5) Any claim of privilege must be asserted by the witness on the record.

(6) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to objection.

(7) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the Secretary may seek enforcement of the subpoena under paragraph (a)(5) of this section.

(8) The proceedings will be recorded and transcribed. The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(9)(i) The transcript will be submitted to the witness for signature.

(A) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the Secretary written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days (computed in the same manner as prescribed under § 160.526 of this part) of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(B) Where, as provided in paragraph (b)(8) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days (computed in the same manner

as prescribed under § 160.526 of this part) of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(ii) The Secretary's proposed corrections to the record of transcript will be attached to the transcript.

(c) Consistent with § 160.310(c)(3), testimony and other evidence obtained in an investigational inquiry may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.

§ 160.316 Refraining from intimidation or retaliation.

A covered entity or business associate may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any individual or other person for—

(a) Filing of a complaint under § 160.306;

(b) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under this part; or

(c) Opposing any act or practice made unlawful by this subchapter, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of opposition is reasonable and does not involve a disclosure of protected health information in violation of subpart E of part 164 of this subchapter.

[71 FR 8426, Feb. 16, 2006, as amended at 78 FR 5691, Jan. 25, 2013]

Subpart D—Imposition of Civil Money Penalties

SOURCE: 71 FR 8426, Feb. 16, 2006, unless otherwise noted.

§ 160.400 Applicability.

This subpart applies to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d-5.

§ 160.401 Definitions.

As used in this subpart, the following terms have the following meanings:

Reasonable cause means an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.

Reasonable diligence means the business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances.

Willful neglect means conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated.

[74 FR 56130, Oct. 30, 2009, as amended at 78 FR 5691, Jan. 25, 2013]

§ 160.402 Basis for a civil money penalty.

(a) *General rule.* Subject to § 160.410, the Secretary will impose a civil money penalty upon a covered entity or business associate if the Secretary determines that the covered entity or business associate has violated an administrative simplification provision.

(b) *Violation by more than one covered entity or business associate.* (1) Except as provided in paragraph (b)(2) of this section, if the Secretary determines that more than one covered entity or business associate was responsible for a violation, the Secretary will impose a civil money penalty against each such covered entity or business associate.

(2) A covered entity that is a member of an affiliated covered entity, in accordance with § 164.105(b) of this subchapter, is jointly and severally liable for a civil money penalty for a violation of part 164 of this subchapter based on an act or omission of the affiliated covered entity, unless it is established that another member of the affiliated covered entity was responsible for the violation.

(c) *Violation attributed to a covered entity or business associate.* (1) A covered entity is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, including a workforce member or business associate, acting within the scope of the agency.

(2) A business associate is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the business associate, including a workforce member or subcontractor, acting within the scope of the agency.

[78 FR 5691, Jan. 25, 2013]

§ 160.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and §§ 160.406, 160.408, and 160.412.

(b) The amount of a civil money penalty that may be imposed is subject to the following limitations:

(1) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty—

(i) In the amount of more than $100 for each violation; or

(ii) In excess of $25,000 for identical violations during a calendar year (January 1 through the following December 31);

(2) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty—

(i) For a violation in which it is established that the covered entity or business associate did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such provision,

(A) In the amount of less than $100 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(ii) For a violation in which it is established that the violation was due to reasonable cause and not to willful neglect,

(A) In the amount of less than $1,000 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iii) For a violation in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than $10,000 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iv) For a violation in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31).

(3) If a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative simplification provision in the same subpart, a civil money penalty may be imposed for a violation of only one of these administrative simplification provisions.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56130, Oct. 30, 2009; 78 FR 5691, Jan. 25, 2013]

§ 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on the nature of the covered entity's or business associate's obligation to act or not act under the provision that is violated, such as its obligation to act in a certain manner, or within a certain time, or to act or not act with respect to certain persons. In the case of continuing violation of a provision, a separate violation occurs each day the covered entity or business associate is in violation of the provision.

[78 FR 5691, Jan. 25, 2013]

§ 160.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary will consider the following factors, which may be mitigating or aggravating as appropriate:

(a) The nature and extent of the violation, consideration of which may include but is not limited to:

(1) The number of individuals affected; and

(2) The time period during which the violation occurred;

(b) The nature and extent of the harm resulting from the violation, consideration of which may include but is not limited to:

(1) Whether the violation caused physical harm;

(2) Whether the violation resulted in financial harm;

(3) Whether the violation resulted in harm to an individual's reputation; and

(4) Whether the violation hindered an individual's ability to obtain health care;

(c) The history of prior compliance with the administrative simplification provisions, including violations, by the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the current violation is the same or similar to previous indications of noncompliance;

(2) Whether and to what extent the covered entity or business associate has attempted to correct previous indications of noncompliance;

(3) How the covered entity or business associate has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the covered entity or business associate has responded to prior complaints;

(d) The financial condition of the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the covered entity or business associate had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the covered entity or business associate to continue to provide, or to pay for, health care; and

(3) The size of the covered entity or business associate; and

(e) Such other matters as justice may require.

[78 FR 5691, Jan. 25, 2013]

§ 160.410 Affirmative defenses.

(a) The Secretary may not:

(1) Prior to February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that the violation is punishable under 42 U.S.C. 1320d-6.

(2) On or after February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that a penalty has been imposed under 42 U.S.C. 1320d-6 with respect to such act.

(b) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violation, including the following:

(1) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the Federal common law of agency, and by exercising reasonable diligence, would not have known that the violation occurred; or

(2) The violation is—

(i) Due to circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated and is not due to willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or by exercising reasonable diligence would have known, that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

(c) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity or business associate for a violation if the covered entity or business associate establishes to the satisfaction of the Secretary that the violation is—

(1) Not due to willful neglect; and

(2) Corrected during either:

(i) The 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred; or

(ii) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

[78 FR 5692, Jan. 25, 2013]

§ 160.412 Waiver.

For violations described in § 160.410(b)(2) or (c) that are not corrected within the period specified under such paragraphs, the Secretary may waive the civil money penalty, in whole or in part, to the extent that the payment of the penalty would be excessive relative to the violation.

[8 FR 5692, Jan. 25, 2013]

§ 160.414 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 160.420, within 6 years from the date of the occurrence of the violation.

§ 160.416 Authority to settle.

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

§ 160.418 Penalty not exclusive.

Except as otherwise provided by 42 U.S.C. 1320d-5(b)(1) and 42 U.S.C. 299b-22(f)(3), a penalty imposed under this part is in addition to any other penalty prescribed by law.

[78 FR 5692, Jan. 25, 2013]

§ 160.420 Notice of proposed determination.

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent, written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include—

(1) Reference to the statutory basis for the penalty;

(2) A description of the findings of fact regarding the violations with respect to which the penalty is proposed (except that, in any case where the Secretary is relying upon a statistical sampling study in accordance with § 160.536 of this part, the notice must provide a copy of the study relied upon by the Secretary);

(3) The reason(s) why the violation(s) subject(s) the respondent to a penalty;

(4) The amount of the proposed penalty and a reference to the subparagraph of § 160.404 upon which it is based.

(5) Any circumstances described in § 160.408 that were considered in determining the amount of the proposed penalty; and

(6) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 90 days permits the imposition of the proposed penalty without the right to a hearing under § 160.504 or a right of appeal under § 160.548 of this part, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed penalty by filing a request in accordance with § 160.504 of this part.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56131, Oct. 30, 2009]

§ 160.422 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 160.504 of this

part and the matter is not settled pursuant to § 160.416, the Secretary will impose the proposed penalty or any lesser penalty permitted by 42 U.S.C. 1320d-5. The Secretary will notify the respondent by certified mail, return receipt requested, of any penalty that has been imposed and of the means by which the respondent may satisfy the penalty, and the penalty is final on receipt of the notice. The respondent has no right to appeal a penalty under § 160.548 of this part with respect to which the respondent has not timely requested a hearing.

§ 160.424 Collection of penalty.

(a) Once a determination of the Secretary to impose a penalty has become final, the penalty will be collected by the Secretary, subject to the first sentence of 42 U.S.C. 1320a-7a(f).

(b) The penalty may be recovered in a civil action brought in the United States district court for the district where the respondent resides, is found, or is located.

(c) The amount of a penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ, or in an appeal under 42 U.S.C. 1320a-7a(e), may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 160.426 Notification of the public and other agencies.

Whenever a proposed penalty becomes final, the Secretary will notify, in such manner as the Secretary deems appropriate, the public and the following organizations and entities thereof and the reason it was imposed: the appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in 42 U.S.C. 1320a-7(h)), the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in 42 U.S.C. 1395aa(a), 1396a(a)(33)).

Subpart E—Procedures for Hearings

SOURCE: 71 FR 8428, Feb. 16, 2006, unless otherwise noted.

§ 160.500 Applicability.

This subpart applies to hearings conducted relating to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d-5.

§ 160.502 Definitions.

As used in this subpart, the following term has the following meaning:

Board means the members of the HHS Departmental Appeals Board, in the Office of the Secretary, who issue decisions in panels of three.

§ 160.504 Hearing before an ALJ.

(a) A respondent may request a hearing before an ALJ. The parties to the hearing proceeding consist of—

(1) The respondent; and

(2) The officer(s) or employee(s) of HHS to whom the enforcement authority involved has been delegated.

(b) The request for a hearing must be made in writing signed by the respondent or by the respondent's attorney and sent by certified mail, return receipt requested, to the address specified in the notice of proposed determination. The request for a hearing must be mailed within 90 days after notice of the proposed determination is received by the respondent. For purposes of this section, the respondent's date of receipt of the notice of proposed determination is presumed to be 5 days after the date of the notice unless the respondent makes a reasonable showing to the contrary to the ALJ.

(c) The request for a hearing must clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the respondent has any knowledge. If the respondent has no knowledge of a particular finding of fact and so states, the finding shall be deemed denied. The request for a hearing must also state the circumstances or arguments that the respondent alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty, except that a respondent may raise an affirmative defense

under § 160.410(b)(1) at any time.

(d) The ALJ must dismiss a hearing request where—

(1) On motion of the Secretary, the ALJ determines that the respondent's hearing request is not timely filed as required by paragraphs (b) or does not meet the requirements of paragraph (c) of this section;

(2) The respondent withdraws the request for a hearing;

(3) The respondent abandons the request for a hearing; or

(4) The respondent's hearing request fails to raise any issue that may properly be addressed in a hearing.

§ 160.506 Rights of the parties.

(a) Except as otherwise limited by this subpart, each party may—

(1) Be accompanied, represented, and advised by an attorney;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery of documents as permitted by this subpart;

(4) Agree to stipulations of fact or law that will be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) A party may appear in person or by a representative. Natural persons who appear as an attorney or other representative must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.

(c) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of 42 U.S.C. 406, which authorizes the Secretary to specify or limit their fees.

§ 160.508 Authority of the ALJ.

(a) The ALJ must conduct a fair and impartial hearing, avoid delay, maintain order, and ensure that a record of the proceeding is made.

(b) The ALJ may—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of documentary discovery as permitted by this subpart;

(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone; and

(13) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact. A summary judgment decision constitutes a hearing on the record for the purposes of this subpart.

(c) The ALJ—

(1) May not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must give deference to published guidance to the extent not inconsistent with statute or regulation;

(2) May not enter an order in the nature of a directed verdict;

(3) May not compel settlement negotiations;

(4) May not enjoin any act of the Secretary; or

(5) May not review the exercise of discretion by the Secretary with respect to whether to grant an extension under § 160.410(b)(2)(ii)(B) or (c)(2)(ii) of this part or to provide technical assistance under 42 U.S.C. 1320d-5(b)(2)(B).

§ 160.510 Ex parte contacts.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 160.512 Prehearing conferences.

(a) The ALJ must schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice, which may not be less than 14 business days, to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this subpart;

(9) The time and place for the hearing;

(10) The potential for the settlement of the case by the parties; and

(11) Other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings, including the protection of privacy of individually identifiable health information that may be submitted into evidence or otherwise used in the proceeding, if appropriate.

(c) The ALJ must issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 160.514 Authority to settle.

The Secretary has exclusive authority to settle any issue or case without the consent of the ALJ.

§ 160.516 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying that are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term "documents" includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section may not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has

been received, within 30 days the party receiving that request must either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part must be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. The party receiving a request for production may also file a motion for protective order any time before the date the production is due.

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

(i) Is irrelevant;

(ii) Is unduly costly or burdensome;

(iii) Will unduly delay the proceeding; or

(iv) Seeks privileged information.

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

§ 160.518 Exchange of witness lists, witness statements, and exhibits.

(a) The parties must exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 160.538, not more than 60, and not less than 15, days before the scheduled hearing, except that if a respondent intends to introduce the evidence of a statistical expert, the respondent must provide the Secretarial party with a copy of the statistical expert's report not less than 30 days before the scheduled hearing.

(b)(1) If, at any time, a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ must determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of that evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure timely to exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief—

(i) The testimony of any witness whose name does not appear on the witness list; and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of that evidence would cause substantial prejudice to the objecting party.

(i) If the ALJ finds that there is no substantial prejudice, the evidence may be admitted.

(ii) If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or, if he or she does not exclude the evidence, must postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence, unless the objecting party waives postponement.

(c) Unless the other party objects within a reasonable period of time before the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 160.520 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any person at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of a person in accordance with paragraph (a) of this section may also require the person (whether or not the person is a party) to produce relevant and material evidence at or before the hearing.

(c) When a subpoena is served by a respondent on a particular employee or official or particular office of HHS, the Secretary may comply by designating any knowledgeable HHS representative to appear and testify.

(d) A party seeking a subpoena must file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ

for good cause shown. That motion must—

(1) Specify any evidence to be produced;

(2) Designate the witnesses; and

(3) Describe the address and location with sufficient particularity to permit those witnesses to be found.

(e) The subpoena must specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena must serve it by delivery to the person named, or by certified mail addressed to that person at the person's last dwelling place or principal place of business.

(h) The person to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in 42 U.S.C. 405(e).

§ 160.522 Fees.

The party requesting a subpoena must pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage must accompany the subpoena when served, except that, when a subpoena is issued on behalf of the Secretary, a check for witness fees and mileage need not accompany the subpoena.

§ 160.524 Form, filing, and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ must include an original and two copies.

(2) Every pleading and paper filed in the proceeding must contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper must be signed by and must contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Board must, at the time of filing, serve a copy of the document on the other party. Service upon any party of any document must be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service must be made upon the attorney in lieu of the party.

(c) *Proof of service.* A certificate of the natural person serving the document by personal delivery or by mail, setting forth the manner of service, constitutes proof of service.

§ 160.526 Computation of time.

(a) In computing any period of time under this subpart or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government must be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 160.504.

§ 160.528 Motions.

(a) An application to the ALJ for an order or ruling must be by motion. Motions must state the relief sought, the authority relied upon and the facts alleged, and must be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions must be in writing. The ALJ

may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to the motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny the motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all outstanding motions before the beginning of the hearing.

§ 160.530 Sanctions.

The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. The sanctions must reasonably relate to the severity and nature of the failure or misconduct. The sanctions may include—

(a) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating the refusal as an admission by deeming the matter, or certain facts, to be established;

(b) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(c) Striking pleadings, in whole or in part;

(d) Staying the proceedings;

(e) Dismissal of the action;

(f) Entering a decision by default;

(g) Ordering the party or attorney to pay the attorney's fees and other costs caused by the failure or misconduct; and

(h) Refusing to consider any motion or other action that is not filed in a timely manner.

§ 160.532 Collateral estoppel.

When a final determination that the respondent violated an administrative simplification provision has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

§ 160.534 The hearing.

(a) The ALJ must conduct a hearing on the record in order to determine whether the respondent should be found liable under this part.

(b) (1) The respondent has the burden of going forward and the burden of persuasion with respect to any:

(i) Affirmative defense pursuant to § 160.410 of this part;

(ii) Challenge to the amount of a proposed penalty pursuant to §§ 160.404-160.408 of this part, including any factors raised as mitigating factors; or

(iii) Claim that a proposed penalty should be reduced or waived pursuant to § 160.412 of this part; and

(iv) Compliance with subpart D of part 164, as provided under § 164.414(b).

(2) The Secretary has the burden of going forward and the burden of persuasion with respect to all other issues, including issues of liability other than with respect to subpart D of part 164, and the existence of any factors considered aggravating factors in determining the amount of the proposed penalty.

(3) The burden of persuasion will be judged by a preponderance of the evidence.

(c) The hearing must be open to the public unless otherwise ordered by the ALJ for good cause shown.

(d)(1) Subject to the 15-day rule under § 160.518(a) and the admissibility of evidence under § 160.540, either party may introduce, during its case in chief, items or information that arose or became known after the date of the issuance of the notice of proposed determination or the request for hearing, as applicable. Such items and information may not be admitted into evidence, if introduced—

(i) By the Secretary, unless they are material and relevant to the acts or omissions with respect to which the penalty is proposed in the notice of proposed determination pursuant to § 160.420 of this part, including circumstances that may increase penalties; or

(ii) By the respondent, unless they are material and relevant to an admission, denial or

explanation of a finding of fact in the notice of proposed determination under § 160.420 of this part, or to a specific circumstance or argument expressly stated in the request for hearing under § 160.504, including circumstances that may reduce penalties.

(2) After both parties have presented their cases, evidence may be admitted in rebuttal even if not previously exchanged in accordance with § 160.518.

[71 FR 8428, Feb. 16, 2006, as amended at 74 FR 42767, Aug. 24, 2009; 78 FR 5692, Jan. 25, 2013]

§ 160.536 Statistical sampling.

(a) In meeting the burden of proof set forth in § 160.534, the Secretary may introduce the results of a statistical sampling study as evidence of the number of violations under § 160.406 of this part, or the factors considered in determining the amount of the civil money penalty under § 160.408 of this part. Such statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitutes prima facie evidence of the number of violations and the existence of factors material to the proposed civil money penalty as described in §§ 160.406 and 160.408.

(b) Once the Secretary has made a prima facie case, as described in paragraph (a) of this section, the burden of going forward shifts to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Secretary will then be given the opportunity to rebut this evidence.

§ 160.538 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing must be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony of witnesses other than the testimony of expert witnesses may be admitted in the form of a written statement. The ALJ may, at his or her discretion, admit prior sworn testimony of experts that has been subject to adverse examination, such as a deposition or trial testimony. Any such written statement must be provided to the other party, along with the last known address of the witness, in a manner that allows sufficient time for the other party to subpoena the witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing must be exchanged as provided in § 160.518.

(c) The ALJ must exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth;

(2) Avoid repetition or needless consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ must permit the parties to conduct cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses, except that the ALJ may not order to be excluded—

(1) A party who is a natural person;

(2) In the case of a party that is not a natural person, the officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

(3) A natural person whose presence is shown by a party to be essential to the presentation of its case, including a person engaged in assisting the attorney for the Secretary.

§ 160.540 Evidence.

(a) The ALJ must determine the admissibility of evidence.

(b) Except as provided in this subpart, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement are inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs, or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. This evidence is admissible regardless of whether the crimes, wrongs, or acts occurred during the statute of limitations period applicable to the acts or omissions that constitute the basis for liability in the case and regardless of whether they were referenced in the Secretary's notice of proposed determination under § 160.420 of this part.

(h) The ALJ must permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.

§ 160.542 The record.

(a) The hearing must be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ. A party that requests a transcript of hearing proceedings must pay the cost of preparing the transcript unless, for good cause shown by the party, the payment is waived by the ALJ or the Board, as appropriate.

(b) The transcript of the testimony, exhibits, and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§ 160.544 Post hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ must fix the time for filing the briefs. The time for filing may not exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. The briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 160.546 ALJ's decision.

(a) The ALJ must issue a decision, based only on the record, which must contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase, or reduce the penalties imposed by the Secretary.

(c) The ALJ must issue the decision to both parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. If the ALJ fails to meet the deadline contained in this paragraph, he or she must notify the parties of the reason for the delay and set a new deadline.

(d) Unless the decision of the ALJ is timely appealed as provided for in § 160.548, the decision of the ALJ will be final and binding on the parties 60 days from the date of service of the ALJ's decision.

§ 160.548 Appeal of the ALJ's decision.

(a) Any party may appeal the decision of the ALJ to the Board by filing a notice of appeal with the Board within 30 days of the date of service of the ALJ decision. The Board may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the Board a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the Board, the ALJ must forward the record of the proceeding to the Board.

(c) A notice of appeal must be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to the exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and the accompanying brief. The Board may permit the parties to file reply briefs.

(d) There is no right to appear personally before the Board or to appeal to the Board any interlocutory ruling by the ALJ.

(e) Except for an affirmative defense under § 160.410(a)(1) or (2) of this part, the Board may not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the Board that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the Board may remand the matter to the ALJ for consideration of such additional evidence.

(g) The Board may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision of the ALJ is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the Board must serve on each party to the appeal a copy of the Board's decision and a statement describing the right of any respondent who is penalized to seek judicial review.

(j)(1) The Board's decision under paragraph (i) of this section, including a decision to decline review of the initial decision, becomes the final decision of the Secretary 60 days after the date of service of the Board's decision, except with respect to a decision to remand to the ALJ or if reconsideration is requested under this paragraph.

(2) The Board will reconsider its decision only if it determines that the decision contains a clear error of fact or error of law. New evidence will not be a basis for reconsideration unless the party demonstrates that the evidence is newly discovered and was not previously available.

(3) A party may file a motion for reconsideration with the Board before the date the decision becomes final under paragraph (j)(1) of this section. A motion for reconsideration must be accompanied by a written brief specifying any alleged error of fact or law and, if the party is relying on additional evidence, explaining why the evidence was not previously available. Any party may file a brief in opposition within 15 days of receiving the motion for reconsideration and the accompanying brief unless this time limit is extended by the Board for good cause shown. Reply briefs are not permitted.

(4) The Board must rule on the motion for reconsideration not later than 30 days from the date the opposition brief is due. If the Board denies the motion, the decision issued under paragraph (i) of this section becomes the final decision of the Secretary on the date of service of the ruling. If the Board grants the motion, the Board will issue a reconsidered decision, after such procedures as the Board determines necessary to address the effect of any error. The Board's decision on reconsideration becomes the final decision of the Secretary on the date of service of the decision, except with respect to a decision to remand to the ALJ.

(5) If service of a ruling or decision issued under this section is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k)(1) A respondent's petition for judicial review must be filed within 60 days of the date on which the decision of the Board becomes the final decision of the Secretary under paragraph (j) of this section.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging the final decision of the Secretary must be sent by certified mail, return receipt requested, to the General Counsel of HHS. The petition copy must be a copy showing that it has been time-stamped by the clerk of the court when the original was filed with the court.

(3) If the General Counsel of HHS received two or more petitions within 10 days after the final decision of the Secretary, the General Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10 day period.

§ 160.550 Stay of the Secretary's decision.

(a) Pending judicial review, the respondent may file a request for stay of the effective date of any penalty with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of the request automatically stays the effective date of the penalty until such

time as the ALJ rules upon the request.

(b) The ALJ may not grant a respondent's request for stay of any penalty unless the respondent posts a bond or provides other adequate security.

(c) The ALJ must rule upon a respondent's request for stay within 10 days of receipt.

§ 160.552 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the Board inconsistent with substantial justice. The ALJ and the Board at every stage of the proceeding must disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

PART 162—ADMINISTRATIVE REQUIREMENTS

Contents

AUTHORITY: Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d-1320d-9), as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031, sec. 105 of Pub. L. 110-233, 122 Stat. 881-922, and sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note), and secs. 1104 and 10109 of Pub. L. 111-148, 124 Stat. 146-154 and 915-917.

SOURCE: 65 FR 50367, Aug. 17, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 162.100 Applicability.

Covered entities (as defined in § 160.103 of this subchapter) must comply with the applicable requirements of this part.

§ 162.103 Definitions.

For purposes of this part, the following definitions apply:

Code set means any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. A code set includes the codes and the descriptors of the codes.

Code set maintaining organization means an organization that creates and maintains the code sets adopted by the Secretary for use in the transactions for which standards are adopted in this part.

Controlling health plan (CHP) means a health plan that—

(1) Controls its own business activities, actions, or policies; or

(2)(i) Is controlled by an entity that is not a health plan; and

(ii) If it has a subhealth plan(s) (as defined in this section), exercises sufficient control over the subhealth plan(s) to direct its/their business activities, actions, or policies.

Covered health care provider means a health care provider that meets the definition at paragraph (3) of the definition of "covered entity" at § 160.103.

Data condition means the rule that describes the circumstances under which a covered entity must use a particular data element or segment.

Data content means all the data elements and code sets inherent to a transaction, and not related to the format of the transaction. Data elements that are related to the format are not data content.

Data element means the smallest named unit of information in a transaction.

Data set means a semantically meaningful unit of information exchanged between two parties to a transaction.

Descriptor means the text defining a code.

Designated standard maintenance organization (DSMO) means an organization designated by the Secretary under § 162.910(a).

Direct data entry means the direct entry of data (for example, using dumb terminals or web browsers) that is immediately transmitted into a health plan's computer.

Format refers to those data elements that provide or control the enveloping or hierarchical structure, or assist in identifying data content of, a transaction.

HCPCS stands for the Health [Care Financing Administration] Common Procedure Coding System.

Maintain or *maintenance* refers to activities necessary to support the use of a standard adopted by the Secretary, including technical corrections to an implementation specification, and enhancements or expansion of a code set. This term excludes the activities related to the adoption of a new standard or implementation specification, or modification to an adopted standard or implementation specification.

Maximum defined data set means all of the required data elements for a particular standard based on a specific implementation specification.

Operating rules means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.

Segment means a group of related data elements in a transaction.

Stage 1 payment initiation means a health plan's order, instruction or authorization to its financial institution to make a health care claims payment using an electronic funds transfer (EFT) through the ACH Network.

Standard transaction means a transaction that complies with an applicable standard and associated operating rules adopted under this part.

Subhealth plan (SHP) means a health plan whose business activities, actions, or policies are directed by a controlling health plan.

[65 FR 50367, Aug. 17, 2000, as amended at 68 FR 8374, Feb. 20, 2003; 74 FR 3324, Jan. 16, 2009; 76 FR 40495, July 8, 2011; 77 FR 1589, Jan. 10, 2012; 77 FR 54719, Sept. 5, 2012]

Subparts B-C [Reserved]

Subpart D—Standard Unique Health Identifier for Health Care Providers

SOURCE: 69 FR 3468, Jan. 23, 2004, unless otherwise noted.

§ 162.402 [Reserved]

§ 162.404 Compliance dates of the implementation of the standard unique health identifier for health care providers.

(a) *Health care providers.* A covered health care provider must comply with the implementation specifications in § 162.410 no later than May 23, 2007.

(b) *Health plans.* A health plan must comply with the implementation specifications in § 162.412 no later than one of the following dates:

(1) A health plan that is not a small health plan—May 23, 2007.

(2) A small health plan—May 23, 2008.

(c) *Health care clearinghouses.* A health care clearinghouse must comply with the implementation specifications in § 162.414 no later than May 23, 2007.

[69 FR 3468, Jan. 23, 2004, as amended at 77 FR 54719, Sept. 5, 2012]

§ 162.406 Standard unique health identifier for health care providers.

(a) *Standard.* The standard unique health identifier for health care providers is the National Provider Identifier (NPI). The NPI is a 10-position numeric identifier, with a check digit in the 10th position, and no intelligence about the health care provider in the number.

(b) *Required and permitted uses for the NPI.* (1) The NPI must be used as stated in § 162.410, § 162.412, and § 162.414.

(2) The NPI may be used for any other lawful purpose.

§ 162.408 National Provider System.

National Provider System. The National Provider System (NPS) shall do the following:

(a) Assign a single, unique NPI to a health care provider, provided that—

(1) The NPS may assign an NPI to a subpart of a health care provider in accordance with paragraph (g); and

(2) The Secretary has sufficient information to permit the assignment to be made.

(b) Collect and maintain information about each health

care provider that has been assigned an NPI and perform tasks necessary to update that information.

(c) If appropriate, deactivate an NPI upon receipt of appropriate information concerning the dissolution of the health care provider that is an organization, the death of the health care provider who is an individual, or other circumstances justifying deactivation.

(d) If appropriate, reactivate a deactivated NPI upon receipt of appropriate information.

(e) Not assign a deactivated NPI to any other health care provider.

(f) Disseminate NPS information upon approved requests.

(g) Assign an NPI to a subpart of a health care provider on request if the identifying data for the subpart are unique.

§ 162.410 Implementation specifications: Health care providers.

(a) A covered entity that is a covered health care provider must:

(1) Obtain, by application if necessary, an NPI from the National Provider System (NPS) for itself or for any subpart of the covered entity that would be a covered health care provider if it were a separate legal entity. A covered entity may obtain an NPI for any other subpart that qualifies for the assignment of an NPI.

(2) Use the NPI it obtained from the NPS to identify itself on all standard transactions that it conducts where its health care provider identifier is required.

(3) Disclose its NPI, when requested, to any entity that needs the NPI to identify that covered health care provider in a standard transaction.

(4) Communicate to the NPS any changes in its required data elements in the NPS within 30 days of the change.

(5) If it uses one or more business associates to conduct standard transactions on its behalf, require its business associate(s) to use its NPI and other NPIs appropriately as required by the transactions that the business associate(s) conducts on its behalf.

(6) If it has been assigned NPIs for one or more subparts, comply with the requirements of paragraphs (a)(2) through (a)(5) of this section with respect to each of those NPIs.

(b) An organization covered health care provider that has as a member, employs, or contracts with, an individual health care provider who is not a covered entity and is a prescriber, must require such health care provider to—

(1) Obtain an NPI from the National Plan and Provider Enumeration System (NPPES); and

(2) To the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

(c) A health care provider that is not a covered entity may obtain, by application if necessary, an NPI from the NPS.

[69 FR 3468, Jan. 23, 2004, as amended at 77 FR 54719, Sept. 5, 2012]

§ 162.412 Implementation specifications: Health plans.

(a) A health plan must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.

(b) A health plan may not require a health care provider that has been assigned an NPI to obtain an additional NPI.

§ 162.414 Implementation specifications: Health care clearinghouses.

A health care clearinghouse must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.

Subpart E—Standard Unique Health Identifier for Health Plans

SOURCE: 77 FR 54719, Sept. 5, 2012, unless otherwise noted.

§ 162.502 [Reserved]

§ 162.504 Compliance requirements for the implementation of the standard unique health plan identifier.

(a) *Covered entities.* A covered entity must comply with the implementation requirements in § 162.510 no later than November 7, 2016.

(b) *Health plans.* A health plan must comply with the implementation specifications in § 162.512 no later than one of the following dates:

(1) A health plan that is not a small health plan— November 5, 2014.

(2) A health plan that is a small health plan— November 5, 2015.

[77 FR 54719, Sept. 5, 2012, as amended at 77 FR 60630, Oct. 4, 2012]

§ 162.506 Standard unique health plan identifier.

(a) *Standard.* The standard unique health plan identifier is the Health Plan Identifier (HPID) that is assigned by the Enumeration System identified in § 162.508.

(b) *Required and permitted uses for the HPID.* (1) The HPID must be used as specified in § 162.510 and § 162.512.

(2) The HPID may be used for any other lawful purpose.

§ 162.508 Enumeration System.

The Enumeration System must do all of the following:

(a) Assign a single, unique—

(1) HPID to a health plan, provided that the Secretary has sufficient information to permit the assignment to be made; or

(2) OEID to an entity eligible to receive one under § 162.514(a), provided that the Secretary has sufficient information to permit the assignment to be made.

(b) Collect and maintain information about each health plan that applies for or has been assigned an HPID and each entity that applies for or has been assigned an OEID, and perform tasks necessary to update that information.

(c) If appropriate, deactivate an HPID or OEID upon receipt of sufficient information concerning circumstances justifying deactivation.

(d) If appropriate, reactivate a deactivated HPID or OEID upon receipt of sufficient information justifying reactivation.

(e) Not assign a deactivated HPID to any other health plan or OEID to any other entity.

(f) Disseminate Enumeration System information upon approved requests.

§ 162.510 Full implementation requirements: Covered entities.

(a) A covered entity must use an HPID to identify a health plan that has an HPID when a covered entity identifies a health plan in a transaction for which the Secretary has adopted a standard under this part.

(b) If a covered entity uses one or more business associates to conduct standard transactions on its behalf, it must require its business associate(s) to use an HPID to identify a health plan that has an HPID when the business associate(s) identifies a health plan in a transaction for which the Secretary has adopted a standard under this part.

§ 162.512 Implementation specifications: Health plans.

(a) A controlling health plan must do all of the following:

(1) Obtain an HPID from the Enumeration System for itself.

(2) Disclose its HPID, when requested, to any entity that needs the HPID to identify the health plan in a standard transaction.

(3) Communicate to the Enumeration System any changes in its required data elements in the Enumeration System within 30 days of the change.

(b) A controlling health plan may do the following:

(1) Obtain an HPID from the Enumeration System for a subhealth plan of the controlling health plan.

(2) Direct a subhealth plan of the controlling health plan to obtain an HPID from the Enumeration System.

(c) A subhealth plan may obtain an HPID from the Enumeration System.

(d) A subhealth plan that is assigned an HPID from the Enumeration System must comply with the requirements that apply to a controlling health plan in paragraphs (a)(2) and (a)(3) of this section.

§ 162.514 Other entity identifier.

(a) An entity may obtain an Other Entity Identifier (OEID) to identify itself if the entity meets all of the following:

(1) Needs to be identified in a transaction for which the Secretary has adopted a standard under this part.

(2) Is not eligible to obtain an HPID.

(3) Is not eligible to obtain an NPI.

(4) Is not an individual.

(b) An OEID must be obtained from the Enumeration System identified in § 162.508.

(c) *Uses for the OEID.* (1) An other entity may use the OEID it obtained from the Enumeration System to identify itself or have itself identified on all covered transactions in which it needs to be identified.

(2) The OEID may be used for any other lawful purpose.

Subpart F—Standard Unique Employer Identifier

SOURCE: 67 FR 38020, May 31, 2002, unless otherwise noted.

§ 162.600 Compliance dates of the implementation of the standard unique employer identifier.

(a) *Health care providers.* Health care providers must comply with the requirements of this subpart no later than July 30, 2004.

(b) *Health plans.* A health plan must comply with the requirements of this subpart no later than one of the following dates:

(1) *Health plans other than small health plans* —July 30, 2004.

(2) *Small health plans* —August 1, 2005.

(c) *Health care clearinghouses.* Health care clearinghouses must comply with the requirements of this subpart no later than July 30, 2004.

§ 162.605 Standard unique employer identifier.

The Secretary adopts the EIN as the standard unique employer identifier provided for by 42 U.S.C. 1320d-2(b).

§ 162.610 Implementation specifications for covered entities.

(a) The standard unique employer identifier of an employer of a particular employee is the EIN that appears on that employee's IRS Form W-2, Wage and Tax Statement, from the employer.

(b) A covered entity must use the standard unique employer identifier (EIN) of the appropriate employer in standard transactions that require an employer identifier to identify a person or entity as an employer, including where situationally required.

(c) Required and permitted uses for the Employer Identifier.

(1) The Employer Identifier must be used as stated in § 162.610(b).

(2) The Employer Identifier may be used for any other lawful purpose.

[67 FR 38020, May 31, 2002, as amended at 69 FR 3469, Jan. 23, 2004]

Subparts G-H [Reserved]

Subpart I—General Provisions for Transactions

§ 162.900 [Reserved]

§ 162.910 Maintenance of standards and adoption of modifications and new standards.

(a) *Designation of DSMOs.* (1) The Secretary may designate as a DSMO an organization that agrees to conduct, to the satisfaction of the Secretary, the following functions:

(i) Maintain standards adopted under this subchapter.

(ii) Receive and process requests for adopting a new standard or modifying an adopted standard.

(2) The Secretary designates a DSMO by notice in the FEDERAL REGISTER.

(b) *Maintenance of standards.* Maintenance of a standard by the appropriate DSMO constitutes maintenance of the standard for purposes of this part, if done in accordance with the processes the Secretary may require.

(c) *Process for modification of existing standards and adoption*

of new standards. The Secretary considers a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if the recommendation is developed through a process that provides for the following:

(1) Open public access.

(2) Coordination with other DSMOs.

(3) An appeals process for each of the following, if dissatisfied with the decision on the request:

(i) The requestor of the proposed modification.

(ii) A DSMO that participated in the review and analysis of the request for the proposed modification, or the proposed new standard.

(4) Expedited process to address content needs identified within the industry, if appropriate.

(5) Submission of the recommendation to the National Committee on Vital and Health Statistics (NCVHS).

§ 162.915 Trading partner agreements.

A covered entity must not enter into a trading partner agreement that would do any of the following:

(a) Change the definition, data condition, or use of a data element or segment in a standard or operating rule, except where necessary to implement State or Federal law, or to protect against fraud and abuse.

(b) Add any data elements or segments to the maximum defined data set.

(c) Use any code or data elements that are either marked "not used" in the standard's implementation specification or are not in the standard's implementation specification(s).

(d) Change the meaning or intent of the standard's implementation specification(s).

[65 FR 50367, Aug. 17, 2000, as amended at 76 FR 40495, July 8, 2011]

§ 162.920 Availability of implementation specifications and operating rules.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 714-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* The materials are also available for inspection by the public at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244. For more information on the availability on the materials at CMS, call (410) 786-6597. The materials are also available from the sources listed below.

(a) *ASC X12N specifications and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3.* The implementation specifications for the ASC X12N and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 (and accompanying Errata or Type 1 Errata) may be obtained from the ASC X12, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (703) 970-4480; and FAX (703) 970-4488. They are also available through the internet at *http://www.X12.org*. A fee is charged for all implementation specifications, including Technical Reports Type 3. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

(1) The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1, as referenced in § 162.1102 and § 162.1802.

(2) The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1, as referenced in § 162.1102 and § 162.1802.

(3) The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as referenced in § 162.1102 and § 162.1802.

(4) The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company, 004010X091A1 as referenced in § 162.1602.

(5) ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1, as referenced in § 162.1502.

(6) The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1, as referenced in § 162.1702.

(7) The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1, as referenced in § 162.1302.

(8) The ASC X12N-276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1, as referenced in § 162.1402.

(9) The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, as referenced in § 162.1202.

(10) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim Dental (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1, as referenced in § 162.1102 and § 162.1802.

(11) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12, 005010X222, as referenced in § 162.1102 and § 162.1802.

(12) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12/N005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1, as referenced in § 162.1102 and § 162.1802.

(13) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221, as referenced in § 162.1602.

(14) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220, as referenced in § 162.1502.

(15) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218, as referenced in § 162.1702.

(16) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services

Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1, as referenced in § 162.1302.

(17) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1, as referenced in § 162.1402.

(18) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279, as referenced in § 162.1202.

(b) *Retail pharmacy specifications and Medicaid subrogation implementation guides.* The implementation specifications for the retail pharmacy standards and the implementation specifications for the batch standard for the Medicaid pharmacy subrogation transaction may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477-1000; FAX (480) 767-1042. They are also available through the Internet at *http://www.ncpdp.org*. A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

(1) The Telecommunication Standard Implementation Guide Version 5, Release 1 (Version 5.1), September 1999, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, § 162.1602, and § 162.1802.

(2) The Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(3) The National Council for Prescription Drug Programs (NCPDP) equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 0, February 1, 1996, as referenced in § 162.1102, § 162.1202, § 162.1602, and § 162.1802.

(4) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(5) The Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(6) The Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902.

(c) Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE), 601 Pennsylvania Avenue, NW. South Building, Suite 500 Washington, DC 20004; Telephone (202) 861-1492; Fax (202) 861- 1454; E-mail *info@CAQH.org*; and Internet at *http://www.caqh.org/benefits.php*.

(1) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase I Policies and Operating Rules, Approved April 2006, v5010 Update March 2011.

(i) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(ii) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version

1.1.0, March 2011, as referenced in § 162.1203.

(v) Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(vi) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(2) ACME Health Plan, HIPAA Transaction Standard Companion Guide, Refers to the Implementation Guides Based on ASC X12 version 005010, CORE v5010 Master Companion Guide Template, 005010, 1.2, (CORE v 5010 Master Companion Guide Template, 005010, 1.2), March 2011, as referenced in §§ 162.1203, 162.1403, and 162.1603.

(3) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase II Policies and Operating Rules, Approved July 2008, v5010 Update March 2011.

(i) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, as referenced in § 162.1403.

(ii) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(v) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011, as referenced in § 162.1203 and § 162.1403.

(4) Council for Affordable Quality Healthcare (CAQH) Phase III Committee on Operating Rules for Information Exchange (CORE) EFT & ERA Operating Rule Set, Approved June 2012, as specified in this paragraph and referenced in § 162.1603.

(i) Phase III CORE 380 EFT Enrollment Data Rule, version 3.0.0, June 2012.

(ii) Phase III CORE 382 ERA Enrollment Data Rule, version 3.0.0, June 2012.

(iii) Phase III 360 CORE Uniform Use of CARCs and RARCs (835) Rule, version 3.0.0, June 2012.

(iv) CORE-required Code Combinations for CORE-defined Business Scenarios for the Phase III CORE 360 Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule, version 3.0.0, June 2012.

(v) Phase III CORE 370 EFT & ERA Reassociation (CCD+/835) Rule, version 3.0.0, June 2012.

(vi) Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012, except Requirement 4.2 titled "Health Care Claim Payment/Advice Batch Acknowledgement Requirements".

(d) The National Automated Clearing House Association (NACHA), The Electronic Payments Association, 1350 Sunrise Valle Drive, Suite 100, Herndon, Virginia 20171 (Phone) (703) 561-1100; (Fax) (703) 713-1641; Email: *info@nacha.org;* and Internet at *http://www.nacha.org.* The implementation specifications are as follows:

(1) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules, Appendix One: ACH File Exchange Specifications (Operating Rule 59) as referenced in § 162.1602.

(2) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules Appendix Three: ACH Record Format Specifications (Operating Rule 78), Part 3.1, Subpart 3.1.8 Sequence of Records for CCD Entries as referenced in § 162.1602.

[68 FR 8396, Feb. 20, 2003, as amended at 69 FR 18803, Apr. 9, 2004; 74 FR 3324, Jan. 16, 2009; 76 FR 40495, July 8, 2011; 77 FR 1590, Jan. 10, 2012; 77 FR 48043, Aug. 10, 2012]

§ 162.923 Requirements for covered entities.

(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts, with another covered entity that is required to comply with a transaction standard adopted

under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.

(b) *Exception for direct data entry transactions.* A health care provider electing to use direct data entry offered by a health plan to conduct a transaction for which a standard has been adopted under this part must use the applicable data content and data condition requirements of the standard when conducting the transaction. The health care provider is not required to use the format requirements of the standard.

(c) *Use of a business associate.* A covered entity may use a business associate, including a health care clearinghouse, to conduct a transaction covered by this part. If a covered entity chooses to use a business associate to conduct all or part of a transaction on behalf of the covered entity, the covered entity must require the business associate to do the following:

(1) Comply with all applicable requirements of this part.

(2) Require any agent or subcontractor to comply with all applicable requirements of this part.

[65 FR 50367, Aug. 17, 2000, as amended at 74 FR 3325, Jan. 16, 2009]

§ 162.925 Additional requirements for health plans.

(a) *General rules.* (1) If an entity requests a health plan to conduct a transaction as a standard transaction, the health plan must do so.

(2) A health plan may not delay or reject a transaction, or attempt to adversely affect the other entity or the transaction, because the transaction is a standard transaction.

(3) A health plan may not reject a standard transaction on the basis that it contains data elements not needed or used by the health plan (for example, coordination of benefits information).

(4) A health plan may not offer an incentive for a health care provider to conduct a transaction covered by this part as a transaction described under the exception provided for in § 162.923(b).

(5) A health plan that operates as a health care clearinghouse, or requires an entity to use a health care clearinghouse to receive, process, or transmit a standard transaction may not charge fees or costs in excess of the fees or costs for normal telecommunications that the entity incurs when it directly transmits, or receives, a standard transaction to, or from, a health plan.

(6) During the period from March 17, 2009 through December 31, 2011, a health plan may not delay or reject a standard transaction, or attempt to adversely affect the other entity or the transaction, on the basis that it does not comply with another adopted standard for the same period.

(b) *Coordination of benefits.* If a health plan receives a standard transaction and coordinates benefits with another health plan (or another payer), it must store the coordination of benefits data it needs to forward the standard transaction to the other health plan (or other payer).

(c) *Code sets.* A health plan must meet each of the following requirements:

(1) Accept and promptly process any standard transaction that contains codes that are valid, as provided in subpart J of this part.

(2) Keep code sets for the current billing period and appeals periods still open to processing under the terms of the health plan's coverage.

[65 FR 50367, Aug. 17, 2000, as amended at 74 FR 3325, Jan. 16, 2009]

§ 162.930 Additional rules for health care clearinghouses.

When acting as a business associate for another covered entity, a health care clearinghouse may perform the following functions:

(a) Receive a standard transaction on behalf of the covered entity and translate it into a nonstandard transaction (for example, nonstandard format and/or nonstandard data content) for transmission to the covered entity.

(b) Receive a nonstandard transaction (for example, nonstandard format and/or nonstandard data content) from the covered entity and translate it into a standard transaction for transmission on behalf of the covered entity.

§ 162.940 Exceptions from standards to permit testing of proposed modifications.

(a) *Requests for an exception.* An organization may request an exception from the use of a standard from the Secretary to test a proposed modification to that standard. For each proposed modification, the organization must meet the following requirements:

(1) *Comparison to a current standard.* Provide a detailed explanation, no more than 10 pages in length, of how the proposed modification would be a significant improvement to the current standard in terms of the following principles:

(i) Improve the efficiency and effectiveness of the health care system by leading to cost reductions for, or improvements in benefits from, electronic health care transactions.

(ii) Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses.

(iii) Be uniform and consistent with the other standards adopted under this part and, as appropriate, with other private and public sector health data standards.

(iv) Have low additional development and implementation costs relative to the benefits of using the standard.

(v) Be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time.

(vi) Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster.

(vii) Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard.

(viii) Be precise, unambiguous, and as simple as possible.

(ix) Result in minimum data collection and paperwork burdens on users.

(x) Incorporate flexibility to adapt more easily to changes in the health care infrastructure (such as new services, organizations, and provider types) and information technology.

(2) *Specifications for the proposed modification.* Provide specifications for the proposed modification, including any additional system requirements.

(3) *Testing of the proposed modification.* Provide an explanation, no more than 5 pages in length, of how the organization intends to test the standard, including the number and types of health plans and health care providers expected to be involved in the test, geographical areas, and beginning and ending dates of the test.

(4) *Trading partner concurrences.* Provide written concurrences from trading partners who would agree to participate in the test.

(b) *Basis for granting an exception.* The Secretary may grant an initial exception, for a period not to exceed 3 years, based on, but not limited to, the following criteria:

(1) An assessment of whether the proposed modification demonstrates a significant improvement to the current standard.

(2) The extent and length of time of the exception.

(3) Consultations with DSMOs.

(c) *Secretary's decision on exception.* The Secretary makes a decision and notifies the organization requesting the exception whether the request is granted or denied.

(1) *Exception granted.* If the Secretary grants an exception, the notification includes the following information:

(i) The length of time for which the exception applies.

(ii) The trading partners and geographical areas the Secretary approves for testing.

(iii) Any other conditions for approving the exception.

(2) *Exception denied.* If the Secretary does not grant an exception, the notification explains the reasons the Secretary considers the proposed modification would not be a significant improvement to the current standard and any other rationale for the denial.

(d) *Organization's report on test results.* Within 90 days after the test is completed, an organization that receives an

exception must submit a report on the results of the test, including a cost-benefit analysis, to a location specified by the Secretary by notice in the FEDERAL REGISTER.

(e) *Extension allowed.* If the report submitted in accordance with paragraph (d) of this section recommends a modification to the standard, the Secretary, on request, may grant an extension to the period granted for the exception.

Subpart J—Code Sets

§ 162.1000 General requirements.

When conducting a transaction covered by this part, a covered entity must meet the following requirements:

(a) *Medical data code sets.* Use the applicable medical data code sets described in § 162.1002 as specified in the implementation specification adopted under this part that are valid at the time the health care is furnished.

(b) *Nonmedical data code sets.* Use the nonmedical data code sets as described in the implementation specifications adopted under this part that are valid at the time the transaction is initiated.

§ 162.1002 Medical data code sets.

The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets:

(a) For the period from October 16, 2002 through October 15, 2003:

(1) *International Classification of Diseases, 9th Edition, Clinical Modification, (ICD-9-CM), Volumes 1 and 2* (including The Official ICD-9-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(2) *International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3 Procedures* (including The Official ICD-9-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

(i) Prevention.

(ii) Diagnosis.

(iii) Treatment.

(iv) Management.

(3) *National Drug Codes* (NDC), as maintained and distributed by HHS, in collaboration with drug manufacturers, for the following:

(i) Drugs

(ii) Biologics.

(4) *Code on Dental Procedures and Nomenclature,* as maintained and distributed by the American Dental Association, for dental services.

(5) The combination of *Health Care Financing Administration Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, and *Current Procedural Terminology, Fourth Edition (CPT-4),* as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:

(i) Physician services.

(ii) Physical and occupational therapy services.

(iii) Radiologic procedures.

(iv) Clinical laboratory tests.

(v) Other medical diagnostic procedures.

(vi) Hearing and vision services.

(vii) Transportation services including ambulance.

(6) The *Health Care Financing Administration Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services. These items include, but are not limited to, the following:

(i) Medical supplies.

(ii) Orthotic and prosthetic devices.

(iii) Durable medical equipment.

(b) For the period on and after October 16, 2003 through September 30, 2014:

(1) The code sets specified in paragraphs (a)(1), (a)(2),(a)(4), and (a)(5) of this section.

(2) *National Drug Codes (NDC),* as maintained and distributed by HHS, for reporting the following by retail pharmacies:

(i) Drugs.

(ii) Biologics.

(3) *The Healthcare Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services, with the exception of drugs and biologics. These items include, but are not limited to, the following:

(i) Medical supplies.

(ii) Orthotic and prosthetic devices.

(iii) Durable medical equipment.

(c) For the period on and after October 1, 2014:

(1) The code sets specified in paragraphs (a)(4), (a)(5), (b)(2), and (b)(3) of this section.

(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) (including The Official ICD-10-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(3) International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) (including The Official ICD-10-PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

(i) Prevention.

(ii) Diagnosis.

(iii) Treatment.

(iv) Management.

[65 FR 50367, Aug. 17, 2000, as amended at 68 FR 8397, Feb. 20, 2003; 74 FR 3362, Jan. 16, 2009; 77 FR 54720, Sept. 5, 2012]

§ 162.1011 Valid code sets.

Each code set is valid within the dates specified by the organization responsible for maintaining that code set.

Subpart K—Health Care Claims or Equivalent Encounter Information

§ 162.1101 Health care claims or equivalent encounter information transaction.

The health care claims or equivalent encounter information transaction is the transmission of either of the following:

(a) A request to obtain payment, and the necessary accompanying information from a health care provider to a health plan, for health care.

(b) If there is no direct claim, because the reimbursement contract is based on a mechanism other than charges or reimbursement rates for specific services, the transaction is the transmission of encounter information for the purpose of reporting health care.

§ 162.1102 Standards for health care claims or equivalent encounter information transaction.

The Secretary adopts the following standards for the health care claims or equivalent encounter information transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drugs claims.* The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standards Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standards Batch Implementation Guide, Version

1, Release 1, (Version 1.1), January 2000, supporting Telecomunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claims: Professional, Volumes 1 and 2, Version 4010, may 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claims: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010x098A1. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1. (Incorporated by reference in § 162.920).

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1)(i) The standards identified in paragraph (a) of this section; and

(ii) For retail pharmacy supplies and professional services claims, the following: The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096, October 2002 (Incorporated by reference in § 162.920); and

(2)(i) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1. (Incorporated by reference in § 162.920.)

(iii) *Professional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in § 162.920.)

(iv) *Institutional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1. (Incorporated by reference in § 162.920.)

(v) *Retail pharmacy supplies and professional services claims.* (A) The Telecommunication Standard, Implementation Guide Version 5, Release 1, September 1999. (Incorporated by reference in § 162.920.)

(B) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs (Incorporated by reference in § 162.920); and

(C) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in § 162.920.)

(c) For the period on and after the January 1, 2012, the standards identified in paragraph (b)(2) of this section, except the standard identified in paragraph (b)(2)(v)(A) of this section.

[68 FR 8397, Feb. 20, 2003; 68 FR 11445, Mar. 10, 2003, as amended at 74 FR 3325, Jan. 16, 2009]

Subpart L—Eligibility for a Health Plan

§ 162.1201 Eligibility for a health plan transaction.

The eligibility for a health plan transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan, or from one health plan to another health plan, to obtain any of the following information about a benefit plan for an enrollee:

(1) Eligibility to receive health care under the health plan.

(2) Coverage of health care under the health plan.

(3) Benefits associated with the benefit plan.

(b) A response from a health plan to a health care provider's (or another health plan's) inquiry described in paragraph (a) of this section.

§ 162.1202 Standards for eligibility for a health plan transaction.

The Secretary adopts the following standards for the eligibility for a health plan transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drugs.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response.* The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1. (Incorporated by reference in § 162.920).

(b) For the period from March 17, 2009 through December 31, 2011 both:

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental, professional, and institutional health care eligibility benefit inquiry and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

[68 FR 8398, Feb. 20, 2003; 68 FR 11445, Mar. 10, 2003, as amended at 74 FR 3326, Jan. 16, 2009]

§ 162.1203 Operating rules for eligibility for a health plan transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase I and Phase II operating rules (updated for Version 5010) for the eligibility for a health plan transaction:

(1) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE v5010 Master Companion Guide Template. (Incorporated by reference in § 162.920).

(2) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(3) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(4) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(5) Phase I CORE 156: Eligibility and Benefits Real Time Response Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(6) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(7) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920).

(8) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0. (Incorporated by reference in § 162.920).

(9) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920).

(10) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

[76 FR 40496, July 8, 2011]

Subpart M—Referral Certification and Authorization

§ 162.1301 Referral certification and authorization transaction.

The referral certification and authorization transaction is any of the following transmissions:

(a) A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care.

(b) A request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider.

(c) A response from a health plan to a health care provider to a request described in paragraph (a) or paragraph (b) of this section.

[74 FR 3326, Jan. 16, 2009]

§ 162.1302 Standards for referral certification and authorization transaction.

The Secretary adopts the following standards for the referral certification and authorization transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drug referral certification and authorization.* The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional referral certification and authorization.* The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1. (Incorporated by reference in § 162.920).

(b) For the period from March 17, 2009 through December 31, 2011 both—

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental, professional, and institutional request for review and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review

and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review-—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

[68 FR 8398, Feb. 20, 2003, as amended at 74 FR 3326, Jan. 16, 2009]

Subpart N—Health Care Claim Status

§ 162.1401 Health care claim status transaction.

The health care claim status transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan to determine the status of a health care claim.

(b) A response from a health plan to a health care provider about the status of a health care claim.

[74 FR 3326, Jan. 16, 2009]

§ 162.1402 Standards for health care claim status transaction.

The Secretary adopts the following standards for the health care claim status transaction:

(a) For the period from October 16, 2003 through March 16, 2009: The ASC X12N-276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3326, Jan. 16, 2009]

§ 162.1403 Operating rules for health care claim status transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase II operating rules (updated for Version 5010) for the health care claim status transaction:

(1) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, and CORE v5010 Master Companion Guide, 00510, 1.2, March 2011. (Incorporated by reference in § 162.920).

(2) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

[76 FR 40496, July 8, 2011]

Subpart O—Enrollment and Disenrollment in a Health Plan

§ 162.1501 Enrollment and disenrollment in a health plan transaction.

The enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information from the sponsor of the insurance coverage, benefits, or policy, to a health plan to establish or terminate insurance coverage.

[74 FR 3327, Jan. 16, 2009]

§ 162.1502 Standards for enrollment and disenrollment in a health plan transaction.

The Secretary adopts the following standards for

enrollment and disenrollment in a health plan transaction.

(a) For the period from October 16, 2003 through March 16, 2009: ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220 (Incorporated by reference in § 162.920)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3327, Jan. 16, 2009]

Subpart P—Health Care Electronic Funds Transfers (EFT) and Remittance Advice

§ 162.1601 Health care electronic funds transfers (EFT) and remittance advice transaction.

The health care electronic funds transfers (EFT) and remittance advice transaction is the transmission of either of the following for health care:

(a) The transmission of any of the following from a health plan to a health care provider:

(1) Payment.

(2) Information about the transfer of funds.

(3) Payment processing information.

(b) The transmission of either of the following from a health plan to a health care provider:

(1) Explanation of benefits.

(2) Remittance advice.

[65 FR 50367, Aug. 17, 2000, as amended at 77 FR 1590, Jan. 10, 2012; 77 FR 48043, Aug. 10, 2012]

§ 162.1602 Standards for health care electronic funds transfers (EFT) and remittance advice transaction.

The Secretary adopts the following standards:

(a) For the period from October 16, 2003 through March 16, 2009: Health care claims and remittance advice. The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company, 004010X091A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both of the following standards:

(1) The standard identified in paragraph (a) of this section.

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in § 162.920.)

(c) For the period from January 1, 2012 through December 31, 2013, the standard identified in paragraph (b)(2) of this section.

(d) For the period on and after January 1, 2014, the following standards:

(1) Except when transmissions as described in § 162.1601(a) and (b) are contained within the same transmission, for Stage 1 Payment Initiation transmissions described in § 162.1601(a), all of the following standards:

(i) The National Automated Clearing House Association (NACHA) Corporate Credit or Deposit Entry with Addenda Record (CCD+) implementation specifications as contained in the 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network as follows (incorporated by reference in § 162.920)—

(A) NACHA Operating Rules, Appendix One: ACH File Exchange Specifications; and

(B) NACHA Operating Rules, Appendix Three: ACH Record Format Specifications, Subpart 3.1.8 Sequence of Records for CCD Entries.

(ii) For the CCD Addenda Record (“7”), field 3, of the

standard identified in 1602(d)(1)(i), the Accredited Standards Committee (ASC) X12 Standards for Electronic Data Interchange Technical Report Type 3, "Health Care Claim Payment/Advice (835), April 2006: Section 2.4: 835 Segment Detail: "TRN Reassociation Trace Number," Washington Publishing Company, 005010X221 (Incorporated by reference in § 162.920).

(2) For transmissions described in § 162.1601(b), including when transmissions as described in § 162.1601(a) and (b) are contained within the same transmission, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, "Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in § 162.920).

[77 FR 1590, Jan. 10, 2012]

§ 162.1603 Operating rules for health care electronic funds transfers (EFT) and remittance advice transaction.

On and after January 1, 2014, the Secretary adopts the following for the health care electronic funds transfers (EFT) and remittance advice transaction:

(a) The Phase III CORE EFT & ERA Operating Rule Set, Approved June 2012 (Incorporated by reference in § 162.920) which includes the following rules:

(1) Phase III CORE 380 EFT Enrollment Data Rule, version 3.0.0, June 2012.

(2) Phase III CORE 382 ERA Enrollment Data Rule, version 3.0.0, June 2012.

(3) Phase III 360 CORE Uniform Use of CARCs and RARCs (835) Rule, version 3.0.0, June 2012.

(4) CORE-required Code Combinations for CORE-defined Business Scenarios for the Phase III CORE 360 Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule, version 3.0.0, June 2012.

(5) Phase III CORE 370 EFT & ERA Reassociation (CCD+/835) Rule, version 3.0.0, June 2012.

(6) Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012, except Requirement 4.2 titled "Health Care Claim Payment/Advice Batch Acknowledgement Requirements".

(b) ACME Health Plan, CORE v5010 Master Companion Guide Template, 005010, 1.2, March 2011 (incorporated by reference in § 162.920), as required by the Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012.

[77 FR 48043, Aug. 10, 2012]

Subpart Q—Health Plan Premium Payments

§ 162.1701 Health plan premium payments transaction.

The health plan premium payment transaction is the transmission of any of the following from the entity that is arranging for the provision of health care or is providing health care coverage payments for an individual to a health plan:

(a) Payment.

(b) Information about the transfer of funds.

(c) Detailed remittance information about individuals for whom premiums are being paid.

(d) Payment processing information to transmit health care premium payments including any of the following:

(1) Payroll deductions.

(2) Other group premium payments.

(3) Associated group premium payment information.

§ 162.1702 Standards for health plan premium payments transaction.

The Secretary adopts the following standards for the health plan premium payments transaction:

(a) For the period from October 16, 2003 through March 16, 2009: The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1.

(Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section, and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3327, Jan. 16, 2009]

Subpart R—Coordination of Benefits

§ 162.1801 Coordination of benefits transaction.

The coordination of benefits transaction is the transmission from any entity to a health plan for the purpose of determining the relative payment responsibilities of the health plan, of either of the following for health care:

(a) Claims.

(b) Payment information.

§ 162.1802 Standards for coordination of benefits information transaction.

The Secretary adopts the following standards for the coordination of benefits information transaction.

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1. (Incorporated by reference in § 162.920).

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1. (Incorporated by reference in § 162.920.)

(iii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222.

(Incorporated by reference in § 162.920.)

(iv) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

[68 FR 8399, Feb. 20, 2003, as amended at 74 FR 3327, Jan. 16, 2009]

Subpart S—Medicaid Pharmacy Subrogation

SOURCE: 74 FR 3328, Jan. 16, 2009, unless otherwise noted.

§ 162.1901 Medicaid pharmacy subrogation transaction.

The Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the State has paid on behalf of a Medicaid recipient.

§ 162.1902 Standard for Medicaid pharmacy subrogation transaction.

The Secretary adopts the Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902 (Incorporated by reference at § 162.920):

(a) For the period on and after January 1, 2012, for covered entities that are not small health plans;

(b) For the period on and after January 1, 2013 for small health plans.

PART 164—SECURITY AND PRIVACY

Contents

AUTHORITY: 42 U.S.C. 1302(a); 42 U.S.C. 1320d-1320d-9; sec. 264, Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note)); and secs. 13400-13424, Pub. L. 111-5, 123 Stat. 258-279.

SOURCE: 65 FR 82802, Dec. 28, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act, section 264 of Public Law 104-191, and sections 13400-13424 of Public Law 111-5.

[78 FR 5692, Jan. 25, 2013]

§ 164.103 Definitions.

As used in this part, the following terms have the following meanings:

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with § 164.105(a)(2)(iii)(D).

Hybrid entity means a single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates health care components in accordance with paragraph § 164.105(a)(2)(iii)(D).

Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

Required by law means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

[68 FR 8374, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009]

§ 164.104 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this part apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) Where provided, the standards, requirements, and implementation specifications adopted under this part apply to a business associate.

[68 FR 8375, Feb. 20, 2003, as amended at 78 FR 5692, Jan. 25, 2013]

§ 164.105 Organizational requirements.

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of this part, other than the requirements of this section, § 164.314, and § 164.504, apply only to the health care component(s) of the entity, as specified in this section.

(2) *Implementation specifications:*

(i) *Application of other provisions.* In applying a provision of this part, other than the requirements of this section, § 164.314, and § 164.504, to a hybrid entity:

(A) A reference in such provision to a "covered entity" refers to a health care component of the covered entity;

(B) A reference in such provision to a "health plan," "covered health care provider," or "health care clearinghouse," refers to a health care component of the covered entity if such health care component performs the functions of a health plan, health care provider, or health care clearinghouse, as applicable;

(C) A reference in such provision to "protected health information" refers to protected health information that is created or received by or on behalf of the health care component of the covered entity; and

(D) A reference in such provision to "electronic protected health information" refers to electronic protected health information that is created, received, maintained, or transmitted by or on behalf of the health care component of the covered entity.

(ii) *Safeguard requirements.* The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this part. In particular, and without limiting this requirement, such covered entity must ensure that:

(A) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which subpart E of this part would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;

(B) Its health care component protects electronic protected health information with respect to another component of the covered entity to the same extent that it would be required under subpart C of this part to protect such information if the health care component and the other component were separate and distinct legal entities;

(C) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by subpart E of this part.

(iii) *Responsibilities of the covered entity.* A covered entity that is a hybrid entity has the following responsibilities:

(A) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility of complying with this part.

(B) The covered entity is responsible for complying with § 164.316(a) and § 164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with applicable requirements of this part, including the safeguard requirements in paragraph (a)(2)(ii) of this section.

(C) The covered entity is responsible for complying with § 164.314 and § 164.504 regarding business associate arrangements and other organizational requirements.

(D) The covered entity is responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation in accordance with paragraph (c) of this section, provided that, if the covered entity designates one or more health care components, it must include any component that would meet the definition of a covered entity or business associate if it were a separate legal entity. Health care component(s) also may include a component only to the extent that it performs covered functions.

(b)(1) *Standard: Affiliated covered entities.* Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this part.

(2) *Implementation specifications.*

(i) *Requirements for designation of an affiliated covered entity.*

(A) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of this part, if all of the covered entities designated are under common ownership or control.

(B) The designation of an affiliated covered entity must be documented and the documentation maintained as required by paragraph (c) of this section.

(ii) *Safeguard requirements.* An affiliated covered entity must ensure that it complies with the applicable requirements of this part, including, if the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, § 164.308(a)(4)(ii)(A) and § 164.504(g), as applicable.

(c)(1) *Standard: Documentation.* A covered entity must maintain a written or electronic record of a designation as required by paragraphs (a) or (b) of this section.

(2) *Implementation specification: Retention period .* A covered entity must retain the documentation as required by paragraph (c)(1) of this section

for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

[68 FR 8375, Feb. 20, 2003, as amended at 78 FR 5692, Jan. 25, 2013]

§ 164.106 Relationship to other parts.

In complying with the requirements of this part, covered entities and, where provided, business associates, are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.

[78 FR 5693, Jan. 25, 2013]

Subpart B [Reserved]

Subpart C—Security Standards for the Protection of Electronic Protected Health Information

AUTHORITY: 42 U.S.C. 1320d-2 and 1320d-4; sec. 13401, Pub. L. 111-5, 123 Stat. 260.

SOURCE: 68 FR 8376, Feb. 20, 2003, unless otherwise noted.

§ 164.302 Applicability.

A covered entity or business associate must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information of a covered entity.

[78 FR 5693, Jan. 25, 2013]

§ 164.304 Definitions.

As used in this subpart, the following terms have the following meanings:

Access means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource. (This definition applies to "access" as used in this subpart, not as used in subparts D or E of this part.)

Administrative safeguards are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's or business associate's workforce in relation to the protection of that information.

Authentication means the corroboration that a person is the one claimed.

Availability means the property that data or information is accessible and useable upon demand by an authorized person.

Confidentiality means the property that data or information is not made available or disclosed to unauthorized persons or processes.

Encryption means the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key.

Facility means the physical premises and the interior and exterior of a building(s).

Information system means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.

Integrity means the property that data or information have not been altered or destroyed in an unauthorized manner.

Malicious software means software, for example, a virus, designed to damage or disrupt a system.

Password means confidential authentication information composed of a string of characters.

Physical safeguards are physical measures, policies, and procedures to protect a covered entity's or business associate's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

Security or Security measures encompass all of the administrative, physical, and technical safeguards in an information system.

Security incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

Technical safeguards means the technology and the policy and procedures for its use that protect electronic protected health information and control access to it.

User means a person or entity with authorized access.

Workstation means an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment.

[68 FR 8376, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009; 78 FR 5693, Jan. 25, 2013]

§ 164.306 Security standards: General rules.

(a) *General requirements.* Covered entities and business associates must do the following:

(1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity or business associate creates, receives, maintains, or transmits.

(2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.

(3) Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under subpart E of this part.

(4) Ensure compliance with this subpart by its workforce.

(b) *Flexibility of approach.*
(1) Covered entities and business associates may use any security measures that allow the covered entity or business associate to reasonably and appropriately implement the standards and implementation specifications as specified in this subpart.

(2) In deciding which security measures to use, a covered entity or business associate must take into account the following factors:

(i) The size, complexity, and capabilities of the covered entity or business associate.

(ii) The covered entity's or the business associate's technical infrastructure, hardware, and software security capabilities.

(iii) The costs of security measures.

(iv) The probability and criticality of potential risks to electronic protected health information.

(c) *Standards.* A covered entity or business associate must comply with the applicable standards as provided in this section and in § 164.308, § 164.310, § 164.312, § 164.314 and § 164.316 with respect to all electronic protected health information.

(d) *Implementation specifications.* In this subpart:

(1) Implementation specifications are required or addressable. If an implementation specification is required, the word "Required" appears in parentheses after the title of the implementation specification. If an implementation specification is addressable, the word "Addressable" appears in parentheses after the title of the implementation specification.

(2) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes required implementation specifications, a covered entity or business associate must implement the implementation specifications.

(3) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes addressable implementation specifications, a covered entity or business associate must—

(i) Assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting electronic protected health information; and

(ii) As applicable to the covered entity or business associate—

(A) Implement the implementation specification if reasonable and appropriate; or

(B) If implementing the implementation specification is not reasonable and appropriate—

(*1*) Document why it would not be reasonable and appropriate to implement the implementation specification; and

(*2*) Implement an equivalent alternative measure if reasonable and appropriate.

(e) *Maintenance.* A covered entity or business associate must review and modify the security measures implemented under this subpart as needed to continue provision of reasonable and appropriate protection of

electronic protected health information, and update documentation of such security measures in accordance with § 164.316(b)(2)(iii).

[68 FR 8376, Feb. 20, 2003; 68 FR 17153, Apr. 8, 2003; 78 FR 5693, Jan. 25, 2013]

§ 164.308 Administrative safeguards.

(a) A covered entity or business associate must, in accordance with § 164.306:

(1)(i) *Standard: Security management process.* Implement policies and procedures to prevent, detect, contain, and correct security violations.

(ii) *Implementation specifications:*

(A) *Risk analysis (Required).* Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity or business associate.

(B) *Risk management (Required).* Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with § 164.306(a).

(C) *Sanction policy (Required).* Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity or business associate.

(D) *Information system activity review (Required).* Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

(2) *Standard: Assigned security responsibility.* Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the covered entity or business associate.

(3)(i) *Standard: Workforce security.* Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.

(ii) *Implementation specifications:*

(A) *Authorization and/or supervision (Addressable).* Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed.

(B) *Workforce clearance procedure (Addressable).* Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate.

(C) *Termination procedures (Addressable).* Implement procedures for terminating access to electronic protected health information when the employment of, or other arrangement with, a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

(4)(i) *Standard: Information access management.* Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part.

(ii) *Implementation specifications:*

(A) *Isolating health care clearinghouse functions (Required).* If a health care clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization.

(B) *Access authorization (Addressable).* Implement policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism.

(C) *Access establishment and modification (Addressable).* Implement policies and procedures that, based upon the covered entity's or the business associate's access authorization policies, establish, document, review, and modify a user's right

of access to a workstation, transaction, program, or process.

(5)(i) *Standard: Security awareness and training.* Implement a security awareness and training program for all members of its workforce (including management).

(ii) *Implementation specifications.* Implement:

(A) *Security reminders (Addressable).* Periodic security updates.

(B) *Protection from malicious software (Addressable).* Procedures for guarding against, detecting, and reporting malicious software.

(C) *Log-in monitoring (Addressable).* Procedures for monitoring log-in attempts and reporting discrepancies.

(D) *Password management (Addressable).* Procedures for creating, changing, and safeguarding passwords.

(6)(i) *Standard: Security incident procedures.* Implement policies and procedures to address security incidents.

(ii) *Implementation specification: Response and reporting (Required).* Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity or business associate; and document security incidents and their outcomes.

(7)(i) *Standard: Contingency plan.* Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information.

(ii) *Implementation specifications:*

(A) *Data backup plan (Required).* Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information.

(B) *Disaster recovery plan (Required).* Establish (and implement as needed) procedures to restore any loss of data.

(C) *Emergency mode operation plan (Required).* Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode.

(D) *Testing and revision procedures (Addressable).* Implement procedures for periodic testing and revision of contingency plans.

(E) *Applications and data criticality analysis (Addressable).* Assess the relative criticality of specific applications and data in support of other contingency plan components.

(8) *Standard: Evaluation.* Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and, subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, that establishes the extent to which a covered entity's or business associate's security policies and procedures meet the requirements of this subpart.

(b)(1) *Business associate contracts and other arrangements.* A covered entity may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a), that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(2) A business associate may permit a business associate that is a subcontractor to create, receive, maintain, or transmit electronic protected health information on its behalf only if the business associate obtains satisfactory assurances, in accordance with § 164.314(a), that the subcontractor will appropriately safeguard the information.

(3) *Implementation specifications: Written contract or other arrangement (Required).* Document the satisfactory assurances required by paragraph (b)(1) or (b)(2) of this section through a written contract or other arrangement with the business associate that

meets the applicable requirements of § 164.314(a).

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.310 Physical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

(a)(1) *Standard: Facility access controls.* Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

(2) *Implementation specifications:*

(i) *Contingency operations (Addressable).* Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency.

(ii) *Facility security plan (Addressable).* Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.

(iii) *Access control and validation procedures (Addressable).* Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.

(iv) *Maintenance records (Addressable).* Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors, and locks).

(b) *Standard: Workstation use.* Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information.

(c) *Standard: Workstation security.* Implement physical safeguards for all workstations that access electronic protected health information, to restrict access to authorized users.

(d)(1) *Standard: Device and media controls.* Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility.

(2) *Implementation specifications:*

(i) *Disposal (Required).* Implement policies and procedures to address the final disposition of electronic protected health information, and/or the hardware or electronic media on which it is stored.

(ii) *Media re-use (Required).* Implement procedures for removal of electronic protected health information from electronic media before the media are made available for re-use.

(iii) *Accountability (Addressable).* Maintain a record of the movements of hardware and electronic media and any person responsible therefore.

(iv) *Data backup and storage (Addressable).* Create a retrievable, exact copy of electronic protected health information, when needed, before movement of equipment.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.312 Technical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

(a)(1) *Standard: Access control.* Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).

(2) *Implementation specifications:*

(i) *Unique user identification (Required).* Assign a unique name and/or number for identifying and tracking user identity.

(ii) *Emergency access procedure (Required).* Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency.

(iii) *Automatic logoff (Addressable).* Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.

(iv) *Encryption and decryption (Addressable).* Implement a mechanism to encrypt and decrypt electronic protected health information.

(b) *Standard: Audit controls.* Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information.

(c)(1) *Standard: Integrity.* Implement policies and procedures to protect electronic protected health information from improper alteration or destruction.

(2) *Implementation specification: Mechanism to authenticate electronic protected health information (Addressable).* Implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner.

(d) *Standard: Person or entity authentication.* Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed.

(e)(1) *Standard: Transmission security.* Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network.

(2) *Implementation specifications:*

(i) *Integrity controls (Addressable).* Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of.

(ii) *Encryption (Addressable).* Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.314 Organizational requirements.

(a)(1) *Standard: Business associate contracts or other arrangements.* The contract or other arrangement required by § 164.308(b)(3) must meet the requirements of paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section, as applicable.

(2) *Implementation specifications (Required).*

(i) *Business associate contracts.* The contract must provide that the business associate will—

(A) Comply with the applicable requirements of this subpart;

(B) In accordance with § 164.308(b)(2), ensure that any subcontractors that create, receive, maintain, or transmit electronic protected health information on behalf of the business associate agree to comply with the applicable requirements of this subpart by entering into a contract or other arrangement that complies with this section; and

(C) Report to the covered entity any security incident of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410.

(ii) *Other arrangements.* The covered entity is in compliance with paragraph (a)(1) of this section if it has another arrangement in place that meets the requirements of § 164.504(e)(3).

(iii) *Business associate contracts with subcontractors.* The requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section apply to the contract or other arrangement between a business associate and a subcontractor required by § 164.308(b)(4) in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(b)(1) *Standard: Requirements for group health plans.* Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to § 164.504(f)(1)(ii) or (iii), or as authorized under § 164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected

health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan.

(2) *Implementation specifications (Required).* The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to—

(i) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan;

(ii) Ensure that the adequate separation required by § 164.504(f)(2)(iii) is supported by reasonable and appropriate security measures;

(iii) Ensure that any agent to whom it provides this information agrees to implement reasonable and appropriate security measures to protect the information; and

(iv) Report to the group health plan any security incident of which it becomes aware.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.316 Policies and procedures and documentation requirements.

A covered entity or business associate must, in accordance with § 164.306:

(a) *Standard: Policies and procedures.* Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in § 164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity or business associate may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

(b)(1) *Standard: Documentation.* (i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and

(ii) If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

(2) *Implementation specifications:*

(i) *Time limit (Required).* Retain the documentation required by paragraph (b)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

(ii) *Availability (Required).* Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

(iii) *Updates (Required).* Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic protected health information.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5695, Jan. 25, 2013]

§ 164.318 Compliance dates for the initial implementation of the security standards.

(a) *Health plan.* (1) A health plan that is not a small health plan must comply with the applicable requirements of this subpart no later than April 20, 2005.

(2) A small health plan must comply with the applicable requirements of this subpart no later than April 20, 2006.

(b) *Health care clearinghouse.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 20, 2005.

(c) *Health care provider.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 20, 2005.

Appendix A to Subpart C of Part 164—Security Standards: Matrix

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
Administrative Safeguards		
Security Management Process	164.308(a)(1)	Risk Analysis (R)
		Risk Management (R)
		Sanction Policy (R)
		Information System Activity Review (R)
Assigned Security Responsibility	164.308(a)(2)	(R)
Workforce Security	164.308(a)(3)	Authorization and/or Supervision (A)
		Workforce Clearance Procedure (A)
		Termination Procedures (A)
Information Access Management	164.308(a)(4)	Isolating Health care Clearinghouse Function (R)
		Access Authorization (A)
		Access Establishment and Modification (A)
Security Awareness and Training	164.308(a)(5)	Security Reminders (A)
		Protection from Malicious Software (A)
		Log-in Monitoring (A)
		Password Management (A)
Security Incident Procedures	164.308(a)(6)	Response and Reporting (R)
Contingency Plan	164.308(a)(7)	Data Backup Plan (R)
		Disaster Recovery Plan (R)
		Emergency Mode Operation Plan (R)
		Testing and Revision Procedure (A)
		Applications and Data Criticality Analysis (A)
Evaluation	164.308(a)(8)	(R)
Business Associate Contracts and Other Arrangement	164.308(b)(1)	Written Contract or Other Arrangement (R)
Physical Safeguards		
Facility Access Controls	164.310(a)(1)	Contingency Operations (A)
		Facility Security Plan (A)
		Access Control and Validation Procedures (A)
		Maintenance Records (A)
Workstation Use	164.310(b)	(R)
Workstation Security	164.310(c)	(R)
Device and Media Controls	164.310(d)(1)	Disposal (R)
		Media Re-use (R)
		Accountability (A)
		Data Backup and Storage (A)
Technical Safeguards(see § 164.312)		
Access Control	164.312(a)(1)	Unique User Identification (R)
		Emergency Access Procedure (R)
		Automatic Logoff (A)

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
		Encryption and Decryption (A)
Audit Controls	164.312(b)	(R)
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication	164.312(d)	(R)
Transmission Security	164.312(e)(1)	Integrity Controls (A)
		Encryption (A)

Subpart D—Notification in the Case of Breach of Unsecured Protected Health Information

SOURCE: 74 FR 42767, Aug. 24, 2009, unless otherwise noted.

§ 164.400 Applicability.

The requirements of this subpart shall apply with respect to breaches of protected health information occurring on or after September 23, 2009.

§ 164.402 Definitions.

As used in this subpart, the following terms have the following meanings:

Breach means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which compromises the security or privacy of the protected health information.

(1) Breach excludes:

(i) Any unintentional acquisition, access, or use of protected health information by a workforce member or person acting under the authority of a covered entity or a business associate, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under subpart E of this part.

(ii) Any inadvertent disclosure by a person who is authorized to access protected health information at a covered entity or business associate to another person authorized to access protected health information at the same covered entity or business associate, or organized health care arrangement in which the covered entity participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under subpart E of this part.

(iii) A disclosure of protected health information where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(2) Except as provided in paragraph (1) of this definition, an acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment of at least the following factors:

(i) The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;

(ii) The unauthorized person who used the protected health information or to whom the disclosure was made;

(iii) Whether the protected health information was actually acquired or viewed; and

(iv) The extent to which the risk to the protected health information has been mitigated.

Unsecured protected health information means protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111-5.

[78 FR 5695, Jan. 25, 2013]

§ 164.404 Notification to individuals.

(a) *Standard* —(1) *General rule.* A covered entity shall, following the discovery of a breach of unsecured protected health information, notify each individual whose unsecured protected health information has been, or is reasonably believed by the covered entity to have been, accessed, acquired, used, or disclosed as a result of such breach.

(2) *Breaches treated as discovered.* For purposes of paragraph (a)(1) of this section, §§ 164.406(a), and 164.408(a), a breach shall be treated as discovered by a covered entity as of the first day on which such breach is known to the covered entity, or, by exercising reasonable diligence would have been known to the covered entity. A covered entity shall be deemed to have knowledge of a breach if such breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is a workforce member or agent of the covered entity (determined in accordance with the federal common law of agency).

(b) *Implementation specification: Timeliness of notification.* Except as provided in § 164.412, a covered entity shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification* —(1) *Elements.* The notification required by paragraph (a) of this section shall include, to the extent possible:

(A) A brief description of what happened, including the date of the

breach and the date of the discovery of the breach, if known;

(B) A description of the types of unsecured protected health information that were involved in the breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(C) Any steps individuals should take to protect themselves from potential harm resulting from the breach;

(D) A brief description of what the covered entity involved is doing to investigate the breach, to mitigate harm to individuals, and to protect against any further breaches; and

(E) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.

(2) *Plain language requirement.* The notification required by paragraph (a) of this section shall be written in plain language.

(d) *Implementation specifications: Methods of individual notification.* The notification required by paragraph (a) of this section shall be provided in the following form:

(1) *Written notice.* (i) Written notification by first-class mail to the individual at the last known address of the individual or, if the individual agrees to electronic notice and such agreement has not been withdrawn, by electronic mail. The notification may be provided in one or more mailings as information is available.

(ii) If the covered entity knows the individual is deceased and has the address of the next of kin or personal representative of the individual (as specified under § 164.502(g)(4) of subpart E), written notification by first-class mail to either the next of kin or personal representative of the individual. The notification may be provided in one or more mailings as information is available.

(2) *Substitute notice.* In the case in which there is insufficient or out-of-date contact information that precludes written notification to the individual under paragraph (d)(1)(i) of this section, a substitute form of notice reasonably calculated to reach the individual shall be provided. Substitute notice need not be provided in the case in which there is insufficient or out-of-date contact information that precludes written notification to the next of kin or personal representative of the individual under paragraph (d)(1)(ii).

(i) In the case in which there is insufficient or out-of-date contact information for fewer than 10 individuals, then such substitute notice may be provided by an alternative form of written notice, telephone, or other means.

(ii) In the case in which there is insufficient or out-of-date contact information for 10 or more individuals, then such substitute notice shall:

(A) Be in the form of either a conspicuous posting for a period of 90 days on the home page of the Web site of the covered entity involved, or conspicuous notice in major print or broadcast media in geographic areas where the individuals affected by the breach likely reside; and

(B) Include a toll-free phone number that remains active for at least 90 days where an individual can learn whether the individual's unsecured protected health information may be included in the breach.

(3) *Additional notice in urgent situations.* In any case deemed by the covered entity to require urgency because of possible imminent misuse of unsecured protected health information, the covered entity may provide information to individuals by telephone or other means, as appropriate, in addition to notice provided under paragraph (d)(1) of this section.

§ 164.406 Notification to the media.

(a) *Standard.* For a breach of unsecured protected health information involving more than 500 residents of a State or jurisdiction, a covered entity shall, following the discovery of the breach as provided in § 164.404(a)(2), notify prominent media outlets serving the State or jurisdiction.

(b) *Implementation specification: Timeliness of notification.* Except as provided in § 164.412, a covered entity shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification.* The notification required by paragraph (a) of this section shall meet the requirements of § 164.404(c).

[74 FR 42740, Aug. 24, 2009, as amended at 78 FR 5695, Jan. 25, 2013]

§ 164.408 Notification to the Secretary.

(a) *Standard.* A covered entity shall, following the discovery of a breach of unsecured protected health information as provided in § 164.404(a)(2), notify the Secretary.

(b) *Implementation specifications: Breaches involving 500 or more individuals.* For breaches of unsecured protected health information involving 500 or more individuals, a covered entity shall, except as provided in § 164.412, provide the notification required by paragraph (a) of this section contemporaneously with the notice required by § 164.404(a) and in the manner specified on the HHS Web site.

(c) *Implementation specifications: Breaches involving less than 500 individuals.* For breaches of unsecured protected health information involving less than 500 individuals, a covered entity shall maintain a log or other documentation of such breaches and, not later than 60 days after the end of each calendar year, provide the notification required by paragraph (a) of this section for breaches discovered during the preceding calendar year, in the manner specified on the HHS web site.

[74 FR 42740, Aug. 24, 2009, as amended at 78 FR 5695, Jan. 25, 2013]

§ 164.410 Notification by a business associate.

(a) *Standard —*(1) *General rule.* A business associate shall, following the discovery of a breach of unsecured protected health information, notify the covered entity of such breach.

(2) *Breaches treated as discovered.* For purposes of paragraph (a)(1) of this section, a breach shall be treated as discovered by a business associate as of the first day on which such breach is known to the business associate or, by exercising reasonable diligence, would have been known to the business associate. A business associate shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the business associate (determined in accordance with the Federal common law of agency).

(b) *Implementation specifications: Timeliness of notification.* Except as provided in § 164.412, a business associate shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification.* (1) The notification required by paragraph (a) of this section shall include, to the extent possible, the identification of each individual whose unsecured protected health information has been, or is reasonably believed by the business associate to have been, accessed, acquired, used, or disclosed during the breach.

(2) A business associate shall provide the covered entity with any other available information that the covered entity is required to include in notification to the individual under § 164.404(c) at the time of the notification required by paragraph (a) of this section or promptly thereafter as information becomes available.

[74 FR 42740, Aug. 24, 2009, as amended at 78 FR 5695, Jan. 25, 2013]

§ 164.412 Law enforcement delay.

If a law enforcement official states to a covered entity or business associate that a notification, notice, or posting required under this subpart would impede a criminal investigation or cause damage to national security, a covered entity or business associate shall:

(a) If the statement is in writing and specifies the time for which a delay is required, delay such notification, notice, or posting for the time period specified by the official; or

(b) If the statement is made orally, document the statement, including the identity of the official making the statement, and delay the notification, notice, or posting temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in paragraph (a) of this section is submitted during that time.

§ 164.414 Administrative requirements and burden of proof.

(a) *Administrative requirements.* A covered entity is required to comply with the administrative requirements of § 164.530(b), (d), (e), (g), (h), (i), and (j) with respect to the requirements of this subpart.

(b) *Burden of proof.* In the event of a use or disclosure in violation of subpart E, the covered entity or business associate, as applicable, shall have the burden of demonstrating that all notifications were made as required by this subpart or that the use or disclosure did not constitute a breach, as defined at § 164.402.

Subpart E—Privacy of Individually Identifiable Health Information

AUTHORITY: 42 U.S.C. 1320d-2, 1320d-4, and 1320d-9; sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2 (note)); and secs. 13400-13424, Pub. L. 111-5, 123 Stat. 258-279.

§ 164.500 Applicability.

(a) Except as otherwise provided herein, the standards, requirements, and implementation specifications of

this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(iv) Section 164.504 relating to the organizational requirements for covered entities;

(v) Section 164.512 relating to uses and disclosures for which individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) Where provided, the standards, requirements, and implementation specifications adopted under this subpart apply to a business associate with respect to the protected health information of a covered entity.

(d) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 78 FR 5695, Jan. 25, 2013]

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons held in lawful custody* includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term *record* means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Health care operations means any of the following activities of the covered entity to the extent that the

activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Except as prohibited under § 164.502(a)(5)(i), underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Inmate means a person incarcerated in or otherwise confined to a correctional institution.

Marketing: (1) Except as provided in paragraph (2) of this definition, marketing means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) Marketing does not include a communication made:

(i) To provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the covered entity in exchange for making the communication is

reasonably related to the covered entity's cost of making the communication.

(ii) For the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication:

(A) For treatment of an individual by a health care provider, including case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual;

(B) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; or

(C) For case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment.

(3) *Financial remuneration* means direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.

Payment means:

(1) The activities undertaken by:

(i) Except as prohibited under § 164.502(a)(5)(i), a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 74 FR 42769, Aug. 24, 2009; 78 FR 5695, Jan. 25, 2013]

§ 164.502 Uses and disclosures of protected health information: General rules.

(a) *Standard.* A covered entity or business associate may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Covered entities: Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §§ 164.502(b), 164.514(d), and 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Except for uses and disclosures prohibited under § 164.502(a)(5)(i), pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, § 164.514(e), (f), or (g).

(2) *Covered entities: Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subchapter.

(3) *Business associates: Permitted uses and disclosures.* A business associate may use or disclose protected health information only as permitted or required by its business associate contract or other arrangement pursuant to § 164.504(e) or as required by law. The business associate may not use or disclose protected health information in a manner that would violate the requirements of this subpart, if done by the covered entity, except for the purposes specified under § 164.504(e)(2)(i)(A) or (B) if such uses or disclosures are permitted by its contract or other arrangement.

(4) *Business associates: Required uses and disclosures.* A business associate is required to disclose protected health information:

(i) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the business associate's compliance with this subchapter.

(ii) To the covered entity, individual, or individual's designee, as necessary to satisfy a covered entity's obligations under § 164.524(c)(2)(ii) and (3)(ii) with respect to an individual's request for an electronic copy of protected health information.

(5) *Prohibited uses and disclosures.*

(i) *Use and disclosure of genetic information for underwriting purposes:* Notwithstanding any other provision of this subpart, a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan*, shall not use or disclose protected health information that is genetic information for underwriting purposes. For purposes of paragraph (a)(5)(i) of this section, underwriting purposes means, with respect to a health plan:

(A) Except as provided in paragraph (a)(5)(i)(B) of this section:

(*1*) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(*2*) The computation of premium or contribution amounts under the plan, coverage, or policy (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(*3*) The application of any pre-existing condition exclusion under the plan, coverage, or policy; and

(*4*) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(B) Underwriting purposes does not include determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy.

(ii) *Sale of protected health information:*

(A) Except pursuant to and in compliance with § 164.508(a)(4), a covered entity or business associate may not sell protected health information.

(B) For purposes of this paragraph, sale of protected health information means:

(*1*) Except as provided in paragraph (a)(5)(ii)(B)(*2*) of this section, a disclosure of protected health information by a covered entity or business associate, if applicable, where the covered entity or business associate directly or indirectly receives remuneration from or on behalf of the recipient of the protected health information in exchange for the protected health information.

(*2*) Sale of protected health information does not include a disclosure of protected health information:

(*i*) For public health purposes pursuant to § 164.512(b) or § 164.514(e);

(*ii*) For research purposes pursuant to § 164.512(i) or § 164.514(e), where the only remuneration received by the covered entity or business associate is a reasonable cost-based fee to cover the cost to prepare and transmit the protected health information for such purposes;

(*iii*) For treatment and payment purposes pursuant to § 164.506(a);

(*iv*) For the sale, transfer, merger, or consolidation of all or part of the covered entity and for related due diligence as described in paragraph (6)(iv) of the definition of health care operations and pursuant to § 164.506(a);

(*v*) To or by a business associate for activities that the business associate undertakes on behalf of a covered entity, or on behalf of a business associate in the case of a subcontractor, pursuant to §§ 164.502(e) and 164.504(e), and the only remuneration provided is by the covered entity to the business associate, or by the business associate to the subcontractor, if applicable, for the performance of such activities;

(*vi*) To an individual, when requested under § 164.524 or § 164.528;

(*vii*) Required by law as permitted under § 164.512(a); and

(*viii*) For any other purpose permitted by and in accordance with the applicable requirements of this subpart, where the only remuneration received by the covered entity or business associate is a reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law.

(b) *Standard: Minimum necessary*

(1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity or business associate, a covered entity or business associate must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under § 164.508;

(iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(v) Uses or disclosures that are required by law, as described by § 164.512(a); and

(vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to § 164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in § 164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.*

(1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that

is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under § 164.514(a) and (b) is considered not to be individually identifiable health information, *i.e.*, de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(ii) A business associate may disclose protected health information to a business associate that is a subcontractor and may allow the subcontractor to create, receive, maintain, or transmit protected health information on its behalf, if the business associate obtains satisfactory assurances, in accordance with § 164.504(e)(1)(i), that the subcontractor will appropriately safeguard the information.

(2) *Implementation specification: Documentation.* The satisfactory assurances required by paragraph (e)(1) of this section must be documented through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual for a period of 50 years following the death of the individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification: unemancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under § 164.524 to a parent, guardian, or other person acting *in loco parentis*, if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of § 164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by § 164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by § 164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in § 164.520(b)(1)(iii)(A)-(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims*

(1) *Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in § 164.512(f)(2)(i).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002; 78 FR 5696, Jan. 25, 2013]

§ 164.504 Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section:

Plan administration functions means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

Summary health information means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at § 164.514(b)(2)(i) has been deleted, except that the geographic information described in § 164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

(b)-(d) [Reserved]

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2), (e)(3), or (e)(5) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in § 164.502(e) and this paragraph, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(iii) A business associate is not in compliance with the standards in § 164.502(e) and this paragraph, if the business associate knew of a pattern of activity or practice of a subcontractor that constituted a material breach or violation of the subcontractor's obligation under the contract or other arrangement, unless the business associate took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of protected health information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards and comply, where applicable, with subpart C of this part with respect to electronic protected health information, to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410;

(D) In accordance with § 164.502(e)(1)(ii), ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) To the extent the business associate is to carry out a covered entity's obligation under this subpart, comply with the requirements of this subpart that apply to the covered entity in the performance of such obligation.

(I) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(J) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with this paragraph and § 164.314(a)(1), if applicable, by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section and § 164.314(a)(2), if applicable.

(B) The covered entity may comply with this paragraph and § 164.314(a)(1), if applicable, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section and § 164.314(a)(2), if applicable.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in § 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph and § 164.314(a)(1), if applicable, provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(2) of this section and § 164.314(a)(1), if applicable, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(iv) A covered entity may comply with this paragraph and § 164.314(a)(1) if the covered entity discloses only a limited data set to a business associate for the business associate to carry out a health care operations function and the covered entity has a data use agreement with the business associate that complies with § 164.514(e)(4) and § 164.314(a)(1), if applicable.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the protected health information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the protected health information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(*1*) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person; and

(*2*) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(5) *Implementation specifications: Business associate contracts with subcontractors.* The requirements of § 164.504(e)(2) through (e)(4) apply to the contract or other arrangement required by § 164.502(e)(1)(ii) between a business associate and a business associate that is a subcontractor in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

(ii) Except as prohibited by § 164.502(a)(5)(i), the group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for purposes of:

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.

(3) *Implementation specifications: Uses and disclosures.* A group health plan may:

(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by § 164.520(b)(1)(iii)(C) is included in the appropriate notice; and

(iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

(g) *Standard: Requirements for a covered entity with multiple covered functions.*

(1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.

(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 78 FR 5697, Jan. 25, 2013]

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) through (4) or that are prohibited under § 164.502(a)(5)(i), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.*

(1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) *Implementation specifications: Treatment, payment, or health care operations.* (1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to other participants in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

[67 FR 53268, Aug. 14, 2002, as amended at 78 FR 5698, Jan. 25, 2013]

§ 164.508 Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures* —(1) *Authorization required: General rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: Psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by § 164.502(a)(2)(ii) or permitted by § 164.512(a); § 164.512(d) with respect to the oversight of the originator of the psychotherapy notes; § 164.512(g)(1); or § 164.512(j)(1)(i).

(3) *Authorization required: Marketing.*

(i) Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves financial remuneration, as defined in paragraph (3) of the definition of marketing at § 164.501, to the covered entity from a third party, the authorization must state that such remuneration is involved.

(4) *Authorization required: Sale of protected health information.*

(i) Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any disclosure of protected health information which is a sale of protected health information, as defined in § 164.501 of this subpart.
(ii) Such authorization must state that the disclosure will result in remuneration to the covered entity.

(b) *Implementation specifications: General requirements*

(1) *Valid authorizations.*

(i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (a)(4)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same or another research study. This exception includes combining an

authorization for the use or disclosure of protected health information for a research study with another authorization for the same research study, with an authorization for the creation or maintenance of a research database or repository, or with a consent to participate in research. Where a covered health care provider has conditioned the provision of research-related treatment on the provision of one of the authorizations, as permitted under paragraph (b)(4)(i) of this section, any compound authorization created under this paragraph must clearly differentiate between the conditioned and unconditioned components and provide the individual with an opportunity to opt in to the research activities described in the unconditioned authorization.

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes.

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations. The prohibition in this paragraph on combining authorizations where one authorization conditions the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits under paragraph (b)(4) of this section does not apply to a compound authorization created in accordance with paragraph (b)(3)(i) of this section.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by § 164.530(j).

(c) *Implementation specifications: Core elements and requirements*

(1) Core elements. A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including

for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by § 164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

[67 FR 53268, Aug. 14, 2002, as amended at 78 FR 5699, Jan. 25, 2013]

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.

(a) *Standard: Use and disclosure for facility directories*

(1) *Permitted uses and disclosure.* Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:

(i) Use the following protected health information to maintain a directory of individuals in its facility:

(A) The individual's name;

(B) The individual's location in the covered health care provider's facility;

(C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and

(D) The individual's religious affiliation; and

(ii) Use or disclose for directory purposes such information:

(A) To members of the clergy; or

(B) Except for religious affiliation, to other persons who ask for the individual by name.

(2) *Opportunity to object.* A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.

(3) *Emergency circumstances.* (i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual's incapacity or an emergency treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility's directory, if such disclosure is:

(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and

(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.

(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.

(b) *Standard: Uses and disclosures for involvement in the individual's care and notification purposes*

(1) *Permitted uses and disclosures.*

(i) A covered entity may, in accordance with paragraphs (b)(2), (b)(3), or (b)(5) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's health care or payment related to the individual's health care.

(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, as applicable.

(2) *Uses and disclosures with the individual present.* If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.

(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or needed for notification purposes. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

(4) *Uses and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of this section apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

(5) *Uses and disclosures when the individual is deceased.* If the individual is deceased, a covered entity may disclose to a family member, or other persons identified in paragraph (b)(1) of this section who were involved in the individual's care or payment for health care prior to the individual's death, protected health information of the individual that is relevant to such person's involvement, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002; 78 FR 5699, Jan. 25, 2013]

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure

permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.*

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: Uses and disclosures for public health activities.* (1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who provides health care to the individual at the request of the employer:

(*1*) To conduct an evaluation relating to medical surveillance of the workplace; or

(*2*) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(*1*) By giving a copy of the notice to the individual at the time the health care is provided; or

(*2*) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(vi) A school, about an individual who is a student or prospective student of the school, if:

(A) The protected health information that is disclosed is limited to proof of immunization;

(B) The school is required by State or other law to have such proof of immunization prior to admitting the individual; and

(C) The covered entity obtains and documents the agreement to the disclosure from either:

(1) A parent, guardian, or other person acting *in loco parentis* of the individual, if the individual is an unemancipated minor; or

(2) The individual, if the individual is an adult or emancipated minor.

(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

(c) *Standard: Disclosures about victims of abuse, neglect or domestic violence*

(1) *Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:

(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(d) *Standard: Uses and disclosures for health oversight activities*

(1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) *Joint activities or investigations.* Nothwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

(4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

(e) *Standard: Disclosures for judicial and administrative proceedings*

(1) *Permitted disclosures.* A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or

(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:

(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or

(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);

(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and

(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:

(*1*) No objections were filed; or

(*2*) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information , if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a *qualified protective order* means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

(vi) Nothwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(iv) of this section.

(2) *Other uses and disclosures under this section.* The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.

(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(*1*) The information sought is relevant and material to a legitimate law enforcement inquiry;

(*2*) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(*3*) De-identified information could not reasonably be used.

(2) *Permitted disclosures: Limited information for identification and location purposes.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

(i) The covered entity may disclose only the following information:

(A) Name and address;

(B) Date and place of birth;

(C) Social security number;

(D) ABO blood type and rh factor;

(E) Type of injury;

(F) Date and time of treatment;

(G) Date and time of death, if applicable; and

(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:

(i) The individual agrees to the disclosure; or

(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:

(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;

(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and

(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.

(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith

constitutes evidence of criminal conduct that occurred on the premises of the covered entity.

(6) *Permitted disclosure: Reporting crime in emergencies.*

(i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:

(A) The commission and nature of a crime;

(B) The location of such crime or of the victim(s) of such crime; and

(C) The identity, description, and location of the perpetrator of such crime.

(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.

(g) *Standard: Uses and disclosures about decedents.*

(1) *Coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.

(2) *Funeral directors.* A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors to carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.

(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

(i) *Standard: Uses and disclosures for research purposes*

(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by § 164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(*1*) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(*2*) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(*3*) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(*1*) An adequate plan to protect the identifiers from improper use and disclosure;

(*2*) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(*3*) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;

(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;

(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

(j) *Standard: Uses and disclosures to avert a serious threat to health or safety*

(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or

(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:

(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or

(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.

(2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:

(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or

(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.

(3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.

(4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

(k) *Standard: Uses and disclosures for specialized government functions.*

(1) *Military and veterans activities*

(i) *Armed Forces personnel.* A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the FEDERAL REGISTER the following information:

(A) Appropriate military command authorities; and

(B) The purposes for which the protected health information may be used or disclosed.

(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Homeland Security may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

(iii) *Veterans.* A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.

(iv) *Foreign military personnel.* A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the FEDERAL REGISTER pursuant to paragraph (k)(1)(i) of this section.

(2) *National security and intelligence activities.* A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (*e.g.*, Executive Order 12333).

(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized Federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056 or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

(4) *Medical suitability determinations.* A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual

was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:

(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12968;

(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or

(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.

(5) *Correctional institutions and other law enforcement custodial situations.*

(i) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:

(A) The provision of health care to such individuals;

(B) The health and safety of such individual or other inmates;

(C) The health and safety of the officers or employees of or others at the correctional institution;

(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;

(E) Law enforcement on the premises of the correctional institution; or

(F) The administration and maintenance of the safety, security, and good order of the correctional institution.

(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.

(iii) *No application after release.* For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

(6) *Covered entities that are government programs providing public benefits.*

(i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government agencies is required or expressly authorized by statute or regulation.

(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.

(l) *Standard: Disclosures for workers' compensation.* A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002; 78 FR 5700, Jan. 25, 2013]

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

(a) *Standard: De-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

(b) *Implementation specifications: Requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with

other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(c) *Implementation specifications: Re-identification.* A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

(1) *Derivation.* The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

(2) *Security.* The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(d)(1) *Standard: Minimum necessary requirements.* In order to comply with § 164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.

(2) *Implementation specifications: Minimum necessary uses of protected health information.*

(i) A covered entity must identify:

(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and

(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.

(3) *Implementation specification: Minimum necessary disclosures of protected health information.*

(i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must

implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.

(ii) For all other disclosures, a covered entity must:

(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:

(A) Making disclosures to public officials that are permitted under § 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);

(B) The information is requested by another covered entity;

(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or

(D) Documentation or representations that comply with the applicable requirements of § 164.512(i) have been provided by a person requesting the information for research purposes.

(4) *Implementation specifications: Minimum necessary requests for protected health information.*

(i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.

(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(5) *Implementation specification: Other content requirement.* For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;

(iv) Fax numbers;

(v) Electronic mail addresses;

(vi) Social security numbers;

(vii) Medical record numbers;

(viii) Health plan beneficiary numbers;

(ix) Account numbers;

(x) Certificate/license numbers;

(xi) Vehicle identifiers and serial numbers, including license plate numbers;

(xii) Device identifiers and serial numbers;

(xiii) Web Universal Resource Locators (URLs);

(xiv) Internet Protocol (IP) address numbers;

(xv) Biometric identifiers, including finger and voice prints; and

(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.*

(i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) *Implementation specifications: Data use agreement*

(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(*4*) Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(*5*) Not identify the information or contact the individuals.

(iii) *Compliance.*

(A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(1) Discontinued disclosure of protected health information to the recipient; and

(2) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

(f) *Fundraising communications.*

(1) *Standard: Uses and disclosures for fundraising.* Subject to the conditions of paragraph (f)(2) of this section, a covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of § 164.508:

(i) Demographic information relating to an individual, including name, address, other contact information, age, gender, and date of birth;

(ii) Dates of health care provided to an individual;

(iii) Department of service information;

(iv) Treating physician;

(v) Outcome information; and

(vi) Health insurance status.

(2) *Implementation specifications: Fundraising requirements.* (i) A covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by § 164.520(b)(1)(iii)(A) is included in the covered entity's notice of privacy practices.

(ii) With each fundraising communication made to an individual under this paragraph, a covered entity must provide the

individual with a clear and conspicuous opportunity to elect not to receive any further fundraising communications. The method for an individual to elect not to receive further fundraising communications may not cause the individual to incur an undue burden or more than a nominal cost.

(iii) A covered entity may not condition treatment or payment on the individual's choice with respect to the receipt of fundraising communications.

(iv) A covered entity may not make fundraising communications to an individual under this paragraph where the individual has elected not to receive such communications under paragraph (f)(2)(ii) of this section.

(v) A covered entity may provide an individual who has elected not to receive further fundraising communications with a method to opt back in to receive such communications.

(g) *Standard: Uses and disclosures for underwriting and related purposes.* If a health plan receives protected health information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may only use or disclose such protected health information for such purpose or as may be required by law, subject to the prohibition at § 164.502(a)(5)(i) with respect to genetic information included in the protected health information.

(h)(1) *Standard: Verification requirements.* Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.

(2) *Implementation specifications: Verification.*

(i) *Conditions on disclosures.* If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.

(A) The conditions in § 164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

(B) The documentation required by § 164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with § 164.512(i)(2)(i) and (v).

(ii) *Identity of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;

(B) If the request is in writing, the request is on the appropriate government letterhead; or

(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

(iii) *Authority of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;

(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.

(iv) *Exercise of professional judgment.* The verification requirements of this paragraph are

met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with § 164.510 or acts on a good faith belief in making a disclosure in accordance with § 164.512(j).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002; 78 FR 5700, Jan. 25, 2013]

§ 164.520 Notice of privacy practices for protected health information.

(a) *Standard: notice of privacy practices,*

(1) *Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) *Exception for group health plans.*

(i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.

(3) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) *Implementation specifications: Content of notice.*

(1) *Required elements.* The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed: "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."

(ii) *Uses and disclosures.* The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.

(E) A description of the types of uses and disclosures that require an authorization under § 164.508(a)(2)-(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by § 164.508(b)(5).

(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement informing the individual of such activities, as applicable:

(A) In accordance with § 164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications;

(B) In accordance with § 164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan; or

(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan*, intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes.

(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under § 164.522(a)(1)(vi);

(B) The right to receive confidential communications of protected health information as provided by § 164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by § 164.524;

(D) The right to amend protected health information as provided by § 164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by § 164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) *Covered entity's duties.* The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices with respect to protected health information, and to notify affected individuals following a breach of unsecured protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).

(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) *Optional elements.*

(i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i).

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii),

the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

(c) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.

(1) *Specific requirements for health plans.*

(i) A health plan must provide the notice:

(A) No later than the compliance date for the health plan, to individuals then covered by the plan;

(B) Thereafter, at the time of enrollment, to individuals who are new enrollees.

(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.

(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.

(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.

(v) If there is a material change to the notice:

(A) A health plan that posts its notice on its web site in accordance with paragraph (c)(3)(i) of this section must prominently post the change or its revised notice on its web site by the effective date of the material change to the notice, and provide the revised notice, or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan.

(B) A health plan that does not post its notice on a web site pursuant to paragraph (c)(3)(i) of this section must provide the revised notice, or information about the material change and how to obtain the revised notice, to individuals then covered by the plan within 60 days of the material revision to the notice.

(2) *Specific requirements for certain covered health care providers.* A covered health care provider that has a direct treatment relationship with an individual must:

(i) Provide the notice:

(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or

(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.

(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;

(iii) If the covered health care provider maintains a physical service delivery site:

(A) Have the notice available at the service delivery site for individuals to request to take with them; and

(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and

(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) of this section, if applicable.

(3) *Specific requirements for electronic notice.*

(i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.

(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided

to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.

(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.

(d) *Implementation specifications: Joint notice by separate covered entities.* Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:

(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;

(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and

(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;

(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and

(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.

(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.

(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by § 164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002; 78 FR 5701, Jan. 25, 2013]

§ 164.522 Rights to request privacy protection for protected health information.

(a)(1) *Standard: Right of an individual to request restriction of uses and disclosures.*

(i) A covered entity must permit an individual to request that the covered entity restrict:

(A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and

(B) Disclosures permitted under § 164.510(b).

(ii) Except as provided in paragraph (a)(1)(vi) of this section, a covered entity is not required to agree to a restriction.

(iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment, the covered entity may use the restricted protected health information, or may disclose such information to a health care provider, to provide such treatment to the individual.

(iv) If restricted protected health information is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.

(v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under §§ 164.502(a)(2)(ii), 164.510(a) or 164.512.

(vi) A covered entity must agree to the request of an individual to restrict

disclosure of protected health information about the individual to a health plan if:

(A) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and

(B) The protected health information pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full.

(2) *Implementation specifications: Terminating a restriction.* A covered entity may terminate a restriction, if:

(i) The individual agrees to or requests the termination in writing;

(ii) The individual orally agrees to the termination and the oral agreement is documented; or

(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is:

(A) Not effective for protected health information restricted under paragraph (a)(1)(vi) of this section; and

(B) Only effective with respect to protected health information created or received after it has so informed the individual.

(3) *Implementation specification: Documentation.* A covered entity must document a restriction in accordance with § 160.530(j) of this subchapter.

(b)(1) *Standard: Confidential communications requirements.*

(i) A covered health care provider must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the covered health care provider by alternative means or at alternative locations.

(ii) A health plan must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual.

(2) *Implementation specifications: Conditions on providing confidential communications.*

(i) A covered entity may require the individual to make a request for a confidential communication described in paragraph (b)(1) of this section in writing.

(ii) A covered entity may condition the provision of a reasonable accommodation on:

(A) When appropriate, information as to how payment, if any, will be handled; and

(B) Specification of an alternative address or other method of contact.

(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.

(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002; 78 FR 5701, Jan. 25, 2013]

§ 164.524 Access of individuals to protected health information.

(a) *Standard: Access to protected health information.*

(1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(i) Psychotherapy notes;

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(iii) Protected health information maintained by a covered entity that is:

(A) Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a, to the extent the provision of access to the individual would be prohibited by law; or

(B) Exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR 493.3(a)(2).

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.

(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

(3) *Reviewable grounds for denial*. A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

(4) *Review of a denial of access*. If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.

(b) *Implementation specifications: Requests for access and timely action*.

(1) *Individual's request for access*. The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.

(2) *Timely action by the covered entity*. (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.

(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access.

(c) *Implementation specifications: Provision of access*. If the covered entity provides an individual with

access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Providing the access requested*. The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.

(2) *Form of access requested.*

(i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.

(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.

(iii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:

(A) The individual agrees in advance to such a summary or explanation; and

(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(3) *Time and manner of access.* (i) The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(ii) If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.

(4) *Fees*. If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(i) Labor for copying the protected health information requested by the individual, whether in paper or electronic form;

(ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;

(iii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and

(iv) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(iii) of this section.

(d) *Implementation specifications: Denial of access*. If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Making other information accessible*. The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) *Denial*. The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and

(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(3) *Other responsibility*. If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) *Review of denial requested.* If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(e) *Implementation specification: Documentation*. A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The designated record sets that are subject to access by individuals; and

(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

[65 FR 82823, Dec. 28, 2000, as amended at 78 FR 5701, Jan. 25, 2013]

§ 164.526 Amendment of protected health information.

(a) *Standard: Right to amend*. (1) *Right to amend*. An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) *Denial of amendment*. A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:

(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;

(ii) Is not part of the designated record set;

(iii) Would not be available for inspection under § 164.524; or

(iv) Is accurate and complete.

(b) *Implementation specifications: Requests for amendment and timely action*.

(1) *Individual's request for amendment*. The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.

(2) *Timely action by the covered entity*.

(i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.

(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.

(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.

(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for an amendment.

(c) *Implementation specifications: Accepting the amendment*. If the covered entity accepts the requested amendment, in whole or in part, the

covered entity must comply with the following requirements.

(1) *Making the amendment*. The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.

(2) *Informing the individual*. In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.

(3) *Informing others*. The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to:

(i) Persons identified by the individual as having received protected health information about the individual and needing the amendment; and

(ii) Persons, including business associates, that the covered entity knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.

(d) *Implementation specifications: Denying the amendment*. If the covered entity denies the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Denial*. The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:

(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;

(ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;

(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and

(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.530(d) or to the Secretary pursuant to the procedures established in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(2) *Statement of disagreement*. The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.

(3) *Rebuttal statement*. The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide a copy to the individual who submitted the statement of disagreement.

(4) *Recordkeeping*. The covered entity must, as appropriate, identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.

(5) *Future disclosures*. (i) If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended in accordance with paragraph (d)(4) of this section, or, at the election of the covered entity, an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.

(ii) If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action in accordance with paragraph (d)(1)(iii) of this section.

(iii) When a subsequent disclosure described in paragraph (d)(5)(i) or (ii) of this section is made using a standard transaction under part 162 of this subchapter that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.

(e) *Implementation specification: Actions on notices of amendment.* A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (c)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (c)(1) of this section.

(f) *Implementation specification: Documentation.* A covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by § 164.530(j).

§ 164.528 Accounting of disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information.* (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

(i) To carry out treatment, payment and health care operations as provided in § 164.506;

(ii) To individuals of protected health information about them as provided in § 164.502;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in § 164.502;

(iv)Pursuant to an authorization as provided in § 164.508;

(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in § 164.510;

(vi) For national security or intelligence purposes as provided in § 164.512(k)(2);

(vii) To correctional institutions or law enforcement officials as provided in § 164.512(k)(5);

(viii) As part of a limited data set in accordance with § 164.514(e); or

(ix) That occurred prior to the compliance date for the covered entity.

(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in § 164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.

(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:

(A) Document the statement, including the identity of the agency or official making the statement;

(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and

(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.

(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

(b) *Implementation specifications: Content of the accounting.* The covered entity must provide the individual with a written accounting that meets the following requirements.

(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:

(i) The date of the disclosure;

(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;

(iii) A brief description of the protected health information disclosed; and

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§ 164.502(a)(2)(ii) or 164.512, if any.

(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the

same person or entity for a single purpose under §§ 164.502(a)(2)(ii) or 164.512, the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with § 164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

(A) The name of the protocol or other research activity;

(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;

(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

(c) *Implementation specifications: Provision of the accounting.* (1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.

(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and

(B) The covered entity may have only one such extension of time for action on a request for an accounting.

(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

(d) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;

(2) The written accounting that is provided to the individual under this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§ 164.530 Administrative requirements.

(a)(1) *Standard: Personnel designations.* (i) A covered entity must designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity.

(ii) A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by § 164.520.

(2) *Implementation specification: Personnel designations.* A covered entity must document the personnel designations in paragraph (a)(1) of this section as required by paragraph (j) of this section.

(b)(1) *Standard: Training.* A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart and subpart D of this part, as necessary and appropriate for the members of the workforce to carry out their functions within the covered entity.

(2) *Implementation specifications: Training.* (i) A covered entity must provide training that meets the requirements of paragraph (b)(1) of this section, as follows:

(A) To each member of the covered entity's workforce by no later than the compliance date for the covered entity;

(B) Thereafter, to each new member of the workforce within a reasonable period of time after the person joins the covered entity's workforce; and

(C) To each member of the covered entity's workforce whose functions are affected by a material change in the policies or procedures required by this subpart or subpart D of this part, within a reasonable period of time after the material change becomes effective in accordance with paragraph (i) of this section.

(ii) A covered entity must document that the training as described in paragraph (b)(2)(i) of this section has been provided, as required by paragraph (j) of this section.

(c)(1) *Standard: Safeguards.* A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.

(2)(i) *Implementation specification: Safeguards.* A covered entity must reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements of this subpart.

(ii) A covered entity must reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.

(d)(1) *Standard: Complaints to the covered entity.* A covered entity must provide a process for individuals to make complaints concerning the covered entity's policies and procedures required by this subpart and subpart D of this part or its compliance with such policies and procedures or the requirements of this subpart or subpart D of this part.

(2) *Implementation specification: Documentation of complaints.* As required by paragraph (j) of this section, a covered entity must document all complaints received, and their disposition, if any.

(e)(1) *Standard: Sanctions.* A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the covered entity or the requirements of this subpart or subpart D of this part. This standard does not apply to a member of the covered entity's workforce with respect to actions that are covered by and that meet the conditions of § 164.502(j) or paragraph (g)(2) of this section.

(2) *Implementation specification: Documentation.* As required by paragraph (j) of this section, a covered entity must document the sanctions that are applied, if any.

(f) *Standard: Mitigation.* A covered entity must mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information in violation of its policies and procedures or the requirements of this subpart by the covered entity or its business associate.

(g) *Standard: Refraining from intimidating or retaliatory acts.* A covered entity—

(1) May not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the exercise by the individual of any right established, or for participation in any process provided for, by this subpart or subpart D of this part, including the filing of a complaint under this section; and

(2) Must refrain from intimidation and retaliation as provided in § 160.316 of this subchapter.

(h) *Standard: Waiver of rights.* A covered entity may not require individuals to waive their rights under § 160.306 of this subchapter, this subpart, or subpart D of this part, as a condition of the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits.

(i)(1) *Standard: Policies and procedures.* A covered entity must implement policies and procedures

with respect to protected health information that are designed to comply with the standards, implementation specifications, or other requirements of this subpart and subpart D of this part. The policies and procedures must be reasonably designed, taking into account the size and the type of activities that relate to protected health information undertaken by a covered entity, to ensure such compliance. This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirement of this subpart.

(2) *Standard: Changes to policies and procedures.* (i) A covered entity must change its policies and procedures as necessary and appropriate to comply with changes in the law, including the standards, requirements, and implementation specifications of this subpart or subpart D of this part.

(ii) When a covered entity changes a privacy practice that is stated in the notice described in § 164.520, and makes corresponding changes to its policies and procedures, it may make the changes effective for protected health information that it created or received prior to the effective date of the notice revision, if the covered entity has, in accordance with § 164.520(b)(1)(v)(C), included in the notice a statement reserving its right to make such a change in its privacy practices; or

(iii) A covered entity may make any other changes to policies and procedures at any time, provided that the changes are documented and implemented in accordance with paragraph (i)(5) of this section.

(3) *Implementation specification: Changes in law.* Whenever there is a change in law that necessitates a change to the covered entity's policies or procedures, the covered entity must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice required by § 164.520, the covered entity must promptly make the appropriate revisions to the notice in accordance with § 164.520(b)(3). Nothing in this paragraph may be used by a covered entity to excuse a failure to comply with the law.

(4) *Implementation specifications: Changes to privacy practices stated in the notice.* (i) To implement a change as provided by paragraph (i)(2)(ii) of this section, a covered entity must:

(A) Ensure that the policy or procedure, as revised to reflect a change in the covered entity's privacy practice as stated in its notice, complies with the standards, requirements, and implementation specifications of this subpart;

(B) Document the policy or procedure, as revised, as required by paragraph (j) of this section; and

(C) Revise the notice as required by § 164.520(b)(3) to state the changed practice and make the revised notice available as required by § 164.520(c). The covered entity may not implement a change to a policy or procedure prior to the effective date of the revised notice.

(ii) If a covered entity has not reserved its right under § 164.520(b)(1)(v)(C) to change a privacy practice that is stated in the notice, the covered entity is bound by the privacy practices as stated in the notice with respect to protected health information created or received while such notice is in effect. A covered entity may change a privacy practice that is stated in the notice, and the related policies and procedures, without having reserved the right to do so, provided that:

(A) Such change meets the implementation specifications in paragraphs (i)(4)(i)(A)-(C) of this section; and

(B) Such change is effective only with respect to protected health information created or received after the effective date of the notice.

(5) *Implementation specification: Changes to other policies or procedures.* A covered entity may change, at any time, a policy or procedure that does not materially affect the content of the notice required by § 164.520, provided that:

(i) The policy or procedure, as revised, complies with the standards, requirements, and implementation specifications of this subpart; and

(ii) Prior to the effective date of the change, the policy or procedure, as revised, is documented as required by paragraph (j) of this section.

(j)(1) *Standard: Documentation.* A covered entity must:

(i) Maintain the policies and procedures provided for in paragraph (i) of this section in written or electronic form;

(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and

(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.

(iv) Maintain documentation sufficient to meet its burden of proof under § 164.414(b).

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation

required by paragraph (j)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.

(k) *Standard: Group health plans.* (1) A group health plan is not subject to the standards or implementation specifications in paragraphs (a) through (f) and (i) of this section, to the extent that:

(i) The group health plan provides health benefits solely through an insurance contract with a health insurance issuer or an HMO; and

(ii) The group health plan does not create or receive protected health information, except for:

(A) Summary health information as defined in § 164.504(a); or

(B) Information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) A group health plan described in paragraph (k)(1) of this section is subject to the standard and implementation specification in paragraph (j) of this section only with respect to plan documents amended in accordance with § 164.504(f).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002; 71 FR 8433, Feb. 16, 2006; 74 FR 42769, Aug. 24, 2009]

§ 164.532 Transition provisions.

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§ 164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, a waiver of informed consent by an IRB, or a waiver of authorization in accordance with § 164.512(i)(1)(i).

(b) *Implementation specification: Effect of prior authorization for purposes other than research.* Notwithstanding any provisions in § 164.508, a covered entity may use or disclose protected health information that it created or received prior to the applicable compliance date of this subpart pursuant to an authorization or other express legal permission obtained from an individual prior to the applicable compliance date of this subpart, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with § 164.522(a).

(c) *Implementation specification: Effect of prior permission for research.* Notwithstanding any provisions in §§ 164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with § 164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either:

(1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;

(2) The informed consent of the individual to participate in the research;

(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research; or

(4) A waiver of authorization in accordance with § 164.512(i)(1)(i).

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this part, a covered entity, or business associate with respect to a subcontractor, may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), only in accordance with paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance.* (1) *Qualification.* Notwithstanding other sections of this part, a covered entity, or business associate with respect to a subcontractor, is deemed to be in compliance with the documentation and contract requirements of §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to January 25, 2013, such covered entity, or business associate with respect to a subcontractor, has entered into and is operating pursuant to a written contract or other written arrangement with the business associate that complies with the applicable provisions of §§ 164.314(a) or 164.504(e) that were in effect on such date; and

(ii) The contract or other arrangement is not renewed or modified from March 26, 2013, until September 23, 2013.

(2) *Limited deemed compliance period.* A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after September 23, 2013; or

(ii) September 22, 2014.

(3) *Covered entity responsibilities.* Nothing in this section shall alter the requirements of a covered entity to comply with part 160, subpart C of this subchapter and §§ 164.524, 164.526, 164.528, and 164.530(f) with respect to protected health information held by a business associate.

(f) *Effect of prior data use agreements.* If, prior to January 25, 2013, a covered entity has entered into and is operating pursuant to a data use agreement with a recipient of a limited data set that complies with § 164.514(e), notwithstanding § 164.502(a)(5)(ii), the covered entity may continue to disclose a limited data set pursuant to such agreement in exchange for remuneration from or on behalf of the recipient of the protected health information until the earlier of:

(1) The date such agreement is renewed or modified on or after September 23, 2013; or

(2) September 22, 2014.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002; 78 FR 5702, Jan. 25, 2013]

§ 164.534 Compliance dates for initial implementation of the privacy standards.

(a) *Health care providers.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 14, 2003.

(b) *Health plans.* A health plan must comply with the applicable requirements of this subpart no later than the following as applicable:

(1) *Health plans other han small health plans.* April 14, 2003.

(2) *Small health plans.* April 14, 2004.

(c) *Health clearinghouses.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 14, 2003.

[66 FR 12434, Feb. 26, 2001]

Selected North Carolina General Statutes
Affecting Confidentiality of NC Local Health Department Records

Privilege Laws

§ 8-53. Communications between physician and patient.

No person, duly authorized to practice physic or surgery, shall be required to disclose any information which he may have acquired in attending a patient in a professional character, and which information was necessary to enable him to prescribe for such patient as a physician, or to do any act for him as a surgeon, and no such information shall be considered public records under G.S. 132-1. Confidential information obtained in medical records shall be furnished only on the authorization of the patient, or if deceased, the executor, administrator, or, in the case of unadministered estates, the next of kin. Any resident or presiding judge in the district, either at the trial or prior thereto, or the Industrial Commission pursuant to law may, subject to G.S. 8-53.6, compel disclosure if in his opinion disclosure is necessary to a proper administration of justice. If the case is in district court the judge shall be a district court judge, and if the case is in superior court the judge shall be a superior court judge. (1885, c. 159; Rev., s. 1621; C.S., s. 1798; 1969, c. 914; 1977, c. 1118; 1983, c. 410, ss. 1, 2; c. 471.)

§ 8-53.13. Nurse privilege.

No person licensed pursuant to Article 9A of Chapter 90 of the General Statutes shall be required to disclose any information that may have been acquired in rendering professional nursing services, and which information was necessary to enable that person to render professional nursing services, except that the presiding judge of a superior or district court may compel disclosure if, in the court's opinion, disclosure is necessary to a proper administration of justice and disclosure is not prohibited by other statute or rule. Nothing in this section shall preclude the admission of otherwise admissible written or printed medical records in any judicial proceeding, in accordance with the procedure set forth in G.S. 8-44.1, after a determination by the court that disclosure should be compelled as set forth herein. (2003-342, s. 1; 2004-186, s. 16.1.)

Public Health Patient Confidentiality

§ 130A-12. Confidentiality of records.

All records containing privileged patient medical information, information protected under 45 Code of Federal Regulations Parts 160 and 164, and information collected under the authority of Part 4 of Article 5 of this Chapter that are in the possession of the Department of Health and Human Services or local health departments shall be confidential and shall not be public records pursuant to G.S. 132-1. Notwithstanding G.S. 8-53, the information contained in the records may be disclosed for purposes of treatment, payment, research, or health care operations to the extent that disclosure is permitted under 45 Code of Federal Regulations §§ 164.506 and 164.512(i). For purposes of this section, the terms "treatment," "payment," "research," and "health care operations" have the meanings given those terms in 45 Code of Federal Regulations § 164.501. (1985, c. 470, s. 2; 1991 (Reg. Sess., 1992), c. 890, s. 9; 1995, c. 428, s. 1.1; 2004-80, s. 4; 2006-255, s. 13.2; 2011-145, s. 13.3(qq); 2011-314, s. 3.)

Communicable Disease Confidentiality

§ 130A-143. Confidentiality of records.

All information and records, whether publicly or privately maintained, that identify a person who has AIDS virus infection or who has or may have a disease or condition required to be reported pursuant to the provisions of this Article shall be strictly confidential. This information shall not be released or made public except under the following circumstances:

(1) Release is made of specific medical or epidemiological information for statistical purposes in a way that no person can be identified;

(2) Release is made of all or part of the medical record with the written consent of the person or persons identified or their guardian;

(3) Release is made for purposes of treatment, payment, research, or health care operations to the extent that disclosure is permitted under 45 Code of Federal Regulations §§ 164.506 and 164.512(i). For purposes of this section, the terms "treatment," "payment," "research," and "health care operations" have the meaning given those terms in 45 Code of Federal Regulations § 164.501;

(4) Release is necessary to protect the public health and is made as provided by the Commission in its rules regarding control measures for communicable diseases and conditions;

(5) Release is made pursuant to other provisions of this Article;

(6) Release is made pursuant to subpoena or court order. Upon request of the person identified in the record, the record shall be reviewed in camera. In the trial, the trial judge may, during the taking of testimony concerning such information, exclude from the courtroom all persons except the officers of the court, the parties and those engaged in the trial of the case;

(7) Release is made by the Department or a local health department to a court or a law enforcement official for the purpose of enforcing this Article or Article 22 of this Chapter, or investigating a terrorist incident using nuclear, biological, or chemical agents. A law enforcement official who receives the information shall not disclose it further, except (i) when necessary to enforce this Article or Article 22 of this Chapter, or when necessary to conduct an investigation of a terrorist incident using nuclear, biological, or chemical agents, or (ii) when the Department or a local health department seeks the assistance of the law enforcement official in preventing or controlling the spread of the disease or condition and expressly authorizes the disclosure as necessary for that purpose;

(8) Release is made by the Department or a local health department to another federal, state or local public health agency for the purpose of preventing or controlling the spread of a communicable disease or communicable condition;

(9) Release is made by the Department for bona fide research purposes. The Commission shall adopt rules providing for the use of the information for research purposes;

(10) Release is made pursuant to G.S. 130A-144(b); or

(11) Release is made pursuant to any other provisions of law that specifically authorize or require the release of information or records related to AIDS. (1983, c. 891, s. 2; 1987, c. 782, s. 13; 2002-179, s. 7; 2011-314, s. 4.)

SAMPSON COUNTY HEALTH DEPARTMENT
BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT (this "Agreement"), effective as of August 1st, 2016 ("Effective Date") is entered into by and between _____(the "Business Associate"), and Sampson County Health Department (the "Covered Entity") (each a "Party" and collectively the "Parties").

WHEREAS, the Parties have entered into an agreement for the use of Business Associate's Cure MD Software for the documentation of Covered Entity's maternal health record and Business Associate's Program Management System for submission of Covered Entity's required reports and applications for achieving and maintaining recognized program status (the "Agreement"), under which the Covered Entity discloses Protected Health Information (individually identifiable health information of patients, as defined in 45 C.F.R. § 160.103) to the Business Associate for the purposes and obligations described below;

WHEREAS, both Parties desire to meet their obligations under: (i) the Standards for Privacy of Individually Identifiable Information ("Privacy Regulation") and the Security Standards ("Security Regulation") published by the U.S. Department of Health & Human Services ("DHHS") at 45 CFR parts 160 through 164 under the Health Insurance Portability and Accountability Act of 1996 ("HIPPA"); (ii) the additional Privacy and Security Regulation requirements pursuant to Subtitle D of the Health Information Technology for Economic and Clinical Health Act ("HITECH"), including 45 CFT Sections 164.308, 164.310, 164.312, and 164.136, as amended from time to time (the "HITECH Standards"); and (iii) the final Omnibus Rule implementing additional Privacy and Security Regulation requirements pursuant to HITECH ("Omnibus Rule"), which requires compliance on and after September 23, 2013, and as further amended from time to time; and

WHEREAS, this Agreement sets forth the terms and conditions pursuant to which Protected Health Information that is created, received, maintained, or transmitted by the Business Associate from or on behalf of the Covered Entity will be handled between the Business Associate and the Covered Entity and with third parties during the term of their Agreement and after its termination.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledges, the Parties hereby agree as follows:

1. DEFINITIONS

1.1 Citation to CFR. Regulatory citations in this Agreements are to the United States Code of Federal Regulations ("CFR"), as promulgated, interpreted, and amended from time to time by DHHS, for so long as such regulations are in effect.

1.2 Definition under Privacy or Security Regulation. Unless otherwise specified in Agreement, all terms not otherwise defined will have the meaning established for purposes of parts 160 through 164 of Title 45 of the CFR, as amended from time to time.

2. PERMITTED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

2.1 Services. Pursuant to the Agreement, the Business Associate provides services or goods for the Covered Entity that involves the creation receipt, maintenance, or transmission of Protected Health Information. Except as otherwise specified herein, the Business Associate may make any and all uses of Protected Health Information necessary to perform its obligations under the Agreement, provided that such use of Protected Health Information would not violate the Privacy Regulation if done by the Covered Entity or the minimum necessary policies and procedures of the Covered Entity. All other uses not authorized by this Agreement or required by law are prohibited. Moreover, Business Associate may disclose Protected Health Information for the purposes authorized by this Agreement only, (i) to its employees, subcontractors and agents, in accordance with Section 3.1(k), (ii) as directed by the Covered Entity, or (iii) as otherwise permitted by the terms of this Agreement including, but not limited to, Section 2.2(b) below.

2.2 Business Activities of the Business Associate. Unless otherwise limited herein, the Business Associate may:

a. Use the Protected Health Information in its possession for its proper management and administration and to fulfill any present or future legal responsibilities of the Business Associate provided that such uses are permitted under state and federal confidentiality laws.

b. Disclose the Protected Health Information in its possession to third parties for the purpose of its proper management and administration or to fulfill any present or future legal responsibilities of the Business Associate, if (i) the disclosures are required by law;, (ii) the disclosures do not require an authorization or an "opportunity to agree", or (iii) the Business Associate obtains and maintains reasonable written assurances from the third party receiving the Protected Health Information that such party will hold and maintain such Protected Health Information as required under 45 C.F.R.§ 164.308 (b)(1) and 164.504(e)(4) and will notify Business Associate if such party becomes aware that the confidentiality of the Protected Health Information has been breached.

2.3 Additional Activities of Business Associate. The Business Associate may also:

a. At the request of the Covered Entity, aggregate the Protected Health Information in its possession with the Protected Health Information of other entities that the Business Associate has in its possession through its capacity as a business associate to said other covered entities provided that the purpose of such aggregation is to provide the Covered Entity with data analyses relating to the Health Care Operations of the Covered Entity. Under no circumstances may the Business Associate disclose Protected Health Information of one Covered Entity to another Covered Entity absent the explicit authorization of the Covered Entity.

b. At the request of the Covered Entity, de-identify any and all Protected Health Information provided that the de-identification conforms to the requirements of 45 C.F.R. § 164.514(b), and further provided that the Covered Entity maintains any documentation required by 45 C.F.R. § 164.514(b) which may be in the form of a written assurance from the Business Associate. Pursuant to 45 C.F.R. § 164.502(d)(2), de-identified information does not constitute Protected Health Information and is not subject to the terms of this Agreement.

3. RESPONSIBILITIES WITH RESPECT TO PROTECTED HEALTH INFORMATION

3.1 Privacy Responsibilities of the Business Associate. With regard to its use or disclosure of Protected Health Information, the Business Associate will:

a. Request from the Covered Entity, access, and disclose to its subcontractors, agents or other third parties, only the minimum amount of Protected Health Information necessary to perform or fulfill a specific function required or permitted under this Agreement or the Agreement.

b. Use or disclose the Protected Health Information only as permitted or required by this agreement or as otherwise required by law.

c. To the extent Business Associate carries out one or more of Covered Entity's obligations under the Privacy Regulation, comply with the same Privacy Regulation requirements that apply to Covered Entity.

d. Develop and maintain a written health information privacy and security program that implements: (i)appropriate policies, procedures, and protections as required by the Privacy Regulation for the privacy of the Protected Health Information; (ii) appropriate administrative, physical, and technical safeguards (collectively, the "Safeguards") as required by the Security Regulation for the

Integrity of the Protected Health Information; and (iii) appropriate policies, procedures, and protections to implement and document such Safeguards.

e. To the extent feasible and commercially reasonable, use efforts to secure the Protected Health Information through security standards that render such Protected Health Information unusable, unreadable, and indecipherable to individuals unauthorized to acquire or otherwise have access to such Protected Health Information in accordance with guidance promulgated by the U.S. Department of Health & Human Services ("DHHS") by the National Institute For Standards and Technology ("NIST") concerning the protection of identifiable data.

f. Report to the designated Privacy Officer of the Covered Entity, in writing, any use or disclosure of the Protected Health Information that is not permitted or required by this Agreement of which Business Associate becomes aware within 5 business days of the Business Associate's discovery of such unauthorized use or disclosure.

g. Establish procedures for mitigating, to the greatest extent possible, any deleterious effects from any improper use or disclosure of Protected Health Information that the Business Associate knows of and reports to the Covered Entity.

h. Report to the Security Officer of the Covered Entity, in writing, any breach in the security, confidentiality, integrity, or availability of Electronic Protected Health Information that the Business Associate creates, receives, maintains or transmits for or on behalf of the Covered Entity of which the Business Associate becomes aware within 30 business days of the Business Associate's discovery of such security breach.

i. Establish procedures for mitigating, to the greatest extent possible, any deleterious effects from any improper breach to the security, confidentiality, integrity, or availability of Electronic Protected Health Information that the Business Associate knows of and reports to the Covered Entity.

j. Notify the Privacy and Security Officer(s) of the Covered Entity as soon as possible, but no later than the 30th day on which a security breach is known by Business Associate or an employee, officer or agent of Business Associate Other than the person committing the breach, or as soon as possible following the first business day on which Business Associate or an employee, officer or agent of the Business Associate or an employee, officer or agent of the Business Associate other than the person committing the breach should have known by exercising reasonable diligence of such breach. "Security Breach" as used herein is defined as an acquisition, access, use, or disclosure of unsecured Electronic Protected Health Information in a manner not permitted under the Privacy or Security Regulation.

k. Require all its subcontractors and agents that receive, use, or have access to Protected Health Information under this Agreement to sign a written Agreement that: (i) binds such subcontractors and agents to the same restrictions and conditions that apply to the Business Associate pursuant to this Agreement as to the use or disclosure, or the security, confidentiality, integrity, and availability, of the Protected Health Information; (ii) requires such subcontractors and agents to provide adequate Safeguards against improper use or disclosure or breach of security related to Electronic Protected Health Information; (iii) contains reasonable assurances from such subcontractors and Agents that the Protected Health Information they hold or maintain will remain confidential as provided in this Agreement and only disclosed as provided in this Agreement or required by law for the purposes of which it was disclosed to the respective subcontractor or agent; and (iv) obligates such subcontractors and agents to immediately notify the Business Associate of any breaches of the confidentiality of the Protected Health Information, including any Security Breach, to the extent the respective subcontractor or agent has knowledge of such a Security Breach.

l. Make available all records, books, agreements, policies, and procedures relating to the confidentiality or integrity of the Protected Health Information to the Secretary of DHHS, in a time and manner designated by the Secretary, for purposes of determining compliance with the Privacy Regulation, Security Regulation, or Omnibus Rule, subject to attorney-client and other applicable Legal privileges.

m. Upon prior written request, make available during normal business hours at Business Associate's offices all records, books, agreements, policies and Procedures relating to the use or disclosure of Protected Health Information to the Covered Entity within 15 days for purposes of enabling the Covered Entity to determine the Business Associate's compliance with the terms of this Agreement.

n. Comply with the applicable HITECH standards on and after the Effective Date, to the extent applicable to services provided by the Business Associate to the Covered Entity pursuant to this Agreement, including, but not limited to: (i))the prohibition of the sale of the Protected Health Information without Authorization, unless an exemption is available under HIPAA or HITECH; (ii)the prohibition on receiving remuneration (directly or indirectly from individual) for certain communications that fall within the exceptions to the definition of marketing, unless permitted by this Agreement and HITECH; and (iii)the requirements regarding accounting of certain disclosures of the Protected Health Information maintained in an electronic health records under HITECH.

o. Within 30 days of receiving a written request from the Covered Entity, provide to the Covered Entity such information as is requested by the Covered Entity to permit the Covered Entity to respond to a request by an individual for an accounting of the disclosures of the individuals Protected Health Information in accordance with 45 C.F.R. § 164.528.

p. Document such disclosures of Protected Health Information and information related to such disclosures, as would be required for Covered Entity to respond to a request by an individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.

3.2 Responsibilities of the Covered Entity. With regard to the use or disclosure of Protected Health Information by the Business Associate, the Covered Entity will:

a. Obtain any consent or authorization that may be required by 45 CFR § 164.506 and 164.508, or applicable state law, prior to furnishing the Business Associate the Protected Health Information pertaining to such individual.

b. Notify the Business Associate of any changes or limitations in the Covered Entity's notice of privacy practices to the extent that such change or limitation may affect the Business Associate's creation, receipt, maintenance, or transmission of the Protected Health Information for or on behalf of the Covered Entity.

c. Not furnish Protected Health Information to the Business Associate that is subject to any arrangements permitted or required of the Covered Entity under the Privacy Regulation, Security Regulation, or HITECH Standards that may impact in any manner the use or disclosure of Protected Health Information by the Business Associate under this Agreement and the Agreement, including but not limited to restrictions on use or disclosure of Protected Health Information as provided for in 45 CFR § 164.522 and agreed to by the Covered Entity.

3.3 Responsibilities of the Parties with Respect to Breach Notification. The Parties with comply with the HITECH Standard related to the notification of affected individuals in the event of a Security Breach of Protected Health Information (the "Breach Notification Rule").

a. Except as provided by 45 CFR § 164.412, the Business Associate will give the Covered Entity notice of any Security Breach of Unsecured Protected Health Information without unreasonable delay and in no event later than the earlier of the maximum time allowable under applicable law or 30 business days after the Business Associate discovers such Security Breach. For purposes of reporting such a Security Breach to the Covered Entity, the discovery of such a Security Breach will be deemed to occur as of the first day on which the Business Associate knows, or by exercising reasonable

diligence, should have known of such Security Breach.

b. Such notice will be written in plain language and will include, to the extent possible or available, the following: (i) the identification and contact information of all individuals whose Unsecured Protected Health Information has been, or is reasonably believed by Business Associate to have been, accessed, acquired, or disclosed during the Security Breach; (ii) a brief description of what happened, including the date of the Security Breach and the date of the discovery of the Security Breach; (iii) a description of the types of Unsecured Protected Health Information that were involved in the Security Breach; (vi) any steps that individuals who were subjects of the Security Breach should take to protect themselves from potential harm that may result from the Security Breach; (v) a brief description of what Business Associate is doing to investigate the Security Breach, to mitigate the harm to affected individuals, and to protect against further breaches; and (vi) contact procedures for affected individuals to ask questions of learn additional information, including a toll-free telephone number, an email address, a website, or postal address.

c. Notwithstanding the provisions of this Section 3.3 and if a law enforcement official states to the Business Associate that notification of a Security Breach would impede a criminal investigation or cause damage to national security, then: (i) the notification will be delayed for the time period specified by the official if the official's statement is in writing and specifies the time for which a delay is required; or (ii) if the official's statement is made orally, the Business Associate will document the oral statement, including the identity of the official making the statement, and delay the breach notification for no longer than 30 days from the date of the oral statement, unless the official submits a written statement during that time period.

d. Cooperate with the Covered Entity as needed to further investigate and evaluate any Security Breach involving the Business Assoicate or of which the Business Associate has become aware.

e. In the event of impermissible use or disclosure is made by the Business Associate or any subcontractor or agent of Unsecured Protected Health Information that, in the reasonable judgement of the Covered Entity, requires a Breach Notification, the Business Associate (or subcontractor or agent) will, at the Covered Entity's direction, provide such Breach Notification in accordance with this Section 3.3 and the HITECH Standards.

f. The Party whose Unsecured Protected Health Information was breached will be responsible for payment of all actual costs associated with the Security Breach, including, but not limited to, costs of notifying affected

individuals, credit monitoring (where applicable) and other efforts to mitigate the harm to affected individuals.

4. ADDITIONAL RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PROTECTED HEALTH INFORMATION

4.1 Responsibilities of the Business Associate with Respect to Handling of designated Record Set. In the event that the Parties mutually agree in writing that the Business Associate will maintain Protected Health Information in Designated Record Sets, the Business Associate will:

a. At the request of, and in the time and manner designated by the Cover Entity, provide access to the Protected Health Information to the Covered Entity or the individual to whom such Protected Health Information relates, or his or her authorized representative, in order to meet a request by such individual under 45 C.F.R. § 164.524.

b. At the request of, and in the time and manner designated by the Covered Entity, make any amendment(s) to the Protected Health Information that the Covered Entity directs pursuant to 45 C.F.R. § 164.526; provided, however that the Covered Entity makes the determination that the amendment(s) are necessary because the Protected Health Information that is the subject of the amendment(s) has been, or could foreseeably be, relied upon by the Business Associate or others to the detriment of the individual who is the Subject of the Protected Health Information to be amended.

4.2 Responsibilities of the Covered Entity with Respect to the Handling of the Designated Record Set. In the event that the Parties mutually agree in writing that the Business Associate will maintain Protected Health Information in Designated Record Sets, the Covered Entity will:

a. Notify the Business Associate, in writing, of any Protected Health Information that Covered Entity seeks to make available to an individual Pursuant to 45 CFR § 164.524 and the time, manner and form in which The Business Associate will provide such access.

b. Notify the Business Associate, in writing, of any amendment(s) to the Protected Health Information in the possession of the Business Associate that the Business Associate will make and inform the Business Associate of the time, form and manner in which such amendment(s) will be made.

5. REPRESENTATIONS AND WARRANTIES OF THE PARTIES

5.1 Workforce Informed of Agreement Terms. All of each Party's employees, agents, representatives and members of its respective workforce who services may be used to fulfill obligations under this Agreement are or will be appropriately informed of the applicable terms and conditions of this Agreement and are under legal obligation to each party, respectively, by contract or otherwise, sufficient to enable each Party to comply fully with all applicable provisions of this Agreement.

5.2 Reasonable Cooperation among the Parties. Each Party will reasonably Cooperate with the other Party in the performance of the mutual obligations under this Agreement.

5.3 Prepared to Comply with HIPAA/HITECH Requirements. Each Party represents and warrants that it has or is prepared to comply with the applicable provisions of this Agreement on or before: (i) April 14, 2003 (Privacy Regulation), April 20, 2005 (Security Regulation), February 17, 2010 (HITECH Standards), and September 23, 2013 (Omnibus Rule), if the Agreement was in effect on such dates; or (ii) The Effective Date, if no Agreement was in effect prior to the Effective Date.

6. TERMS AND TERMINATION

6.1 Term. This Agreement will become effective on the Effective Date and will continue in effect until all obligations of the Parties have been met, unless terminated as provided in this Section 6. In addition, certain provisions and requirements of this Agreement will survive its expiration or other termination in accordance with Section 7.1 herein.

6.2 Termination by the Parties. As provided for under 45 CFR § 164.504(e) (2)(iii), The Covered Entity or Business Associate may immediately terminate the Agreement and this Agreement if the non-breaching Party makes the determination that the other Party has breached a material term of this Agreement. Alternatively, the non-breaching Party may choose to: (i) provide the breaching Party with 30 days written notice of the Existence of an alleged material breach; and (ii) afford the breaching Party an opportunity to cure said alleged material breach upon mutually agreeable terms. Nonetheless, in the event that mutually agreeable terms cannot be achieved within 30 days, the breaching Party must cure said breach to the satisfaction of the non-breaching Party within a reasonable and mutually agreed upon time period. Failure to cure in the manner set forth in this Section 6.2 is grounds for the immediate termination of the Agreement and this Agreement. If neither termination nor cure is feasible, the non-breaching Party will report the violation to the Secretary of DHHS.

6.3 Automatic Termination. This Agreement will automatically terminate without any further action of the Parties upon the termination or expiration of the Agreement.

6.4 Effect of Termination. Upon the event of termination pursuant to this Section 6, The Business Associate will return or destroy all Protected Health Information, including Electronic Protected Health Information, pursuant to 4 CFR § 164.504(e)(2)(1), if it is feasible to do so. Prior to doing so, the Business Associate further will recover any Protected Health Information in the possession of its subcontractors or agents. If it is not feasible for the Business Associate to return or destroy said Protected Health Information, the Business Associate will notify the Covered Entity in writing. Said notification will include: (i) a statement that the Business Associate; has determined that it is infeasible to return or destroy the Protected Health Information in its possession, and (ii) the specific reasons for such determination. In such event, the Business Associate will extend any and all protections, limitations and restrictions contained in this Agreement to the Business Associate's use or disclosure of any Protected Health Information retained after the termination of this Agreement or the Agreement, and to limit any further uses or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible. If it is infeasible for the Business Associate to obtain, from a subcontractor or agent any Protected Health Information in the possession of the subcontractor or agent, the Business Associate must provide a written explanation to the Covered Entity and require the subcontractors and agents to agree to extend any and all protections, limitations and restrictions contained in this Agreement to the subcontractors' or agents' use or disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible.

7. MISCELLANEOUS

7.1 Survival. The respective rights and obligations of the Business Associate and Covered Entity under the provisions of Sections 3.1, 3.2, 3.4 and 6.4, solely with respect to Protected Health Information that the Business Associate retains in accordance with Section 6.4 because it is not feasible to return or destroy such Protected Health Information, will survive termination of this Agreement indefinitely. In addition, Section 4 will survive termination of this Agreement, provided that the Covered Entity determines that the Protected Health Information being retained pursuant to Section 6.4 constitutes a Designated Record Set.

7.2 Change of Law. Each Party will notify the other within 90 days of any amendment to any provision of HIPAA or HITECH, or their implementing regulations, which such Party reasonably believes will materially alter either Party's or both Parties' obligations under this Agreement. Upon provision of such notice, the Parties will negotiate in good faith mutually acceptable and appropriate amendment(s) to this Agreement to give effect to such revised obligations, provided, however, that if the Parties are unable to agree on such amendment(s) with 90 days of the relevant change of law, either Party may terminate this Agreement consistent with Sections 6.2 and 6.4 herein.

7.3 Amendments: Wavier. This Agreement may not be modified, not will any provision be waived or amended, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event will not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

7.4 Assignment of Rights and Delegation of Duties. This Agreement is binding upon and inures to the benefit of the Parties and their respective successors and permitted assigns. However, neither Party may assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of the other Party, which consent will not be unreasonably withheld or delayed. Assignments made in violation of this Section 7.4 will be null and void.

7.5 No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor will anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

7.6 Notices. Any notices to be given will be made via fax or express courier to the address given below, except that notice of a Security Breach will also be given as provided in section 3.2(c) of this Agreement.

7.7 Interpretation. Any ambiguity in this Agreement and the Agreement will be resolved to permit Covered Entity to comply with the Privacy and Security Rules and the HITECH Act and applicable regulations and guidance documents.

7.8 Counterparts; Facsimiles. This Agreement may be executed in any number of counterparts, each of which will be deemed an original. Facsimile copies hereof will be deemed to be originals.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf effective as of the Effective Date state above herein.

COVERED ENTITY	**BUSINESS ASSOCIATE**
By:_____	By:_____
Name:	Name:
Title: Health Director Sampson County Health Department	Title: Chief Executive Officer
Date:_____	Date:_____

REVISED 7/2018

Sampson County Health Department

360 County Complex Rd, Suite 200
Clinton NC 28328
910-592-1131

Your Information. Your Rights. Our Responsibilities.

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. **Please review it carefully.**

Your Rights

You have the right to:

- Get a copy of your paper or electronic medical record
- Correct your paper or electronic medical record
- Request confidential communication
- Ask us to limit the information we share
- Get a list of those with whom we've shared your information
- Get a copy of this privacy notice
- Choose someone to act for you
- File a complaint if you believe your privacy rights have been violated

➤ ***See page 2*** *for more information on these rights and how to exercise them*

Your Choices

You have some choices in the way that we use and share information as we:

- Tell family and friends about your condition
- Provide disaster relief
- Include you in a hospital directory
- Provide mental health care
- Market our services and sell your information
- Raise funds

➤ ***See page 3*** *for more information on these choices and how to exercise them*

Our Uses and Disclosures

We may use and share your information as we:

- Treat you
- Run our organization
- Bill for your services
- Help with public health and safety issues
- Do research
- Comply with the law
- Respond to organ and tissue donation requests
- Work with a medical examiner or funeral director
- Address workers' compensation, law enforcement, and other government requests
- Respond to lawsuits and legal actions

➤ ***See pages 3 and 4*** *for more information on these uses and disclosures*

Your Rights

When it comes to your health information, you have certain rights.
This section explains your rights and some of our responsibilities to help you.

Get an electronic or paper copy of your medical record	• You can ask to see or get an electronic or paper copy of your medical record and other health information we have about you. Ask us how to do this. • We will provide a copy or a summary of your health information, usually within 30 days of your request. We may charge a reasonable, cost-based fee.
Ask us to correct your medical record	• You can ask us to correct health information about you that you think is incorrect or incomplete. Ask us how to do this. • We may say "no" to your request, but we'll tell you why in writing within 60 days.
Request confidential communications	• You can ask us to contact you in a specific way (for example, home or office phone) or to send mail to a different address. • We will say "yes" to all reasonable requests.
Ask us to limit what we use or share	• You can ask us **not** to use or share certain health information for treatment, payment, or our operations. We are not required to agree to your request, and we may say "no" if it would affect your care. • If you pay for a service or health care item out-of-pocket in full, you can ask us not to share that information for the purpose of payment or our operations with your health insurer. We will say "yes" unless a law requires us to share that information.
Get a list of those with whom we've shared information	• You can ask for a list (accounting) of the times we've shared your health information for six years prior to the date you ask, who we shared it with, and why. • We will include all the disclosures except for those about treatment, payment, and health care operations, and certain other disclosures (such as any you asked us to make). We'll provide one accounting a year for free but will charge a reasonable, cost-based fee if you ask for another one within 12 months.
Get a copy of this privacy notice	• You can ask for a paper copy of this notice at any time, even if you have agreed to receive the notice electronically. We will provide you with a paper copy promptly.
Choose someone to act for you	• If you have given someone medical power of attorney or if someone is your legal guardian, that person can exercise your rights and make choices about your health information. • We will make sure the person has this authority and can act for you before we take any action.
File a complaint if you feel your rights are violated	• You can complain if you feel we have violated your rights by contacting us using the information on page 5 of this notice; **OR** • You can file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by sending a letter to 200 Independence Avenue, S.W., Washington, D.C. 20201, calling 1-877-696-6775, or visiting **www.hhs.gov/ocr/privacy/hipaa/complaints/.** • We will not retaliate against you for filing a complaint.

Your Choices

For certain health information, you can tell us your choices about what we share. If you have a clear preference for how we share your information in the situations described below, talk to us. Tell us what you want us to do, and we will follow your instructions.

In these cases, you have both the right and choice to tell us to:	• Share information with your family, close friends, or others involved in your care • Share information in a disaster relief situation • Include your information in a hospital directory *If you are not able to tell us your preference, for example if you are unconscious, we may go ahead and share your information if we believe it is in your best interest. We may also share your information when needed to lessen a serious and imminent threat to health or safety.*
In these cases we *never* share your information unless you give us written permission:	• Marketing purposes • Sale of your information • Most sharing of psychotherapy notes

Our Uses and Disclosures

How do we typically use or share your health information?

We typically use or share your health information in the following ways.

Treat you	• We can use your health information and share it with other professionals who are treating you.	***Example:*** *A doctor treating you for an injury asks another doctor about your overall health condition.*
Run our organization	• We can use and share your health information to run our practice, improve your care, and contact you when necessary.	***Example:*** *We use health information about you to manage your treatment and services.*
Bill for your services	• We can use and share your health information to bill and get payment from health plans or other entities.	***Example:*** *We give information about you to your health insurance plan so it will pay for your services.*

continued on next page

How else can we use or share your health information? We are allowed or required to share your information in other ways – usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your information for these purposes. For more information see: **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html.**

Help with public health and safety issues	• We can share health information about you for certain situations such as:
	  • Preventing disease
	  • Helping with product recalls
	  • Reporting adverse reactions to medications
	  • Reporting suspected abuse, neglect, or domestic violence
	  • Preventing or reducing a serious threat to anyone's health or safety

Do research	• We can use or share your information for health research.
Comply with the law	• We will share information about you if state or federal laws require it, including with the Department of Health and Human Services if it wants to see that we're complying with federal privacy law.
Respond to organ and tissue donation requests	• We can share health information about you with organ procurement organizations.
Work with a medical examiner or funeral director	• We can share health information with a coroner, medical examiner, or funeral director when an individual dies.

Address workers' compensation, law enforcement, and other government requests	• We can use or share health information about you:
	  • For workers' compensation claims
	  • For law enforcement purposes or with a law enforcement official
	  • With health oversight agencies for activities authorized by law
	  • For special government functions such as military, national security, and presidential protective services

Respond to lawsuits and legal actions	• We can share health information about you in response to a court or administrative order, or in response to a subpoena.

We do not create or manage any hospital directories at this practice.

We do not create psychotherapy notes at this practice; however, we may maintain such information in your health record if they are received from another provider.

We comply with all federal and state laws regarding your protected health information at this practice.

Our Responsibilities

- We are required by law to maintain the privacy and security of your protected health information.
- We will let you know promptly if a breach occurs that may have compromised the privacy or security of your information.
- We must follow the duties and privacy practices described in this notice and give you a copy of it.
- We will not use or share your information other than as described here unless you tell us we can in writing. If you tell us we can, you may change your mind at any time. Let us know in writing if you change your mind.

For more information see: **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/noticepp.html.**

Changes to the Terms of this Notice

We can change the terms of this notice, and the changes will apply to all information we have about you. The new notice will be available upon request, in our office, and on our web site.

August 1, 2018

Sampson County Health Department Privacy Officer

Wanda Robinson, Health Director

360 County Complex Rd, Suite 200

Clinton NC 28328

910-592-1131, ext. 4971

wrobinson@sampsonnc.com

Departamento de Salúd del Condado de Sampson

360 County Complex Rd., Suite 200
Clinton, NC 28328
910-592-1131

Su información. Sus derechos. Nuestras responsabilidades.

Esta notificación describe cómo puede utilizarse y divulgarse su información médica, y cómo puede acceder usted a esta información. **Revísela con cuidado.**

Sus derechos

Usted cuenta con los siguientes derechos:

- Obtener una copia de su historial médico en papel o en formato electrónico.
- Corregir en papel o en formato electrónico su historial médico.
- Solicitar comunicación confidencial.
- Pedirnos que limitemos la información que compartimos.
- Recibir una lista de aquellos con quienes hemos compartido su información.
- Obtener una copia de esta notificación de privacidad.
- Elegir a alguien que actúe en su nombre.
- Presentar una queja si considera que se violaron sus derechos de privacidad.

➢ ***Ver página 2*** *para mayor información sobre estos derechos y cómo ejercerlos.*

Sus opciones

Tiene algunas opciones con respecto a la manera en que utilizamos y compartimos información cuando:

- Le contamos a su familia y amigos sobre su estado personal.
- Proporcionamos alivio en caso de una catástrofe.
- Lo incluimos en un directorio hospitalario.
- Proporcionamos atención médica mental.
- Comercializamos nuestros servicios y vendemos su información.
- Recaudamos fondos.

➢ ***Ver página 3*** *para mayor información sobre estas opciones y cómo ejercerlas.*

Nuestros usos y divulgaciones

Podemos utilizar y compartir su información cuando:

- Lo atendemos.
- Dirigimos nuestra organización.
- Facturamos por sus servicios.
- Ayudamos con asuntos de seguridad y salud pública.
- Realizamos investigaciones médicas.
- Cumplimos con la ley.
- Respondemos a las solicitudes de donación de órganos y tejidos.
- Trabajamos con un médico forense o director funerario.
- Tratamos la compensación de trabajadores, el cumplimiento de la ley y otras solicitudes gubernamentales.
- Respondemos a demandas y acciones legales.

➢ ***Ver páginas 3 y 4*** *para mayor información sobre estos usos y divulgaciones.*

Sus derechos

Cuando se trata de su información médica, usted tiene ciertos derechos.
Esta sección explica sus derechos y algunas de nuestras responsabilidades para ayudarlo.

Obtener una copia en formato electrónico o en papel de su historial médico	• Puede solicitar que le muestren o le entreguen una copia en formato electrónico o en papel de su historial médico y otra información médica que tengamos de usted. Pregúntenos cómo hacerlo. • Le entregaremos una copia o un resumen de su información médica, generalmente dentro de 30 días de su solicitud. Podemos cobrar un cargo razonable en base al costo.
Solicitarnos que corrijamos su historial médico	• Puede solicitarnos que corrijamos la información médica sobre usted que piensa que es incorrecta o está incompleta. Pregúntenos cómo hacerlo. • Podemos decir "no" a su solicitud, pero le daremos una razón por escrito dentro de 60 días.
Solicitar comunicaciones confidenciales	• Puede solicitarnos que nos comuniquemos con usted de una manera específica (por ejemplo, por teléfono particular o laboral) o que enviemos la correspondencia a una dirección diferente. • Le diremos "sí" a todas las solicitudes razonables.
Solicitarnos que limitemos lo que utilizamos o compartimos	• Puede solicitarnos que no utilicemos ni compartamos determinada información médica para el tratamiento, pago o para nuestras operaciones. No estamos obligados a aceptar su solicitud, y podemos decir "no" si esto afectara su atención. • Si paga por un servicio o artículo de atención médica por cuenta propia en su totalidad, puede solicitarnos que no compartamos esa información con el propósito de pago o nuestras operaciones con su aseguradora médica. Diremos "sí" a menos que una ley requiera que compartamos dicha información.
Recibir una lista de aquellos con quienes hemos compartido información	• Puede solicitar una lista (informe) de las veces que hemos compartido su información médica durante los seis años previos a la fecha de su solicitud, con quién la hemos compartido y por qué. • Incluiremos todas las divulgaciones excepto aquellas sobre el tratamiento, pago y operaciones de atención médica, y otras divulgaciones determinadas (como cualquiera de las que usted nos haya solicitado hacer). Le proporcionaremos un informe gratis por año pero cobraremos un cargo razonable en base al costo si usted solicita otro dentro de los 12 meses.
Obtener una copia de esta notificación de privacidad	• Puede solicitar una copia en papel de esta notificación en cualquier momento, incluso si acordó recibir la notificación de forma electrónica. Le proporcionaremos una copia en papel de inmediato.
Elegir a alguien para que actúe en su nombre	• Si usted le ha otorgado a alguien la representación médica o si alguien es su tutor legal, aquella persona puede ejercer sus derechos y tomar decisiones sobre su información médica. • Nos aseguraremos de que la persona tenga esta autoridad y pueda actuar en su nombre antes de tomar cualquier medida.
Presentar una queja si considera que se violaron sus derechos	• Si considera que hemos violado sus derechos, puede presentar una queja comunicándose con nosotros por medio de la información de la página 5 de esta notificación; O • Puede presentar una queja en la Oficina de Derechos Civiles del Departamento de Salud y Servicios Humanos enviando una carta a: Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201, llamando al 1-800-368-1019 o visitando **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/factsheets_spanish.html**, los últimos dos disponibles en español. • No tomaremos represalias en su contra por la presentación de una queja.

Sus opciones

Para determinada información médica, puede decirnos sus decisiones sobre qué compartimos. Si tiene una preferencia clara de cómo compartimos su información en las situaciones descritas debajo, comuníquese con nosotros. Díganos qué quiere que hagamos, y seguiremos sus instrucciones.

En estos casos, tiene tanto el derecho como la opción de pedirnos que:	• Compartamos información con su familia, amigos cercanos u otras personas involucradas en su atención. • Compartamos información en una situación de alivio en caso de una catástrofe. • Incluyamos su información en un directorio hospitalario. *Si no puede decirnos su preferencia, por ejemplo, si se encuentra inconsciente, podemos seguir adelante y compartir su información si creemos que es para beneficio propio. También podemos compartir su información cuando sea necesario para reducir una amenaza grave e inminente a la salud o seguridad.*
En estos casos, nunca compartiremos su información a menos que nos entregue un permiso por escrito:	• Propósitos de mercadeo. • Venta de su información. • La mayoría de los casos en que se comparten notas de psicoterapia.

Nuestros usos y divulgaciones

Por lo general, ¿cómo utilizamos o compartimos su información médica? Por lo general, utilizamos o compartimos su información médica de las siguientes maneras.

Tratamiento	• Podemos utilizar su información médica y compartirla con otros profesionales que lo estén tratando.	***Ejemplo:*** *Un médico que lo está tratando por una lesión le consulta a otro doctor sobre su estado de salud general.*
Dirigir nuestra organización	• Podemos utilizar y divulgar su información para llevar a cabo nuestra práctica, mejorar su atención y comunicarnos con usted cuando sea necesario.	***Ejemplo:*** *Utilizamos información médica sobre usted para administrar su tratamiento y servicios.*
Facturar por sus servicios	• Podemos utilizar y compartir su información para facturar y obtener el pago de los planes de salud y otras entidades.	***Ejemplo:*** *Entregamos información acerca de usted a su plan de seguro médico para que éste pague por sus servicios.*

continúa en la próxima página

¿De qué otra manera podemos utilizar o compartir su información médica? Se nos permite o exige compartir su información de otras maneras (por lo general, de maneras que contribuyan al bien público, como la salud pública e investigaciones médicas). Tenemos que reunir muchas condiciones legales antes de poder compartir su información con dichos propósitos. Para más información, visite: **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/factsheets_spanish.html**, disponible en español.

Ayudar con asuntos de salud pública y seguridad	• Podemos compartir su información médica en determinadas situaciones, como: • Prevención de enfermedades. • Ayuda con el retiro de productos del mercado. • Informe de reacciones adversas a los medicamentos. • Informe de sospecha de abuso, negligencia o violencia doméstica. • Prevención o reducción de amenaza grave hacia la salud o seguridad de alguien.
Realizar investigaciones médicas	• Podemos utilizar o compartir su información para investigación de salud.
Cumplir con la ley	• Podemos compartir su información si las leyes federales o estatales lo requieren, incluyendo compartir la información con el Departamento de Salud y Servicios Humanos si éste quiere comprobar que cumplimos con la Ley de Privacidad Federal.
Responder a las solicitudes de donación de órganos y tejidos	• Podemos compartir su información médica con las organizaciones de procuración de órganos.
Trabajar con un médico forense o director funerario	• Podemos compartir información médica con un oficial de investigación forense, médico forense o director funerario cuando un individuo fallece.
Tratar la compensación de trabajadores, el cumplimiento de la ley y otras solicitudes gubernamentales	• Podemos utilizar o compartir su información médica: • En reclamos de compensación de trabajadores. • A los fines de cumplir con la ley o con un personal de las fuerzas de seguridad. • Con agencias de supervisión sanitaria para las actividades autorizadas por ley. • En el caso de funciones gubernamentales especiales, como los servicios de protección presidencial, seguridad nacional y servicios militares.
Responder a demandas y acciones legales	• Podemos compartir su información médica en respuesta a una orden administrativa o de un tribunal o en respuesta a una citación.

Nosotros no creamos o manejamos directorios de ningún hospital en este consultorio.

Nosotros no creamos notas de sicoterapia en este consultorio; sin embargo, podemos mantener información en su expediente médico si lo hemos recibido de otro proveedor.

En este consultorio nos acatamos a todas las leyes federales e estatales con respecto a su información médica protejida.

Nuestras responsabilidades

- Estamos obligados por ley a mantener la privacidad y seguridad de su información médica protegida.
- Le haremos saber de inmediato si ocurre un incumplimiento que pueda haber comprometido la privacidad o seguridad de su información.
- Debemos seguir los deberes y prácticas de privacidad descritas en esta notificación y entregarle una copia de la misma.
- No utilizaremos ni compartiremos su información de otra manera distinta a la aquí descrita, a menos que usted nos diga por escrito que podemos hacerlo. Si nos dice que podemos, puede cambiar de parecer en cualquier momento. Háganos saber por escrito si usted cambia de parecer.

Para mayor información, visite: **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/factsheets_spanish.html**, disponible en español.

Cambios a los términos de esta notificación

Podemos modificar los términos de esta notificación, y los cambios se aplicarán a toda la información que tenemos sobre usted. La nueva notificación estará disponible según se solicite, en nuestra oficina, y en nuestro sitio web.

Agosto 1, 2018

Dirigente de Privacidad Del Departamento de Salúd del Condado de Sampson

Wanda Robinson, Directora de Salúd

360 County Complex Rd, Suite 200

Clinton, NC 28328

910-592-1131, ext. 4971

wrobinson@sampsonnc.com

BECAUSE THIS FORM IS USED BY VARIOUS GOVERNMENT AND PRIVATE HEALTH PROGRAMS, SEE SEPARATED INSTRUCTIONS ISSUED BY APPLICABLE PROGRAMS.

NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.

REFERS TO GOVERNMENT PROGRAMS ONLY

MEDICARE AND TRICARE PAYMENTS: A patient's signature requests that payment be made and authorizes release of any information necessary to process the claim and certifies that the information provided in Blocks 1through 12 is true, accurate and complete. In the case of a Medicare claim, the patient's signature authorizes any entity to release to Medicare medical and nonmedical information and whether a person has employer group health insurance, liability, no-fault, worker's compensation or other insurance which is responsible to pay for the services for which the Medicare claim is made. See 42 CFR 411.24(a). If Item 9 is completed, the patient's signature authorizes the release of the information to the health plan or agency shown.
In Medicare assigned or TRICARE participation cases, the physician agrees to accept the charge determination of the Medicare carrier or TRICARE fiscal intermediary as the full charge and the patient is responsible only for the deductible, coinsurance and non-covered services. Coinsurance and the deductible are based upon the charge determination of the Medicare carrier or TRICARE fiscal intermediary if this is less than the charge submitted. TRICARE is not a health insurance program but makes payment for health benefits provided through certain affiliations with the Uniformed Services. Information on the patient's sponsor should be provided in those items captioned in "Insured"; i.e., items 1a, 4, 6, 7, 9, and 11.

BLACK LUNG AND FECA CLAIMS

The provider agrees to accept the amount paid by the Government as payment in full. See Black Lung and FECA instructions regarding required procedure and diagnosis coding systems.

SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE, TRICARE, FECA AND BLACK LUNG)

In submitting this claim for payment from federal funds, I certify that: 1) The Information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5} the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI license #, or SSN) of the primary individual rendering each service is reported in the designated section. For services to be considered "incident to" a physician's professional services, 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills.

For TRICARE claims, I further certify that I (or any employee) who rendered services am not an active duty member of the Uniformed Services or a civilian employee of the United States Government or a contract employee of the United States Government, either civilian or military (refer to 5 USC 5536). For Black-Lung claims, I further certify that the services performed were for a Black Lung-related disorder.

No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations (42 CFR 424.32).

NOTICE: Anyone who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF MEDICARE, TRICARE, FECA, AND BLACK LUNG INFORMATION (PRIVACY ACT STATEMENT)

We are authorized by CMS, TRICARE and OWCP to ask you for information needed in the administration of the Medicare, TRICARE, FECA, and Black Lung programs. Authority to collect information is in section 205(a), 1862, 1872 and 1874 of the Social Security Act as amended, 42 CFR 411.24(a} and 424.5(a) (6), and 44 USC 3101;41 CFR 101 el seq and 10 USC 1079 and 1086; 5 use 8101et seq; and 30 use 901 et seq; 38 use 613;E.O. 9397.

The information we obtain to complete claims under these programs is used to identify you and to determine your eligibility. It is also used to decide if the services and supplies you received are covered by these programs and to insure that proper payment is made.

The information may also be given to other providers of services, carriers, intermediaries, medical review boards, health plans,

and other organizations or Federal agencies, for the effective administration of Federal provisions that require other third parties payers to pay primary to Federal program, and as otherwise necessary to administer these programs. For example, it may be necessary to disclose information about the benefits you have used to a hospital or doctor. Additional disclosures are made through routine uses tor information contained in systems of records.

FOR MEDICARE CLAIMS: See the notice modifying system No. 09-70-0501, titled, 'carrier Medicare Claims Record,' published in the Federal Register, Vol. 55 No. 177, page 37549, Wed. Sept. 12, 1990, or as updated and republished.

FOR OWCP CLAIMS: Department of Labor, Privacy Act of 1974, "Republication of Notice of Systems of Records," Federal Register Vol.55 No. 40, Wed Feb. 28, 1990, See ESA-5, 6, 12, 13, 30, or as updated and republished.

FOR TRICARE CLAIMS: PRINCIPLE PURPOSE(S): To evaluate eligibility for medical care provided by civilian sources and to issue payment upon establishment of eligibility and determination that the services/supplies received are authorized by law.

ROUTINE USE(S) ·Information from claims and related documents may be given to the Dept. of Veterans Affairs, the Dept. of Health and Human Services and/or the Dept. of Transportation consistent with their statutory administrative responsibilities under TRICARE/CHAMPVA; to the Dept. of Justice for representation of the Secretary of Defense in civil actions; to the Internal Revenue Service, private collection agencies, and consumer reporting agencies in connection with recoupment claims; and to Congressional Offices in response to inquiries made at the request of the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, local, foreign government agencies, private business entities, and individual providers of care, on matters relating to entitlement, claims adjudication, fraud, program abuse, utilization review, quality assurance, peer review, program integrity, third-party liability, coordination of benefits, and civil and criminal litigation related to the operation of TRICARE.

DISCLOSURES· Voluntary; however, failure to provide information will result in delay in payment or may result in denial of claim. With the one exception discussed below, there are no penalties under these programs for refusing to supply information. However, failure to furnish information regarding the medical services rendered or the amount charged would prevent payment of claims under these programs. Failure to furnish any other information, such as name or claim number, would delay payment of the claim. Failure to provide medical information under FECA could be deemed an obstruction.

It is mandatory that you tell us if you know that another party is responsible for paying tor your treatment. Section 1128B of the Social Security Act and 31 USC 3801-3812 provide penalties for withholding this information.

You should be aware that P.L. 100-503, the "Computer Matching and Privacy Protection Act of 1988", permits the government to verify Information by way of computer matches.

MEDICAID PAYMENTS (PROVIDER CERTIFICATION)

I hereby agree to keep such records as are necessary to disclose fully the extent of services provided to individuals under the State's Title XIX plan and to furnish information regarding any payments claimed for providing such services as the Stale Agency or Dept. of Health and Human Services may request.

I further agree to accept, as payment in full, the amount paid by the Medicaid program for those claims submitted for payment under that program, with the exception of authorized deductible, coinsurance, co-payment or similar cost-sharing charge.

SIGNATURE OF PHYSICIAN (OR SUPPLIER): I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.

NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1197. The time required to complete this information collection is estimated to average 10 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PAA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. This address is for comments and/or suggestions only. **DO NOT MAIL COMPLETED CLAIM FORMS TO THIS ADDRESS.**

POR QUE ESTE FORMULARIO ES USADO POR VARIOS PROGRAMAS DE SALÚD PRIVADO O DEL GOBIERNO, VEA LAS INSTRUCCIONES SEPARADAS EMITIDAS POR LOS PROGRAMAS PERTINENTES.

AVISO: Cualquier persona que deliberadamente entabla una declaración de reclamo conteniendo cualquier tergiversación o información fraudulenta, incompleta o engañosa podria ser culpable de un acto criminal castigado bajo la ley y puede ser sometido a penalizaciónes civil.

SE REFIERE A PROGRAMAS DEL GOBIERNO SOLAMENTE

PAGOS DE MEDICAID Y TRICARE: La firma del paciente pide que el pago se haga e autoriza divulgar cuaquier información necesaria para procesar el reclamo y certifica que la información proveida en Bloc 1 al 12 es verdadero, exacto y completo. En el caso de reclamo de Medicare, la firma del paciente autoriza cualquier entidad divulgar a Medicare información médica o no médica y si la persona tiene seguro médico de grupo por parte del empleado, responsabilidad civil, sin responsabilidad, compensación de trabajadores e otro seguro cual es responsable de pagar por los servicios por cual el reclamo de Medicare es hecho. Vea 42 CFR 411.24(a). Si el articulo 9 ha sido completo, la firma del paciente autoriza divulgar la información al plan de seguro o la agencia demostrada. En Medicare asignado o casos de participación de TRICARE, el médico está de acuerdo aceptar el cargo determinado por el portador de Medicare o intermediario fiscal de TRICARE como el cobro total y el paciente es responsable solamente por el deducible, coseguro o servicios no cubiertos. Coseguro y el deducible son basados en los cargos determinados por el portador de Medicare y el intermediario fiscal de TRICARE si esto es menos que los cargos sumetidos. TRICARE no es un programa de seguro médico pero hace pagos por benificios de salúd proveidos por ciertas afiliaciones con el Servicio Uniformado. Información del patrocinador del paciente debe ser proveido en los articulos indicado en “azegurado”; como articulos 1a, 4, 6, 7, 9 y 11.

RECLAMOS DE BLACK LUNG AND FECA

El proveedor esta de acuerdo en aceptar la cantidad pagado por el Gobierno como pago en totalidad. Vea las instrucciones de Black Lung and FECA sobre el procedimiento requerido y los sistemas de códigos diagnosticos.

FIRMA DEL PROVEEDOR O SUMINISTRADOR (MEDICARE, TRICARE, FECA Y BLACK LUNG)

Al someter este reclamo de pago de fondos federales, Yo certifico que: 1) La información en este formulario es verdadera, exacta y completa; 2) Me he familiarizado con las leyes pertinentes, reglamentos, e instrucciones del programa, cuales son disponibles por parte del contratista de Medicare; 3) He proveido o voy a proveer suficiente información requerida para permitir al gobierno hacer una decision informada de eligibilidad y pago; 4) este reclamo, sea presentado por mi o en mi nombre por una compania de pago designado, acata con las leyes pertinentes de Medicare y/o Medicaid, reglamentos, e instrucciones del programa para el pago incluyendo pero no limitado al decreto Federal anti-tajada y la ley de Auto-Referencia de Médico (generalmente conocido como Stark Law); 5) los servicios en este formulario fueron hechos por necesidad médica y suministrados por mi personalmente o fueron suministrados incidente a mi servicio profesional por mi empleado bajo mi supervisión directa,al menos de otro modo permitido expresamente por Medicare o Tricare; 6) por cada servicio incidente prestado por mi servicio profesional, la identidad (nombre legal y # de licensia NPI, o NSS) del individuo primario prestando cada servicio es reportado en la sección designada. Para que los servicios sean considerados “incidente a” los servicios profesionales del médico, 1) debe ser prestado bajo la supervisión directa del médico o por su empleado, 2) debe ser integral, aunque una parte incidental al servico cubierto por el médico, 3) deben ser de los tipos normalmente sumistrados en oficinas médicas, y 4) los servicios de los que no son médicos deben ser incluidos en las facturas del médico.

Para reclamos de Tricare, yo certifico que yo (o cualquier empleado) que suministró servicios no soy un miembro del servicio activo de los Servicios Uniformados o un empleado civil del Gobierno de los Estados Unidos o un empleado contratado del Gobierno de los Estados Unidos, sea civil o militar (remitir a 5 USC5536). Para reclamos de Black-Lung, yo certifico que los servicios que fueron hechos eran para un trastorno relacionado con Black Lung.

Ningún beneficio de Medicare Parte B será pagado a menos que el formulario sea recibido como es requerido por las leyes pertinentes y reglamentos (42 CFR 424.32).

Aviso: Cualquiera que haga tergiversación o falsificación de información esencial para recibir pago de fondos Federales solicitados por este formulario puede ser condenado y sujeto a una multa o encarcelamiento bajo las leyes Federales pertinentes.

AVISO AL PACIENTE SOBRE LA COLECCIÓN E USO DE LA INFORMACIÓN DE MEDICARE, TRICARE, FECA Y BLACK LUNG (DECLARACIÓN DEL ACTA DE PRIVACIDAD)

Somos autorizados por CMS, TRICARE y OWCP para preguntarle por información necesaria en la administración de los programas de Medicare, TRICARE, FECA, y Black Lung. Autoridad para coleccionar información está en la sección 205(a), 1862, 1872 y 1874 del Acta de Seguro Social como enmendado, 42 CFR 411.24(a) y 424.5(a) (6), y 44 USC 3101;41 CFR 101 el seq y 10 USC 1079 y 1086; 5 use 8101 et seq; y 30 use 901 et seq; 38 use 613;E.O.9397.

La información obtenida para completar los reclamos bajo estos programas es usado para identificar a usted y para determiner su eligibilidad. También es usada para decidir si los servicios y suministros recibidos son cubiertos por estos programas y para asegurar que el pago apropiado sea hecho.

La información también puede ser porporcionada a otros proveedores de servicios, portadores, intermediarios, junta de revisión médica, planes de salúd, e otras organizaciones o agencias Federales, para la administración efectiva de provisiones Federales, cual requiere otros pagadores de tercer parte pagar primero al programa Federal, y como otro modo sea necesario para administrar estos programas. Por ejemplo, puede ser necesario divulger información sobre los benificios que usted ha usado al hospital o al médico. Divulgaciones adicionales son hechos por uso de rutina de información contenida en el sistemas de registro.

PARA RECLAMOS DE MEDICAID: Vea el sistema de modificación de aviso No. 09-70-0501,titulado, 'Registro de Reclamos del portador de Medicare,' publicado en el Registro Federal, Vol. 55 No. 177, pagina 37549, Miercoles 12 de Septiembre, 1990, o como sea actualizado y reeditado.

PARA RECLAMOS OWCP: Departamento de Labor, Acta de Privacidad de 1974, "Republicación de Notificación de Sistemas de Registro," Registro Federal Vol.55 No. 40, Miercoles 28 de Febrero, 1990, Vea ESA-5, 6, 12, 13, 30, o como sea actualizado y reeditado.

PARA RECLAMOS DE TRICARE: PROPÓSITO(S) PRINCIPAL: Para evaluar la elegibilidad para atención médica proporcionada por fuentes civiles y para emitir el pago tras el establecimiento de elegibilidad y determinación de que los servicios/suplementos recibidos esten autorizados por ley.

USO(S) RUTINARIO(S): Información de reclamos y documentos relacionados se pueden ser otorgados al Departmento de Asuntos de Veteranos, el Departamento de Salúd y Servicios Humanos y/o el Departamento de Transportación consistente con sus responsabilidades administrativas estatuarias bajo TRICARE/CHAMPVA; al Departamento de Justicia para representación del Secretario de Defensa en acciones civiles; al Servicio de Ingreso Interno, agencias de colección privada, y agencias de reportes del consumidor en conexión con reclamos de recuperación; y a las Oficinas del Congreso en respuesta a las preguntas hechas por petición de la persona a quien le pertenece el registro. Se pueden hacer divulgaciones apropiadas a otras agencias del gobierno federal, estatal, local, extranjeros, entidad de negocios privados, y proveedores individuales de cuidado, en asuntos relacionados con el derecho, adjudicación de reclamos, fraude, abuso del programa, revision de utilización, garantia de calidad, revision del par, programa de integridad, responsabilidad del tercer partido, coordinación de beneficios, y litigio civil y criminal relaciónado con la operación de TRICARE.

DIVULGACIÓNES: Voluntario; Sin embargo, al no proporcionar información resultará en un retraso en el pago o puede resultar en la desaprobación del reclamo. Con la única excepción mencionada abajo, no hay sanciones bajo este programa por negarse a dar información. Sin embargo, el incumplimento de proveer la información relacionada con los servicios medicos prestados o cantidad que cobren impediria el pago de los reclamos bajo este programa. Incumplimiento de proporcionar cualquier información, tal como nombre o numero de reclamo, retrasaria el pago de reclamo. Incumplimiento de proveer información médica bajo FECA se podria considera una obstrucción.

Es obligatorio que usted nos diga si sabe que otro partido es responsible de pagar por su tratamiento. Sección 1128B del Acta Ley de Servicio Social y 31 USC 3801-3812 suministran sanciones por retener esta información.

Usted debe estar percatado de que P.L.100-503, el " Igualar la computadora y el acta de Proteccion de Privacidad de 1988", permite al gobierno verificar Información atraves de Igualamiento de la computadora.

PAGOS DE MEDICAID (CERTIFICACIÓN DEL PROVEEDOR)

Por lo presente acepto mantener los registros que sean necesarios para divulgar completamente el alcance de los servicios proveidos al individual bajo el plan del Titulo XIX del Estado y para proporcionar información sobre cualquier pago reclamado por proveer tales servicios como la Agencias Estatal o Departamento de Salúd y Servicios Humanos puedan solicitar.

Yo estoy de acuerdo aceptar, como pago completo, la cantidad pagada por el programa de Medicaid para los reclamos presentados para el pago bajo ese programa,con la excepción del deducible autorizado, coseguro, copago o cobro similar a reparto de gastos.

FIRMA DEL MÉDICO (O PROVEEDOR): Certifico que los servicios escritos arriba fueron médicalmente indicados y necesarios por la salúd de este paciente y fueron suministrados por mi o mi empleado bajo mi dirección personal.

AVISO: Esto es para certificar que la información previa es verdadera, precisa y completa. Entiendo que el pago y la satisfacción de este reclamo será de fondos Federales e Estatales, y que cualquier reclamo falso, declaración, o documento, o encubrimiento de un hecho material, puede ser juzgudo bajo las leyes Federales e Estatales pertinentes.

De auerdo con el acto de Reducción de Papeleo de 1995, no se requiere que las personas respondan a la colección de información a menos de que muestre un número de control valido de OMB. El número de control valido de OMB para esta colección de información es 0938-1197. El tiempo requerido para completar esta colección de información se estima en un promedio de 10 minutos por respuesta, incluyendo el tiempo para revisar las instrucciones, buscar recursos de datos existentes, reunir los datos necesarios, y completar y revisar la colección de información. Si tiene algun comentario acerca de la exactitude de la(s) estimación(es) de tiempo o sugerencias para mejorar este formulario, por favor escriba a: CMS, 7500 Security Boulevard, Attn: PAA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850, Esta dirección es solamente para comentarios y/o sugerencias. **NO ENVIE POR CORREO FORMULARIOS DE RECLAMOS A ESTA DIRECCION.**

PATIENT AUTHORIZATION to Permit Use and Disclosure of Health Information

Last Name **First Name** **MI**

Date of Birth: / /

Patient's Contact Number / /

Sampson County Health Department
360 County Complex Road, Suite 200
Clinton, NC 28328
Phone: 910-592-1131 **Fax: 910-590-1050**

I am either the patient named above or the patient's legally authorized representative.

By signing this form, I authorize _____
Person or class of persons authorized to use or disclose the information

to use or disclose to _____
Person or class of persons to whom use or disclosure would be made

the following protected health information (*identify the information in a specific and meaningful fashion):*

_____

_____

_____

The purpose of the use or disclosure is *(describe each purpose of the requested use or disclosure):*

_____

I understand that, with certain exceptions, I have the right to revoke this Authorization at any time. If I want to revoke this authorization, I must do so in writing. The procedure for how I may revoke the authorization, as well as the exceptions to my right to revoke, are explained in **Sampson County Health Department's** Notice of Privacy Practices, a copy of which will be provided to me upon request.

I understand that I may refuse to sign this authorization. I also understand that **Sampson County Health Department** cannot deny or refuse to provide treatment, payment, enrollment in a health plan, or eligibility for benefits if I refuse to sign this Authorization

I understand that, once information is disclosed pursuant to this Authorization, it is possible that it will no longer be protected by the federal medical privacy law and could be re-disclosed by the person or agency that receives it.

This authorization expires automatically upon _____
Date or event that relates to the patient or the purpose of the use or disclosure

_____ _____
*Signature of patient **OR** Authorized representative* *Date*

_____
Please print name of patient or authorized representative who signed above

Please explain representative's authority to act on behalf of the patient: _____

AUTORIZACION DEL PACIENTE Para Permitir El Uso Y Divulgacion De Información De Salúd

Sampson County Health Department
360 County Complex Road, Suite 200
Clinton, NC 28328

Phone: 910-592-1131 Fax: 910-590-1050

Last Name **First Name** **MI**

Date of Birth: / /

Patient's Contact Number / /

Yo soy el paciente mencionado anteriormente o el representante legal de dicho paciente.

Firmando esta planilla, autorizo a _____
Persona o clase de personas autorizadas a usar o divulger la información

A usar o divulgar a _____
Persona o clase de personas a quien se les suministrará el uso o divulgación

La siguiente información de salúd protegida *(identifique la información de una forma clara y especifica).*

_____

_____

_____

El propósito de esta divulgación es *(describir cada propósito del solicitado uso de información solicitado odivulgación):*

_____

Yo entiendo que, con ciertas excepciones, yo tengo el derecho en cualquier momento de anular esta Autorización. Si quisiera anular esta autorización, lo debo hacer por escrito. El proceso a seguir para anular esta autorizacón, así como las excepciones a mi derecho de anularlo, están explicades en el documento "Notificación de Prácticas Privadas" **del Departamento de Salúd del Condado de Sampson**, una copia que me daran a mi petición.

Yo entiendo que puedo negarme a firmar esta authorización. También entiendo que la Entidad **del Departamento de Salud del Condado de Sampson** no puede negarse a proveerme tratamiento, pago o inscripción en un plan de salud, o de quitarme el derecho a beneficios porque me niege a firmar esta Autorización.

Yo entiendo que, una vez que la información ha sido divulgada basada en esta Autorización, es possible que deje de estar protegida por la ley federal de privacidad médica y que pudiera ser divulgada de nuevo por la persona o agencia que la reciba.

Esta autorización se vence automáticamente el _____
Fecha o evento relacionado con el paciente o propósito del uso o divulgación

_____ _____
Firma del Paciente o Representante Autorizado *Fecha*

_____
Nombre (en letra de imprenta) del Paciente o Representante Autorizado que firmó planilla

Por favor explique la autoridad que tiene el Representante para actuar en nombre del Paciente: _____

Revised 7/10

HIPPA OMNIBUS RULE
PATIENT ACKNOWLEDGEMENT OF RECEIPT OF NOTICE OF PRIVACY PRACTICES
AND CONSENT/LIMITED AUTHORIZATION & RELEASE FORM
You may refuse to sign this acknowledgement & authorization. In refusing we may not be able to process your insurance claims.

Date: _____
The undersigned acknowledges receipt of a copy of the currently effective Notice of Privacy Practices for This healthcare facility. A copy of this signed, dated document shall be as effective as the original.
MY SIGNATURE WILL ALSO SERVE AS AUTHORIZATION TO SHARE INFORMATIONS AS INDICATED BELOW.
«Patient Last Name»,«Patient First Name» « Signature »

PLEASE LIST ANY OTHER PARTIES WHO CAN HAVE ACCESS TO YOUR HEALTH INFORMATION: (This includes step parents, grandparents and any care takers who can have access to this patient's records)
Name: _____ Relationship: _____ Phone: _____ _____

Name: _____ Relationship: _____Phone: _____ _____

I AUTHORIZE CONTACT FROM THIS OFFICE TO **CONFIRM MY APPOINTMENTS, TREATMENT & BILLING INFORMATION** VIA:
____ Cell Phone Confirmation/Text Confirmation
____ Home Phone Confirmation
____ Work Phone Confirmation
____ Any of the Above

I AUTHORIZE **INFORMATION ABOUT MY HEALTH** BE CONVEYED VIA:
____ Cell Phone Confirmation/Text Confirmation
____ Home Phone Confirmation
____ Work Phone Confirmation
____ Any of the Above
In signing this HIPPA Patient Acknowledgement Form, you acknowledge and authorize, that this office may recommend products or services to promote your improved health. This office may or may not receive third party renumeration from these affiliated companies. We, under current HIPPA Omnibus Rule, provide you this information with your knowledge and consent.

Office Use Only

I attempted to obtain the patient's (or representatives) signature on this Acknowledgement but did not because:
____ It was emergency treatment
____ I could not communicate with the patient
____ The patient refused to sign
____ The patient was unable to sign because _____
____ Other (please describe) _____ _____

« Signature »
Signature of SCHD Employee

Revised November 9, 2015

REGLAS DEL OMNIBUS DE HIPPA
RECONOCIMIENTO DE ACEPTACION POR PARTE DEL PACIENTE DEL AVISO DE PRACTICAS PRIVADAS Y CONSENTIMIENTO/AUTORIZACIÓN LIMITADA Y FORMA DE ENTREGA DE INFORMACIÓN
Usted puede rehusarse a firmar este reconocimiento & autorizacion. Al rehusarse, es posible que no podamos procesar su reclamacion de seguro.

Fecha: _____
El suscrito reconoce que ha recibido una copia del actual Aviso de Practicas Privadas de este centro de cuidado de salud. Una copia de este formulario con fecha y firma sera tan efectivo como el original.
MI FIRMA TAMBIEN SIRVE COMO AUTORIZACION PARA COMPARTIR INFORMACIONES COMO SE INDICA ABAJO.
«Patient Last Name»»,««Patient First Name»» « Signature »

POR FAVOR MENCIONE OTROS INDIVIDUOS QUE PUEDEN TENER ACCESO A SU INFORMACION MEDICA: (Esto incluye padrastros, abuelos y cualquier persona de cuidado quien pueda tener acceso al expediente del paciente)

Nombre: _____ Parentesco: _____Telefono: _____

Nombre: _____ Parentesco: _____Telefono: _____

YO AUTORIZO CONTACTO DE ESTA OFICINA A **CONFIRMAR MIS CITAS, INFORMACION DE TRATAMIENTO Y COBRO** VIA:
____ Confirmacion por Telefono Celular/Confirmacion por texto
____ Confirmacion por Telefono de Hogar
____ Confirmacion por Telefono de mi Empleo
____ Cualquier mencionado arriba

YO AUTORIZO QUE **INFORMACION SOBRE MI SALUD** SEA COMUNICADA VIA:
____ Confirmacion por Telefono Celular/Confirmacion por texto
____ Confirmacion por Telefono de Hogar
____ Confirmacion por Telefono de mi Empleo
____ Cualquier mencionado arriba
Al firmar esta forma de Reconocimiento del Paciente sobre el HIPPA, usted reconoce y autoriza, que esta oficina puede recomendar productos o servicios para promover su salud mejorada. Esta oficina podra o no podra recibir remuneracion de estas companies afiliadas. Nosotros, bajo la actual Regla del Ominbus de HIPPA, le provee esta informacion para su conocimiento y consentimiento.

Office Use Only
I attempted to obtain the patient's (or representatives) signature on this Acknowledgement but did not because:
____ It was emergency treatment
____ I could not communicate with the patient
____ The patient refused to sign
____ The patient was unable to sign because _____
____ Other (please describe) _____

« Signature »
Signature of SCHD Employee

Revised November 9, 2015

Release of Health Information

«Patient Last Name», «Patient First Name»
«Patient SSN»
«Patient DOB»

NC Department of Health and Human Services
Public Health Nursing and Professional Development

PATIENT AUTHORIZATION to Permit Use and Disclosure of Health Information

I am either the patient named above or the patient's legally authorized representative. By signing this form, I authorize _____ to use or disclose to_____ the following protected health information (identify the information in a specific and meaningful fashion):

The purpose of the use or disclosure is (describe each purpose of the requested use or disclosure):

I understand that, with certain exceptions, I have the right to revoke this Authorization at any time. If I want to revoke this authorization, I must do so in writing. The procedure for how I may revoke the authorization, as well as the exceptions to my right to revoke, are explained in _____'s Notice of Privacy Practices, a copy which has been provided to me.

I understand that I may refuse to sign this authorization. I also understand that _____ cannot deny or refuse to provide treatment, payment, enrollment in a health plan, or eligibility for benefits if I refuse to sign this Authorization.

I understand that, once information is disclosed pursuant to this Authorization, it is possible that it will no longer be protected by the federal medical privacy law and could be re-disclosed by the person or agency that receives it.

This authorization expires automatically upon_____

« Signature »
Signature of patient OR authorized representative
Please print name of patient or authorized representative who signed above

Please explain representative's authority to act on behalf of the patient:

Release of Health Information - Spanish

«Patient Last Name», «Patient First Name»
«Patient SSN»
«Patient DOB»

Departmento de Salud y Servicios Sociales de Carolina del Norte
Enfermeria de Salud Publica

AUTORIZACION DEL PACIENTE PARA PERMITIR EL USO Y DIVULGACION DE INFORMACION DE SALUD

Yo soy el paciente mencionado anteriormente o el representante legal de dicho paciente.

Firmando esta planilla, autorizo a _____a usar o divulgar a _____ la siguiente informatcion de salud protegida (identifique la informacion de una forma clara y especifica):

El proposito de esta divulgacion es (describir cada proposito del solicitado uso o divulgacion):

Yo entiendo que, con ciertas excepciones, yo tengo el derecho en cualquier momento de anular esta Autorizacion. Si quisiera anular esta autorizacion, lo debo hacer por escrito. El proceso a sequir para anular esta autorizacion, asi como las escepcions a mi derecho de anularlo, estan explicadas en el documento "Notificacion de Practicas Privadas" de la entidad_____.
Una copia de dicho documento se me ha sido entregado anteriormente.

Yo entiendo que puedo negarme a firmar esta autorizacion. Tambien entiendo que la Entidad_____ no puede negarse a proveerme tratamiento, pago o inscription en un plan de salud, o de quitarme el derecho a beneficios porque me niegue a firmar esta Autorizacion.

Yo entiendo que, una vez que la informacion ha sido divulgada basada en esta Autorizacion, es posible que deje de estar protegida por la ley federal de privacidad medica y que pudiera ser divulgada de nuevo por la persona o agencia que la reciba.

Esta autorizacion vence automaticamente el _____

« Signature »
Firma del Paciente o Representante Autorizado

_____
Nombre (en latra de imprenta) del Paciente o Representante Autorizado que firmo planilla

Favor ezplique la autoridad que tiene el Representante para actuar en nombre del Paciente:

Documentation of Released Medical Information

Accounting for Disclosure

Patient Name: «Patient First Name» «Patient Last Name»
Account Number: «Patient Account No.»
DOB: «Patient DOB»

Name of entity(ies) to whom disclosure was made:

Date of Disclosure: «Current Date»

Reason for Disclosure: Authorization Referral MD Lab Request Personal Other: Work

Type of Disclosure:

Optional
Patient Signature:
« Signature »

Attachment H: Email sent by Frances Taylor June 28, 2012 (Two Attachments - See Below):

From: Reed, Joy [mailto:joy.reed@dhhs.nc.gov]
Sent: Thursday, June 28, 2012 4:43 PM
To: The phleaders mailing list
Subject: [phleaders] FW: HIPAA-Text Messaging Guidance for LHDs
Importance: High

Forwarded at request of Frances Taylor.

Many questions have arisen as to whether or not it is permissible for a local health department's workforce to communicate with clients via text messaging. Text messaging between the local health department's workforce and patients/clients is not generally recommended. If, however, a local health department wishes to allow its workforce to communicate with patients/clients via text messaging, the attached guidance, in conjunction with the attached Appointment Card & Return Address Guidance, should be followed in making that decision and develop appropriate guidelines for the workforce. It is not recommended to communicate with clients via text messaging beyond what is provided in the guidance.

No matter what decision is made by the local health department, the decision should be documented in the form of policy/procedure and the workforce should be trained as indicated in the Text Messaging Guidance.

Frances Q. Taylor
N. C. Division of Public Health
Office of Administrative, Local & Community Support
HIPAA Liaison to Local Public Health Departments
DPH Office (voice mail only) (919) 707-5149
Home Office: (704) 784-2758
Email: frances.q.taylor@dhhs.nc.gov

Guidance on Text Messaging For Local Public Health Departments; June 1, 2012

Guidance on Text Messaging
For Local Public Health Departments
June 1, 2012

Text messaging between local health department staff and patients/clients is not generally recommended. However, if a covered entity wishes to allow its workforce to communicate with patients/clients via text messaging, the information below should be followed in making that decision and develop appropriate guidelines for staff.

No matter what decision is made by the covered entity, the decision should be documented in the form of policy/procedure and could also be included as part of the covered entity's existing internal Safeguards Policy or as a separate policy/procedure. The Privacy Rule requires that the workforce of the covered entity is to be trained on its policies/procedures and the training must be documented. Training of the workforce should be completed prior to the effective date of the policy/procedure. Documentation of the training should be kept on file by the covered entity for 6 years from the date it was created or from the date it was last in effect, whichever is longer.

> ***Q:*** *Many questions have arisen regarding whether or not it is permissible under HIPAA to text clients via cell phones and, if so, what safeguards should be used to ensure the client's confidentiality. The questions center on whether or not it is permissible to use text messaging to remind clients of appointments.*
>
> ***A:*** *HIPAA does not directly address the use of text messaging as HIPAA is intended to be technology neutral. However, HIPAA does provide information about mailings to patients and leaving voice messages for patients about appointments reminders. (See Q&A from OCR Privacy Guidance document, which is included as part of the attached "*Appointment Card & Return Address Guidance*.") It is reasonable to extrapolate this position to using text messaging for the same limited purpose, with some caveats.*

Staff may send a text message to a client with MINIMAL information, using texting in the same way that regular telephone voicemail is used, protecting patient confidentiality and not disclosing any protected health information.

Staff should first confirm with the client whether or not they agree to receive text messages about appointment reminders and other brief messages. It is possible clients may prefer receiving appointment reminders and other brief messages via text. Some clients may believe they have more privacy receiving and replying to a text and calling back at their convenience rather than answering a cell call directly. Or, in other situations, clients may have limited phone minutes on a pre-paid plan and text may be less expensive for them.

After consulting with a client as to whether or not they wish to receive text messages, staff should document the client's preferences in the client's record (paper and/or electronic). Documentation could be in a consistent place in the client's record readily available for all staff to reference. If a client declines to receive text messages, this most likely would be considered a privacy restriction and should also be documented. In situations where a client has requested privacy restrictions and the covered entity agrees to a reasonable privacy restriction request, the covered entity must accommodate and abide by the request until the client revokes the restriction. Privacy restriction revocations by the client should also be documented.

Before texting, staff should verify that the number is correct.

Additional Tips:

1. Use a work phone to communicate directly with clients. If a personal phone is used to conduct public business with clients, the phone or its records may be subject to subpoena during any discovery.
2. Delete the message from your cell phone after it is sent.
3. Protect your work phone with a PIN or password when not in use in case it is lost or stolen.
4. Report loss or theft of any device to appropriate authorities immediately.

Staff should use general rather than specific names, such as an organization or program name. Minimal information should be used in appointment reminders or other text messages. The reason for the appointment, the program name, and clinic name should not be used. Examples of appropriate general appointment reminders and other brief text messages would be:

INCORRECT - *This approach does not sufficiently protect patient privacy.*
Do not say, for example:
"I am your care manager from the Health Department, working with your Pregnancy Medical Home, calling about your prenatal appointment."

CORRECT
More appropriate general messages would be:

- "This is Lynn, please call me at 919-987-6543."
- "Hi, this is Lynn from your doctor's office. Please give me a call at 919-987-6543."
- "Hi Maria, this is a friendly reminder of your appointment on July 1st at 10 AM. Please call Lynn at 919-987-6543 if you have questions or need to re-schedule."

Caveats to Consider:

- Cell phones usually don't have security software. Even if the sender has security software, the sender doesn't know whether or not the receiver has it.
- Cell phone signals travel the airways and can be intercepted. Or, cell phone texts sometime travel the internet and there is no security.

- Cell phone texts and phone conversations reside somewhere on the cell phone carriers' servers for who knows how long. The information on these servers can be read by the carriers' server administrators. Even though the employees of cell phone companies (and

server hubs) may have confidentiality policies/procedures, carriers and server hubs are not covered entities (and are not business associates) and are not required to abide by HIPAA.

- Information on cell phone servers can be, and has been, requested by law enforcement agencies with and without the proper paperwork: law enforcement may be privy to information they may not otherwise be allowed to have under HIPAA.
- If a cell phone owner is not diligent about deleting their text history on their phone, the cell phone user then has client information stored on their phone for anyone who uses the phone (and looks at the history) can read.

Appointment Card & Return Address Guidance

March 3, 2003

There have been many questions and concerns regarding the use of appointment cards and return addresses on correspondence. After researching this information as well as seeking guidance from the Institute of Government, the following guidance is provided.

The Privacy Rule establishes a Federal floor of safeguards to protect the confidentiality of medical information. State laws which provide stronger privacy protections will continue to apply over and above the new Federal privacy standards.

Health care providers have a strong tradition of safeguarding private health information. However, in today's world, the old systems are sometimes not enough. With information broadly held and transmitted electronically, the Rule provides clear standards for the protection of personal health information.

Appointment Cards:

The following question appeared in the US DHHS Privacy Rule Guidance Document published 12/4/02 by the Office of Civil Rights. (The entire document may be downloaded at http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacy.html) (Click on the section entitled, "Incidental Uses and Disclosures")

"Q. May physician's offices or pharmacists leave messages for patients at their homes, either on an answering machine or with a family member, to remind them of appointments or to inform them that a prescription is ready? May providers continue to mail appointment or prescription refill reminders to patients' homes?

A. Yes. The HIPAA Privacy Rule permits health care providers to communicate with patients regarding their health care. This includes communicating with patients at their homes, whether through the mail or by phone or in some other manner. In addition, the Rule does not prohibit covered entities from leaving messages for patients on their answering machines. However, to reasonably safeguard the individual's privacy, covered entities should take care to limit the amount of information disclosed on the answering machine. For example, a covered entity might want to consider leaving only its name and number and other information necessary to confirm an appointment or ask the individual to call back.

A covered entity also may leave a message with a family member or other person who answers the phone when the patient is not home. The Privacy Rule permits covered entities to disclose limited information to family members, friends, or other persons regarding an individual's care, even when the individual is not present. However, covered entities should use professional judgment to assure that such disclosures are in the best interest of the individual and limit the information disclosed. See 45 CFR 164.510(b)(3).

In situations where a patient has requested that the covered entity communicate with him in a confidential manner, such as by alternative means or at an alternative location, the covered entity must accommodate that request, if reasonable. For example, the Department considers a request to receive mailing from the covered entity in a closed envelope rather than by postcard to be a

reasonable request that should be accommodated. Similarly, a request to receive mail from the covered entity at a post
office box rather than at home, or to receive calls at the office rather than at home are also considered to be reasonable requests, absent extenuating circumstances. See 45 CFR 164.522(b)."

The above guidance indicates that appointment reminders are permissible; however, the covered entity must use reasonable professional judgment as to what is written on the reminder. Minimal information should be included on the reminder, i.e. name of client, date and time of appointment. The reason for the appointment or the clinic name (Example: STD Clinic or Family Planning Clinic) should not be included on the appointment reminder. A recommendation for using appointment cards instead of letters would be to use fold-over cards rather than post cards.

Return Addresses:

(The following information was also excerpted from the above mentioned guidance document.)

Many customary health care communications and practices play an important or even essential role in ensuring that individuals receive prompt and effective health care. Due to the nature of these communications and practices, as well as the various environments in which individuals receive health care or other services from covered entities, the potential exists for an individual's health information to be disclosed incidentally. The HIPAA Privacy Rule is not intended to impede these customary and essential communications and practices and, thus, does not require that all risk of incidental use or disclosure be eliminated to satisfy its standards. Rather, the Privacy Rule permits certain incidental uses and disclosures of protected health information (PHI) to occur when the covered entity has in place reasonable safeguards and minimum necessary policies and procedures to protect an individual's privacy.

The Privacy Rule permits certain incidental uses and disclosures that occur as a by-product of another permissible or required use or disclosure, as long as the covered entity has applied *reasonable safeguards* and implemented the *minimum necessary standard,* where applicable, with respect to the primary use or disclosures. See 45 CFR 164.502(a)(1)(iii).

An incidental use or disclosure is a secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and that occurs as a result of another use or disclosure that is permitted by the Rule. However, an incidental use or disclosure is not permitted if it is a by-product of an underlying use or disclosure which violates the Privacy Rule.

A covered entity must have in place appropriate administrative, technical, and physical safeguards that protect against uses and disclosures not permitted by the Privacy Rule, as well as that limit incidental uses or disclosures. See 45 CFR 164.530(c) It is not expected that a covered entity's safeguards guarantee the privacy of protected health information from any and all potential risks. Reasonable safeguards will vary from covered entity to covered entity depending on factors, such as the size of the covered entity and the nature of its business. In implementing reasonable safeguards, covered entities should analyze their own needs and circumstances, such as the nature of the PHI it holds, and assess the potential risks to patients' privacy. Covered entities should also take into account the potential effects on patient care and may consider other issues, such as the financial and administrative burden of implementing particular safeguards.

If the provider made reasonable efforts to apply reasonable safeguards and implemented the minimum necessary standard an incidental use or disclosure would be permissible under the Rule. The HIPAA Privacy Rule does not require that all risk of incidental use or disclosure be eliminated to satisfy its standards. Rather, the Rule requires only that covered entities implement reasonable safeguards to limit incidental uses or disclosures. See 45 CFR 164.530(c)(2).

The above guidance indicates that return addresses would be considered incidental disclosures and permissible under the Privacy Rule; however, the covered entity must implement reasonable safeguards and also adhere to the minimum necessary standard as to the content of the return address. Minimal information should be included in the return address, i.e. name of organization, street address or post office box, city/state and zip code. The specific name of the clinic should not be included in the content of the return address, i.e. STD Clinic, Family Planning Clinic, etc.

PROGRAM NUMBERS FOR MAIL/COURIER

PROGRAM	Abbrev.	NUMBER
Adult Health	AH	1
Aids	Aids	2
BCCCP	BCCCP	3
Bioterrorism (Smallpox)	BIO	4
Communicable Disease	CD	5
Child Health	CH	6
CC4C	CC4C	7
H1N1	H1N1	8
Family Planning	FP	9
General	Gen	10
Health Promotion	HP	11
Immunizations	Imm	12
Maternal Health	MH	13
Diabetes/Prescription Assistance	DB/PCP	14
Healthy Carolinians	HC	15
Tuberculosis	TB	16
WIC	WIC	17
Child Fatality	CFPT	18
Carolina Access	Car. Access	19
Environmental Health	EH	20
OBCM	PCM	21

Attachment I: Leaving Messages for Patients:

https://www.hhs.gov/hipaa/for-professionals

May physician's offices or pharmacists leave messages for patients at their homes, either on an answering machine or with a family member, to remind them of appointments or to inform them that a prescription is ready? May providers continue to mail appointment or prescription refill reminders to patients' homes?

The HIPAA Privacy Rule permits health care providers to communicate with patients regarding their health care. This includes communicating with patients at their homes, whether through the mail or by phone or in some other manner. In addition, the Rule does not prohibit covered entities from leaving messages for patients on their answering machines. However, to reasonable safeguard the individual's privacy, covered entities should take care to limit the amount of information disclosed on the answering machine. For example, a covered entity might want to consider leaving only its name and number and other information necessary to confirm an appointment, or ask the individual to call back.

A covered entity also may leave a message with a family member or other person who answers the phone when the patient is not home. The Privacy Rule permits covered entities to disclose limited information to family members, friends, or other persons regarding an individual's care, even when the individual is not present. However, covered entities should use professional judgement to assure that such disclosures re in the best interest of the individual and limit the information disclosed. See 45 CFR 164.510(b)(3).

In situations where a patient has requested that the covered entity communicate with him in a confidential manner, such as by alternative means or at an alternative location, the covered entity must accommodate that request, if reasonable. For example, the Department considers a request to receive mailings from the covered entity in a closed envelope rather than by postcard to be a reasonable request that should be accommodated. Similarly, a request to received mail from the covered entity at a post office box rather than at home, or to receive calls at the office rather than at home are also considered to be reasonable request, absent extenuating circumstances. See 45 CFR 164.522(b).

NC DHHS DPH HIPAA Information:

https://schs.dph.ncdhhs.gov/hipaa/policy.html

NC DHHS DPH HIPAA Privacy & Security PP

https://www2.ncdhhs.gov/info/olm/manuals/dhs/pol-80/man/

SAMPSON COUNTY HEALTH DEPARTMENT
Telehealth Medical Services Policy and Procedure

Program: Telehealth	Applicable Signatures/Title
Title: Telehealth Medical Services Policy & Procedures	Program Coordinator: Emily Spell
□ Program Policy:	Supervisor: Kelly Parrish
□ Program Procedure:	Director of Nursing: Kelly Parrish
□ Management/Department-wide Policy	Medical Director: Dr. Timothy Smith
□ Personnel/Fiscal Policy	Health Director: Wanda Robinson
Distributed to: Clinical Staff	Board of Health Chair: Clark Wooten
	Effective Date: August 1, 2020
	Supersedes: N/A

Purpose:

To ensure adherence to all applicable laws, rules, and regulations while ensuring patient access and reducing barriers to healthcare and/or medical management services using telehealth services. By implementing these procedures, Sampson County Health Department will provide telehealth services to patients regardless of where the patient or the provider is located. Telehealth services are provided to better enable the delivery of remote care to patients. This current policy reflects NC DHHS recommendations.

Policy:

Sampson County Health Department will utilize these procedures to provide quality telehealth services for our clients.

Definitions:

1. Telemedicine: Telemedicine is the use of two-way-real-time interactive audio and video to provide and support health care when participants are in different physical locations.

2. Virtual Patient Communication: Virtual Patient Communication is the use of technologies other than video to enable remote evaluation and consultation support between a provider and a patient or a provider and another provider. Covered virtual patient communication services include telephone conversations (audio only); virtual portal communications (e.g., secure messaging); and store and forward (e.g., transfer of data from beneficiary using a camera or similar device that records (stores) an image that is sent by telecommunication to another site for consultation).

3. Originating Site: The site where the patient is located.

4. Distant Site: The site where the provider is located. Providers must ensure that patient privacy is protected (e.g., taking calls from private, secure spaces and/or using headsets).

Applicable Laws, Rules & Regulations:

1. NC Division of Health Benefits (DHB) SPECIAL BULLETIN COVID-19 #28 [ADDENDUM to Bulletin#9 Effective March 30, 2020]; Telehealth Provisions – Clinical Policy Modification. https://mediciaid.ncdddhs.gov/providers/mediciaid-bulletin
2. Office of Civil Rights, *OCR Announces Notification of Enforcement Discretion for Telehealth Remove Communications During the COVID-19 Nationwide Public Health Emergency FAQ's* https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf
3. HIPAA Health Insurance Portability and Accountability Act of 1996
4. G.S. 90-171.20 (7) & (8) – Nursing Practice Act https://www.ncleg.net/enactedlegislation/statues/html/byarticle/chapter_90/article_9a.html
5. North Carolina General Statutes 90-21.5 and 90-21.4 Minor's Consent Law
6. 45 CFR Parts 160 and 164 Standards for Privacy of Individually Identifiable Health Information; Final Rule
7. NC General Statue 143-518. Confidentiality of patient information
8. 42 CFR Part 2 – Confidentiality of Substance Use Disorder Patient Records

Responsible Person(s):

Clinical Staff
Fiscal Staff
Management Support
Information Technology (IT)

Procedures:

Scope of Service:

1. The following services will be available using the telehealth modalities: (Telemedicine and Virtual Patient Communication) as defined above.

    A. Medical services via telehealth will not deviate from standards of care applicable to in-person assessment, diagnosis and treatment plan.

B. The telehealth medical service by the Physician or Physician Extender may be an adjunct to periodic in-person contact or it may be the only contact by the Physician or Physician Extender.
C. Telephonic visits (audio only) can only be provided to established patients.

2. Contraindications for Use of Telehealth Services- The Physician or Physician Extender should request an in-person visit if any of the following occur:

A. The patient's condition does not lend itself to a telehealth visit as deemed by the provider.
B. There is a lack of equipment
C. Equipment failure
D. Inadequate visual or sound quality

Telehealth appointments will be offered for the following services: FP problem, pill refill, and FP PE. The provider will need to ensure they are logged in through Chrome to utilize the telehealth functionality of CureMD.

Appointment Scheduling:

1. Client will be given information and the option for a telehealth service. If client agrees and has access to an electronic device, an appointment will be scheduled.
2. The appointment clerk will obtain demographic information to include mobile number **AND** email address.

A. The client will be scheduled on designated telehealth days and timeframes.
B. Appointment reason will be selected using the pre-designated telehealth visits.
C. Appointment will be linked with the provider who will be seeing client.
D. Clients will be informed that they will receive the following reminders (will receive both email and text if mobile number is provided in chart) of appointment:

a. One notification will be sent immediately once appointment is scheduled.
b. One notification will be sent two-hours prior to appointment.
c. An additional notification will be sent ten minutes prior to the appointment.

3. Once the telehealth appointment is made, the appointment clerk will initiate an encounter form and complete a half-sheet which will signify this as a "Telehealth Visit".
4. The encounter form and half-sheet will be placed in a designated tray in Cindi's office.

Intake/Eligibility Process:

1. Cindi (Sandra will be her back-up) will instruct the client to click on link to join the visit.
2. The consents will upload and the patient will review the General Consent for Services and the HIPAA Consent.
3. The client will type their name and then click the "Sign Electronically" option.
4. I/E will update insurance and household income eligibility and fill in encounter form per Fiscal Policy.
5. Encounter form with half-sheet will be placed in the designated areas of the provider's offices.

Telehealth Visit:

1. On the day of the visit, the client will receive the notification about their telehealth appointment.
2. The client will open the email notification and click on the link to join the visit.
3. The consents will already be completed (see I/E Process above) and the client will be in virtual lobby awaiting the provider to join.
4. The provider will receive an email notification alerting the provider that the patient is waiting.
5. The provider will navigate to their home screen of the CureMD application and click on "Novel Health" located in the top right corner.
6. This link will open their "Today's Patients" dashboard for all telehealth visits.
7. The provider will click "Start Meeting" for the designated client.
8. The provider will then click "Okay I'm Ready" once ready for the meeting to begin.
9. The provider will ensure the camera and microphone are turned on to access the functionality of the visit.
10. Once the meeting has started, the provider will right click in the screen during the video and click "View Picture in Picture" feature. This will allow the provider to still see the client in a small window with the ability to document in CureMD.
11. The provider would then navigate to the scheduler and check patient in.
12. The provider will proceed with building the note based on programmatic guidelines.
13. The provider can choose to "Share Screen" with patient, if desired, to review lab results or education materials. However, if this is done, caution needs to be exercised to ensure other patient information is not visible to the patient during the visit.

14. The provider will ensure to designate in the SOAP note that this was a "Telehealth" visit and any other pertinent information as it relates to the client per program guidelines.
15. Once the visit is complete, the provider will click on the red "X" to end meeting. An option will appear to make notes about the visit but this needs to be skipped as all pertinent information will be documented in the client's EHR.

Billing and Reimbursement

1. The provider will complete the encounter form and e-bill for the telehealth visit based on the services provided.
2. Telehealth services will be billed per Program Guidelines and Insurance reimbursement guidelines.
3. Providers shall comply with the, NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, DHB's clinical coverage policies and other relevant documents for specific coverage and reimbursement for Medicaid and NCHC.
4. The CR modifier is to be used with telemedicine that was COVID-19 related.
    a. COVID-19 related telemedicine and VPC is interpreted as providing services by Telemedicine & VPC due to COVID-19 and the state of emergency.
    b. For example, seeing a patient by Telemedicine/VPC rather than having the patient come into the clinic. (e.g., patient who needs follow up for chronic illness by telemedicine and they should not come to the office).
    c. The CR modifier is not exclusively for those patients being seen virtually because they are sick or suspected with COVID19.
5. Refer to the Medicaid Telehealth Billing Code Summary Document for changes and updates which can be found here: https://files.nc.gov/ncdma/covid19/NCMedicaid-Telehealth-Billing-Code-Summary.pdf.
6. Unless otherwise stated, services will be billed and coded as they are in face-to-face encounters.
7. Once completed, the encounter form will be given to the I/E staff to process.

Environmental Security:

1. The privacy and confidentiality of the telehealth medical services will be maintained by ensuring that the locations of the patient and providers are secure. The services will be provided in a controlled environment (closed doors) where there is a

reasonable expectation of absence from intrusion by individuals not involved in the patient's direct care.
2. Signage will be posted (i.e. such as "Telehealth Exam in Progress Do Not Enter") where telehealth services are provided.
3. Whenever possible, the presence of non-clinical staff during medical service will be avoided.
4. The physical environments of the distant site provider should ensure that the patient's protected health information remains confidential.

Patient Health Information, Privacy, Confidentiality and Security:

1. Guidance from Office of Civil Rights (OCR):
   A. "OCR expects health care providers will ordinarily conduct telehealth in private settings, such as a doctor in a clinic or office connecting to a patient who is at home or at another clinic. Providers should always use private locations and patients should not receive telehealth services in public or semi-public settings, absent patient consent or exigent circumstances. A parent or legal guardian may be physically located in the patient site during a telehealth service with a child."

   B. "If telehealth cannot be provided in a private setting, covered health care providers should continue to implement reasonable HIPAA safeguards to limit incidental uses or disclosures of protected health information (PHI). Such reasonable precautions could include using lowered voices, not using speakerphone, or recommending that the patient move to a reasonable distance from others when discussing PHI."
2. Responsible staff of telehealth services must follow the agency's policy and procedures on confidentiality and HIPAA—see Administrative Manual.
3. All staff must follow the agency's policy and procedure on release of information.
4. Applications – Covered virtual patient communication services will be used.
   A. Telephone conversations (audio only)
   B. Virtual portal communications (e.g., secure messaging)
   C. Virtual visits with secured video capability will be provided via electronic health record system, Cure MD.

5. Informed Consent:

   A. Follow agency policy on informed consent to include minor's consent laws.
   B. Informed consent for telehealth medical services will be obtained from the patient and/or patient's legal guardian prior to the service and documented in the EHR.
   C. The patient and/or patient's legal guardian will be made aware of the potential risks and consequences as well as the likely benefits of the telehealth medical services and will be given the option of not participating. Patients and/or patient's legal guardian will be informed that services will not be withheld if the telehealth medical encounter is refused, although such care will depend on availability of alternative resources.

Required Documentation:

All documentation of telehealth medical services will be documented in accordance with applicable standards, guidelines, by-laws, rules and regulations.

1. All patient health information and services provided through telehealth will be documented in the EHR per agency policy and procedures.
2. Informed consent for telehealth medical services will be obtained from the patient and/or patient's legal guardian prior to the service and documented in the EHR per programmatic requirements.
3. The Physician or Physician Extender will document each visit with the patient including: the date of service, start and stop time, additional people who participated in the visit at either site and the location of the patient with enough detail to satisfy an audit.
4. Provider notes will contain all components required in order to support the medical care provided and services billed per the Sampson County Health Department policies and procedures.
5. If there is a lack of equipment or equipment failure that prevents adequate diagnosis or treatment, a provider note should be written in the EHR to document lack of equipment or equipment failure and a follow-up in-person visit should be scheduled with the provider. If the provider cannot make and in-person visit on that day and the patient has an urgent problem the patient should be referred to their primary care provider or other provider of choice.
6. The provider should note what modality was used to deliver the service rendered.
7. The provider will document and assign appropriate codes for reimbursement of services.
8. Providers shall ensure the availability for appropriate follow-up care and maintain a complete health record that is available to all other rendering providers.

Training:

1. All staff members involved in telehealth services will have training on approved technology used for telehealth services. Training will be provided by Sampson County Health Department.
2. Training must be provided initially and annually per agency workforce training policy and procedures.

Equipment for Telehealth:

1. Sampson County Health Department is only responsible for their equipment and connectivity.
2. Sampson County Information Technology (IT) support will be provided for telehealth services and will be compliant with the agency IT (Information Security policy, procedures and standards.
3. Sampson County Health Department will work to deliver clear audio/visuals to allow for optimal communication and assessment of each patient served.

Quality Assurance and Quality Improvements:

Quality Assurance (QA) and/or Quality Improvements (QI) related to telehealth services are covered in the agency's QA/QI policy and procedures.

References:

1. Sampson County Health Department (SCHD) Policy on Policies
2. SCHD QA/QI Policy
3. SCHD HIPAA Policy
4. SCHD Information Security Policy
5. SCHD Fiscal Policy
6. SCHD Confidentiality Policy
7. SCHD Informed Consent
8. SCHD EHR Policy (Documentation section)
9. SCHD Workforce Development Policy
10. (If applicable, add any program policies and procedures delivered by telehealth)
11. HIPAA Privacy and Security Act, 1996
12. NC Health Check Program Guide
13. NC Tracks Provider Claims and Billing Assistance Guide
14. NC Division of Medical Assistance Telemedicine and Telepsychiatry Policy, Amended 1/1/2018
15. Special Bulletin COVID-19 #2: General Guidance and Policy Modifications (Bulletin #9 and #28 supersede this bulletin)
16. Special Bulletin COVID-19 #9 Telehealth Provisions March 20, 2020
17. Special Bulletin Covid-19 #28 {Addendum to Bulletin#9} March 30, 2020 https://medicaid.nc.dhhs.gov/provider/medicaid-bulletin
18. CCNC – See COVID-19 tab_ https://www.communitycarenc.cor/
19. Telemedicine Clinical Coverage Policy_ https://files.nc.gov/ncdma/documents/files/1-H_3.pdf

Sampson County Health Department

Telehealth Medical Services

Policy & Procedures

Table of Contents

SAMPSON COUNTY HEALTH DEPARTMENT
Telehealth Medical Services Policy and Procedure
Annual Review/Policy Update Review Form

Program: Telehealth	Applicable Signatures/Title
Title: Telehealth Medical Services Policy and Procedures	Program Coordinator: Emily Spell
X Program Policy:	Supervisor: Kelly Parrish
X Program Procedure:	Director of Nursing: Kelly Parrish
□ Management/Department-wide Policy	Medical Director: Dr. Timothy Smith
□ Personnel/Fiscal Policy	Health Director: Wanda Robinson
Distributed to: Clinical Staff	Board of Health Chair: Clark Wooten
	Effective Date: August 1st, 2020
	Supersedes: N/A

Review/Revision Date: 08/01/2020

_____ _____
Medical Director Date

_____ _____
Health Director Date

_____ _____
Nursing Director Date

_____ _____
Program Coordinator Date

SAMPSON COUNTY HEALTH DEPARTMENT

Sampson County Health Department
Telehealth Medical Services Policy Review & Revision Form

Annual Review Date	Revision Date	Revision: Name, Location, Page # of Section w/ Revision(s)	Changes Made By	Date Staff Notified

SAMPSON COUNTY
BOARD OF COMMISSIONERS

ITEM ABSTRACT ITEM NO. **3**

Meeting Date: March 1, 2021

x	Information Only	___	Public Comment
___	Report/Presentation	___	Closed Session
___	Action Item	___	Planning/Zoning
___	Consent Agenda	___	Water District Issue

INFORMATION ONLY

For all Board Information items, please contact the County Manager's Office if you wish to have additional information on any of the following.

From the Health Advisory Board, for information only:

a. Health Advisory Board Minutes, November 16, 2020

b. 2019-2020 Health Department Annual Report

c. 2021 Communicable Disease Report

SAMPSON COUNTY HEALTH DEPARTMENT

Wanda Robinson
Health Director

360 County Complex Road, Suite 200
Clinton, NC 28328

To: Mr. Edwin Causey
County Manager

Susan Holder
Assistant County Manager

From: Wanda Robinson
Health Director

Subject: County Commissioner's Information Items

Date: February 15, 2021

Attached are items approved by the Health Advisory Committee on January 25th, 2021 and is being submitted for review by the County Commissioners.

I. Advisory Board Meeting Minutes November 16, 2020

II. 2019-2020 Annual Report

III. 2021 Communicable Disease Report

Attachments

Advisory Board Meeting Minutes November 16, 2020
2019-2020 Annual Report
2021 Communicable Disease Report

SCHD Advisory Committee Meeting Minutes
November 16, 2020

Attendance: Dr. Jeffrey Bell, Dr. Elizabeth Bryan, Robert Butler, Cassie Faircloth, Yire Hernandez, Jacqueline Howard, Allie Ray McCullen, Commissioner Harry Parker and Linda Peterson.

Health Department and Administration: Wanda Robinson, Perry Solice, Kelly Parrish, Tamra Jones, Sally DeMay, Edward Causey and Joel Starling.

I. **Call to Order:**
Jacqueline Howard, Chair called meeting to order.

II. **Invocation:**
Commissioner Harry Parker gave invocation.

III. **Approval of Minutes:**

a. **September 21, 2020:**
Motion to accept the committee meeting minutes for September 21, 2020 made by Commissioner Harry Parker, seconded by Dr. Jeffrey Bell. All in favor. Motion carried.

b. **September 29, 2020-Dangerous Dog Appeal Hearing Minutes:**
Motion to accept the Dangerous Dog Appeal Hearing minutes made by Robert Butler and seconded by Dr. Elizabeth Bryan. All in favor. Motion carried.

IV. **COVID-19 Update:**
Kelly Parrish gave update on the COVID-19. As of 3 pm today, North Carolina has had over 300,000 cases; 1,424 hospitalized; 4,814 deaths. State is at an 8.1% positivity rate. Demographic for state overall is 60% white with 28% being Hispanic ethnicity, 22% black; 40% are between the ages of 25 - 49, 19% between the ages of 50 – 64.

Sampson County has received over 9,000 tests, 3, 351 positives, 39 new cases reported today, 34 deaths with one new death reported today. Sampson County is at 9.9% positivity rate. This rate has doubled since the beginning of November. Demographics for Sampson County 73% white with 50% being Hispanic ethnicity, 19% black; 50-50 on gender and 43% are between the ages of 25-49 and 19% between the ages of 50 -64.

Update on clusters and outbreaks in Sampson County are: Department of Social Services, Goshen Medical Center Fairview office, Migrant Farm Camp, Mingo Baptist Church, Southwood and Mary Gran nursing homes, Smithfield, Tarheel Challenge. Have a new cluster identified at Migrant Farm Camp on Dave Bright Road.

Wanda Robinson reported on phone call from the state regarding review of data and identified Sampson County as one of the red (hot spot) counties with a higher positivity rate. This based on number of cases and trends for the last 14 days. Sampson County has had 150 to 200 cases over the last 14 days. This is widespread over the county, not in one place. State also uses another method called Hospital Impact Metric. The state will be working closely with us to bring our numbers down. Meetings will be planned with state and local leaders to develop plans to lower rates in Sampson County.

V. **EH Department Update:**

Perry Solice reporting on handout attached. Perry reviewed the blue EH Activities graph pointing out the three months over 70 applications (March 75, June 76, & September 73) received and a total of 581 applications received from January through September 2020. Environmental Health is staying remarkably busy with applications.

Perry also reviewed EH Revenues handout attached. Graph shows revenues budgeted for all services; actual revenues received; revenues less non-onsite services; and revenues adjusted actual. The column labeled less non-onsite services takes out services such as well applications. Months of May and July had revenues of 1600 and 1000 were probably well applications and at $300 an application only takes 3 or 4 to get close to 1000 or more in revenues. The far column is the adjusted actual revenues and only a few months did not break the $10,000 mark. All the other months were above the $10,000 mark.

Perry pointed out that interest rate is down therefore housing is up. Children home from school along with people being out of work need for more repairs or upgrades. EH department is busy meeting with clients to fulfil their needs. EH is down one position currently but trying extremely hard to keep up with the pace.

Wanda Robinson spoke of turn over in the department with some upcoming retirements, going to keep close eye on services and meeting the needs of our county.

VI. **HIPAA Policy Revision:** Moved to January 2020 meeting.

VII. **EHR Imaging Policy Review:**

Sally DeMay reviewed policy changes with the addition of the outsourced scanning process of the paper medical records. Motion made to accept updated EHR Imaging Policy made by Robert Butler seconded by Commissioner Harry Parker. All in favor. Motion carried.

VIII. **Advisory Board Policy Review:**

a. **Operating Policy:**

Wanda Robinson reviewed policy; no changes were made except to dates. Motion to approve with no revisions made by Linda Peterson, seconded by Commissioner Harry Parker. All in favor. Motion carried.

b. **Conflict of Interest Policy:**

Wanda Robinson reviewed policy; no changes made. Motion to approve with no revisions made by Robert Butler, seconded by Dr. Jeffrey Bell. All in favor. Motion carried.

c. **2021 Meeting Dates:**

Wanda Robinson reviewed the handout attached, noting the meeting place is to be determined until COVID-19 situation is over.

d. **Committee Appointment:**

Wanda Robinson discussed two appointments for the board. Plan to submit appointment considerations for Linda Peterson. Mrs. Peterson has agreed to serve

another three-year term. Commissioner Parker will be rotating off the board, will request for an appointment of a Commissioner to sit on our board.

IX. Financial:

a. Fiscal Policy Review:

Tamra Jones reviewed the Fiscal Policy annual policy update changes with the following being the most significant changes. Added statement "Any fees collected for services in any program, including Environmental Health, that are not provided will be refunded either the same day, if determined services was not provide the same day, or by county check with the next available check write date." Change made with the 340B drug pricing. For a long time, state has allowed us to use the average cost for billing Medicaid. Now the state is requiring actual acquisition cost. Update to #4 on page 24 to read: "Fees for medications purchased through the 340B program will be set based on the cost of acquisition for each time purchased. Fees will be updated in the system according to the most current purchase price per state guidelines." This does not affect the cost the clients pay. Wanda Robinson requested to be able to change this price as purchased. Report would be made to the board every quarter. Page 36, wording changed to reflect current process. Page 40, added I, regarding hotel reservations to be made by Management Support Administrative Assistant. Motion made to accept the changes and updates to the Fiscal Policy made by Dr. Jeffrey Bell, seconded by Robert Butler. All in favor. Motion carried.

b. Immunization AA715 Funding:

Tamra Jones discussed funding for Flu through Immunization AA715 for $33,466. Plan to use in Salary/Fringe, Travel, Equipment/Supplies, miscellaneous advertising on a billboard, ads on local newspaper, radio, and regional radio. Motion to accept the $33,466 funding made by Dr. Jeffrey Bell, seconded by Linda Peterson. All in favor. Motion carried.

c. Monthly Activity Summary:

Tamra Jones reviewed the attached monthly activity summary. Numbers are remaining constant with Immunizations up to 511 from 279 last month. Maternal Health and WIC numbers are up. Environmental Health activities are up as well. Tamra Jones reviewed the revenues graphs and numbers attached. Local and Medicaid revenues are above projected at this point.

X. Annual Report:

Wanda stated Annual Report will be presented at the January meeting.

XI. Health Directors Report:

Wanda Robinson reported that Sally DeMay Administrative Assistant will be retiring December 2020.

XII. Public Comment:

No public comment.

XIII. Adjournment:

Jacqueline Howard and Wanda Robinson spoke of Commissioner Parker's service to the Health Department Advisory Committee, thanking him for his time and many acts on behalf of the Health Department. Commissioner Parker gave a few remarks.

No further business, motion to adjourn meeting made by Robert Butler, seconded by Dr. Jeffrey Bell. All in favor. Motion carried.

Jeffrey G Burrows 2-16-2021

Chair Date

Wanda Robinson 2/16/21

Secretary Date

Sampson County Health Department

Annual Report 2019-2020

www.facebook.com/Sampson-County-Health-Department

GRANTS & AWARDS

Grants

Infant Mortality Reduction Grant - $63,500
This grant supplies long-acting contraceptives to reduce the infant mortality rate.

OBCM Non-Medicaid Grant - $45,817
This grant provides prenatal and postpartum care management services to uninsured, low income women ineligible for Medicaid, who are at high risk for poor birth outcomes, including low birth weight babies and premature delivery.

Rural Health Grant - $150,000
This grant provides quality healthcare access to uninsured or underinsured clients.

United Way of Sampson County Grant - $5,000
This grant provides mammograms to uninsured or underinsured minority females.

COVID-19 Response Funds- $80,061
These funds were allocated to local health departments to support COVID-19 staffing, infection controls, testing and tracing, IT infrastructure and data sharing and visualization.

HIGHLIGHTS

Breast & Cervical Cancer Awareness
Sampson County BCCCP Advisory Board sponsored the 20th Annual BCCCP Rally and distributed 240 pink lapel pins to local churches & organizations. The BCCCP Clinic met the target goal of 37 women to receive screening services.

Diabetes Self-Management Education
After receiving diabetes education, there was a 1.8% average decrease in patient A1C.

COVID-19 Response
Since the start of the pandemic, health department staff have worked around the clock to protect Sampson County residents and slow the spread of the virus. The health department is on the frontline supporting people with getting tested for COVID-19 and knowing if they have been exposed. Testing and contact tracing are core public health activities and all these responsibilities are in addition to ongoing work to promote health and prevent disease. In collaboration with Emergency Management and Goshen Medical, two free drive-thru testing events were held in which over 1,000 tests were performed. In collaboration with Sampson County Government, three video public service announcements were created and overall received 10,000+ views.

Sampson County Health Department

Annual Report

Message from the Health Director

The Sampson County Board of Health and the staff of the Sampson County Health Department are pleased to provide you with our annual report for fiscal year 2019-2020. The Sampson County Health Department works hard to accomplish our mission—to preserve, protect and promote the health, environment and well-being of the citizens of Sampson County. This report was developed to inform Sampson County residents and officials of the progress made by their Public Health Department to meet this mission.

Since March 2020, the main focus of the health department has been on COVID-19. As of October 31st, Sampson County has provided 9,451 COVID-19 Tests with 3,312 positives. This has created additional workload on the staff and the department. Much work has been done on contact investigation, contact tracing, isolation and quarantine of county residents. I am sure these preventative efforts will continue through next fiscal year as public health takes the lead role in the pandemic.

The demand for our services has increased over the past year due to the economy. Our case management services have doubled due to policy changes by the Division of Medical Assistance. Clinic numbers continue to increase due to the need for client services. United Way and Sampson County BCCCP continue to provide Breast and Cervical Cancer services and virtual outreach due to the pandemic. We continue to work with the Sampson County Healthy Carolinians Task Force to partner and focus on the areas identified in our community health assessment while continuing to provide much needed safety net services to Sampson County residents. I am proud of the many programs provided by our staff and the diligence with which they work to improve the health of Sampson County.

Thank you for taking the time to review our annual report and join us as we observe the three 'W's: Wear, Wait, Wash.

Wanda Robinson
Health Director

360 County Complex Rd.
Suite 200
Clinton, NC 28328
(910) 592-1131
www.sampsonnc.com

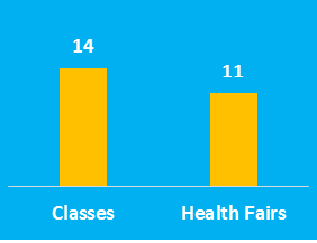
Sampson County Health Department

FY 2019-2020 by the numbers

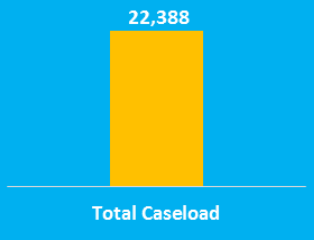
CLINICS

Adult Health (visits)	1,119
Breast & Cervical Cancer Control Program (visits)	42
Care Coordination for Children (average caseload)	102
Child Health (visits)	283
Communicable Disease (total)	79
Diabetes Self-Management Education (visits)	56
Family Planning (visits)	1,115
Immunizations (total)	3,535
Laboratory Services (total)	4,791
Maternal Health (visits)	2,365
Sexually Transmitted Disease (visits)	949
Newborn Home (visits)	15
Postpartum Home Assessments	15
Pregnancy Care Management (average caseload)	107
Tuberculosis (cases)	2

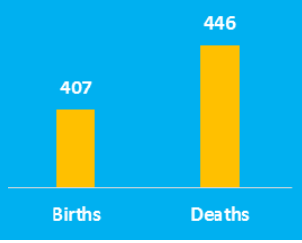
HEALTH PROMOTION



WIC



VITAL RECORDS

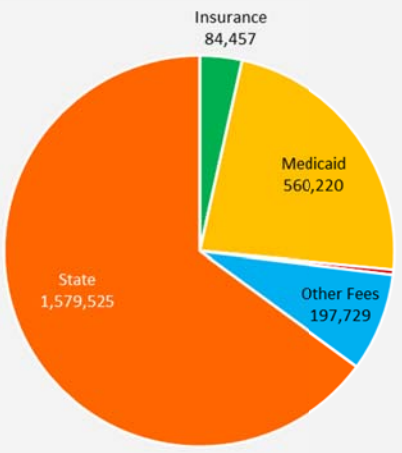


ENVIRONMENTAL HEALTH

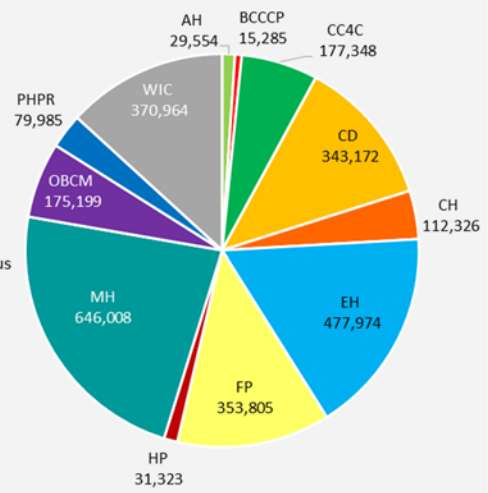
Food & Lodging	
Inspections	420
Visits	473
Septic Systems	
Permits	943
Site Visits	1,045
Evaluations	348
Water	
Visits	301
Samples Collected	263
Wells	
Permits Issued	109

FINANCE

Revenues



Expenses



Sampson County Board of Health
Communicable Disease Report 2020

The Health Department Communicable Disease (CD) Program involves several communicable disease sections that include: Communicable Diseases, such as Rabies or Salmonella; Tuberculosis; Vaccine-Preventable Diseases, such as Pertussis/Whooping Cough; and Sexually Transmitted Diseases, such as HIV or Gonorrhea. In 2020, the novel Coronavirus emerged in the United States. Sampson County identified its first case of the virus in March. COVID-19 presented unique challenges to us and put public health at the forefront of this global pandemic.

The Communicable Disease (CD) Program staff normally consists of four nurses that are responsible for the surveillance, reporting, investigation and follow-up of communicable diseases in our county. However, with the COVID-19 pandemic and the surge in cases, several additional staff had to be utilized to assist us in our response efforts. The CD staff works with medical providers and the public to prevent, manage, and provide treatment for disease cases and their contacts. The staff follows the North Carolina Communicable Disease Branch guidelines and notifies the appropriate authorities as needed regarding specific communicable diseases.

The CD Program staff is required to use NCEDSS, the North Carolina Electronic Disease Surveillance System, which is an electronic data entry system for monitoring, managing and reporting of diseases in Sampson County and throughout the North Carolina. Due to COVID-19 and the increase in data, NC DHHS developed a separate system, NC COVID, for the management of COVID-19 cases. The staff is responsible for monitoring NCEDSS and NC COVID daily to identify and follow-up on any diseases reported through the system.

COVID-19

In addition to our other CD events during 2020, Sampson County identified 5,004 cases of COVID-19. Unfortunately, of those cases, 74 were deaths related to COVID-19. SCHD staff performed case investigations and contact tracing for these cases which proved to be a daunting task. Additional staff were trained in Communicable Disease investigation and outbreak management to expand our response efforts. Clinics had to be sized down to allow us to utilize the staff needed for the response and to limit the amount of people in our building. Appointments were prioritized and the staff adapted well as roles and responsibilities were shifted. In the summer of 2020, testing became a desperate need as the goal was early detection and isolation of those that were positive for COVID-19. SCHD, along with community partners, held three successful mass testing events which led to over 1,300 citizens being tested.

Sampson County CD Report 2020			Sampson County CD Report 2019	
All Communicable Diseases	**Totals**		**All Communicable Diseases**	**Totals**
Communicable Disease			**Communicable Disease**	
COVID-19	5,004		Campylobacter Infection	11
Campylobacter Infection	3		Legionellosis	2
Carbapenem-Resistant Enterobacteriaceae (CRE)	1		Carbapenem-Resistant Enterobacteriaceae (CRE)	6
Hepatitis C	36		Hepatitis C	41
Lyme disease	1		Lyme disease	1
Rocky Mountain Spotted Fever	0		Rocky Mountain Spotted Fever	7
Salmonellosis	1		Salmonellosis	25
Cryptosporidium	3		Cryptosporidium	4
Ehrlichiosis	0		Ehrlichiosis	1
E. Coli	1		E. Coli	3
Total	**5,050**		**Total**	**90**
Tuberculosis			**Tuberculosis**	
TB Disease Cases	1		TB Disease Cases	0
Vaccine-Preventable Disease			**Vaccine-Preventable Disease**	
Influenza, death	0		Influenza, death	1
Pertussis	0		Pertussis	1
Hepatitis B - Chronic	0		Hepatitis B - Chronic	2
Hepatitis A	0		Hepatitis A	0
Total	**1**		**Total**	**4**
Sexually Transmitted Disease			**Sexually Transmitted Disease**	
AIDS	0		AIDS	0
HIV	5		HIV	9
Chlamydia	335		Chlamydia	368
Gonorrhea	150		Gonorrhea	121
Syphilis	19		Syphilis	12
NGU	9		NGU	11
Total	**518**		**Total**	**521**
TOTAL	**5,569**		**TOTAL**	**615**

PUBLIC COMMENT POLICIES AND PROCEDURES
Revised June, 2018

In accordance with NCGS 153A-52.1, a period reserved for comments from the public on topics not otherwise included on that evening's agenda will be included as an item of business on all agendas of regularly-scheduled Board of Commissioners meetings and shall be deemed the "Public Comment" segment of the agenda. The Public Comment segment of the agenda will be placed at the end of the agenda, following the conclusion of all other open session business. Because subjects of Special and Emergency Meetings are often regulated by General Statutes, there will be no Public Comments segment reserved on agendas of these meetings; however, Special and Emergency Meetings are open for public attendance.

As with public hearings, the Chair (or presiding officer) will determine and announce limits on speakers at the start of the Public Comment period. Each speaker will be allocated no more than five (5) minutes. The Chairman (or presiding officer) may, at their discretion, decrease this time allocation if the number of persons wishing to speak would unduly prolong the meeting. A staff member will be designated as official timekeeper, and the timekeeper will inform the speaker when they have one minute remaining of their allotted time. When the allotted time is exhausted, the speaker will conclude their remarks promptly and leave the lectern. Speakers may not yield their time to another speaker, and they may not sign up to speak more than once during the same Public Comment period.

An individual wishing to address the Board during the Public Comment period shall register with the Clerk/Deputy Clerk to the Board prior to the opening of the meeting by signing his or her name, and providing an address and short description of his or her topic on a sign-up sheet stationed at the entrance of the meeting room. Any related documents, printed comments, or materials the speaker wishes distributed to the Commissioners shall be delivered to the Clerk/Deputy Clerk in sufficient amounts (10 copies) at least fifteen minutes prior to the start of the meeting. Speakers will be acknowledged to speak in the order in which their names appear on the sign-up sheet. Speakers will address the Commissioners from the lectern, not from the audience, and begin their remarks by stating their name and address.

To ensure the safety of board members, staff and meeting attendees, speakers are not allowed to approach the Board on the seating platform, unless invited by the Board to approach.

Speakers who require accommodation for a disabling condition should contact the office of the County Clerk or County Manager not less than twenty-four (24) hours prior to the meeting.

If time allows, those who fail to register before the meeting may be allowed speak during the Public Comment period. These individuals will be offered the opportunity to speak following those who registered in advance. At this time in the agenda, an individual should raise his or her hand and ask to be recognized by the Board Chair (or presiding officer) and then state his or her name, address and introduce the topic to be addressed.

A total of thirty (30) minutes shall be set aside for public comment. At the end of this time, those who signed up to speak but have not yet been recognized may be requested to hold their comments until the next meeting's public comment period, at which time they will be given priority for expression. Alternatively, the Board, in its discretion, may extend the time allotted for public comment.

Items of discussion during the Public Comment segment of the meeting will be only those appropriate to Open Meetings. Closed Meeting topics include, but are not limited to, such subjects as personnel, acquisition of real property, and information protected by the client-attorney privilege. Closed Meeting subjects will not be entertained. Speakers will not discuss matters regarding the candidacy of any person seeking public office, including the candidacy of the person addressing the Board.

Speakers will be courteous in their language and presentation, shall not use profanity or racial slurs and shall not engage in personal attacks that by irrelevance, duration or tone may threaten or perceive to threaten the orderly and fair progress of the discussion. Failure to abide by this requirement may result in forfeiture of the speaker's right to speak.

The Public Comments segment of the agenda is intended to provide a forum for the Board of Community to listen to citizens; there shall be no expectation that the Board will answer impromptu questions. However, Board members, through the presiding officer, may ask the speaker questions for clarification purposes. Any action on items brought up during the Public Comment period will be at the discretion of the Board. When appropriate, items will be referred to the Manager or the proper Department Head for further review.

A copy of the Public Comments Policy will be included in the agenda of each regular meeting agenda and will be made available at the speaker registration table. The policy is also available on the County's website.