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2003 HOUSE HUMAN SERVICES

HB 1438

2003 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1438

House Human Services Committee

☐ Conference Committee

Hearing Date February 10, 2003

Tape Number	Side A	Side B	Meter #
1	x		0.5 -25.8
Committee Clerk Signature	Sharon Rentfrow		

Minutes:

Arnold Thomas, Pres. of the ND Health Care Association appeared in support stating this is a policy recommendation that would bring North Dakota into compliance with Federal Regulations. A variety of groups would be impacted by these federal requirements that address the whole note of patient information protection. Those involved that have been preparing this bill are: hospitals, doctors, Blue Cross/Blue Shield, Attorney General's Office, the Health Dept. and the Dept. of Human Services.

Mike Mullen of the Attorney General's Office appeared to explain the bill with written testimony and (yellow) HIPAA Sheet. Also stating that hospitals and physicians must come into compliance by April 14th.

Darlene Bartz, Health Resources Section Chief with the Dept. of Health appeared in support with written testimony.

Larry Shireley, State Epidemiologist, appeared in support with written testimony.

David Boeck, Lawyer for Protection & Advocacy Project appeared in support with written testimony and offered amendments.

No Opposition.

Closed hearing.

2003 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1438

House Human Services Committee

☐ Conference Committee

Hearing Date February 11, 2003

Tape Number	Side A	Side B	Meter #
1	x		44.5 - 51.9
Committee Clerk Signature	Sharon Rexford		

Minutes: Committee Work

Rep. Porter moved the amendment on page 12, change 164 to 160 and change 502 to 103 and delete line 8, second by Rep. Pietsch.

VOTE: 12 - 0 - 1 Amendment Passed

Rep. Porter made a motion for DO PASS as AMENDED, second by Rep. Potter

VOTE: 12 - 0 - 1 Rep. Price will carry the bill

38332.0101
Title.0200

Adopted by the Human Services Committee
February 11, 2003

VR
2/11/03

HOUSE AMENDMENTS TO HOUSE BILL NO. 1438 **2-12-03 HS**

Page 12, line 7, replace "164" with "160" and replace "502." with "103."

Page 12, remove line 8

Renumber accordingly

Date: 2/11/03 ~~January 22, 2003~~
Roll Call Vote #:

2003 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. HB ~~1315~~ 1438

House HUMAN SERVICES Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 38332.0101 · 0200

Action Taken Do Pass As Amended

Motion Made By Rep. Potter Seconded By Rep. Potter

Representatives	Yes	No	Representatives	Yes	No
Rep. Clara Sue Price - Chair	✓		Rep. Sally Sandvig	✓	
Rep. Bill Devlin, Vice-Chair	✓		Rep. Bill Amerman	✓	
Rep. Robin Weisz	✓		Rep. Carol Niemeier	AB	
Rep. Vonnie Pietsch	✓		Rep. Louise Potter	✓	
Rep. Gerald Uglem	✓				
Rep. Chet Pollert	✓				
Rep. Todd Porter	✓				
Rep. Gary Kreidt	✓				
Rep. Alon Wieland	✓				

Total (Yes) 12 No 0

Absent 1

Floor Assignment Rep. Price

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE (410)
February 12, 2003 8:14 a.m.

Module No: HR-27-2348
Carrier: Price
Insert LC: 38332.0101 Title: .0200

REPORT OF STANDING COMMITTEE

HB 1438: Human Services Committee (Rep. Price, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (12 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). HB 1438 was placed on the Sixth order on the calendar.

Page 12, line 7, replace "164" with "160" and replace "502," with "103."

Page 12, remove line 8

Renumber accordingly

2003 SENATE HUMAN SERVICES

HB 1438

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1438

Senate Human Services Committee

☐ Conference Committee

Hearing Date March 3, 2003

Tape Number	Side A	Side B	Meter #
1	X		2 - 5499
Committee Clerk Signature	Donna Kramer, Clerk		

Minutes:

SENATOR JUDY LEE opened the public hearing for HB 1438.

Roll call was read. All were present.

REPRESENTATIVE CLARA SUE PRICE, from District 40, as one of the sponsors introduced the HB 1438. HIPAA was enacted by the Federal Government, she stated. (Meter # 2 - 197)

ARNOLD THOMAS, of the Healthcare Association, testified in favorable support of the bill. He stated this bill puts North Dakota into compliance. Acknowledged Mike Mullen, Assistant Attorney General, who had put in a lot of time on the bill. (Meter # 233 - 350)

SENATOR LEE acknowledged the students from St. Mary's High School in Bismarck and gave a brief description of what the bill was about and what kinds of bills the committee does hear.

MIKE MULLEN, Assistant Attorney General, testified in favor of the bill. Gave a summarization of the amendments on various sections. Introduced people who have helped amend this bill. It sets a floor on privacy. ... Health care providers have to come into

compliance with the rules. All covered entities must be in compliance with the privacy rule by April 14 of this year. (Written testimony) (Meter # 491 - 1189)

SENATOR LEE asked that Mr. Mullen walk the committee through the amendments.

MIKE MULLEN: Explained HIPAA was the requirements of the federal Health Insurance Portability and Accountability Act related to the privacy rule. Answered questions clarifiying terminology and whether there is a concern as to sharing data for research purposes. What information to be confidential. (Proposed Amendments copy provided) (Meter # 1200 - 1982)

DARLEEN BARTZ, Health Resources Section Chief with the North Dakota Department of Health, testified in support of HB 1438. (Written testimony) (Meter # 2080 - 2207)

LARRY SHIRELEY, State Epidemiologist with the North Dakota Department of Health, testified in favor. (Written testimony) (Meter # 2260 - 2351)

DAVID BOECK, state employee and Special Assistant Attorney General for the Protection & Advocacy Project. Appeared in opposition to HB 1438. Testified and answered questions regarding definitions, amendments proposed, whether current state law is better, best interests of the patient, and problems in other states (Written testimony) (Meter # 2380 - 4427)

SENATOR FAIRFIELD asked if this is a compliance issue and what are the changes ... loosen private laws?

MIKE MULLEN responded and did not feel the bill should be defeated. This bill is neutral. Mentioned North Dakota HIPAA Coalition. More discussion regarding definition on "personal representative".(Meter #4445 - 5415)

SENATOR LEE closed the public hearing for HB 1438. (Meter # 5499)

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO HB 1438 and HB 1221

Senate Human Services Committee

☐ Conference Committee

Hearing Date March 11, 2003

Tape Number	Side A	Side B	Meter #
3	X		4550 - end
		X	0 - 1040
Committee Clerk Signature	Donna Kramer, Clerk		

Minutes:

SENATOR JUDY LEE opened the committee discussion on HB 1438 relating to the disclosure of health information and HB 1221 relating to testing for contagious diseases.

MIKE MULLEN, from the Attorney General's office, came to talk to the committee about the amendments to HB 1438. He had made changes to match up language with both bills. He used language to match the HIPAA rule and matches ND law.

SENATOR LEE asked the committee for questions and discussion on the amendments.

SENATOR BROWN made a motion to move the amendments for HB 1438.

SENATOR ERBELE seconded the motion.

Roll call was read. 6 yeas 0 nays. All in favor.

MIKE MULLEN further explained the "privacy rule" ... federal government created rule ... indirect way to try to control parties ... statutory provision is simply to eliminate some of the paperwork ...

SENATOR LEE stated that the discussion we had about information concerning physician's decisions ... that didn't deal with a couple of pharmacists ... that it is not the pharmacists that are releasing information - it is the software vendors who had provided the software for the electronic billing ... transmitted from the pharmacy to Blue Cross or whomever and they can pick it off. .... This kind of thing would cover that. ... (Meter # 4550 -end)

SENATOR FISCHER stated that this has happened - example given. (Tape 3, Side B, Meter # 37 - 85)

SENATOR LEE quoted Mr. Jorde about information being peeled off without anybody knowing it and pharmacies will purchase the software programs for doing this work, and (Senator Lee said I don't know if any in ND do this) the pharmacies can pay a lower price for their software if the software company can peel off that information and sell it. .... "other little fingers in this loop" ... (Meter #86 - 160)

SENATOR FISCHER: Mentioned internet hub ... In HIPAA, do they provided for those kind of prohibitions? (Meter #161- 218)

MIKE MULLEN: Yes, to some extent ... Business Associate Agreement ... security rule ... safe guard medical information ... encryption ... (Meter # 261 - 496)

Continued committee discussion regarding suspicious mail ... credit cards ... (Meter # 497 - 600)

SENATOR LEE stated that Mr. Boeck from Protection & Advocacy left amendments that he wants to be here to discuss. ... Committee discussion to continue tomorrow morning at 8:30 am.

(Meter # 601 - 1040)

MIKE MULLEN reviewed the proposed amendments to HB 1221 regarding law enforcements exposed to HIV. Amends some of the same sections related to testing individuals for HIV as related to HB 1438. ... Amend terminology so that it matched up ... reads same as HB 1438 ...

(Tape 3, Side B, Meter # 1305 - 1908)

SENATOR LEE: Asked for any questions and motion.

SENATOR FISCHER moved that we accept the amendments on HB 1221

SENATOR ERBELE seconded the motion.

Roll call was read. 6 yeas 0 nays.

SENATOR FISCHER made a motion to DO PASS AS AMENDED.

SENATOR ERBELE seconded the motion.

Roll call was read. 6 yeas 0 nays.

SENATOR BROWN will be the carrier. (Meter # 2050)

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1438

Senate Human Services Committee

☐ Conference Committee

Hearing Date March 12, 2003

Tape Number	Side A	Side B	Meter #
1	X		0 - 1180
	X		1465 - 3380
Committee Clerk Signature	Donna Kramer, Clerk		

Minutes:

SENATOR JUDY LEE called the Human Services Committee to order for committee work on HB 1438 at 8:30 am on this date.

Roll call was read. All present except SENATOR FAIRFIELD.

DAVID BOECK, a lawyer for the Protection & Advocacy, spoke before the committee. (Written testimony and Proposed amendments to Engrossed HB 1438. He explained the changes he had made with the amendments. ... Had added two more definitions from federal regulations ... (Meter # 58 - 789)

SENATOR LEE: Understand intent.

MIKE MULLEN: Want to study matters ... will come back after 3 pm today ... working with state agencies for HIPAA. ... (Meter # 823 - 1050)

SENATOR LEE: Review by afternoon will be fine. Discussion closed for now. (Meter # 1110)

SENATOR LEE reconvened the committee discussion for HB 1438 regarding the pharmacy privacy issue ... include the portion about physicians - records being kept confidential ... so there is some information. (Meter # 1465 - 1505)

GALEN JORDE, Executive Vice President of North Dakota Pharmaceutical Association - organization that represents the 700 pharmacists practicing in the state. He stated they were opposed to the amendments proposed for HB 1438. He had written amendments proposed. (Written testimony plus proposed amendments) (Meter # 1506 - 1784)

Continued discussion with the committee members regarding the amendments ... data - IMS ... goal not to stop information ... cannot control completely ... with HIPAA - possibility to try mechanism ... pharmacies have responsibilities ... BSBS and Medicaid rely on information ... marketing ... connections with insurance companies ... (Meter # 1785 - 2550)

MIKE MULLEN, from Attorney General's office, looked at amendments. Made changes to proposed amendments and reviewed with committee. (Meter # 2553 - 2740)

SENATOR LEE: Asked for any more comments?

JOHN OLSON, from the Board of Medical Examiners, stated the amendment that the committee had before them was the "heartburn". Our exemptions would be the "Rolaids."

ARNOLD THOMAS, President of Healthcare Association, stated if it is going to take some time to work out the amendment that is before you with your desire to move the HIPAA language forward, that basically it appears to me the committee is agreed upon. Maybe with HB 1283, you might want to reconsider with the amendments out and see whether or not you have an agreement, then run hog house HB 1283 and then run 1283. We haven't put 1283 to the desk as we wanted to hold it ... to see what we would do with 1438 ... (Meter # 2946 - 3030)

SENATOR LEE: Figure out a way to address this doctor privacy issue. Continued discussion with Mr. Thomas regarding the measure and HIPAA provisions. (Meter # 3031 - 3239)

DAVE PESKE, of the ND Medical Association, stated provision was recently contained in SB 2399 which was heard in Judiciary and the Medical Association supported that section of the bill for the reasons that you have been discussing. So our prospective is fine with us if you would like to take that provision and amend it into a bill, of your choosing 1438 or 1283, is fine with the Medical Association. (Meter # 3278 - 3374)

SENATOR LEE: Discussion on HB 1438 closed. (Meter # 3380)

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1438

Senate Human Services Committee

☐ Conference Committee

Hearing Date March 12, 2003

Tape Number	Side A	Side B	Meter #
2		X	3380 - 5445
Committee Clerk Signature	Donna Kramer, Clerk		

Minutes:

SENATOR JUDY LEE opened the committee discussion for HB 1438 regarding disclosure of health information and persons to be tested and the timing of testing for the human immunodeficiency virus.

MIKE MULLEN, of the Attorney General's office, spoke. He stated he did have the opportunity to review the materials. I do not think there is anything contained in the second set of amendments that justify amending the bill. I think the bill is suitable as is. I do have one technical amendment based on this error that came up regarding numbers. And I would like to add to those amendments that I previously submitted to you an additional amendment. It would be on page 12, line 7, after 103, part 164, section 502, subsection G, respectively. Correct numerical reference. (Meter # 2380 - 3572)

SENATOR LEE: Thank you for your review and summary.

Continued discussion on the amendments regarding pharmaceutical issue - hog house amendment which relates to the disclosure of the physician drug profiles - info does not contain the names of patients ... what is appropriate? ... concern electronic intercept between pharmacy and insurance company ... clearing house - might be aggregate information ... any complaint coming through HIPAA will stop any kind of practice ... example of information leaked out of the clinic or electronically between the clinic and the insurance provider ... more technology - more thieves ... (Meter # 3575 - 5087)

SENATOR LEE and committee discussed how to amend the bill. Asked the committee if they were comfortable with Mr. Mullen's amendments as they are with the additional corrected amendments. (Meter # 5100 - 5190

SENATOR ERBELE made a motion to further amend.

SENATOR BROWN seconded the motion.

Roll call was held. 6 yeas 0 nays.

SENATOR BROWN made a motion to DO PASS AS AMENDED.

SENATOR ERBELE seconded the motion.

SENATOR FAIRFIELD: Questions Mr. Mullen if this does in any way, shape or form reduce the privacy standards that we currently have in this state to meet federal requirements?

MIKE MULLEN: No, I can't think of any part that would do that.

Roll call was read. 6 yeas 0 nays

SENATOR LEE will be the carrier. (Meter # 5445)

38332.0201
Title.0300

Adopted by the Human Services Committee
March 12, 2003

3-14-03
1 of 2

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1438

Page 1, line 1, after "25-01.3-01" insert "and a new section to chapter 44-04"

Page 1, line 2, after "definitions" insert "and duties to protect information", replace "sections" with "section", and after the second comma insert "subsection 1 of section 23-07-01.1, sections"

Page 1, line 3, remove the first comma and replace "sections" with "section"

Page 1, line 5, replace "and" with a comma and remove "subsection 1"

Page 1, line 6, remove the first "of section" and replace the second "section" with "and"

Page 2, after line 3, insert:

"**SECTION 2. AMENDMENT.** Subsection 1 of section 23-07-01.1 of the North Dakota Century Code is amended and reenacted as follows:

1. ~~All physicians and other medical professionals~~ A physician or other health care provider may report immediately to the department of transportation in writing, the name, date of birth, and address of every ~~person~~ individual fourteen years of age or over coming before them for examination, attendance, care, or treatment ~~when~~ if there is reasonable cause to believe that ~~such person~~ the individual due to physical or mental reason is incapable of safely operating a motor vehicle or diagnosed as a case of a disorder defined as characterized by lapses of consciousness, gross physical or mental impairments, and the report is necessary to prevent or lessen a serious and imminent threat to the health or safety of the individual or the public."

Page 6, line 22, after "and" insert "any other person"

Page 8, line 26, remove "An exposed", overstrike "person" and insert immediately thereafter "An exposed individual", and replace "source individual" with "test subject"

Page 8, line 30, overstrike the comma

Page 8, line 31, remove "source" and overstrike "person" and insert immediately thereafter "test subject"

Page 9, line 12, after the first "the" insert "test"

Page 9, line 13, after the first "the" insert "test"

2 of 2

Page 12, line 7, after "103" insert "and part 164, section 5-02, subsection g, respectively"

Page 12, line 8, replace "Subsection 1 of section" with "Section"

Page 12, after line 9, insert:

"**25-01.3-10. Confidentiality and privileged information."**

Page 13, after line 3, insert:

"2. Unless ordered by a court of competent jurisdiction, the name of ~~a person~~ an individual who in good faith makes a report or complaint may not be ~~released or~~ disclosed by the committee or the project."

Page 18, after line 6, insert:

"**SECTION 25.** A new section to chapter 44-04 of the North Dakota Century Code is created and enacted as follows:

Business associate - Duty to protect information.

1. As used in this section, "business associate" has the meaning set forth in title 45, Code of Federal Regulations, part 160, section 103.

2. If a public entity is acting as a business associate of another public entity, the entity acting as a business associate shall comply with all the requirements applicable to a business associate under title 45, Code of Federal Regulations, part 164, section 504, subsection e, paragraph 2."

Renumber accordingly

Date: 03-11-03
Roll Call Vote #: 1

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1438

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Amendments Do Pass

Motion Made By Sen. Brown Seconded By Sen. Erbele

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee - Chairman	✓				
Senator Richard Brown - V. Chair.	✓				
Senator Robert S. Erbele	✓				
Senator Tom Fischer	✓				
Senator April Fairfield	✓				
Senator Michael Polovitz	✓				

Total (Yes) 6 No 0

Absent

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Date: 03-12-03
Roll Call Vote #: 2

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1438

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Further Amendments Do Pass

Motion Made By Sen. Erbele Seconded By Sen. Brown

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee - Chairman	✓				
Senator Richard Brown - V. Chair.	✓				
Senator Robert S. Erbele	✓				
Senator Tom Fischer	✓				
Senator April Fairfield	✓				
Senator Michael Polovitz	✓				

Total (Yes) 6 No 0

Absent _____

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date: 03-12-03
Roll Call Vote #: 3

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1438

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass with both Amendments

Motion Made By Sen. Brown Seconded By Sen. Erbele

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee - Chairman	✓				
Senator Richard Brown - V. Chair.	✓				
Senator Robert S. Erbele	✓				
Senator Tom Fischer	✓				
Senator April Fairfield	✓				
Senator Michael Polovitz	✓				

Total (Yes) 6 No 0

Absent

Floor Assignment Sen. Lee

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE (410)
March 14, 2003 11:00 a.m.

Module No: SR-46-4782
Carrier: J. Lee
Insert LC: 38332.0201 Title: .0300

REPORT OF STANDING COMMITTEE

HB 1438, as engrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1438 was placed on the Sixth order on the calendar.

Page 1, line 1, after "25-01.3-01" insert "and a new section to chapter 44-04"

Page 1, line 2, after "definitions" insert "and duties to protect information", replace "sections" with "section", and after the second comma insert "subsection 1 of section 23-07-01.1, sections"

Page 1, line 3, remove the first comma and replace "sections" with "section"

Page 1, line 5, replace "and" with a comma and remove "subsection 1"

Page 1, line 6, remove the first "of section" and replace the second "section" with "and"

Page 2, after line 3, insert:

"**SECTION 2. AMENDMENT.** Subsection 1 of section 23-07-01.1 of the North Dakota Century Code is amended and reenacted as follows:

1. ~~All physicians and other medical professionals~~ A physician or other health care provider may report immediately to the department of transportation in writing, the name, date of birth, and address of every ~~person~~ individual fourteen years of age or over coming before them for examination, attendance, care, or treatment ~~when~~ if there is reasonable cause to believe that ~~such person~~ the individual due to physical or mental reason is incapable of safely operating a motor vehicle or diagnosed as a case of a disorder defined as characterized by lapses of consciousness, gross physical or mental impairments, and the report is necessary to prevent or lessen a serious and imminent threat to the health or safety of the individual or the public."

Page 6, line 22, after "and" insert "any other person"

Page 8, line 26, remove "An exposed", overstrike "person" and insert immediately thereafter "An exposed individual", and replace "source individual" with "test subject"

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Page 8, line 31, remove "source" and overstrike "person" and insert immediately thereafter "test subject"

Page 9, line 12, after the first "the" insert "test"

Page 9, line 13, after the first "the" insert "test"

Page 12, line 7, after "103" insert "and part 164, section 5-02, subsection g, respectively"

Page 12, line 8, replace "Subsection 1 of section" with "Section"

Page 12, after line 9, insert:

"**25-01.3-10. Confidentiality and privileged information.**"

Page 13, after line 3, insert:

"2. Unless ordered by a court of competent jurisdiction, the name of ~~a person~~ an individual who in good faith makes a report or complaint may not be ~~released or~~ disclosed by the committee or the project."

Page 18, after line 6, insert:

"**SECTION 25.** A new section to chapter 44-04 of the North Dakota Century Code is created and enacted as follows:

Business associate - Duty to protect information.

1. As used in this section, "business associate" has the meaning set forth in title 45, Code of Federal Regulations, part 160, section 103.

2. If a public entity is acting as a business associate of another public entity, the entity acting as a business associate shall comply with all the requirements applicable to a business associate under title 45, Code of Federal Regulations, part 164, section 504, subsection e, paragraph 2."

Renumber accordingly

2003 HOUSE HUMAN SERVICES

CONFERENCE COMMITTEE

HB 1438

2003 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1438

House Human Services Committee

☑ Conference Committee

Hearing Date 3-31-031

Tape Number	Side A	Side B	Meter #
1	x		0-42.9
Committee Clerk Signature	Sharon Berglund		

Minutes: Chairman Devlin: called the conference meeting to order on HB 1438.

Representative Devlin, Senator Lee, Representative Wieland, Senator Brown, Representative Niemeier, Senator Fairfield were present.

Representative Devlin: we have a couple concerns, members of the Senate want to make sure that we weren't going any further then what the federal regulations required, and Senator Mathern asked to bring a possible amendment forward on Section 12, I don't know if you heard his amendment on the Senate side or not, but we will give him a moment to present his concerns, if that is O.K.. with the Senate.

Senator Mathern: I'm handing out amendments on Section 12, in the past few weeks a attorney contacted me about controversy on the cost of copies of medical records I got a hold of L.C. and said why don't we draft a bill on that and see where this can be addressed, L.C. said the issue is really within 1438 and they suggested that 1438 conference committee by that time because it had already gone through both chambers. I found out that there had already been a Attorney

Generals opinion on the issue what is a proper charge for a medical record, so it does appear to need some clarification, the first hand out you have is a copy of the attorney generals opinion that out lines in detail what's proper for the board of nursing to charge for records which would be considered if somebody raised the question about medical records that are in 1438.

Representative Devlin: as I recall we had a bill either last session or the session from Representative DeKrey that did this very thing and its 2 bills, and the language that is in 1438 repeals what someone else outlined.

Mike Mullen: it is true that HB 1438 removes the provision of the current century code that was enacted in 1999, however this was discussed by the informal group that we had studying this, and they came to the conclusion that the rules with in HIPPA addresses the issue about the disclosure of protected health information to an individual which provides adequate limitations on the cost of copying because it says that the cost be related to the reasonable cost of making copies, and that combined with the Attorney Generals opinion to the board of nursing, which I think is about 3 cents a page, we reached the conclusion that this would provide adequate limitations combined with the fact that there is a $100.00 penalty for any violations that the provider would not try to gouge people or charge excessive amounts. Under the amendment the limit would be 25 cents per page and that works if it is text, but x-rays, the cost would be more.

Representative Devlin: we understood that it was fully covered in HIPPA.

Representative DeKrey: I have gone over the language and I really feel it is O.K. I really don't think it does what we wanted it to do 2 years ago, and I guess we are just 2 years ahead of the curve.

Representative Devlin: you would rather leave the existing language in there?

Representative DeKrey: I'm comfortable with the new language, when I put that bill in there I never thought about x-rays, all I was thinking was paper.

Senator Mathern: the Attorney who brought this to my attention Mark Schneider, Fargo, was concerned that the costs were to high if the interpretation of the HIPPA language is such, probably be looking at the attorney generals guidelines as a range that would be used.

Mike Mullen: the cost should be less and it will be in the future.

Senator Lee: in the first place in the attorney generals opinion I'm just appalled that anyone would charge $3.98 for copies. Who knows in the next several years what kind of coping will be done, I'm glad to hear that there is some consensus on the language being O.K. I will support Representative DeKrey.

Representative Devlin: we are assuming that there is no further information that some other language has to be added to bring us into compliance.

Senator Lee: exactly and with your permission I would refer to Mr. Mullen, he has the summary of the information he provided for us that would be helpful for the House members.

Mike Mullen: presented summary of amendments to committee. **(SEE ATTACHED TESTIMONY).**

Representative Wieland: we added a new Section 2 and I'm assuming that all sections are moved up one and we will end up on the back page with Section 29.

Representative Neimeier: pages 10 and 11 I'm trying to find a fee area.

Mike Mullen: its begins on line 28 through 30 and the first 2 lines on page 10 and the first 2 lines on page 11. That relates to the discussion of Senator Mathern concern HIPPA specifically provides that you can only charge a reasonable cost for making a copy of a document and that

combined with the attorney general opinion showing how to calculate those kind of fees we believe will provide a good objective basis for determining what should be charged, it will have to be related to the cost of producing the documents.

Senator Lee: we spent at least as much time as deserved on some concerns of protection of advocacy, but we did not think that it was appropriate to have their rules be different from everyone else, because once we get through the initial flurry of HIPPA people will get into a groove and I think it will be more confusing to have different sets of rules for certain situations.

Mike Mullen: since your last meeting in the Senate, the protection advocacy project has still made additional comments to me, and to the Attorney General and I did look at one thing that they recommended, the definition about relating to identifiable information, and I will pass out amendment **(SEE ATTACHED TESTIMONY).**

Senator Lee: I don't see a significant difference in what it means, but if they would feel that we give them some consideration after all the work they did and we discarded everything, and it doesn't make a significant negative impact, I guess we can attach it on and it flows much better with this language.

Representative Devlin: I don't have a problem with it, if everyone is more comfortable with it doesn't matter to me.

Senator Fairfield: I do think there is a subtle difference in the language, I like it better. On bill 1425, the developmentally disabled, opening the records, the Galvanized Bill, would this have an impact on this, would this close up what we are doing in 1425?

Mike Mullen: no, I don't believe it will.

Representative Niemeier: on page 12, line 20-21 seem to be related to the line 11 issue.

Mike Mullen: I looked at that language, and frankly I'm not able to distinguish any big difference.

Representative Fairfield: what exactly, if you don't see any change here what is the purpose of wanting this change, the way I look at it is changing this language broadens it just a bit ever so slightly.

Mike Mullen: I didn't think that change was required but they feel strongly about it and its fine if conference wants to go with that.

Senator Lee: not just from which that individual would be identified but any information relating to that individual which I guess broadens it but it is a hard distinction to make.

Senator Lee: I would move to accept the amendments presented by Mike Mullen.

Representative Wieland: **SECOND** the motion.

All were in favor of motion.

Representative Wieland: motion to House Accede to Senate Amendments, further amend and renumbered accordingly.

Representative Niemeier: SECOND the motion.

VOTE: 6-YES 0-NO 0-ABSENT.

Motion passed.

Representative Devlin will carry the bill.

By Mike Mullen

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL 1438

Page 12, line ~~22~~ 11, replace "from which" with "relating to"

Page 12, line ~~23~~ 12 remove "may be identified"

Renumber accordingly

38332.0301
Title.

Prepared by the Legislative Council staff for
Senator Mathern
March 27, 2003

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1438

Page 10, line 28, overstrike "1."

Page 11, line 2, remove the overstrike over the overstruck colon

Page 11, line 3, after "~~a.~~" insert "1.", remove the overstrike over "~~Provide~~", and remove "provide"

Page 11, line 8, after "~~b.~~" insert "2.", remove the overstrike over "~~Provide a copy of a patient's~~", after "~~medical~~" insert "health care", and remove the overstrike over "~~records requested for any purpose other~~"

Page 11, line 9, remove the overstrike over "~~than the continuation of~~" and insert immediately thereafter "health" and remove the overstrike over "~~care for a~~"

Page 11, line 11, after "~~twenty-five~~" insert "reasonable, cost-based fee" and remove the overstrike over "~~. This~~"

Page 11, line 12, after "~~expense~~" insert "fee may include the cost of copying and postage but may not include the cost of retrieving or handling the records or the cost of handling the request" and remove the overstrike over the period and insert immediately thereafter "The total cost of copying may not exceed twenty-five cents per page."

Renumber accordingly

38332.0202
Title.0400

Adopted by the Conference Committee
April 1, 2003

VR
4/1/03

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1438

That the House accede to the Senate amendments as printed on pages 951 and 952 of the House Journal and pages 778-780 of the Senate Journal and that Engrossed House Bill No. 1438 be further amended as follows:

Page 12, line 11, replace "from which" with "relating to"

Page 12, line 12, remove "may be identified"

Renumber accordingly

REPORT OF CONFERENCE COMMITTEE
(ACCEDE/RECEDE) - 420

(Bill Number) **HB 1438** (, as (re)engrossed):

Your Conference Committee for HOUSE HUMAN SERVICES

For the Senate:		**For the House:**	
Rep. Devlin	yes ✓	Senator J. Lee	yes ✓
Rep. Wieland	yes ✓	Senator Fairfield	yes ✓
Rep. Niemeier	yes ✓	Senator R. Brown	yes ✓

____ recommends that the (SENATE/HOUSE) (ACCEDE to) (RECEDE FROM)

the (Senate/House) amendments on (SJ/HJ) page(s) 790 -- _____

____ and place _____ on the Seventh order.

✓, adopt (further) amendments as follows, and place HB 1438 on the Seventh order:

____ having been unable to agree, recommends that the committee be discharged and a new committee be appointed.

((Re)Engrossed) _____ was placed on the Seventh order of business on the calendar.

DATE: 3/31/03

CARRIER: Rep. Devlin

LC NO. _____ . _____ of amendment

LC NO. _____ . _____ of engrossment

Emergency clause added or deleted _____

Statement of purpose of amendment _____

(1 & 2) LC (3) DESK (4) COMM.

REPORT OF CONFERENCE COMMITTEE (420)
April 10, 2003 11:20 a.m.

Module No: HR-65-7316

Insert LC: 38332.0202

REPORT OF CONFERENCE COMMITTEE

HB 1438, as engrossed: Your conference committee (Sens. J. Lee, Brown, Fairfield and Reps. Devlin, Wieland, Niemeier) recommends that the **HOUSE ACCEDE** to the Senate amendments on HJ page 1191, adopt further amendments as follows, and place HB 1438 on the Seventh order:

That the House accede to the Senate amendments as printed on pages 951 and 952 of the House Journal and pages 778-780 of the Senate Journal and that Engrossed House Bill No. 1438 be further amended as follows:

Page 12, line 11, replace "from which" with "relating to"

Page 12, line 12, remove "may be identified"

Renumber accordingly

Engrossed HB 1438 was placed on the Seventh order of business on the calendar.

2003 TESTIMONY

HB 1438

TESTIMONY OF THE OFFICE OF ATTORNEY GENERAL
ON HOUSE BILL 1438 REGARDING THE PRIVACY HEALTH INFORMATION

BEFORE
HOUSE COMMITTEE ON HUMAN SERVICES
FEBRUARY 10, 2003

MICHAEL J. MULLEN
ASSISTANT ATTORNEY GENERAL

Chairman Price and Members of the Committee, I am pleased to be here on behalf of Attorney General Stenehjem, and on behalf of several departments and agencies, who asked me to present testimony explaining House Bill 1438, which clarifies the relationship between state law requiring the confidential treatment of health information, and the federal HIPAA privacy rule. Before I address the provisions of House Bill 1438, let me briefly outline the background and purpose of the federal HIPAA privacy rule.

Background on the HIPAA Rule for the Privacy of Health Information

The federal regulation entitled *Standards for Privacy of Individually Identifiable Health Information* (the Privacy Rule), which was promulgated by the Department of Health and Human Services (HHS), became effective on April 14, 2001. [The regulations are found at *45 CFR [Code of Federal Regulations] Parts 160 and 164.*] The Privacy Rule is the first comprehensive federal protection for the privacy of health information.

The privacy rule came about as a result of the Health Insurance Portability and Accountability Act [commonly called "HIPAA"], 29 U.S.C. §§ 1181 – 1191c (enacted in 1996), which established a number of rules to provide greater access to health insurance regardless of a person's health status. Title II, subtitle F sections 261-264 of HIPAA, 42 U.S.C. §§ 1320d -- 1320d-8, sets forth a program for "administrative

simplification," which requires all health care providers and insurers to establish uniform billing and coding systems in order to simplify and reduce the administrative costs of the health care system. Congress also recognized, however, that a uniform electronic billing system, which would necessarily include detailed information about the diagnosis and treatment received by individual patients, would also greatly increase the capacity for accidental or intentional disclosure of *individually identifiable* health information. Therefore, Congress required the Secretary of Health and Human Services to establish regulations to protect the privacy and security of health information.

On December 28, 2000, the final rules on the privacy of individually identifiable health information were published. The effective date of the privacy rules is April 14, 2001. In addition, under the rules, the *compliance date* for most organizations is two years following the effective date. Thus, doctors, dentists, hospitals, clinics, health insurance companies, and specified government health plans have until April 14, 2003, to bring their operations into compliance with the HIPAA privacy rules. (Small insurers, roughly those with an annual premium revenue of $5 million or less, have an additional year to come into compliance.)

Because of concern that the privacy rule had certain unintended consequences that could have impaired the treatment of patients and made practical compliance with the privacy rule difficult, the Secretary of Health and Human Services made several changes to the rule, which were published on August 14, 2002. And, as I mentioned, all covered entities (except small health plans) must be in compliance with the privacy rule by April 14 of this year.

The Purpose of House Bill 1438

The purpose of House Bill 1438 is to clarify North Dakota law and make it easier for government agencies to comply with the requirements of both the federal HIPAA privacy rule, and numerous sections of the Century Code that specify the conditions under which protected health information may be disclosed. The bill does not reduce the privacy protection that is given to health information. The bill also does not place unreasonable restrictions on the use of this information -- to the extent disclosure is needed to permit state agencies to carry out their responsibilities under the law.

Let me now turn to the substantive provisions of House Bill 1438.

Section-By-Section Analysis

Section 1 amends section 23-01.3-02 to permit a "privacy board" as well as an institutional review board to authorize a research project. In addition, the section clarifies a reference to "protected health information" in place of an incorrect reference to "public health information."

Section 2 amends section 23-07-02.1 relating to reports of human immunodeficiency virus infection by replacing the term "release" with the term "disclosure" because disclosure is a defined term and is used throughout the HIPAA privacy rule. Section 2 also provides that in addition to disclosure to a health care provider providing "direct care," disclosure may be made "as otherwise provided by law."

Section 3 amends section 23-07-02.2 which relates to the confidentiality of reports regarding human immunodeficiency virus cases. Again, the term "released" is

replaced by the term "disclosed." In addition the term "epidemiologic" is replaced by "epidemiological."

Section 4 amends subsections 6, 7, and 8 of section 23-07.5-01 to distinguish between "informed consent for testing" for the human immunodeficiency virus and legal permission for "disclosure" of the test results. In addition, the section is clarified to provide that the test is for the presence of "the human immunodeficiency virus" and not just for "an antibody" to that virus. Third, the definition of "personal physician" is clarified to more clearly cover situations in which the patient has not designated a personal physician.

Section 5 amends section 23-07.5-02 relating to the situations in which a test for the human immunodeficiency virus may be conducted without the informed consent of the individual who has exposed other persons. Subdivision a of subsection 2 is clarified to state that the "consent" is informed consent for "testing," not an "authorization" for disclosure of the test results.

Third, subdivision b of subsection 2 is amended to provide that the "form" given to the subject who will be tested must contain a statement explaining that the test results may be disclosed as authorized by law. This will permit disclosure as authorized by the federal HIPAA privacy rule.

Subdivision c of subsection 2 is amended by deleting several items that must be contained in a consent form because these items are specified in some detail in the "authorization form" that is required under the federal HIPAA privacy rule.

Subdivision b of subsection 3 is amended to clarify which person is to be tested for the presence of human immunodeficiency virus.

Subdivision d of subsection 3 is amended to clarify that the patient may always obtain the test results (which is required by the federal HIPAA privacy rule) and to specify that the test results may be disclosed to others as authorized by law. In addition, subdivision d is amended by deleting the "buried" criminal penalty for person who discloses the identity of a patient in violation of various subsections of this section. A criminal penalty for disclosure of protected health information with intent to disclose the "test subject" is set forth in section 23-07.5-08, the primary criminal section of this chapter, which is amended under section 9 of this bill.

Subdivision c of subsection 4 is amended to include not only the provider but also a good Samaritan who renders aid and is exposed to blood or body tissue.

Subdivision d of subsection 4 is amended to make clear that the provider may receive a copy of their own test results and that the results may be disclosed "as authorized by law." Finally, this subdivision is amended to clarify that the patient (who potentially has been exposed) may not disclose the "provider's identity" i.e., the identity of the provider who has been tested.

Subsection 5 is clarified to address situations in which a patient has died and the facility was not aware of a possible exposure to the human immunodeficiency virus, or it was not reasonably possible for the facility to conduct a test and provide the results of the test to any physician providing care, an exposed emergency medical service provider, other health care provider, or a good Samaritan who rendered aid to the deceased person.

Subsection 6 is clarified to provide that any test done pursuant to subsection 3, 4, or 5 must be conducted in a "reasonably expedient manner," not the "most" expedient manner possible (which is potentially contestable).

Subsection 7 is clarified to refer to "an exposed person" who may request a test of a "source person," the individual who has caused a "significant exposure" to the "exposed person." Under current law, the first test may be requested within ten days after exposure and a second test may be requested not earlier than five months, nor later than six months after significant exposure. The amendment provides that an exposed person may request two tests. "[E]ach test may be requested as soon as practicable, consistent with the recommendations of the United States public health service, but in no event later than nine months after a significant exposure." This will provide more flexibility regarding the timing of these tests: more time to request the first test; and, a larger time frame in which to request the second test.

Subsection 8 of section 5, contains a clarifying form and style amendment.

Section 6 amends subsection 1 of section 23-07.5-04 to clarify that the section applies to informed consent for testing, i.e., the legal permission to test an individual, but does not address disclosure of the test results, which requires an "authorization" meeting the requirements of the HIPAA privacy rule. Subsection 1 is also amended to provide that testing may be conducted only pursuant to informed consent, "unless testing is otherwise authorized by law."

Section 7 amends section 23-07.5-06 and clarifies that a person to whom the results of a test have been disclosed "may not disclose the test results except as authorized by law," which is a reference to disclosure authorized under the federal

HIPAA privacy rule. A reference to section 23-05.5-05, which is repealed by this bill, is deleted.

Section 8 amends section 23-07.5-07, which relates to civil liability for unauthorized disclosure, is amended by deleting references two sections of the Century Code that are repealed, and by repealing an unnecessary sentence regarding the burden of proof – a preponderance of evidence – which is generally applicable in a civil action.

Section 9 amends section 23-07.5-08, which provides a criminal penalty for unlawful disclosure of individually identifiable information regarding the results of a test for HIV. The amended section now applies to a person who "knowingly" discloses the results of a test in violation of the chapter, and instead of referring to the harm to the subject, applies if the offense is committed "with intent to disclose the identity of the individual who was tested."

Section 10 amends subsection 3 of section 23-07.7-02 by removing a reference to section 23-07.5-03, which is repealed by section 25 of this bill.

Section 11 amends 23-12-14 relating to copies of health care records. Subsection 1 is amended to refer to a "health care provider" rather than a "medical provider" since that is the term used in the federal HIPAA privacy rule. The second sentence of subsection 1 is removed because it is unnecessary. Subdivision a of subsection 1 is amended to refer to "health care" rerecords rather than "medical rerecords," the terminology used in the federal privacy rule.

Subdivision b of subsection 1, relating to the cost of a copy of health care records provided to an individual (for a purpose other than disclosure to another provider for

treatment), is repealed. The HIPAA privacy rule contains detailed limitations on the charges for providing a copy of health care records to a patient.

Subsection 2 (a), which provides that an authorization to disclose an individual's health care records is limited to the time specified, but no longer than three years, is repealed. The federal HIPAA privacy rule does not impose any time limit on the period during which an authorization is legally valid. In some cases, an individual may authorize the disclosure of their individual information regarding diabetes, asthma, or cancer to a semi-permanent research database. Since an individual may revoke their consent at any time, and since the legislative history of this provision shows that the current three-year time limit was intended to extend the period of an authorization, the subdivision is repealed.

Subsection 2(b) authorizing a patient to revoke their authorization at any time also is repealed; this right is clearly established under the federal privacy rule.

Subsection 3, which provides that a health care provider may disclose a patient's health care records to another provider "during the time necessary to complete a patient's course of treatment" and conclude all medical and payment transactions related to the individual, is repealed. Under the federal HIPAA privacy rule, a health care provider and a health plan may use protected health information for treatment or payment without the consent of the patient. Therefore, this subsection is unnecessary.

Subsection 4 provides that it is "not a prohibited practice" for a health insurance company with participating provider agreement to require that subscribers or members are responsible for providing the insurer with copies of health care records used for claims processing when an individual uses a nonparticipating provider. This provision,

which relates to insurance law, is transferred to section 26.1-04-03 by section 16 of this bill.

Section 12 amends section 23-16-09, which relates to individually identifiable health information obtained by the Department of Health in the course of a survey or inspection of a hospital, nursing home, or similar facility. This section, which was enacted in 1947, permits disclosure of information to a social service agency relating to a newborn without an authorization from the newborn's parents. Such a broad disclosure is not permitted under the federal privacy rule – which preempts any provision of state law that is contrary to the rule's requirements (unless the state law is "more stringent" with respect to the disclosure of protected health information).

Section 13, which amends section 25-01.3-01, adds a new definition of individually identifiable health information and personal representative (adopted from the federal HIPAA privacy regulation) to clarify the class of information and the persons to whom information about an individual with a developmental disability may be used or disclosed.

Section 14, amends subsection 1 of section 25-01.3-10, to clarify the legal authority to disclose information about an individual with a developmental disability (or as defined by federal law, a person with a "disability"). Specifically, the terminology is amended to refer to "individually identifiable health information," an "authorization" for "disclosure," and "personal representative," which are the terms used in the federal HIPAA privacy rule. This subsection is also amended to permit disclosure as otherwise authorized by this chapter, or any other state or federal law. (Subdivision c, of subsection 10, section 25-01.3-10.)

Section 15, amends section 25-16-07, relating to the treatment records of a resident of the developmental center at Westwood Park in Grafton. The terminology is amended to conform with the federal privacy rule; specifically, to permit disclosure for "treatment, payment, or health care operations," and "to arrange, facilitate, or coordinate service" to a person with a disability.

Section 16 amends section 26.1-04-03 by adding language that it is not a prohibited practice for health insurance company with a participating provider agreement to require that a subscriber or member using a nonparticipating provider be responsible for providing the insurer with a copy of the health care records used for claims processing. This amendment simply moves virtually identical language from section 23-12-14 to the insurance code.

Section 17 amends section 28-01-46.1 which relates to the disclosure of information among parties in a malpractice claim against health care provider in order to facilitate the resolution of these claims. Specifically, the section is amended to use the term "authorization," which is the term used in the federal privacy rule for disclosure of health information not related to treatment payment or health care operations. The amendment also provides that if the party commencing the action fails to provide appropriate authorizations at the time the action is commenced, the health care provider may use a subpoena or other means to obtain the records, and may seek costs if required to do so.

Section 18, amends subsection 6 of section 37-18-11, relating to the disclosure of protected health information by the North Dakota Veterans Home. The amendment substitutes the term "disclosed" for "release" and substitutes "resident" for "veteran"

because spouses of a veteran are now permitted to become residents at the Veterans Home. In addition, subsection 6 is amended to permit the Veterans Home to "use and disclose" "protected health information" for treatment, payment, or health care operations (the privacy rule terminology) without the consent of a resident. This is consistent with the federal HIPAA privacy rule and the law applicable to other nursing homes in North Dakota. The section also permits disclosure as "otherwise authorized by law."

Section 19 amends subsection 9 section 37-18-11 to make the disclosure of protected health information about a resident of the Veterans Home to a member of the legislative assembly subject to the limitations of any other law. This might apply with respect to the disclosure of information relating to treatment for substance abuse. See 42 C.F.R. part 2. This is just a technical amendment to make it clear that if a more restrictive law applies to a certain class of health information, that limitation applies with respect to disclosure to a member of the legislative assembly.

Section 20 amends subsection 4 of section 43-15-01 relating to the definition of confidential information in the law establishing the Board of Pharmacy. The amendment references the term "individually identifiable health information" which is a key term in the HIPAA privacy rule. The amendment also deletes language describing the purposes for which protected health information may be disclosed because the permitted use and disclosure of protected health information is set forth in the operational sections of the chapter 43-15, the Board's charter.

Section 21, which amends subdivision n of subsection 1 of section 43-15-10, clarifies the law with respect to prohibited disclosure of protected health information

("confidential information") by a pharmacist (or pharmacy). Specifically, the amendment uses the term "discloses" which is the term used in the privacy rule rather than using the indefinite to "an unauthorized person," and, disclosure is permitted "as authorized by law."

Section 22, amends section 43-47-09, which relates to disclosure of information obtained by a counselor rendering counseling services, to provide a broader reference. Currently, the only exception requires disclosure under chapter 50-25.1 (relating to child abuse); the amendment permits disclosure as authorized by law. The practice of professional counseling includes mental, family therapy, school guidance, and vocational counselors.

Section 23 amends subsection 1 of section 44-04-18.1 which is a section of the open records law relating to records of a public employee's medical treatment or use of an employee assistance program, to provide that these records are "confidential," except "as otherwise authorized by law." (Thus, permitting disclose for treatment and payment.) This section also incorporates the HIPAA privacy rule terminology by replacing "release" with "used or disclosed," and replacing "consent" with "authorization, which is the term used for a disclosure of protected health information for a reason other than "treatment, payment, or health care operations."

Section 24 amends section 50-19-10 which relates to disclosure of records of a maternity home. The amendment provides that "except as otherwise provided by law disclosure may be made only in a judicial or administrative proceeding in response to an order of the court or an administrative tribunal, or for a law enforcement purpose to a law enforcement officer, or to a health oversight agency for oversight activities

authorized by law." General authority to disclose information to agencies serving the interests of a patient or a newborn infant is repealed because it is inconsistent with the federal privacy rule, which prohibits such a disclosure unless authorized by the parents of the infant.

Section 25 repeals three sections of the Century Code: sections 23-01.3-03, 23-07.5-03, and 23-07.5-05.

Section 23-01.3-03 is repealed because the HIPAA privacy rule provides an individual with a comprehensive right to obtain copies of their own medical records. See 45 C.F.R. 164.502.

Section 23-07.5-03, which relates to consent for disclosure of HIV test results, is repealed because the HIPAA privacy rule contains detailed requirements for an "authorization," i.e., legal permission, to disclose protected health information, including the results of a test for HIV.

Section 23-07.5-05, relating to the disclosure of HIV test results, is repealed because the HIPAA privacy rule contains detailed requirements and limitations regarding the disclosure of any protected health information without the individual's specific "authorization."

Section 26 provides that this bill is an emergency measure.

Section 27 provides that the bill is effective April 14, 2003, which is the date on which all covered providers and health plans (except "small' health plans) must be in compliance with the HIPAA privacy rule.

Chairman Price, thank you for providing me an opportunity to discuss the provisions of House Bill 1438, which clarifies the relationship between state law

requiring the confidential treatment of health information, and the federal HIPAA privacy rule. I will be pleased to answer any questions you or other members of the committee have regarding the bill, which we believe aligns North Dakota law with the federal HIPAA privacy rule, and in turn will assist providers, payers, and government agencies in achieving compliance with the privacy rule.

#a

HIPAA: Overview of Final Privacy Rule

The Final Rule for privacy was published by the Department of Health and Human Services on December 28, 2000. This rule describes new federal requirements for safeguarding the privacy of protected health information (PHI), and stipulates when entities like the Department of Human Services, the Department of Health, the North Dakota Public Employees Retirement System Health Plans (and other state and local entities that maintain a health plan or are a covered health care provider) must comply with these new standards. The deadline for compliance is April 14, 2003. Below is an overview of what's included in the Final Rule for privacy. If you would like to view the complete text of the Rule, see -- http://aspe.hhs.gov/admnsimp/bannerps.htm

The privacy rule includes key provisions for both "covered entities" (which include health plans, health care providers, and health care clearinghouses), as well as new rights for patients.

Provisions for covered entities include:

Notice of Privacy Practices (NPP)
Authorizations
Minimum necessary requirement
Administrative responsibilities
Business associate obligations

Rights for patients include:

to receive notice of privacy practices
to request restriction of disclosures
to access their PHI
to request amendment of PHI
to an accounting of disclosures
to request restrictions on communication of PHI

What is protected health information (PHI)?

PHI is individually identifiable health information which is created or received by a health care provider, health plan, employer, or health care clearinghouse. It is any such information that relates to the past, present, or future physical health, mental health or condition of an individual. PHI either identifies or could be used to identify the individual. Health information which includes any of the following identifiers is considered PHI, and thus subject to the regulations contained in the privacy rule:

Name
Address (includes street address, city, county, zip code)
Names of relatives
Names of employers
E-mail address
Fax number
Telephone number

Birth date
Finger or voiceprints
Photographic images
Social security number
Internet protocol (IP) address
Any vehicle or device serial number
Medical record number
Health plan beneficiary number
Account number
Certificate/license number
Web URL
Any other unique identifying number, characteristic, or code

Notice of Privacy Practices (NPP)

Under HIPAA, health care providers must give patients a notice of privacy practices. This document explains how patients' information is used and disclosed in the course of treatment, payment, and operations, and explains patients' rights. It must be written in plain language, and must identify a contact person for privacy complaints. A health care provider must give this notice to patients upon the first date of service. The provider must also make a good faith effort to obtain the patient's written acknowledgement that they have received this notice.

Authorizations

An authorization is a customized document that gives ***the covered entity*** permission to use specific PHI for specific purposes, usually purposes other than treatment, payment, or operations. An authorization must specifically describe the PHI to be released, who may release it, who may receive it, and must be signed and dated by the patient.. Some examples of activities that would require authorization are using PHI for marketing activities, research, or to make employment determinations.

Minimum necessary requirement

Consider a hypothetical situation. Suppose I am an employer, and I require all new employees to have a pre-employment physical. Jane Doe is a new hire. I request the results of her physical, and instead of just sending me those results, her physician sends a copy of her entire medical record. Obviously, as an employer, I do not have a "need to know" Jane's entire medical history. Instead, under HIPAA, PHI is subject to a minimum necessary standard. Covered entities (in this case, the physician) must put policies and procedures in place to limit disclosure of PHI to the minimum necessary to achieve the purpose of that disclosure. The purpose of my request for Jane's PHI was to determine the results of her physical. That is all the information I need to know, and so that is all that the physician should provide.

Administrative Responsibilities

The Final Rule describes four administrative requirements for covered entities. These are:

Designate a Privacy Officer

This person is responsible for overseeing the development and implementation of privacy policies and procedures, and for making sure that they are followed.

Designate a contact person for complaints

This person is responsible for fielding and addressing patient complaints if they feel that the privacy and/or confidentiality of their medical information have been compromised.

Train staff in privacy policies and procedures

All employees must be trained in how HIPAA requirements apply to their organization, as well in any HIPAA-related privacy policies and procedures. This training is a federal requirement and must be documented.

Enforcement and sanctions

Covered entities must decide what they will do if patient privacy is compromised. They must develop and impose sanctions against employees who don't comply with the requirements of the Rule. Covered entities must have written policies and procedures for what to do in these kinds of situations.

Business Associates obligations

The Privacy Rule applies only to health plans, health care providers, and health care clearinghouses. However, when PHI is provided to outside organizations, such as vendors and contractors, covered entities must have contracts in place which make sure that business associates will use the PHI appropriately. Business Associates can only use PHI for the purposes for which they were engaged by the entity (for instance, a transcription service hired by ***a covered entity*** can use PHI in the course of transcribing records, but not for targeting marketing materials to the subjects of that PHI). Furthermore, Business Associates must agree that they will safeguard the information from misuse, and will help the covered entity provide individuals with access to health information and an accounting of certain disclosures (see below, under "Right to receive an accounting of disclosures.")

Right to receive notice of privacy practices

A health plan and a provider with a direct patient relationship must give patients a written description of our privacy practices. This notice must be written in plain language, must explain how health care information is used and disclosed by the covered entity, and must identify a contact person for complaints.

Right to request restriction of disclosures

As a health care consumer, you have a right to request certain restrictions on the disclosure of your PHI. For instance, suppose that for some reason you do not want any of your health information released to any labs, even though this kind of release is permitted under HIPAA as part of treatment. You are allowed to request such restrictions, although a covered entity does not have to agree to them. However, if a covered entity agrees to a restriction, they must honor it.

Right of individuals to access their PHI

You have a right to access (which includes inspecting and/or copying) any health information that is used to make decisions about your care. Covered entities must act on a request for access within 30 days of receiving it.

Right to request amendment of PHI

You have the right to request that a covered entity amend your PHI. For instance, suppose that you have inspected your PHI, and feel that a lab result was not recorded correctly. The covered entity does not necessarily have to agree to a request for amendment (for instance, if the entity determines that the information is complete and accurate as recorded), but they must act on a request for amendment (whether this request is granted or denied) within 60 days of receiving it.

Right to an accounting of disclosures

You have a right to know of any disclosures of your PHI made by a covered entity that fall outside the scope of treatment, payment, and operations. Covered entities must provide an accounting of any such disclosure made within the last six years, and must provide a requested accounting within 60 days of receiving the request. You can get one free accounting per 12-month period; for any additional requests within that time, the entity may charge a nominal fee.

Right to request restrictions on communication of PHI

You have the right to request restrictions on how your PHI is communicated. For instance, if you don't want a provider to mail an appointment reminder to you on a post card, you can ask for it to be mailed in an envelope. According to the Final Rule, covered entities must accommodate any "reasonable" request.

Testimony

House Bill 1438

House Human Services Committee

February 10, 2003

8:30 a.m.

North Dakota Department of Health

Madam Chair and members of the committee, my name is Darleen Bartz and I am the Health Resources Section Chief with the North Dakota Department of Health. I also am responsible for coordinating implementation of the federal Health Insurance Portability and Accountability Act within the Department. I am here to provide testimony in support of House Bill 1438.

Sections 1 through 12 of House Bill 1438 pertain to activities carried out by the Department of Health. The changes requested in this bill clarify existing law and make it easier for the Department to comply with the requirements of the federal Health Insurance Portability and Accountability Act related to the privacy rule.

House Bill 1438 maintains protection of private health information and does not place unreasonable restrictions on the use of information. However, these changes do clarify existing statutes while increasing the consistency in language related to privacy on the state and federal level.

In addition to language concerning the Health Insurance Portability and Accountability Act, House Bill 1438 contains clarifying language regarding HIV issues. Larry Shireley, State Epidemiologist, will provide testimony to support the need for these changes.

The Department of Health requests your favorable response to House Bill 1438. I am happy to answer any questions you may have.

Testimony

House Bill 1438

House Human Services Committee

February 10, 2003

8:30 a.m.

North Dakota Department of Health

Madam Chair and members of the committee, my name is Larry Shireley and I am the State Epidemiologist with the North Dakota Department of Health. I am here to provide testimony in support of House Bill 1438.

In addition to language concerning the Health Insurance Portability and Accountability Act, House Bill 1438 contains clarifying language drafted by the Department of Health regarding HIV issues and changes related to testing for HIV after a significant exposure. The proposed changes regarding testing after a significant exposure include following the recommendations of the United States Public Health Service and changing the time periods for when the tests should be conducted.

The Department of Health requests your favorable response to House Bill 1438 with the amendment as proposed. I am happy to answer any questions you may have.

House Human Services Committee
Fifty-eighth Legislative Assembly of North Dakota
House Bill No. 1438
February 10, 2003

Good morning, Chairman Price and Members of the House Human Services Committee. I am David Boeck, a State employee and lawyer for the Protection & Advocacy Project. I am testifying only about the portion of HB 1438 that amends the Century Code chapter on the Protection & Advocacy (P&A) Project.

Section 13 of the bill (page 12, lines 4 to 8) proposes two new definitions for the P&A chapter, "individually identifiable health information" and "personal representative." I ask that these definitions not be included in the P&A chapter because, as I propose the amendments, neither term would appear in the chapter.

P&A operates in North Dakota under state and federal laws. The federal P&A laws consistently use their own P&A terms. The federal P&A laws differ from the HIPAA language. It is more important for the North Dakota P&A to use the federal P&A language. This does not create a conflict with HIPAA regulations.

The scope of P&A's confidentiality obligations is a primary reason for using different terms. P&A has the obligation to keep confidential all information about clients and protected persons, not just "individually identifiable health information." While the HIPAA definition of "personal

representative" is good, federal P&A laws, federal P&A regulations, judicial decisions in other states, and federal judicial decisions govern the North Dakota P&A. This law covers persons who may have access to a client's files and persons who may consent to disclosure of information from them.

Section 14 of the bill (page 12, lines 9 to 31, and page 13, lines 1 to 4) would introduce the HIPAA language into one section of the North Dakota P&A laws. Here, where HIPAA language is compatible with current P&A law, amendment is appropriate. This means "authorization" should replace "consent" and "disclose" should replace "release."

In place of HB 1438's current section 13, I propose replacing "consent" with "authorize" in another section of P&A law that is not covered in HB 1438. This section covers P&A authority and the discussions about HIPAA philosophy convince me that "authorize" should replace "consent."

As we examine possible amendments to P&A law, I am proposing that we simply the statutory language. Assistant Attorney General Michael Mullen has graciously included these changes in HB 1438. These changes substitute "disability" for "developmental disability and mental illness." The current language is both too broad and too narrow.

The law is too broad because mental illness is usually not disabling and P&A serves only those whose mental illness is disabling. The law is too narrow because, under authority of federal law, P&A serves people who have

disabilities that are neither developmental disabilities nor mental illnesses. An example is a person who survives a car accident but who now has a disabling spinal cord injury or a disabling traumatic brain injury.

Thank you. I am happy to answer any questions you may have.

Proposed Amendments to House Bill No. 1438

Page 1, lines 1 and 2, remove "to create and enact a new subsection to section 25-01.3-01 of the North Dakota Century Code, relating to definitions;"

Page 1, line 5, after "23-16-09," insert "section 25-1.3-06," and remove "subsection 1 of"

Page 12, lines 4 through 8, after "section 13.", replace the remainder of the section with "**AMENDMENT**. The introductory paragraph that precedes subsections 1 through 13 of section 25-01.3-06 of the North Dakota Century Code is amended and enacted as follows:

"25-01.3-06. **Authority of project**. Pursuant to rules adopted by the committee, the project, within the limits of legislative appropriations, shall provide advocacy and protective services for persons with ~~developmental~~ disabilities ~~and persons with mental illnesses~~. The rules adopted by the committee relating to the need for ~~the consent of~~ authorization from the client must balance the rights of persons with ~~developmental~~ disabilities ~~or mental illnesses~~ to privacy and to refuse services under section 25-01.3-11 with the committee's duties to protect the human and legal rights of persons eligible for services and to monitor facilities for compliance with federal and state laws and rules. The project may:"

Page 12, line 9, replace "Subsection 1 of section" with "Section"

Page 12, line 11, replace "from which" with "related to"

Page 12, line 12, remove "may be identified, including individually identifiable health information"

Page 12, lines 20 and 21, replace "who may be identifiable from the information, or that individual's personal representative" with each individual with a disability to whom the information relates"

Page 12, line ~~24~~ 25, remove ", a health oversight agency,"

Page 12, line ~~25~~ 26, after "to" insert "a health oversight agency or"

Page 13, line 3, after "when" overstrike "such", remove "a disclosure", and overstrike "is prohibited by"

Page 13, line 4, after "law" insert "prohibits that disclosure"

Page 13, after line 4, insert "2. Unless ordered by a court of competent jurisdiction, the name of a person who in good faith makes a report or complaint may not be ~~released or~~ disclosed by the committee or the project."

Renumber accordingly.

MEMORANDUM

To: Rep. Clara Sue Price, Chairman House Human Services Committee
From: Michael J. Mullen, Assistant Attorney General
Re: HB 1438; Communications with the Protection and Advocacy Project
Date: February 10, 2003

1. E-mail to David BOECK regarding Omnibus HIPAA Bill, later introduced as HB 1438. Thursday, January 9, 2003, 2:28 PM (4 pages).

2. E-mail to David BOECK suggesting modified HIPAA amendment. Sunday, January 12, 2003, 1:00 PM (5 pp).

3. E-mail to Omnibus HIPAA Bill Review Committee, including agenda discussion of proposed amendments relating to P&A (Protection and Advocacy Project). Tuesday, January 14, 2003, 10:06 AM (1 p.).

4. Meeting with David BOECK regarding HIPAA and the Protection and Advocacy project. Tuesday, January 14, 2003, 10:30 AM - 11:50 AM.

5. E-mail to David BOECK with notes of Tuesday morning meeting, including attached revised, proposed P&A (protection and advocacy) amendment. Tuesday, January 14, 2003, 12:37 PM.

6. E-mail to David BOECK regarding further comments on legislative language. Tuesday, January 14, 2003, 6:19 PM (2 pp).

7. E-mail to David BOECK regarding further legislative changes suggested by the Department of Health. Wednesday, January 15, 2003, 6:01 PM (1 p., with attached 4-page draft).

8. E-mail to David BOECK in response to questions about North Dakota confidentiality laws relating to health information. Thursday, January 16, 2003, 9:33 AM (2 pp).

9. E-mail to David BOECK providing further background on drafting of privacy language regarding P&A (the Protection and Advocacy Project). Thursday, January 16, 2003, 1:16 PM (4 pp).

10. E-mail to David BOECK providing further analysis of the basis for legislative language regarding P&A (the Protection and Advocacy Project). Friday, February 7, 2003, 12:08 PM (1 p.; with a 3-page attachment).

Enclosures: Copies of emails and selected attachments

Senate Human Services Committee
Fifty-eighth Legislative Assembly of North Dakota
House Bill No. 1438
March 3, 2003

Good morning, Chairman Lee and Members of the Senate Human Services Committee. I am David Boeck, a State employee and Special Assistant Attorney General for the Protection & Advocacy (P&A) Project. I appear in opposition to HB 1438.

I testified in support of this bill at the House Human Services Committee's hearing on HB 1438. At that time, I offered amendments to put the bill in harmony with the protection and advocacy laws.

The House Human Services Committee amendment to the bill did not resolve the problems I identified. For that reason, I appear today in opposition to the bill. I hope to clarify my position and make my testimony more persuasive to you.

My concern with the bill is limited to sections 13 and 14 on pages 12 and 13 of the First Engrossment of HB 1438. These sections would amend only the Century Code chapter on P&A, chapter 25-01.3.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) governs record-keeping activities of health plans, health care clearinghouses, and health care providers. See 42 U.S.C. § 1320d-1 (a). HIPAA does not apply to the record-keeping activities of P&A.

Federal protection and advocacy laws govern the record-keeping activities of protection and advocacy systems that serve the states, territories, the District of Columbia, and American Indian tribes. These laws are both narrower and broader than HIPAA. Federal protection and advocacy laws are narrower because they apply to the record-keeping activities only of protection and advocacy systems; they are broader because they cover more records than "individually identifiable health information."

As the federal HIPAA statute does not cover P&A's record-keeping activities, neither do the federal HIPAA privacy regulations. HB 1438 would amend the State P&A laws to adopt the style of federal HIPAA privacy regulations. Engrafting the HIPAA privacy regulations on the State protection and advocacy laws would be confusing, ineffective, and unwelcome.

Congress has not amended federal protection and advocacy laws to mirror the HIPAA privacy regulations. Protection and advocacy systems have different laws because they are much different from the health plans, health care clearinghouses, and health care providers covered by the HIPAA record-keeping laws.

Section 13 of the bill (page 12, lines 4 to 7) would cast two new definitions into state P&A law, "individually identifiable health information"

and "personal representative." These definitions would not improve State P&A laws and threaten conflict with federal P&A laws.

Under current federal and state protection and advocacy laws, P&A has an obligation to keep confidential all information about clients and protected persons, not just "individually identifiable health information." These obligations are part of well-established federal-state protection and advocacy laws. State and federal judicial decisions have already interpreted and enforced these laws.

Section 14 of the bill (page 12, lines 8 to 31, and page 13, lines 1 to 3) would amend one section of the North Dakota P&A laws. There is no convincing reason to tamper with this state law; it works very well as it is and HIPAA privacy regulations do not apply to P&A's record-keeping practices.

The North Dakota protection and advocacy laws will remain consistent with federal laws if the Legislature defeats HB 1438.

Attached to my testimony is a February 28 letter from Gary P. Gross, Senior Public Policy Counsel for the National Association of Protection & Advocacy Systems. Mr. Gross wrote about the NAPAS interpretation of the relevant federal laws. The position I present today is consistent with the NAPAS interpretation. Mr. Gross states, "Congress and the responsible federal agencies have created a comprehensive and exclusive scheme

regarding the operation of P&As, including their record keeping requirements."

Nonetheless, attached to my testimony is a proposed compromise amendment that would adopt some HIPAA terminology without compromising consistency with federal P&A law.

In place of HB 1438's current section 13, I propose replacing "consent" with "authorize" in another section of P&A law that is not covered in HB 1438. This section covers P&A authority and replacing "consent" with "authorize" will not interfere with current operation of the law.

Section 14 of HB 1438 would not interfere with current operation of the law if limited to replacing "consent" with "authorize" and replacing "release" with "disclose."

While we consider amendments to P&A law, I propose that we simplify the statutory language. Assistant Attorney General Michael Mullen has graciously included these changes in HB 1438. These changes substitute "disability" for "developmental disability and mental illness." The current language is both too broad and too narrow.

Current language is too broad because mental illness is usually not disabling and P&A serves only those whose mental illness is disabling. The law is too narrow because, under authority of federal law, P&A serves people who have disabilities that are neither developmental disabilities nor mental

illnesses. An example is a person who survives a car accident but who now has a disabling spinal cord injury or a disabling traumatic brain injury.

Thank you. I am happy to answer any questions you may have.

NAPAS National Association of Protection & Advocacy Systems

February 28, 2003

Teresa Larsen
Executive Director
Protection & Advocacy Project
400 East Boulevard Avenue
Suite 409
Bismarck, ND 58501-4071

Subject: State Application of Privacy Requirements in HIPAA to Protection and Advocacy Systems

Dear Ms. Larsen:

We understand that the North Dakota State Legislature is considering legislation that would impose new record keeping and confidentiality requirements on your agency. Those new requirements would be based on with those which are applicable to health care providers and other covered entities under the regulations implementing the federal Health Insurance Portability and Accountability Act (HIPAA). We believe that such legislation would be prohibited by existing Federal law, which comprehensively and exclusively governs the operation of all P&As nationwide.

[The following is provided for the benefit of others who may be reviewing this opinion: NAPAS is the voluntary membership organization for the Protection and Advocacy (P&A) System, the congressionally-mandated nationwide network of disability rights agencies. As a long-time contractor to the Department of Health and Human Services, NAPAS provides P&As with training and technical assistance, coordinates their activities, and renders advice on their statutory authority. It is in this capacity that NAPAS has developed an intimate familiarity with the interpretation of the federal laws governing the P&A System, and in which we are providing this opinion. For more information, see the annual report of the P&A System, which is available on-line at www.napas.org]

As you know, P&As were established in each state and U.S. territory under the Developmental Disabilities Assistance and Bill of Rights ("DD") Act of 1975 (which was replaced by the DD Act of 2000, codified at 42 U.S.C. 15001 et seq.). The DD Act authorizes P&As to investigate abuse and neglect of persons with developmental disabilities, and to provide these individuals with a full range of advocacy and legal services.

National Association of Protection & Advocacy Systems, Inc.
900 Second Street, NE, Suite 211
Washington, DC 20002
(202) 408-9514 FAX: (202) 408-9520 TTY: (202) 408-9521

The DD Act and its implementing regulations (at 45 CFR Part 1386) established a comprehensive federal scheme setting out authority for P&As and governing their operations. The statute and regulations, along with the administrative policies of the Department of Health and Human Services, which oversees the P&A System, set out detailed requirements concerning confidentiality of agency and client records and related record keeping requirements. The Federal Office of Management and Budget also has issued additional regulations that supplement these requirements and are applicable to P&As and other grantees of the federal government.

Indeed, the DD Act, at 42 U.S.C. 15043(a)(2)(K), provides that the "State shall not apply policies" that would burden P&A staff functions funded under the Act. More generally, the regulations implementing the Act provide on this point that "State law must not diminish the required authority of the Protection and Advocacy System." 42 CFR 1386.21(f).

Accordingly, Congress and the responsible federal agencies have created a comprehensive and exclusive scheme regarding the operation of P&As, including their record keeping requirements. Under constitutional principles of Supremacy, it would be improper for state authorities to impose additional administrative requirements, given this comprehensive statutory and regulatory scheme regarding P&A operations.

Please let me know if we can provide any further information on this matter.

Sincerely,

Gary P. Gross
Senior Public Policy Counsel

Proposed Amendments to House Bill No. 1438

Page 1, lines 1 and 2, remove "to create and enact a new subsection to section 25-01.3-01 of the North Dakota Century Code, relating to definitions;"

Page 1, line 5, after "23-16-09," insert "section 25-1.3-06," and remove "subsection 1 of"

Page 12, lines 4 through 7, after "section 13.", replace the remainder of the section with "**AMENDMENT**. The introductory paragraph that precedes subsections 1 through 13 of section 25-01.3-06 of the North Dakota Century Code is amended and reenacted as follows:

"25-01.3-06. **Authority of project**. Pursuant to rules adopted by the committee, the project, within the limits of legislative appropriations, shall provide advocacy and protective services for persons with ~~developmental~~ disabilities ~~and persons with mental illnesses~~. The rules adopted by the committee relating to the need for ~~the consent of~~ authorization from the client must balance the rights of persons with ~~developmental~~ disabilities ~~or mental illnesses~~ to privacy and to refuse services under section 25-01.3-11 with the committee's duties to protect the human and legal rights of persons eligible for services and to monitor facilities for compliance with federal and state laws and rules. The project may:"

Page 12, line 8, replace "Subsection 1 of section" with "Section"

Page 12, line 11, replace "from which" with "related to"

Page 12, line 12, remove "may be identified, including individually identifiable health information,"

Page 12, lines 20 and 21, replace "who may be identifiable from the information, or that individual's personal representative" with "a disability to whom the information relates"

Page 12, line 24, remove ", a health oversight agency,"

Page 12, line 25, after "to" insert "a health oversight agency or"

Page 13, line 2, after "when" overstrike "such", remove "a disclosure", and overstrike "is prohibited by"

Page 13, line 3, after "law" insert "prohibits that disclosure"

Page 13, after line 4, insert "2. Unless ordered by a court of competent jurisdiction, the name of a person who in good faith makes a report or complaint may not be ~~released or~~ disclosed by the committee or the project."

Renumber accordingly.

TESTIMONY OF THE OFFICE OF ATTORNEY GENERAL
ON HOUSE BILL 1438 REGARDING THE PRIVACY HEALTH INFORMATION

BEFORE
SENATE COMMITTEE ON HUMAN SERVICES
MARCH 3, 2003

MICHAEL J. MULLEN
ASSISTANT ATTORNEY GENERAL

Chairman Lee and Members of the Committee, I am pleased to be here on behalf of Attorney General Stenehjem, and on behalf of several departments and agencies, who asked me to present testimony explaining House Bill 1438, which clarifies the relationship between state law requiring the confidential treatment of health information, and the federal HIPAA privacy rule. Before I address the provisions of House Bill 1438, let me briefly outline the background and purpose of the federal HIPAA privacy rule.

Background on the HIPAA Rule for the Privacy of Health Information

The federal regulation entitled *Standards for Privacy of Individually Identifiable Health Information* (the Privacy Rule), which was promulgated by the Department of Health and Human Services (HHS), became effective on April 14, 2001. [The regulations are found at *45 CFR [Code of Federal Regulations] Parts 160 and 164.*] The Privacy Rule is the first comprehensive federal protection for the privacy of health information.

The privacy rule came about as a result of the Health Insurance Portability and Accountability Act [commonly called "HIPAA"], 29 U.S.C. §§ 1181 – 1191c (enacted in 1996), which established a number of rules to provide greater access to health insurance regardless of a person's health status. Title II, subtitle F sections 261-264 of HIPAA, 42 U.S.C. §§ 1320d -- 1320d-8, sets forth a program for "administrative

simplification," which requires all health care providers and insurers to establish uniform billing and coding systems in order to simplify and reduce the administrative costs of the health care system. Congress also recognized, however, that a uniform electronic billing system, which would necessarily include detailed information about the diagnosis and treatment received by individual patients, would also greatly increase the capacity for accidental or intentional disclosure of *individually identifiable* health information. Therefore, Congress required the Secretary of Health and Human Services to establish regulations to protect the privacy and security of health information.

On December 28, 2000, the final rules on the privacy of individually identifiable health information were published. The effective date of the privacy rules is April 14, 2001. In addition, under the rules, the *compliance date* for most organizations is two years following the effective date. Thus, doctors, dentists, hospitals, clinics, health insurance companies, and specified government health plans have until April 14, 2003, to bring their operations into compliance with the HIPAA privacy rules. (Small insurers, roughly those with an annual premium revenue of $5 million or less, have an additional year to come into compliance.)

Because of concern that the privacy rule had certain unintended consequences that could have impaired the treatment of patients and made practical compliance with the privacy rule difficult, the Secretary of Health and Human Services made several changes to the rule, which were published on August 14, 2002. And, as I mentioned, all covered entities (except small health plans) must be in compliance with the privacy rule by April 14 of this year.

The Purpose of House Bill 1438

The purpose of House Bill 1438 is to clarify North Dakota law and make it easier for government agencies to comply with the requirements of both the federal HIPAA privacy rule, and numerous sections of the Century Code that specify the conditions under which protected health information may be disclosed. The bill does not reduce the privacy protection that is given to health information. The bill also does not place unreasonable restrictions on the use of this information -- to the extent disclosure is needed to permit state agencies to carry out their responsibilities under the law.

Let me now turn to the substantive provisions of House Bill 1438.

Section-By-Section Analysis

Section 1 amends section 23-01.3-02 to permit a "privacy board" as well as an institutional review board to authorize a research project. In addition, the section clarifies a reference to "protected health information" in place of an incorrect reference to "public health information."

Section 2 amends section 23-07-02.1 relating to reports of human immunodeficiency virus infection by replacing the term "release" with the term "disclosure" because disclosure is a defined term and is used throughout the HIPAA privacy rule. Section 2 also provides that in addition to disclosure to a health care provider providing "direct care," disclosure may be made "as otherwise provided by law."

Section 3 amends section 23-07-02.2, which relates to the confidentiality of reports regarding human immunodeficiency virus cases. Again, the term "released" is

replaced by the term "disclosed." In addition the term "epidemiologic" is replaced by "epidemiological."

Section 4 amends subsections 6, 7, and 8 of section 23-07.5-01 to distinguish between "informed consent for testing" for the human immunodeficiency virus and legal permission for "disclosure" of the test results. In addition, the section is clarified to provide that the test is for the presence of "the human immunodeficiency virus" and not just for "an antibody" to that virus. Third, the definition of "personal physician" is clarified to more clearly cover situations in which the patient has not designated a personal physician.

Section 5 amends section 23-07.5-02 relating to the situations in which a test for the human immunodeficiency virus may be conducted without the informed consent of the individual who has exposed other persons. Subdivision a of subsection 2 is clarified to state that the "consent" is informed consent for "testing," not an "authorization" for disclosure of the test results.

Third, subdivision b of subsection 2 is amended to provide that the "form" given to the subject who will be tested must contain a statement explaining that the test results may be disclosed as authorized by law. This will permit disclosure as authorized by the federal HIPAA privacy rule.

Subdivision c of subsection 2 is amended by deleting several items that must be contained in a consent form because these items are specified in some detail in the "authorization form" that is required under the federal HIPAA privacy rule.

Subdivision b of subsection 3 is amended to clarify which person is to be tested for the presence of human immunodeficiency virus.

Subdivision d of subsection 3 is amended to clarify that the patient may always obtain the test results (which is required by the federal HIPAA privacy rule) and to specify that the test results may be disclosed to others as authorized by law. In addition, subdivision d is amended by deleting the "buried" criminal penalty for person who discloses the identity of a patient in violation of various subsections of this section. A criminal penalty for disclosure of protected health information with intent to disclose the "test subject" is set forth in section 23-07.5-08, the primary criminal section of this chapter, which is amended under section 9 of this bill.

Subdivision c of subsection 4 is amended to include not only the provider but also a Good Samaritan who renders aid and is exposed to blood or body tissue.

Subdivision d of subsection 4 is amended to make clear that the provider may receive a copy of their own test results and that the results may be disclosed, "as authorized by law." Finally, this subdivision is amended to clarify that the patient (who potentially has been exposed) may not disclose the "provider's identity" i.e., the identity of the provider who has been tested.

Subsection 5 is clarified to address situations in which a patient has died and the facility was not aware of a possible exposure to the human immunodeficiency virus, or it was not reasonably possible for the facility to conduct a test and provide the results of the test to any physician providing care, an exposed emergency medical service provider, other health care provider, or a Good Samaritan who rendered aid to the deceased person.

Subsection 6 is clarified to provide that any test done pursuant to subsection 3, 4, or 5 must be conducted in a "reasonably expedient manner," not the "most" expedient manner possible (which is potentially contestable).

Subsection 7 is clarified to refer to "an exposed person" who may request a test of a "source person," the individual who has caused a "significant exposure" to the "exposed person." Under current law, the first test may be requested within ten days after exposure and a second test may be requested not earlier than five months, nor later than six months after significant exposure. The amendment provides that an exposed person may request two tests. "[E]ach test may be requested as soon as practicable, consistent with the recommendations of the United States public health service, but in no event later than nine months after a significant exposure." This will provide more flexibility regarding the timing of these tests: more time to request the first test; and, a larger time frame in which to request the second test.

Subsection 8 of section 5, contains a clarifying form and style amendment.

Section 6 amends subsection 1 of section 23-07.5-04 to clarify that the section applies to informed consent for testing, i.e., the legal permission to test an individual, but does not address disclosure of the test results, which requires an "authorization" meeting the requirements of the HIPAA privacy rule. Subsection 1 is also amended to provide that testing may be conducted only pursuant to informed consent, "unless testing is otherwise authorized by law."

Section 7 amends section 23-07.5-06 and clarifies that a person to whom the results of a test have been disclosed "may not disclose the test results except as authorized by law," which is a reference to disclosure authorized under the federal

HIPAA privacy rule. A reference to section 23-05.5-05, which is repealed by this bill, is deleted.

Section 8 amends section 23-07.5-07, which relates to civil liability for unauthorized disclosure, is amended by deleting references two sections of the Century Code that are repealed, and by repealing an unnecessary sentence regarding the burden of proof – a preponderance of evidence – which is generally applicable in a civil action.

Section 9 amends section 23-07.5-08, which provides a criminal penalty for unlawful disclosure of individually identifiable information regarding the results of a test for HIV. The amended section now applies to a person who "knowingly" discloses the results of a test in violation of the chapter, and instead of referring to the harm to the subject, applies if the offense is committed "with intent to disclose the identity of the individual who was tested."

Section 10 amends subsection 3 of section 23-07.7-02 by removing a reference to section 23-07.5-03, which is repealed by section 25 of this bill.

Section 11 amends 23-12-14 relating to copies of health care records. Subsection 1 is amended to refer to a "health care provider" rather than a "medical provider" since that is the term used in the federal HIPAA privacy rule. The second sentence of subsection 1 is removed because it is unnecessary. Subdivision a of subsection 1 is amended to refer to "health care" rerecords rather than "medical rerecords," the terminology used in the federal privacy rule.

Subdivision b of subsection 1, relating to the cost of a copy of health care records provided to an individual (for a purpose other than disclosure to another provider for

treatment), is repealed. The HIPAA privacy rule contains detailed limitations on the charges for providing a copy of health care records to a patient.

Subsection 2 (a), which provides that an authorization to disclose an individual's health care records is limited to the time specified, but no longer than three years, is repealed. The federal HIPAA privacy rule does not impose any time limit on the period during which an authorization is legally valid. In some cases, an individual may authorize the disclosure of their individual information regarding diabetes, asthma, or cancer to a semi-permanent research database. Since an individual may revoke their consent at any time, and since the legislative history of this provision shows that the current three-year time limit was intended to extend the period of an authorization, the subdivision is repealed.

Subsection 2(b) authorizing a patient to revoke their authorization at any time also is repealed; this right is clearly established under the federal privacy rule.

Subsection 3, which provides that a health care provider may disclose a patient's health care records to another provider "during the time necessary to complete a patient's course of treatment" and conclude all medical and payment transactions related to the individual, is repealed. Under the federal HIPAA privacy rule, a health care provider and a health plan may use protected health information for treatment or payment without the consent of the patient. Therefore, this subsection is unnecessary.

Subsection 4 provides that it is "not a prohibited practice" for a health insurance company with participating provider agreement to require that subscribers or members are responsible for providing the insurer with copies of health care records used for claims processing when an individual uses a nonparticipating provider. This provision,

which relates to insurance law, is transferred to section 26.1-04-03 by section 16 of this bill.

Section 12 amends section 23-16-09, which relates to individually identifiable health information obtained by the Department of Health in the course of a survey or inspection of a hospital, nursing home, or similar facility. This section, which was enacted in 1947, permits disclosure of information to a social service agency relating to a newborn without an authorization from the newborn's parents. Such a broad disclosure is not permitted under the federal privacy rule – which preempts any provision of state law that is contrary to the rule's requirements (unless the state law is "more stringent" with respect to the disclosure of protected health information).

Section 13, which amends section 25-01.3-01, adds a new definition of individually identifiable health information and personal representative (adopted from the federal HIPAA privacy regulation) to clarify the class of information and the persons to whom information about an individual with a developmental disability may be used or disclosed.

Section 14, amends subsection 1 of section 25-01.3-10, to clarify the legal authority to disclose information about an individual with a developmental disability (or as defined by federal law, a person with a "disability"). Specifically, the terminology is amended to refer to "individually identifiable health information," an "authorization" for "disclosure," and "personal representative," which are the terms used in the federal HIPAA privacy rule. This subsection is also amended to permit disclosure as otherwise authorized by this chapter, or any other state or federal law. (Subdivision c, of subsection 10, section 25-01.3-10.)

Section 15, amends section 25-16-07, relating to the treatment records of a resident of the developmental center at Westwood Park in Grafton. The terminology is amended to conform to the federal privacy rule; specifically, to permit disclosure for "treatment, payment, or health care operations," and "to arrange, facilitate, or coordinate service" to a person with a disability.

Section 16 amends section 26.1-04-03 by adding language that it is not a prohibited practice for health insurance company with a participating provider agreement to require that a subscriber or member using a nonparticipating provider be responsible for providing the insurer with a copy of the health care records used for claims processing. This amendment simply moves virtually identical language from section 23-12-14 to the insurance code.

Section 17 amends section 28-01-46.1, which relates to the disclosure of information among parties in a malpractice claim against health care provider in order to facilitate the resolution of these claims. Specifically, the section is amended to use the term "authorization," which is the term used in the federal privacy rule for disclosure of health information not related to treatment payment or health care operations. The amendment also provides that if the party commencing the action fails to provide appropriate authorizations at the time the action is commenced, the health care provider may use a subpoena or other means to obtain the records, and may seek costs if required to do so.

Section 18, amends subsection 6 of section 37-18-11, relating to the disclosure of protected health information by the North Dakota Veterans Home. The amendment substitutes the term "disclosed" for "release" and substitutes "resident" for "veteran"

because spouses of a veteran are now permitted to become residents at the Veterans Home. In addition, subsection 6 is amended to permit the Veterans Home to "use and disclose" "protected health information" for treatment, payment, or health care operations (the privacy rule terminology) without the consent of a resident. This is consistent with the federal HIPAA privacy rule and the law applicable to other nursing homes in North Dakota. The section also permits disclosure as "otherwise authorized by law."

Section 19 amends subsection 9 section 37-18-11 to make the disclosure of protected health information about a resident of the Veterans Home to a member of the Legislative Assembly subject to the limitations of any other law. This might apply with respect to the disclosure of information relating to treatment for substance abuse. See 42 C.F.R. part 2. This is just a technical amendment to make it clear that if a more restrictive law applies to a certain class of health information, that limitation applies with respect to disclosure to a member of the Legislative Assembly.

Section 20 amends subsection 4 of section 43-15-01 relating to the definition of confidential information in the law establishing the Board of Pharmacy. The amendment references the term "individually identifiable health information" which is a key term in the HIPAA privacy rule. The amendment also deletes language describing the purposes for which protected health information may be disclosed because the permitted use and disclosure of protected health information is set forth in the operational sections of the chapter 43-15, the Board's charter.

Section 21, which amends subdivision n of subsection 1 of section 43-15-10, clarifies the law with respect to prohibited disclosure of protected health information

('confidential information") by a pharmacist (or pharmacy). Specifically, the amendment uses the term "discloses" which is the term used in the privacy rule rather than using the indefinite to "an unauthorized person," and, disclosure is permitted "as authorized by law."

Section 22, amends section 43-47-09, which relates to disclosure of information obtained by a counselor rendering counseling services, to provide a broader reference. Currently, the only exception requires disclosure under chapter 50-25.1 (relating to child abuse); the amendment permits disclosure as authorized by law. The practice of professional counseling includes mental, family therapy, school guidance, and vocational counselors.

Section 23 amends subsection 1 of section 44-04-18.1 which is a section of the open records law relating to records of a public employee's medical treatment or use of an employee assistance program, to provide that these records are "confidential," except "as otherwise authorized by law." (Thus, permitting disclose for treatment and payment.) This section also incorporates the HIPAA privacy ruie terminology by replacing "release" with "used or disclosed," and replacing "consent" with "authorization, which is the term used for a disclosure of protected health information for a reason other than "treatment, payment, or health care operations."

Section 24 amends section 50-19-10, which relates to disclosure of records of a maternity home. The amendment provides that "except as otherwise provided by law disclosure may be made only in a judicial or administrative proceeding in response to an order of the court or an administrative tribunal, or for a law enforcement purpose to a law enforcement officer, or to a health oversight agency for oversight activities

authorized by law." General authority to disclose information to agencies serving the interests of a patient or a newborn infant is repealed because it is inconsistent with the federal privacy rule, which prohibits such a disclosure unless authorized by the parents of the infant.

Section 25 repeals three sections of the Century Code: sections 23-01.3-03, 23-07.5-03, and 23-07.5-05.

Section 23-01.3-03 is repealed because the HIPAA privacy rule provides an individual with a comprehensive right to obtain copies of their own medical records. See 45 C.F.R. 164.502.

Section 23-07.5-03, which relates to consent for disclosure of HIV test results, is repealed because the HIPAA privacy rule contains detailed requirements for an "authorization," i.e., legal permission, to disclose protected health information, including the results of a test for HIV.

Section 23-07.5-05, relating to the disclosure of HIV test results, is repealed because the HIPAA privacy rule contains detailed requirements and limitations regarding the disclosure of any protected health information without the individual's specific "authorization."

Section 26 provides that this bill is an emergency measure.

Section 27 provides that the bill is effective April 14, 2003, which is the date on which all covered providers and health plans (except "small' health plans) must be in compliance with the HIPAA privacy rule.

Chairman Lee, thank you for providing me an opportunity to discuss the provisions of House Bill 1438, which clarifies the relationship between state law

requiring the confidential treatment of health information, and the federal HIPAA privacy rule. I will be pleased to answer any questions you or other members of the committee have regarding the bill, which we believe aligns North Dakota law with the federal HIPAA privacy rule, and in turn will assist providers, payers, and government agencies in achieving compliance with the privacy rule.

# # #

AMENDMENT TO HB ~~2059~~ 1438 **03-03-03**

SECTION 2. A new section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

Prohibited disclosures. A pharmacist and any employee of a pharmacy may not disclose to any third person any information regarding the prescriptive practices of a practitioner which identifies the practitioner. This section does not limit disclosures within the pharmacy; between a pharmacist or an employee of a pharmacy and the practitioner or the practitioner's office staff; consented to by the practitioner; and disclosures otherwise required by law.

Page 2, line 17, after "practitioner" insert "unless the practitioner consents to disclosure of the information in writing"

Page 2, line 19, delete "consented to by the practioner;"

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL 1438

Page 2, after line 3, insert:

SECTION 2. AMENDMENT. Subsection 1 of section 23-07-01.1 of the North Dakota Century Code is amended and reenacted as follows:

1. ~~All physicians and other medical professionals~~ A physician or other health care provider may report immediately to the department of transportation in writing, the name, date of birth, and address of every person fourteen years of age or over coming before them for examination, attendance, care, or treatment ~~when~~ if there is reasonable cause to believe that ~~such~~ the person due to physical or mental reason is incapable of safely operating a motor vehicle or diagnosed as a case of a disorder defined as characterized by lapses of consciousness, gross physical or mental impairments, and such a report is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.

Page 13, after line 4, insert:

"2. Unless ordered by a court of competent jurisdiction, the name of a person who in good faith makes a report or complaint may not be ~~released or~~ disclosed by the committee or the project."

On page 18 after line 6, insert:

"**SECTION 24.** A new section 44-04-18.18 of the North Dakota of the North Dakota Century Code is created and enacted as follows:

44-04-18.18. Business Associate – Duty to protect information.

1. As used in this section:

'Business associate' has the meaning set forth in title 45, Code of Federal Regulations, part 160,section 103; and

'Public entity' has the meaning set forth in section 44-04-17.1(12).

2. If a public entity is acting as a business associate of another public entity, the entity acting as a business associate shall comply with all of the requirements applicable to a business associate under title 45, Code of Federal Regulations, part 164, section 504, subsection e, paragraph 2."

Renumber accordingly

The basis for the "BA" amendment is the authority set forth regarding Business Associate Contracts in 45 CFR § 164.504(e)(3)(i)(B), which provides:
The covered entity may comply with paragraph (e) of this section, 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.

If section 44-04-18.18 is enacted, government-to-government BA agreements may not be needed, or can be accomplished with a 1-page note specifying the authority of the BA to use and disclose PHI; the other "boilerplate" BA requirements will not be required.

2/21/2003 10:14 AM

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March 5, 2003

The Honorable Judy Lee
Chairman
Senate Human Services Committee
North Dakota Legislative Assembly
Bismarck North Dakota 58505

Re: HB 1438, and Protection and Advocacy Authority

Dear Senator Lee:

I would like to comment on the testimony and amendments proposed by the Protection & Advocacy Project, particularly the letter which the Project solicited from the National Association of Protection & Advocacy Systems.

The letter from the National Association states "we understand" that HB 1438 "would impose new record keeping and confidentiality requirements on your [the North Dakota P&A Project] agency." This is incorrect; the changes in terminology [to conform to] the use of terms contained in the federal HIPAA privacy rule are intended to clarify sections of the North Dakota Century Code applicable to the Protection and Advocacy Project. These changes neither impose any additional requirements on P&A nor diminish the Project's authority.

The letter further states: "[federal laws and regulations] set out detailed requirements concerning confidentiality of agency and client records and related record keeping requirements," and continues "that the [quoting federal law] 'State shall not apply policies' that would <u>burden P&A staff functions</u> funded under the [federal] Act. ... [And that] the regulations implementing the Act provide on this point that 'State law must not <u>diminish the required authority</u> of the Protection and Advocacy System.' 42 C.F.R. 1386.21(f)." (Emphasis added.)

Again, nothing in HB 1438, would impose any burden on P&A staff functions, and nothing in HB 1438 would "diminish" the authority of the Protection and Advocacy Project; and, nothing in P&A's testimony specifically identifies any such effect.

Finally, the P&A System letter argues that Congress "created a comprehensive and exclusive scheme regarding the operation of P&As," and that "[u]nder the constitutional principles of Supremacy, it would be improper for state authorities to impose additional administrative requirements..." First, as noted above, nothing in HB 1438 would impose any additional administrative requirements on the P&A Project. Second, the letter misstates the nature of the federal requirements regarding a state protection and advocacy program. Congress did not create an "exclusive" federal scheme for regulating these programs, such as the scheme under which the Federal Aviation Administration provides direct regulation of commercial aviation. Rather, Congress established certain general requirements for these projects, but permitted the states to enact laws that would qualify these programs for federal grants. Nothing in HB1438 conflicts with federal law.

The testimony of P&A primarily relates to the use of terminology. P&A suggests that the use of terms regarding health information, such as "individually identifiable health information," which will be used by every hospital and nursing home and virtually every medical clinic, optometrist, pharmacist, and other health care provider under the HIPAA privacy rule "would be confusing" for the P&A Project. On the contrary, most of the patients and residents for whom the Project provides protection will be treated by providers who will use these terms. [The confusion will more likely come about if P&A does not use the same terminology used by the health care providers involved with P&A's clients.]

P&A, in its testimony, also suggested that there might be possible confusion regarding the use of the term "personal representative" because that term is also used in the probate code. This is surprising, because if this is a problem, it will be a problem in virtually all of the many states that have adopted the Uniform Probate Code. If a person who is a personal representative as defined under the HIPAA privacy rule requests health information relating to the individual they represent in that capacity, a hospital, nursing home, residential treatment center, group home, etc., is required to disclose that information to this representative. And alternatively, if a person who is a "personal representative" as defined in N.D.C.C. § 30.1-01-06(40) (for a person with a "disability" for whom a protective order as described in N.D.C.C. § 30.1-29-01 has been issued), the health care facility will disclose identifiable information as authorized and required under title 30.1, the Uniform Probate Code.

P&A also suggests that confusion might arise because it "has an obligation to keep confidential all information about clients and protected persons, not just "individually identifiable health information." The committee is invited to study the clause of the bill in which this terminology is used:

> All information from which an individual with a disability may be identified, including individually identifiable health information, that is in the possession of the committee, project, or any advocate is confidential and is not subject to disclosure except...

Engrossed House Bill 1438, Page 12, lines 10-15.

It is difficult to understand how a sentence stating: "All information from which an individual with a disability may be identified... is confidential," can be characterized as ambiguous, or as lessening privacy protection.

The Committee should note that the Protection & Advocacy Project proposed an amendment to subsection 1 of section 25-01.3-10 (section 14 of Engrossed HB 1438, p. 12, lines 24 and 25): instead of permitting the disclosure of confidential information from P&A to a "health oversight agency," such a disclosure would be made only "at the discretion of the [protection and advocacy] committee," which was not mentioned in Mr. Boeck's testimony. This change is not required by the HIPAA privacy rule and may be of concern to the Department of Health.

Finally, amendments suggested by P&A were incorporated into HB 1438. In addition, I met with or sent e-mails to Mr. Boeck regarding this legislation on ten occasions during January and February.

Please let me know if you have any further questions regarding this matter.

Sincerely,

Michael J. Mullen
Assistant Attorney General

vkk
Enclosure
cc: Sandi Tabor
Darleen Bartz

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Testimony before the Senate Human Services Committee
HB 1438
Wednesday, March 12, 2003
Galen Jordre – Executive Vice President

On behalf of the North Dakota Pharmaceutical Association (NDPhA) an organization that represents the 700 pharmacists practicing in the state I want to indicate our opposition to the amendments proposed for HB 1438.

One way that physician information is disclosed is through software vendors. When providing price updates and other information to the pharmacies, the vendors will obtain non-patient specific information about prescription use that includes the name of the physician. The data is aggregated on a national basis to produce sales reports and studies of prescription trends. Drug manufacturers are big purchasers of this information and use it extensively for their marketing efforts. The pharmacy will receive a small payment from the software vendor or reduction in maintenance contract costs in return for this service. Many of our pharmacies participate in this arrangement and many do not. We do not take a position on this practice but our concern is that even if local pharmacies are prohibited from disclosing this information it will still be available through benefits managers and other sources. In other words, we will increase the cost to pharmacies in the state and the flow of information will continue.

We feel that the way the amendment is written, it would interfere with many legitimate practices where the pharmacy discloses physician prescribing information. There are different ways that these disclosures are made. The most obvious example is that when a pharmacist transmits a third party prescription to a claims processor for payment. The name of the physician or a physician identifier is transmitted along with the prescription data. As this bill is written the pharmacy would not be able to transmit the claim. These types of systems include the State Medicaid program and BlueCross BlueShield of North Dakota. Other disclosures include those to patients or patient representatives, disclosure to other health care facilities or health care practitioners involved in the patient care, and to regulatory bodies as part of investigations or inspections.

I have included amendments that would protect pharmacies for the transmission of claims for payment and to allow the Board of Pharmacy and Board of Medicine to obtain physician data as a part of investigations.

We ask that you consider these amendments if you move this legislation forward.

AMENDMENTS TO HB 1438

Add new sections to chapter 43-15 of the North Dakota century Code is created and enacted as follows:

SECTION 1.

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

SECTION 2.

Prohibited disclosures. A pharmacists and any employee of a pharmacy may not disclose to any third person any information regarding the prescriptive practices of a practitioner that identifies the practitioner. This section does not limit the following:

1. disclosures within the pharmacy;
2. disclosures to the patient or the patient's representative;
3. disclosures between a pharmacist or an employee of a pharmacy and the practitioner or the practitioner's office staff;
4. disclosure made to other health care practitioners or facilities that are involved in a patient's care;
5. disclosures to the North Dakota State Board of Pharmacy or to the North Dakota State Board of Medical Examiners as a part of an inspection or investigation;
6. disclosures made by a pharmacy necessary to receive payment for provision of prescription medications;
7. disclosures consented to by the practitioner; and
8. disclosures otherwise required by law.

Memorandum - Protection & Advocacy Project

TO: Members, Senate Human Services Committee
FROM: David Boëck
DATE: March 12, 2003
SUBJECT: HB 1438

I have a new proposal for a Protection & Advocacy amendment to HB 1438. See attached. I believe this will meet with your approval.

Background

Testimony on March 3 revealed some of the history behind HB 1438. As I understand it, a "HIPAA coalition" met over the course of a year. Currently, the HIPAA coalition has an emailing list of 192 people.

The coalition appears to include primarily health care industry participants. The State Department of Human Services and the State Department of Health participate in the coalition. There may be other participants from outside the health care industry.

The coalition did not invite the Protection & Advocacy Project to join the coalition or to participate in its work. I suspect the coalition focused on planning for how the health industry participants would comply with HIPAA. I imagine the group worked to help participants develop internal policies, practices, and forms.

It appears the coalition did not include any participants appointed to represent health care consumers. Apparently, no coalition participant was concerned primarily with protecting the privacy of patients' medical records. Apparently, all participants have email addresses.

When the coalition undertook to review the Century Code, its identified goal was to establish HIPAA compliance while disrupting state law as little as possible. At this point, the coalition should have consulted patient advocates and individuals whose primary concern was the privacy of their own medical records. The coalition's Century Code recommendations are weaker because of this omission.

Uniformity

I have quickly identified several government entities that handle individual medical records but that are left out of the push for uniformity. That is, their laws were not HIPAA-ized. These include

Senate Human Services Committee
HB 1438
March 12, 2003

1. Law enforcement, which frequently receives individual medical information when responding to accidents, covering violent incidents, and investigating crime reports. These are
   - Highway Patrol
   - Sheriffs
   - Police
   - Bureau of Criminal Investigation
   - Attorney General
2. The Attorney General, who also receives individual medical information when processing various claims against the state, such as (a) people injured by state negligence (icy walkways on state property, ...), (b) people discriminated against by the state on account of disability, (c) people injured by exposure to hazardous substances that belong to the state or are regulated by the state
2. State Radio, which handles medical emergency communications
3. Tax Department, which receives itemized deductions that include information about taxpayers' medical care
4. Insurance Department, which investigates complaints (involving personal medical information) against health insurers, life insurers, accident insurers, disability insurers, and long term care insurers. The Insurance Department also receives individual medical information when conducting audits of regulated insurance companies.
5. CHAND, which processes applications, claims, and complaints for which it receives individual medical information
6. Numerous professional boards, which receive medical information about some applicants (especially applicants with disabilities) and regulated professionals. When investigating complaints against a professional for the care of a patient, these boards receive individual medical information about the patient. These include boards that regulate
   - Nurses
   - Occupational Therapists
   - Physical Therapists
   - Speech Pathologists
   - Social Workers
   - Counselors
   - Attorneys
7. City and County Health Inspectors
8. County Coroners
9. Courts

These omissions suggest the need for an interim study.

Alternative "A" Proposed Amendments

This part of the letter briefly introduces Alternative "A" proposed amendments. I have previously presented Alternative "B" to the Committee.

Section 13

HB 1438, § 13, still contains an error. "Personal representative" is not defined at 45 C.F.R. § 160.103. It appears that HIPAA privacy regulations do not define "personal representative."

The regulations establish "standards" for personal representatives at 45 C.F.R. § 164.502 (g). It is possible to construct a definition of personal representative from the standards regulation. A draft definition appears in my Alternative "A" proposed amendments.

A decision to adopt the entire federal "standards" regulation would change the substantive law that governs P&A. P&A is not a HIPAA "covered entity" and the coalition intended that HB 1438 would not change P&A law. Consequently, it was necessary to draft a definition of personal representative.

Two other HIPAA definitions apply to P&A, "health oversight agency" and "law enforcement official." P&A is not a "covered entity" but P&A is a HIPAA health oversight agency and P&A employees are HIPAA law enforcement officials. Including these definitions in HB 1438 will clarify their use.

New Section

I am offering a new section to HB 1438. This amendment appears in the second attachment to my testimony. This is a terminology amendment. I believe AAG M. Mullen accepts this proposal.

Section 14

a. In this proposed change, I am offering improved language. For example, AAG M. Mullen and I agreed to replace "documents, records, information, memoranda, reports, complaints, or written or nonwritten communication" with "information." At the end of paragraph (1)(d), I substituted active voice for passive voice.

b. Section 14 would narrow P&A's obligation to keep information confidential. All of P&A's information about persons with disabilities is

confidential. Engrossed HB 1438 would cancel the confidential nature of this information if a person with a disability were not identifiable from the information.

All parts of each P&A file about an individual are confidential. If the terms of engrossed HB 1438 applied, a P&A employee would decide whether a person with a disability would be identifiable from the information. If the P&A employee were unable to imagine some possibility, confidential information might be disclosed in error.

The provision in engrossed HB 1438 is a provision crafted to cover individually identifiable health information. When applied to other confidential information, it does not fit. P&A information must remain confidential regardless of whether the person with a disability might be identifiable from it.

c. "Personal representative" has meaning for individually identifiable health information. It is not relevant to the other categories of information to which this language would apply here. It is not necessary to repeat the personal representative concept here.

d. Engrossed HB 1438 adds "health oversight agency" to the law. Currently, health oversight agencies are among the other legally constituted boards or agencies that serve the interests of a person with a disability. P&A exercises discretion over whether to disclose specific confidential information and to which agencies it makes disclosure.

HB 1438 inserts "health oversight agency" to make it mandatory that P&A disclose information to every health oversight agency. This is not merely a matter of terminology. P&A must exercise its discretion to serve the interests of the person with a disability. Engrossed HB 1438 would defeat that obligation. This change would diminish P&A authority.

I would be happy to provide any additional information you request. Thank you.

Protection & Advocacy Project
Proposed Alternative A

Proposed Amendments to Engrossed House Bill No. 1438

Page 1, lines 1 and 2, replace the second "a" with "four" and replace "subsection" with "subsections"

Page 1, line 5, after "23-16-09," insert "section 25-1.3-06," and remove "subsection 1 of"

Page 12, line 4, replace "A" with "Four" and replace "subsection" with "subsections"

Page 12, line 5, replace "is" with "are"

Page 12, lines 5 and 6, replace

"'Individually identifiable health information' and 'personal representative' have the meaning set forth in title 45, Code of Federal Regulations, part 160, section 103."

with

"'Health oversight agency' has the meaning assigned to it in title 45, Code of Federal Regulations, part 164, section 501. The project is a health oversight agency.

"'Individually identifiable health information' has the meaning assigned to it in title 45, Code of Federal Regulations, part 160, section 103. The project has authority to receive, copy, and keep individually identifiable health information.

"'Law enforcement official' has the meaning assigned to it in title 45, Code of Federal Regulations, part 164, section 501. The project's employees are law enforcement officials.

"'Personal representative' means a person with legal authority to make health care decisions on behalf of another person. A personal representative's authority over personal health information is coextensive with the personal representative's authority to make health care decisions."

Page 12, after line 7, insert

"Section 14. **AMENDMENT**. The introductory paragraph that precedes subsections 1 through 13 of section 25-01.3-06 of the North Dakota Century Code is amended and reenacted as follows:

"25-01.3-06. **Authority of project**. Pursuant to rules adopted by the committee, the project, within the limits of legislative appropriations, shall provide advocacy and protective services for persons with ~~developmental~~ disabilities ~~and persons with mental illnesses~~. The rules adopted by the committee relating to the need for ~~the consent of~~ authorization from the client must balance the rights of persons with ~~developmental~~ disabilities ~~or mental illnesses~~ to privacy and to refuse services under section 25-01.3-11 with the committee's duties to protect the human and legal rights of persons eligible for services and to monitor facilities for compliance with federal and state laws and rules. The project may:"

Page 12, line 8, replace "Subsection 1 of section" with "Section"

Page 12, line 11, replace "from which" with "related to"

Page 12, line 12, remove "may be identified, including individually identifiable health information,"

Page 12, lines 20 and 21, replace "who may be identifiable from the information, or that individual's personal representative" with "a disability to whom the information relates"

Page 12, line 24, remove ", a health oversight agency,"

Page 12, line 25, after "to" insert "a health oversight agency or"

Page 13, line 2, after "when" overstrike "such", remove "a disclosure", and overstrike "is prohibited by"

Page 13, line 3, after "law" insert "prohibits that disclosure"

Page 13, after line 4, insert "2. Unless ordered by a court of competent jurisdiction, the name of a person who in good faith makes a report or complaint may not be ~~released or~~ disclosed by the committee or the project."

Renumber accordingly.

Prepared by Office of Attorney General (MJM)
March 17, 2003

SUMMARY OF AMENDMENTS TO HB 1438

1. The first amendment (which adds a new section 2 to the bill on page 2 after line 3), amends subsection 1 of section 23-07-01.1 by adding to current law, which permits a physician or other health care provider to report to the Department of Transportation, if the physician (or other provider) has --

> "reasonable cause to believe that the individual due to physical or mental reason is incapable of safely operating a motor vehicle or [is] diagnosed as a case of a disorder defined as characterized by lapses of consciousness, gross physical or mental impairments" --

New language from the federal HIPAA privacy rule --

> "and the report is necessary to prevent or lessen a serious and imminent threat to the health or safety of the individual or public."

The difference between North Dakota law and the federal privacy rule was noted in a report comparing North Dakota law to HIPAA, but initially was not included in the omnibus HIPAA bill, HB 1438. After further review, it was determined that all of the other differences between North Dakota law and the federal privacy rule noted in a "Summary of Differences" are amended to conform to the language of North Dakota law to the privacy rule.

Therefore, to avoid the necessity of going back and forth -- reading North Dakota law and then the privacy rule, and possibly requiring a physician to consult a with an attorney whenever the physician believed a report might be appropriate, this amendment has been added to the bill.

In the great run of cases, it will not change the outcome. The North Dakota Medical Association and the Department of Transportation reviewed the amendment, and concurred with this recommendation.

It should be noted that, under subsection (4) of the section we are amending (§ 23-07-01.1), a physician who makes a report, or in good faith fails to make a report, is immune from liability.

2. Page 6, line 22 -- This is merely a style and form change -- -- so the phrase as amended would read "*any other person* as authorized by law."

3. On page 8 and 9 there are technical and conforming amendments relating to sections of the Century Code regarding the procedures for testing a person for the presence of HIV and reporting the results of such a test. Another bill, HB 1221, amends similar sections of the Code to facilitate testing of an individual who may have exposed a law enforcement officer to HIV. The only effect of these amendments is to match up the terminology in HB 1438 and HB 1221.
For example, on page 8, line 31 "source person" is changed to "test subject."

4. On page 12, line 7, an amendment inserts a reference to the correct section of the privacy rule. (Some sections of the privacy rule were amended in August 2002 and in February of this year.)

5. On page 12, after line 3, section 25-01.3-10 is amended by removing "released or" -- -- so that the section uses only the term "disclosed," which is a defined term under the privacy rule. (Similar changes in terminology -- using terms used in the privacy rule, are made in other sections of HB 1438.)

6. The final amendment (which is inserted on page 18, after line 6) adds a new section 25 to the bill. This section specifies that if a government agency is acting as a "business associate" of another government agency, the "business associate" must comply with all the requirements applicable to a business associate under the HIPAA privacy rule.

Under the privacy rule, a covered entity includes a "health plan" such as Medicaid, and a "covered provider" includes an entity such as a human service center or a local public health district that submits claims in an electronic form. If a "covered entity" has another agency perform services "on their behalf," -- such as the office of Attorney General, with respect to legal services, or the Information Technology Department, with respect to the storage and transmission of claims information, those agencies are a business associate of the covered entity.

Under the privacy rule, a covered entity must enter into a boilerplate contract, generally five or six pages long, specifying all the limitations and duties of the business associate with respect to their use and disclosure of protected health information. But, the rule also provides, that if a government agency is required by law to adhere to these requirements, a full-fledged contract is not required.

This amendment will save paperwork and simplify *business associate* relationships among government agencies. A simple, 1-page Memorandum or letter specifying the limitations and duties of the agency performing services is all that will be required.

# # #

3/11

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL 1438

Page 2, after line 3, insert:

SECTION 2. AMENDMENT. Subsection 1 of section 23-07-01.1 of the North Dakota Century Code is amended and reenacted as follows:

1. ~~All physicians and other medical professionals~~ A physician or other health care provider may report immediately to the department of transportation in writing, the name, date of birth, and address of every person fourteen years of age or over coming before them for examination, attendance, care, or treatment ~~when~~ if there is reasonable cause to believe that ~~such~~ the person due to physical or mental reason is incapable of safely operating a motor vehicle or diagnosed as a case of a disorder-defined as characterized by lapses of consciousness, gross physical or mental impairments, and such a report is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.

Page 6, line 22, after "and" insert "any other person"

Page 8, line 26, replace "person" with ""individual" and replace "source individual" with "test subject"

Page 8, line 31, replace "source person" with ""test subject"

Page 9, line 12, after the first "the" insert "test"

Page 9, line 13, after the first "the" insert "test"

Page 13, after line 4, insert:

"2. Unless ordered by a court of competent jurisdiction, the name of a person who in good faith makes a report or complaint may not be ~~released or~~ disclosed by the committee or the project."

On page 18 after line 6, insert:

"SECTION 24. A new section 44-04-18.18 of the North Dakota of the North Dakota Century Code is created and enacted as follows:

44-04-18.18. Business Associate -- Duty to protect information.

1. As used in this section:

'Business associate' has the meaning set forth in title 45, Code of Federal Regulations, part 160,section 103; and

'Public entity' has the meaning set forth in section 44-04-17.1(12).

2. If a public entity is acting as a business associate of another public entity, the entity acting as a business associate shall comply with all of the requirements applicable to a business associate under title 45, Code of Federal Regulations, part 164, section 504, subsection e, paragraph 2."

Renumber accordingly

The basis for the "BA" amendment is the authority set forth regarding Business Associate Contracts in 45 CFR § 164.504(e)(3)(i)(B), which provides:
The covered entity may comply with paragraph (e) of this section, 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.

If section 44-04-18.18 is enacted, government-to-government BA agreements may not be needed, or can be accomplished with a 1-page note specifying the authority of the BA to use and disclose PHI; the other "boilerplate" BA requirements will not be required.

3/1/03 adopt

6/6 Do Pass as amended

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0201
0300

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Page 9, line 13, after the first "the" insert "test"

Page 13, after line 4, insert:

pg 12 line 7 after 103 insert:

part 164, and section 5-02, subsection g, respectively.

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On page 18 after line 6, insert:

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disclosures authorized by

¶ 8 disclosures otherwise authorized by law

OPEN RECORDS AND MEETINGS OPINION
2002-O-04

DATE ISSUED: February 25, 2002

ISSUED TO: Cal Rolfson, Special Assistant Attorney General, North Dakota Board of Nursing

CITIZEN'S REQUEST FOR OPINION

On January 22, 2002, this office received a request for an opinion under N.D.C.C. § 44-04-21.1 from Penni Weston asking whether the North Dakota Board of Nursing violated N.D.C.C. § 44-04-18 by charging her a fee for copies of open public records that exceeded the Board's actual cost of making the requested copies.

FACTS PRESENTED

In December 2001, Ms. Weston requested and received more than 60 pages of records from the North Dakota Board of Nursing (Board). The Board waived the fee for making and mailing the requested copies because Ms. Weston is a current licensee of the Board. After Ms. Weston reviewed the copies initially provided by the Board, she requested copies of additional records. The Board provided 21 regular sized pages with copies on both sides of the page and five legal sized pages with copies on only one side. Ms. Weston was charged $8.15 for the copies. The January 7, 2002, invoice she was given by the Board breaks down the fee as follows:

$1.00/FIRST PAGE	$1.00
$ .25/PAGE X 25 PAGES	$6.25
$ .90/STAFF TIME	$0.90
NO POSTAGE CHARGE	

Ms. Weston paid for the copies when she picked them up at the Board office.

Ms. Weston made a third request for records and the Board responded on January 10, 2002, by mailing her seven regular sized pages with copies on both sides of the page and one regular sized page with a copy on only one side. The Board charged Ms. Weston

$3.75 for the copies using the same fee schedule in the prior invoice but did not charge her for mailing the records. The fee consisted of $1.00 for the first page, $0.25 per page for the additional seven pages, and $1.00 for staff time. In the Board's explanation of the fee to Ms. Weston, the Board indicated the $1.00 for the first page was to cover "the time it takes to locate the documents and verification of request and cost of photocopying." The $1.00 charge for "staff time" was based on the hourly wage and time necessary for a Board employee to "process the request." Ms. Weston did not pay the $3.75 fee and requested this opinion.

ISSUE

Whether the North Dakota Board of Nursing violated N.D.C.C. § 44-04-18 by charging a fee for copies of open public records that exceeded the Board's actual cost of making the requested copies.

ANALYSIS

Section 44-04-18, N.D.C.C., specifies the fee that a public entity may charge for providing access to open public records or making copies of those records.

> Upon request for a copy of specific public records, any entity subject to subsection 1 shall furnish the requester one copy of the public records requested. A request need not be made in person or in writing, and the copy must be mailed upon request. The entity may charge a reasonable fee for making or mailing the copy, or both. An entity may require payment before making or mailing the copy, or both. . . . As used in this subsection, "reasonable fee" means the actual cost to the public entity of making or mailing a copy of a record, or both, including labor, materials, postage, and equipment, but excluding any cost associated with excising confidential or closed material under section 44-04-18.8. An entity may impose a fee not exceeding twenty-five dollars per hour per request, excluding the initial hour, for locating records if locating the records requires more than one hour. This subsection does not apply to copies of public records for which a different fee is specifically provided by law.

N.D.C.C. § 44-04-18(2). This subsection authorizes two separate fees, one for copying public records and one for locating records if it takes the public entity longer than one hour to find the requested records. See 2000 N.D. Op. Att'y Gen. O-11. In this case, it did not take the Board longer than one hour to find the requested records and the question in this

opinion is limited to the "reasonable fee" authorized in N.D.C.C. § 44-04-18(2) for making copies of public records.

Unless it takes a public entity longer than one hour to find the requested records, N.D.C.C. § 44-04-18(2) effectively maintains free access to public records, but allows a public entity to offset its entire cost of making copies of those records upon request. 1998 N.D. Op. Att'y Gen. O-03. "The definition of 'reasonable fee' in N.D.C.C. § 44-04-18(2) limits a public entity to charging no more than its actual cost of making the copies, including labor, materials, and equipment." 1998 N.D. Op. Att'y Gen. O-22. See also 1998 N.D. Op. Att'y Gen. O-04. "[T]he largest part of a public entity's actual expense in making copies will usually be the labor charge . . . ." 1998 N.D. Op. Att'y Gen. O-03.

In 1998 N.D. Op. Att'y Gen. O-22, the public entity charged a flat fee of $0.25 per page. However, when asked to itemize its actual cost of copying public records, the public entity conceded its actual cost was slightly less than $0.08 per page. While the fee in that opinion may not have included the full cost of the labor involved in making copies, the conclusion is relevant to this opinion: even a nominal fee of $0.25 per page may be too much for a public entity to charge for copies of public records under N.D.C.C. § 44-04-18(2) if the total copying charge exceeds the public entity's actual cost of making the copies.

In reviewing a public entity's actual cost of making photocopies of documents, it is helpful to separate the fixed costs associated with each copy (materials, equipment and postage) from the labor cost that will vary with each request. In the Board's response to the request for this opinion, it indicates an average fixed cost of $0.03 per image, taking into account that some documents were copied on both sides of a page and that some documents needed to be copied on legal sized paper. Thus, the actual cost to the Board of making the copies requested by Ms. Weston, excluding labor, was $1.41 for the second request (47 images [21 two-sided copies, 5 one-sided copies] at $0.03 per image) and $0.45 for the third request (15 images [7 two-sided copies, 1 one-sided copy] at $0.03 per image), for a total of $1.86.

With regard to the labor expense incurred by the Board in making the copies requested by Ms. Weston, the Board indicated that a Board employee spent four minutes on each request to make the copies. The hourly wage of the employee is $17.62, so the labor cost for making the copies requested by Ms. Weston was $0.29 per minute for a total labor expense of $2.32 (4 minutes for 2 requests at $0.29 per minute). The overall expense to the Board of providing the copies requested by Ms. Weston was $4.18, but she was charged a total of $11.90.

It is not clear how the Board determined the rates listed in its invoices to Ms. Weston. The three entries on each invoice (first page, additional pages, and staff time) appear to reflect duplicate charges for the labor expense to the Board for making the requested copies. In response to this opinion request, the Board suggests its actual copying expense per page is $0.32, based on its fixed cost of $0.03 per image and the labor charge of $0.29. However, this figure is clearly in error because the Board's employee is able to make more than one copy per minute on average.

In her request for this opinion, Ms. Weston disagrees with the higher rate of $1.00 for the first page copied by the Board. However, this higher rate can be easily understood. It takes a certain amount of time for an employee to leave the employee's desk, make a copy of a one-page document, and put the document in an envelope for mailing to the requester. The amount of time it takes for an employee to make and mail a requested document does not double if the document is two pages long rather than one page. Rather, the labor expense to a public entity for each additional page is significantly less than for the first page. This fact is proven in this case, where an employee spent roughly the same amount of time (four minutes) to make 47 copies and 15 copies.

While a public entity may reasonably spread out the initial labor cost over a number of copies by charging a flat fee such as $0.25 per page, N.D.C.C. § 44-04-18(2) prohibits a public entity from charging more than its actual expense in making the requested copies. At some point, the flat fee for each additional copy may need to be reduced due to a corresponding decrease in the time needed to prepare the copy.

The situation in this opinion is very different from the situation in 1998 N.D. Op. Att'y Gen. O-04, in which the public entity charged $1.00 per page for each page. In this case, Ms. Weston was only charged that rate for the first page that was copied at her request. The Board charged a significantly lower rate for each additional page. Nevertheless, the overall charge to Ms. Weston exceeded the Board's actual cost of making the requested copies and it is my opinion the Board violated N.D.C.C. § 44-04-18(2).

Although the amount of the copying fee at issue in this case is small and out of proportion to the time spent responding to the request, I am hopeful this opinion will be instructive on the copying fee public entities are permitted to charge under N.D.C.C. § 44-04-18(2).

CONCLUSION

The North Dakota Board of Nursing violated N.D.C.C. § 44-04-18 by charging a fee for copies of open public records that exceeded the Board's actual cost of making the requested copies.

STEPS NEEDED TO REMEDY VIOLATION

Ms. Woston has already paid $8.15 for copies of records and the Board has given her an invoice for an additional $3.75. The total fee the Board should have charged for the two requests, as computed in this opinion, is $4.18. Accordingly, the Board needs to cancel its second invoice and refund Ms. Weston her overpayment of $3.97 ($8.15 - $4.18).

Failure to take the corrective measures described in this opinion within seven days of the date this opinion is issued will result in mandatory costs, disbursements, and reasonable attorney fees if the person requesting the opinion prevails in a civil action under N.D.C.C. § 44-04-21.2. N.D.C.C. §44-04-21.1(2). It may also result in personal liability for the person or persons responsible for the noncompliance. Id.

Wayne Stenehjem
Attorney General

Assisted by: James C. Fleming
Assistant Attorney General

vkk

Testimony of Mike Mullen (AGS office)

HIPAA privacy rule. A reference to section 23-05.5-05, which is repealed by this bill, is deleted.

Section 8 amends section 23-07.5-07, which relates to civil liability for unauthorized disclosure, is amended by deleting references two sections of the Century Code that are repealed, and by repealing an unnecessary sentence regarding the burden of proof – a preponderance of evidence – which is generally applicable in a civil action.

Section 9 amends section 23-07.5-08, which provides a criminal penalty for unlawful disclosure of individually identifiable information regarding the results of a test for HIV. The amended section now applies to a person who "knowingly" discloses the results of a test in violation of the chapter, and instead of referring to the harm to the subject, applies if the offense is committed "with intent to disclose the identity of the individual who was tested."

Section 10 amends subsection 3 of section 23-07.7-02 by removing a reference to section 23-07.5-03, which is repealed by section 25 of this bill.

→ 45 CFR 164.524(c)(4)

Section 11 amends 23-12-14 relating to copies of health care records. Subsection 1 is amended to refer to a "health care provider" rather than a "medical provider" since that is the term used in the federal HIPAA privacy rule. The second sentence of subsection 1 is removed because it is unnecessary. Subdivision a of subsection 1 is amended to refer to "health care" rerecords rather than "medical rerecords," the terminology used in the federal privacy rule.

Subdivision b of subsection 1, relating to the cost of a copy of health care records provided to an individual (for a purpose other than disclosure to another provider for

treatment), is repealed. The HIPAA privacy rule contains detailed limitations on the charges for providing a copy of health care records to a patient.

Subsection 2 (a), which provides that an authorization to disclose an individual's health care records is limited to the time specified, but no longer than three years, is repealed. The federal HIPAA privacy rule does not impose any time limit on the period during which an authorization is legally valid. In some cases, an individual may authorize the disclosure of their individual information regarding diabetes, asthma, or cancer to a semi-permanent research database. Since an individual may revoke their consent at any time, and since the legislative history of this provision shows that the current three-year time limit was intended to extend the period of an authorization, the subdivision is repealed.

Subsection 2(b) authorizing a patient to revoke their authorization at any time also is repealed; this right is clearly established under the federal privacy rule.

Subsection 3, which provides that a health care provider may disclose a patient's health care records to another provider "during the time necessary to complete a patient's course of treatment" and conclude all medical and payment transactions related to the individual, is repealed. Under the federal HIPAA privacy rule, a health care provider and a health plan may use protected health information for treatment or payment without the consent of the patient. Therefore, this subsection is unnecessary.

Subsection 4 provides that it is "not a prohibited practice" for a health insurance company with participating provider agreement to require that subscribers or members are responsible for providing the insurer with copies of health care records used for claims processing when an individual uses a nonparticipating provider. This provision,

which relates to insurance law, is transferred to section 26.1-04-03 by section 16 of this bill.

Section 12 amends section 23-16-09, which relates to individually identifiable health information obtained by the Department of Health in the course of a survey or inspection of a hospital, nursing home, or similar facility. This section, which was enacted in 1947, permits disclosure of information to a social service agency relating to a newborn without an authorization from the newborn's parents. Such a broad disclosure is not permitted under the federal privacy rule – which preempts any provision of state law that is contrary to the rule's requirements (unless the state law is "more stringent" with respect to the disclosure of protected health information).

Section 13, which amends section 25-01.3-01, adds a new definition of individually identifiable health information and personal representative (adopted from the federal HIPAA privacy regulation) to clarify the class of information and the persons to whom information about an individual with a developmental disability may be used or disclosed.

Section 14, amends subsection 1 of section 25-01.3-10, to clarify the legal authority to disclose information about an individual with a developmental disability (or as defined by federal law, a person with a "disability"). Specifically, the terminology is amended to refer to "individually identifiable health information," an "authorization" for "disclosure," and "personal representative," which are the terms used in the federal HIPAA privacy rule. This subsection is also amended to permit disclosure as otherwise authorized by this chapter, or any other state or federal law. (Subdivision c, of subsection 10, section 25-01.3-10.)

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PROVISION OF ACCESS
SECTION 164.524(c)
As Contained in the HHS Final HIPAA Privacy Rules

HHS Regulations
Provision of Access - § 164.524(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 or format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.

   ii. 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.* The covered entity must provide the

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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.

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. Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;

   ii. Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and

   iii. Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(ii) of this section.

45 CFR 164.524(c)(4)

HHS Description
Provision of Access

In the NPRM, we proposed to require covered health care providers and health plans, upon accepting a request for access, to notify the individual of the decision and of any steps necessary to fulfill the request; to provide the information requested in the form or format requested, if readily producible in such form or format; and to facilitate the process of inspection and copying.

We generally retain the proposed approach in the final rule. If a covered entity accepts a request, in whole or in part, it must notify the individual of the decision and provide the access requested. Individuals have the right both to inspect and to copy protected health information in a designated record set. The individual may choose whether to inspect the information, to copy the information, or to do both.

In the final rule, we clarify that if the same protected health information is maintained in more than one designated record set or at more than one location, the covered entity is required to produce the information only once per request for access. We intend this provision to reduce covered entities' burden in complying with requests without reducing individuals' access to protected health information. We note that summary information and reports are not the same as the underlying information on which the summary or report was based. Individuals have the right to obtain access both to summaries and to the underlying information. An individual retains the right of access to the underlying information even if the individual requests access to, or production of, a summary. (See below regarding requests for summaries.)

The covered entity must provide the information requested in the form or format requested if it is readily producible in such form or format. For example, if the covered entity maintains health information electronically and the individual requests an electronic copy, the covered entity must accommodate such request, if possible. Additionally, we specify that if the information is not available in the form or format requested, the covered entity must produce a readily readable hard copy of the information or another form or format to which the individual and covered entity can agree. If the individual agrees, including agreeing to any associated fees (see below), the covered entity may

provide access to a summary of information rather than all protected health information in designated record sets. Similarly, a covered entity may provide an explanation in addition to the protected health information, if the individual agrees in advance to the explanation and any associated fees.

The covered entity must provide the access requested in a timely manner, as described above, and arrange for a mutually convenient time and place for the individual to inspect the protected health information or obtain a copy. If the individual requests that the covered entity mail a copy of the information, the covered entity must do so, and may charge certain fees for copying and mailing. For requests to inspect information that is maintained electronically, the covered entity may print a copy of the information and allow the individual to view the print-out on-site. Covered entities may discuss the request with the individual as necessary to facilitate the timely provision of access. For example, if the individual requested a copy of the information by mail, but the covered entity is able to provide the information faster by providing it electronically, the covered entity may discuss this option with the individual.

We proposed in the NPRM to permit the covered entity to charge a reasonable, cost-based fee for copying the information.

We clarify this provision in the final rule. If the individual requests a copy of protected health information, a covered entity may charge a reasonable, cost-based fee for the copying, including the labor and supply costs of copying. If hard copies are made, this would include the cost of paper. If electronic copies are made to a computer disk, this would include the cost of the computer disk. Covered entities may not charge any fees for retrieving or handling the information or for processing the request. If the individual requests the information to be mailed, the fee may include the cost of postage. Fees for copying and postage provided under state law, but not for other costs excluded under this rule, are presumed reasonable. If such per page costs include the cost of retrieving or handling the information, such costs are not acceptable under this rule.

If the individual requests an explanation or summary of the information provided, and agrees in advance to any associated fees, the covered entity may charge for preparing the explanation or summary as well.

The inclusion of a fee for copying is not intended to impede the ability of individuals to copy their records. Rather, it is intended to reduce the burden on covered entities. If the cost is excessively high, some individuals will not be able to obtain a copy. We encourage covered entities to limit the fee for copying so that it is within reach of all individuals.

We do not intend to affect the fees that covered entities charge for providing protected health information to anyone other than the individual. For example, we do not intend to affect current practices with respect to the fees one health care provider charges for forwarding records to another health care provider for treatment purposes.

HHS Response to Comments Received
Provision of Access

Note: The HHS Response to Comments Received is the same as in § 164.524(a)

Comment: Some commenters recommended that there be no access to disease registries.

Response: Most entities that maintain disease registries are not covered

entities under this regulation; examples of such non-covered entities are public health agencies and pharmaceutical companies. If, however, a disease registry is maintained by a covered entity and is used to make decisions about individuals, this rule requires the covered entity to provide access to information about a requesting individual unless one of the rule's conditions for denial of access is met. We found no persuasive reasons why disease registries should be given special treatment compared with other information that may be used to make decisions about an individual.

Comment: Some commenters stated that covered entities should be held accountable for access to information held by business partners so that individuals would not have the burden of tracking down their protected health information from a business partner. Many commenters, including insurers and academic medical centers, recommended that, to reduce burden and duplication, only the provider who created the protected health information should be required to provide individuals access to the information. Commenters also asked that other entities, including business associates, the Medicare program, and pharmacy benefit managers, not be required to provide access, in part because they do not know what information the covered entity already has and they may not have all the information requested. A few commenters also argued that billing companies should not have to provide access because they have a fiduciary responsibility to their physician clients to maintain the confidentiality of records.

Response: A general principle in responding to all of these points is that a covered entity is required to provide access to protected health information in accordance with the rule regardless of whether the covered entity created such information or not. Thus, we agree with the first point: in order to meet its requirements for providing access, a covered entity must not only provide access to such protected health information it holds, but must also provide access to such information in a designated record set of its business associate, pursuant to its business associate contract, unless the information is the same as information maintained directly by the covered entity. We require this because an individual may not be aware of business associate relationships. Requiring an individual to track down protected health information held by a business associate would significantly limit access. In addition, we do not permit a covered entity to limit its duty to provide access by giving protected health information to a business associate.

We disagree with the second point: if the individual directs an access request to a covered entity that has the protected health information requested, the covered entity must provide access (unless it may deny access in accordance with this rule). In order to assure that an individual can exercise his or her access rights, we do not require the individual to make a separate request to each originating provider. The originating provider may no longer be in business or may no longer have the information, or the non-originating provider may have the information in a modified or enhanced form.

We disagree with the third point: other entities must provide access only if they are covered entities or business associates of covered entities, and they must provide access only to protected health information that they maintain (or that their business associates maintain). It would not be efficient to require a covered entity to compare another entity's information with that of the entity to which the request was addressed. (See the discussion regarding covered entities for information about whether a pharmacy benefit manager is a covered entity.)

We disagree with the fourth point: a billing company will be required by its business associate contract only to provide the requested protected health information to its physician client. This action will not violate any fiduciary responsibility. The physician client would in turn be required by the rule to provide access to the individual.

Comment: Some commenters asked for clarification that the clearinghouse function of turning non-standardized data into standardized data does not create non-duplicative data and that "duplicate" does not mean "identical." A few commenters suggested that duplicated information in a covered entity's designated record set be supplied only once per request.

Response: We consider as duplicative information the same information in different formats, media, or presentations, or which have been standardized. Business associates who have materially altered protected health information are obligated to provide individuals access to it. Summary information and reports, including those of lab results, are not the same as the underlying information on which the summaries or reports were based. A clean document is not a duplicate of the same document with notations. If the same information is kept in more than one location, the covered entity has to produce the information only once per request for access.

Comment: A few commenters suggested requiring covered entities to disclose to third parties without exception at the requests of individuals. It was argued that this would facilitate disability determinations when third parties need information to evaluate individuals' entitlement to benefits. Commenters argued that since covered entities may deny access to individuals under certain circumstances, individuals must have another method of providing third parties with their protected health information.

Response: We allow covered entities to forward protected health information about an individual to a third party, pursuant to the individual's authorization under § 164.508. We do not require covered entities to disclose information pursuant to such authorizations because the focus of the rule is privacy of protected health information. Requiring disclosures in all circumstances would be counter to this goal. In addition, a requirement of disclosing protected health information to a third party is not a necessary substitute for the right of access to individuals, because we allow denial of access to individuals under rare circumstances. However, if the third party is a personal representative of the individual in accordance with § 164.502(g) and there is no concern regarding abuse or harm to the individual or another person, we require the covered entity to provide access to that third party on the individual's behalf, subject to specific limitations. We note that a personal representative may obtain access on the individual's behalf in some cases where covered entity may deny access to the individual. For example, an inmate may be denied a copy of protected health information, but a personal representative may be able to obtain a copy on the individual's behalf. See § 164.502(g) and the corresponding preamble discussion regarding the ability of a personal representative to act on an individual's behalf.

Comment: The majority of commenters supported granting individuals the right to access protected health information for as long as the covered entity maintains the protected health information; commenters argued that to do otherwise would interfere with existing record retention laws. Some commenters advocated for limiting the right to information that is less than one or two years old. A few commenters explained that frequent changes in technology makes it more difficult to access stored data. The commenters noted that the information obtained prior to the effective date of the rule should not be required to be accessible.

Response: We agree with the majority of commenters and retain the proposal to require covered entities to provide access for as long as the entity maintains the protected health information. We do not agree that information created prior to the effective date of the rule should not be accessible. The reasons for granting individuals access to information about them do not vary with the date the information was created.

Comment: A few commenters argued that there should be no grounds for

denying access, stating that individuals should always have the right to inspect and copy their protected health information.

Response: While we agree that in the vast majority of instances individuals should have access to information about them, we cannot agree that a blanket rule would be appropriate. For example, where a professional familiar with the particular circumstances believes that providing such access is likely to endanger a person's life or physical safety, or where granting such access would violate the privacy of other individuals, the benefits of allowing access may not outweigh the harm. Similarly, we allow denial of access where disclosure would reveal the source of confidential information because we do not want to interfere with a covered entity's ability to maintain implicit or explicit promises of confidence.

We create narrow exceptions to the rule of open access, and we expect covered entities to employ these exceptions rarely, if at all. Moreover, we require covered entities to provide access to any protected health information requested after excluding only the information that is subject to a denial. The categories of permissible denials are not mandatory, but are a means of preserving the flexibility and judgment of covered entities under appropriate circumstances.

Comment: Many commenters supported our proposal to allow covered entities to deny an individual access to protected health information if a professional determines either that such access is likely to endanger the life or physical safety of a person or, if the information is about another person, access is reasonably likely to cause substantial harm to such person.

Some commenters requested that the rule also permit covered entities to deny a request if access might be reasonably likely to cause psychological or mental harm, or emotional distress. Other commenters, however, were particularly concerned about access to mental health information, stating that the lack of access creates resentment and distrust in patients.

Response: We disagree with the comments suggesting that we expand the grounds for denial of access to an individual to include a likelihood of psychological or mental harm of the individual. We did not find persuasive evidence that this is a problem sufficient to outweigh the reasons for providing open access. We do allow a denial for access based on a likelihood of substantial psychological or mental harm, but only if the protected health information includes information about another person and the harm may be inflicted on such other person or if the person requesting the access is a personal representative of the individual and the harm may be inflicted on the individual or another person.

We generally agree with the commenters concerns that denying access specifically to mental health records could create distrust. To balance this concern with other commenters' concerns about the potential for psychological harm, however, we exclude psychotherapy notes from the right of access. This is the only distinction we make between mental health information and other types of protected health information in the access provisions of this rule. Unlike other types of protected health information, these notes are not widely disseminated through the health care system. We believe that the individual's privacy interests in having access to these notes, therefore, are outweighed by the potential harm caused by such access. We encourage covered entities that maintain psychotherapy notes, however, to provide individuals access to these notes when they believe it is appropriate to do so.

Comment: Some commenters believed that there is a potential for abuse of the provision allowing denial of access because of likely harm to self. They questioned whether there is any experience from the Privacy Act of 1974 to

suggest that patients who requested and received their records have ever endangered themselves as a result.

Response: We are unaware of such problems from access to records that have been provided under the Privacy Act but, since these are private matters, such problems might not come to our attention. We believe it is more prudent to preserve the flexibility and judgment of health care professionals familiar with the individuals and facts surrounding a request for records than to impose the blanket rule suggested by these commenters.

Comment: Commenters asserted that the NPRM did not adequately protect vulnerable individuals who depend on others to exercise their rights under the rule. They requested that the rule permit a covered entity to deny access when the information is requested by someone other than the subject of the information and, in the opinion of a licensed health care professional, access to the information could harm the individual or another person.

Response: We agree with the commenters that such protection is warranted and add a provision in § 164.524(a)(3), which permits a covered health care provider to deny access if a personal representative of the individual is making the request for access and a licensed health care professional has determined, in the exercise of professional judgment, that providing access to such personal representative could result in substantial harm to the individual or another person. Access can be denied even if the potential harm may be inflicted by someone other than the personal representative.

This provision is designed to strike a balance between the competing interests of ensuring access to protected health information and protecting the individual or others from harm. The "substantial harm" standard will ensure that a covered entity cannot deny access in cases where the harm is de minimus.

The amount of discretion that a covered entity has to deny access to a personal representative is generally greater than the amount of discretion that a covered entity has to deny access to an individual. Under the final rule, a covered entity may deny access to an individual if a licensed health care professional determines that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person. In this case, concerns about psychological or emotional harm would not be sufficient to justify denial of access. We establish a relatively high threshold because we want to assure that individuals have broad access to health information about them, and due to the potential harm that comes from denial of access, we believe denials should be permitted only in limited circumstances.

The final rule grants covered entities greater discretion to deny access to a personal representative than to an individual in order to provide protection to those vulnerable people who depend on others to exercise their rights under the rule and who may be subjected to abuse or neglect. This provision applies to personal representatives of minors as well as other individuals. The same standard for denial of access on the basis of potential harm that applies to personal representatives also applies when an individual is seeking access to his or her protected health information, and the information makes reference to another person. Under these circumstances, a covered entity may deny a request for access if such access is reasonably likely to cause substantial harm to such other person. The standard for this provision and for the provision regarding access by personal representatives is the same because both circumstances involve one person obtaining information about another person, and in both cases the covered entity is balancing the right of access of one person against the right of a second person not to be harmed by the disclosure.

Under any of these grounds for denial of access to protected health

information, the covered entity is not required to deny access to a personal representative under these circumstances, but has the discretion to do so.

In addition to denial of access rights, we also address the concerns raised by abusive or potentially abusive situations in the section regarding personal representatives by giving covered entities discretion to not recognize a person as a personal representative of an individual if the covered entity has a reasonable belief that the individual has been subjected to domestic violence, abuse, or neglect by or would be in danger from a person seeking to act as the personal representative. (See § 164.502(g))

Comment: A number of commenters were concerned that this provision would lead to liability for covered entities if the release of information results in harm to individuals. Commenters requested a "good faith" standard in this provision to relieve covered entities of liability if individuals suffer harm as a result of seeing their protected health information or if the information is found to be erroneous. A few commenters suggested requiring providers (when applicable) to include with any disclosure to a third party a statement that, in the provider's opinion, the information should not be disclosed to the patient.

Response: We do not intend to create a new duty to withhold information nor to affect other laws on this issue. Some state laws include policies similar to this rule, and we are not aware of liability arising as a result.

Comment: Some commenters suggested that both the individual's health care professional and a second professional in the relevant field of medicine should review each request. Many commenters suggested that individuals have a right to have an independent review of any denial of access, e.g., review by a health care professional of the individual's choice.

Response: We agree with the commenters who suggest that denial on grounds of harm to self or others should be determined by a health professional, and retain this requirement in the final rule. We disagree, however, that all denials should be reviewed by a professional of the individual's choice. We are concerned that the burden such a requirement would place on covered entities would be significantly greater than any benefits to the individual. We believe that any health professional, not just one of the individual's choice, will exercise appropriate professional judgment. To address some of these concerns, however, we add a provision for the review of denials requiring the exercise of professional judgment. If a covered entity denies access based on harm to self or others, the individual has the right to have the denial reviewed by another health care professional who did not participate in the original decision to deny access.

Comment: A few commenters objected to the proposal to allow covered entities to deny a request for access to health information if the information was obtained from a confidential source that may be revealed upon the individual's access. They argued that this could be subject to abuse and the information could be inherently less reliable, making the patient's access to it even more important.

Response: While we acknowledge that information provided by confidential sources could be inaccurate, we are concerned that allowing unfettered access to such information could undermine the trust between a health care provider and patients other than the individual. We retain the proposed policy because we do not want to interfere with a covered entity's ability to obtain important information that can assist in the provision of health care or to maintain implicit or explicit promises of confidence, which may be necessary to obtain such information. We believe the concerns raised about abuse are mitigated by the fact that the provision does not apply to promises of confidentiality made to a health care provider. We note that a covered entity

may provide access to such information.

Comment: Some commenters were concerned that the NPRM did not allow access to information unrelated to treatment, and thus did not permit access to research information.

Response: In the final rule, we eliminate the proposed special provision for "research information unrelated to treatment." The only restriction on access to research information in this rule applies where the individual agrees in advance to denial of access when consenting to participate in research that includes treatment. In this circumstance, the individual's right of access to protected health information created in the course of the research may be suspended for as long as the research is in progress, but access rights resume after such time. In other instances, we make no distinction between research information and other information in the access provisions in this rule.

Comment: A few commenters supported the proposed provision temporarily denying access to information obtained during a clinical trial if participants agreed to the denial of access when consenting to participate in the trial. Some commenters believed there should be no access to any research information. Other commenters believed denial should occur only if the trial would be compromised. Several recommended conditioning the provision. Some recommended that access expires upon completion of the trial unless there is a health risk. A few commenters suggested that access should be allowed only if it is included in the informed consent and that the informed consent should note that some information may not be released to the individual, particularly research information that has not yet been validated. Other commenters believed that there should be access if the research is not subject to IRB or privacy board review or if the information can be disclosed to third parties.

Response: We agree with the commenters that support temporary denial of access to information from research that includes treatment if the subject has agreed in advance, and with those who suggested that the denial of access expire upon completion of the research, and retain these provisions in the final rule. We disagree with the commenters who advocate for further denial of this information. These comments did not explain why an individual's interest in access to health information used to make decisions about them is less compelling with respect to research information. Under this rule, all protected health information for research is subject either to privacy board or IRB review unless a specific authorization to use protected health information for research is obtained from the individual. Thus, this is not a criterion we can use to determine access rights.

Comment: A few commenters believed that it would be "extremely disruptive of and dangerous" to patients to have access to records regarding their current care and that state law provides sufficient protection of patients' rights in this regard.

Response: We do not agree. Information about current care has immediate and direct impact on individuals. Where a health care professional familiar with the circumstances believes that it is reasonably likely that access to records would endanger the life or physical safety of the individual or another person, the regulation allows the professional to withhold access.

Comment: Several commenters requested clarification that a patient not be denied access to protected health information because of failure to pay a bill. A few commenters requested clarification that entities may not deny requests simply because producing the information would be too burdensome.

Response: We agree with these comments, and confirm that neither failure to pay a bill nor burden are lawful reasons to deny access under this rule.

Covered entities may deny access only for the reasons provided in the rule.

Comment: Some commenters requested that the final rule not include detailed procedural requirements about how to respond to requests for access. Others made specific recommendations on the procedures for providing access, including requiring written requests, requiring specific requests instead of blanket requests, and limiting the frequency of requests. Commenters generally argued against requiring covered entities to acknowledge requests, except under certain circumstances, because of the potential burden on entities.

Response: We intend to provide sufficient procedural guidelines to ensure that individuals have access to their protected health information, while maintaining the flexibility for covered entities to implement policies and procedures that are appropriate to their needs and capabilities. We believe that a limit on the frequency of requests individuals may make would arbitrarily infringe on the individual's right of access and have, therefore, not included such a limitation. To limit covered entities' burden, we do not require covered entities to acknowledge receipt of the individuals' requests, other than to notify the individual once a decision on the request has been made. We also permit a covered entity to require an individual to make a request for access in writing and to discuss a request with an individual to clarify which information the individual is actually requesting. If individuals agree, covered entities may provide access to a subset of information rather than all protected health information in a designated record set. We believe these changes provide covered entities with greater flexibility without compromising individuals' access rights.

Comment: Commenters offered varying suggestions for required response time, ranging from 48 hours because of the convenience of electronic records to 60 days because of the potential burden. Others argued against a finite time period, suggesting the response time be based on mutual convenience of covered entities and individuals, reasonableness, and exigencies. Commenters also varied on suggested extension periods, from one 30-day extension to three 30- day extensions to one 90-day extension, with special provisions for off-site records.

Response: We are imposing a time limit because individuals are entitled to know when to expect a response. Timely access to protected health information is important because such information may be necessary for the individual to obtain additional health care services, insurance coverage, or disability benefits, and the covered entity may be the only source for such information. To provide additional flexibility, we eliminate the requirement that access be provided as soon as possible and we lengthen the deadline for access to off-site records. For on-site records, covered entities must act on a request within 30 days of receipt of the request. For off-site records, entities must complete action within 60 days. We also permit covered entities to extend the deadline by up to 30 days if they are unable to complete action on the request within the standard deadline. These time limits are intended to be an outside deadline rather than an expectation. We expect covered entities to be attentive to the circumstances surrounding each request and respond in an appropriate time frame.

Comment: A few commenters suggested that, upon individuals' requests, covered entities should be required to provide protected health information in a format that would be understandable to a patient, including explanations of codes or abbreviations. The commenters suggested that covered entities be permitted to provide summaries of pertinent information instead of full copies of records; for example, a summary may be more helpful for the patient's purpose than a series of indecipherable billing codes.

Response: We agree with these commenters' point that some health

information is difficult to interpret. We clarify, therefore, that the covered entity may provide summary information in lieu of the underlying records. A summary may only be provided if the covered entity and the individual agree, in advance, to the summary and to any fees imposed by the covered entity for providing such summary. We similarly permit a covered entity to provide an explanation of the information. If the covered entity charges a fee for providing an explanation, it must obtain the individual's agreement to the fee in advance.

Comment: Though there were recommendations that fees be limited to the costs of copying, the majority of commenters on this topic requested that covered entities be able to charge a reasonable, cost-based fee. Commenters suggested that calculation of access costs involve factors such as labor costs for verification of requests, labor and software costs for logging of requests, labor costs for retrieval, labor costs for copying, expense costs for copying, capital cost for copying, expense costs for mailing, postal costs for mailing, billing and bad-debt expenses, and labor costs for refiling. Several commenters recommended specific fee structures.

Response: We agree that covered entities should be able to recoup their reasonable costs for copying of protected health information, and include such provision in the regulation. We are not specifying a set fee because copying costs could vary significantly depending on the size of the covered entity and the form of such copy (e.g., paper, electronic, film). Rather, covered entities are permitted to charge a reasonable, cost-based fee for copying (including the costs of supplies and labor), postage, and summary or explanation (if requested and agreed to by the individual) of information supplied. The rule limits the types of costs that may be imposed for providing access to protected health information, but does not preempt applicable state laws regarding specific allowable fees for such costs. The inclusion of a copying fee is not intended to impede the ability of individuals to copy their records.

Comment: Many commenters stated that if a covered entity denies a request for access because the entity does not hold the protected health information requested, the covered entity should provide, if known, the name and address of the entity that holds the information. Some of these commenters additionally noted that the Uniform Insurance Information and Patient Protection Act, adopted by 16 states, already imposes this notification requirement on insurance entities. Some commenters also suggested requiring providers who leave practice or move offices to inform individuals of that fact and of how to obtain their records.

Response: We agree that, when covered entities deny requests for access because they do not hold the protected health information requested, they should inform individuals of the holder of the information, if known; we include this provision in the final rule. We do not require health care providers to notify all patients when they move or leave practice, because the volume of such notifications would be unduly burdensome.