MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

1283

DESCRIPTION

2003 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1283

2003 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. 1283

House Industry, Business and Labor Committee

☐ Conference Committee

Hearing Date January 28, 2003

Tape Number	Side A	Side B	Meter #
1		X	0.2-1412
Committee Clerk Signature	Elizabeth R. Keiser		

Minutes: **CHAIR KEISER:** Opened hearing on HB 1283

REP. KASPER: Gave overview of bill concerning consumer profiling.

REP. EKSTROM: Is this in line with national standards? Rep. Kasper deferred to representatives from the Pharmaceutical Association.

GALEN JORDE (ND Pharmaceutical Assoc.): Supports with written testimony. Offered amendments.

REP. KEISER: Will the amendments offer protection for in-house hospital pharmacies to operate? Jorde responded that yes it would.

REP. SEVERSON: Is there a reason for the amendment to include a 5 yr. or unlimited expiration date? Jorde responded that there is no set standard, but they need to have an expiration date. Cannot get a blanket authorization. You need to know the for whom, for what purpose, and how the information is going to be used. No opportunities for a long, open-ended date.

CHAIR KEISER: Closed hearing on HB 1283 with no opposition testimony.

Rep. Johnson moved to adopt the amendments by Rep. Kasper. Seconded by Rep. Severson.

Voice vote. Motion adopted. Rep. Severson moved to adopt the amendments from the ND Pharmaceutical Association. Rep. Klein seconded. Discussion followed on getting the amendments into proper format. Voice vote. Motion adopted.

Rep. Severson moved to recommend DO PASS AS AMENDED. Rep. Dosch seconded. 14-0-0 Roll call vote.

30167.0101
Title.

Prepared by the Legislative Council staff for
Representative Kasper
January 24, 2003

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1283

Page 1, line 1, remove ", a new section to chapter"

Page 1, line 2, remove "43-15.1, and a new subsection to section 43-17-31"

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

Page 1, line 4, remove "physicians, and wholesale drug distributors"

Page 2, remove lines 3 through 16

Renumber accordingly

30167.0102
Title.0200

Adopted by the Industry, Business and Labor Committee
January 28, 2003

VK 1/28/03

HOUSE AMENDMENTS TO HOUSE BILL NO. 1283 IBL 1-29-03

Page 1, line 1, remove ", a new section to chapter"

Page 1, line 2, remove "43-15.1, and a new subsection to section 43-17-31"

Page 1, line 3, replace the first comma with "and" and replace the second comma with a period

Page 1, remove line 4

Page 1, line 11, replace "identifying customer" with "individually identifiable health"

Page 1, line 15, replace "an" with "a business associate"

Page 1, line 16, remove "affiliate or a third party"

Page 1, line 17, replace "administration" with "treatment or health care operations"

Page 1, line 18, replace "identifying customer" with "individually identifiable"

Page 1, line 20, replace "is valid for no more than" with "must include an expiration date"

Page 1, line 21, remove "one year" and replace "identifying customer" with "individually identifiable"

Page 1, line 22, replace "identifying customer" with "individually identifiable health"

Page 2, remove lines 3 through 16

Renumber accordingly

Date: 1-28-03
Roll Call Vote #: 1

2003 HOUSE STANDING COMMITTEE ROLL CALL VOTES 1283
BILL/RESOLUTION NO.

House **Industry, Business & Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 30167.0102

Action Taken DP as Amended

Motion Made By Severson Seconded By Dosch

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	✓		Rep.Boe	✓	
Rep.Severson, Vice-Chair	✓		Rep.Ekstrom	✓	
Rep.Dosch	✓		Rep.Thorpe	✓	
Rep. Froseth	✓		Rep. Zaiser	✓	
Rep. Johnson	✓				
Rep.Kasper	✓				
Rep. Klein	✓				
Rep. Nottlestad	✓				
Rep. Ruby	✓				
Rep.Tieman	✓				

Total (Yes) 14 No 0

Absent

Floor Assignment Froseth

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

REPORT OF STANDING COMMITTEE (410)
January 29, 2003 11:49 a.m.

Module No: HR-17-1244
Carrier: Froseth
Insert LC: 30167.0102 Title: .0200

REPORT OF STANDING COMMITTEE

HB 1283: Industry, Business and Labor Committee (Rep. Keiser, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (14 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1283 was placed on the Sixth order on the calendar.

Page 1, line 1, remove ", a new section to chapter"

Page 1, line 2, remove "43-15.1, and a new subsection to section 43-17-31"

Page 1, line 3, replace the first comma with "and" and replace the second comma with a period

Page 1, remove line 4

Page 1, line 11, replace "identifying customer" with "individually identifiable health"

Page 1, line 15, replace "an" with "a business associate"

Page 1, line 16, remove "affiliate or a third party"

Page 1, line 17, replace "administration" with "treatment or health care operations"

Page 1, line 18, replace "identifying customer" with "individually identifiable"

Page 1, line 20, replace "is valid for no more than" with "must include an expiration date"

Page 1, line 21, remove "one year" and replace "identifying customer" with "individually identifiable"

Page 1, line 22, replace "identifying customer" with "individually identifiable health"

Page 2, remove lines 3 through 16

Renumber accordingly

2003 SENATE HUMAN SERVICES

HB 1283

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1283

Senate Human Services Committee

☐ Conference Committee

Hearing Date March 3, 2003

Tape Number	Side A	Side B	Meter #
1	X		5586 - end
		X	0 - 4671
Committee Clerk Signature			

Minutes:

SENATOR JUDY LEE opened the public hearing for HB 1283.

REPRESENTATIVE JIM KASPER introduced HB 1283 relating to confidentiality of identifying information and prohibited acts by pharmacies and pharmacists. Said it was a very important bill. Pharmacies and pharmacists may not disclose their customers' confidential information to market a service or a product. ... Consumer direct marketing. ... Information should be private. Pharmacy companies developing new and more potent and much more expensive drugs all the time -- some drugs not needed. ... Stop third parties from getting information. Open to amendments to work on HIPAA requirements. (Meter # 5634 - 6170)

SENATOR FISCHER: Is this covered under HIPAA information now?

REPRESENTATIVE KASPER: I don't believe it is. Intent is to prevent third party marketing with pharmaceutical companies. (Tape 1, Side A, Meter # 6177 - end and Side B, Meter 0 - 14)

SENATOR FAIRFIELD: Pharmacies pressuring doctors? Protect doctors as well?

REPRESENTATIVE KASPER It could be amended to do that. (Meter # 30 - 120)

SENATOR LEE: Individuals contacted by name?

REPRESENTATIVE KASPER: Not in ND. Happening nationwide. Directing marketing. Continued discussion with committee regarding higher drug costs, suppliers of info to third parties, important bill for senior citizens who are vulnerable, bill to stop direct abuse, and privacy. (Meter # 190 - 845)

GALEN JORDRE, with ND Pharmaceutical Association, testified in support of the intent of this bill. Gave a little background on how ND has worked in relation to privacy. ... Need additional amendments on bill primarily to make sure that the definition of marketing would be understood. (Meter # 913 - 1154)

SENATOR FAIRFIELD: Federal HIPAA rules on privacy are standard, states can go beyond if they feel there is a compelling reason to ensure privacy beyond what the Federal standards have put in place? (Meter # 1167 - 1196)

Continued discussion between the committee and GALEN JORDRE regarding marketing provision - negotiated, and restrictions being tighter. Will be willing to work with amendments. (Meter # 1195 - 1618)

CAL ROLFSON, Attorney for PhRMA, testified in opposition to the bill. (Written testimony and a brochure on "Direct-To-Consumer Advertising of Prescription Medicines" provided)

HB 1283 would limit the ability of pharmaceutical manufacturers to directly provide educational materials to patient consumers on issues pertaining to their health care needs. ... Impede the quality of health care and cost effectiveness. ... Referred to HB 1438 which was intended to

comply with HIPAA ... blend with the state and with HB 1283, it is trying to separate. Come into compliance with HIPAA by modifying this bill. (Meter # 1672 - 2688)

Continued discussion with committee members regarding newest drug therapy, blanket advertising, manufacturers utilize confidential information through pharmacists, and flow of information. (Meter # 2701 - 3268)

MIKE MULLEN, Assistant Attorney General, testified in a neutral position. (Written testimony) (Meter # 3314 - 3920)

SENATOR LEE: Requested Mr. Mullen visit with Mr. Jordre and bring back things that are not in conflict.

Discussion with the committee regarding HIPAA as an opt-in rule, and business association provision - pharmaceutical company. (Meter # 4027 - 4655)

SENATOR LEE closed the public hearing at this time. (Meter # 4671)

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1283

Senate Human Services Committee

☐ Conference Committee

Hearing Date March 4, 2003

Tape Number	Side A	Side B	Meter #
1		X	3352 - 5060
Committee Clerk Signature			

Minutes:

SENATOR JUDY LEE opened the committee discussion on HB 1283 relating to confidentiality of identifying information and prohibited acts by pharmacies and pharmacists. She stated everything in the bill is covered by HIPAA with the exception of restricting information. ... Amendment will be put on HB 1438. ... Continued discussion regarding HIPAA, regulation not necessary, and listings for research.

Students in the room from Golden Valley and St. Mary's High Schools were acknowledged.

(Meter # 3352 - 4710)

SENATOR ERBELE made a motion to DO NOT PASS.

SENATOR POLOVITZ seconded the motion.

Committee discussion.

Roll call was read. 4 yeas 1 nay and 1 absent.

SENATOR BROWN will be the carrier. (Meter # 5060)

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1283

Senate Human Services Committee

☐ Conference Committee

Hearing Date March 12, 2003

Tape Number	Side A	Side B	Meter #
2		X	5510 - END
3	X		0 - 365
Committee Clerk Signature	Donna Kramer, Clerk		

Minutes:

SENATOR JUDY LEE reopened the committee discussion on HB 1283 and the committee to reconsider the action previously taken.

SENATOR FISCHER made a motion to reconsider action on HB 1283.

SENATOR POLOVITZ seconded the motion.

SENATOR LEE asked for discussion. All in favor to reconsider our actions on HB 1283 signify by saying aye. 6 yes and 0 no. Carried. Pull back for reconsideration.

SENATOR FAIRFIELD stated Mr. Mullen had talked about putting authorizations, health care utilization in this amendment.

MIKE MULLEN: Reviewed amendments prepared by ND Pharmaceutical Association with the committee. ... Made notations. ... (Tape 2, Side B, Meter # 5860 - end and Tape 3, Side A, Meter 0 - 35)

DAVID PESKE, of the Medical Association, in response to Senator Lee asking if he had any comments, stated he had talked to Mike Mullen with TaLisa and had talked with Mr. Jorde out in the hall. If everyone is happy with the amendments as proposed, he was too. (Meter # 40 - 108)

SENATOR LEE discussed with the committee the changes of the amendments. ... Instructed TaLisa to hoghouse the bill. ... Look again at the bill on Monday. Discussion closed. (Meter # 110 - 365)

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. **HB 1283**

Senate Human Services Committee

☐ Conference Committee

Hearing Date 03/17/03

Tape Number	Side A	Side B	Meter #
Tape 3	x		0
Committee Clerk Signature	Donna Kramer, Clerk		

Minutes:

Senator Lee opens HB 1283. Senator Fairfield Absent.

Senator Brown moves for a Do Not Pass

Sentor Polovitz 2nd

5 Yes 0 No 1 Absent

03-12-03
Pulled back

Held for Hearing until 1438 is done

Date: 03-04-03
Roll Call Vote #: 1

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1283

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Not Pass

Motion Made By Sen. Erbele Seconded By Sen. Polovitz

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) 4 No 1

Absent 1

Floor Assignment Sen. Brown

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

Date: 3/17/03
Roll Call Vote #: 1

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1283

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Not Pass

Motion Made By Brown Seconded By Polovitz

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) 5 No 0

Absent 1

Floor Assignment Brown

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

REPORT OF STANDING COMMITTEE (410)
March 18, 2003 8:29 a.m.

Module No: SR-48-4987
Carrier: Brown
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

HB 1283, as engrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO NOT PASS** (5 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). Engrossed HB 1283 was placed on the Fourteenth order on the calendar.

2003 TESTIMONY

HB 1283

NORTH DAKOTA PHARMACEUTICAL ASSOCIATION

1906 E Broadway Ave.
Bismarck, ND 58501-4700
Tel. 701-258-4968
Fax 701-258-9312
e-mail ndpha@nodakpharmacy.com

Testimony before the House IBL Committee
HB 1283
Tuesday, January 28, 2003
Galen Jordre – Executive Vice President

My name is Galen Jordre and I am the Executive Vice President of the North Dakota Pharmaceutical Association (NDPhA) an organization that represents the 700 pharmacists practicing in the state. The NDPhA is here to support the intent of HB 1283. North Dakota pharmacists have always been very conservative when releasing patient identifiable information. The North Dakota State Board of Pharmacy currently has rules that prevent the release of information without patient authorization.

We have consulted with the prime sponsor of this Act and are offering friendly amendments to place the Act in line with the federal privacy rules adopted to implement the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Because the terms in the amendments are the same as those used in HIPAA, there is no need to additionally define them in the Pharmacy Act. These amendments are attached to this testimony and I would like to explain them now.

On lines 4, 8, 12, 17 and 18 the term "identifying customer information" is replaced with "individually identifiable information" a term that is defined by HIPAA to include demographic information related to the patient.

On line 9 the term "affiliate or third party" is replaced by "business associate". Under HIPAA a business associate uses information to carry out functions for the pharmacy but cannot use the information for its own purposes.

On line 11 the term "administration" is replaced with "treatment" and "health care operations". Both of these terms relate to specific functions performed by the pharmacy in order to carry out its health care activities.

Examples of what Section 2 allows are: software vendor is permitted to use individually identifiable information when doing software checks and upgrades; a mailing agency prepares and mails refill reminders or notices of supplies and services offered by the pharmacy; or use of collection agency for bill collection.

On line 16 and 17 the one-year expiration date is replaced with a requirement that the authorization have an expiration date – the same as the HIPAA requirement.

We ask that you accept these amendments.

Proposed Amendments to HB 1283

SECTION 1.

1. Unless a customer provides express authorization under this section, a pharmacist or pharmacy may not:
   a. Disclose ~~identifying customer~~ individually identifiable health information to a third party for the purpose of marketing a product or service, or
   b. Participate in for-profit marketing of a product or service to a customer if the marketing to the customer is based upon identifying customer information.
2. A pharmacist or pharmacy may disclose ~~identifying customer~~ individually identifiable health information to ~~an affiliate or a third party~~ a business associate without the express authorization under this section if the disclosure is related to ~~administration~~ treatment or health care operations of the pharmacy and if that disclosure is not for marketing purposes. The recipient of ~~identifying customer~~ individually identifiable health information under this subsection shall keep the information confidential.
3. An express authorization by a customer under this section ~~is valid for no more than one year~~ must include an expiration date; must clearly identify who will be provided the ~~identifying customer~~ individually identifiable health information; must clearly identify what the ~~identifying customer~~ individually identifiable health information will be used for; must be in writing; and must be made knowingly by the customer.

HB
1283

American Medical Association

Physicians dedicated to the health of America

515 North State Street
Chicago, Illinois 60610

A Message from the AMA About Physician Data Distribution and Privacy

For nearly a century, the American Medical Association (AMA) has been recognized as a trusted source of information on all physicians in the U.S. The AMA began collecting information on physicians as early as 1906 for the purposes of membership recruitment and retention activities as well as credentials verification. The Association began licensing an extract of its unique database known as the Physician Masterfile to external users *over 50 years ago.*

What kind of physician data does the AMA collect in its Physician Masterfile and from where?

The AMA collects Masterfile data on all physicians in the U.S. who have completed or are completing requirements to practice medicine and about U.S. trained physicians temporarily located overseas. Through the voluntary cooperation of health-related agencies, institutions, and organizations the Masterfile includes both members and non-members of the AMA and graduates of international medical schools (IMGs) who reside in the U.S. Each physician record consists of *historic* and *current* practice data sections. The historic section contains demographic, educational, and permanent professional information. Data in this section are obtained *only from primary sources*, including medical schools, hospitals, medical societies, the Educational Commission for Foreign Medical Graduates (ECFMG), state licensing agencies, medical groups, federal agencies, the Drug Enforcement Administration (DEA) and others. Physicians' current practice information (phone and fax numbers, for example) are obtained directly from physicians themselves through the Physicians' Professional Activities (PPA) survey, or other data sources.

Does the AMA Masterfile include prescribing data?

The AMA does not, and never has, compiled or sold physician prescribing data.

Why does the AMA maintain the Masterfile?

As the nation's leading physician organization, the AMA strives to maintain the most reliable source for accurate information on physicians available anywhere. AMA physician data serves many useful purposes for the public good, ranging from helping to identify employment trends in the medical profession to protecting patients by verifying that physicians have proper credentials for the practice of medicine. As more and more information becomes digitally available, the AMA Masterfile now fills an important role in authenticating physicians for various online medical transactions as well. All physicians in the Masterfile are eligible for a free digital certificate, called an AMA Internet ID, enabling them to protect their identities online and to securely transmit medical information (please visit www.ama-assn.org/go/internetid to enroll). While data verification and authentication are the primary purposes for the Masterfile, it has also provided a revenue source for the AMA, supporting the advocacy and services the association provides all physicians and their patients. Masterfile information is made available to Database Licensees, who operate under carefully restricted information usage agreements. The Database Licensees who utilize the AMA's Masterfile work primarily with a variety of health-care related companies that offer a wide range of products for physicians and the larger medical community. Some of these offerings include:

- More than 250 medical and professional journals
- Continuing medical education (CME) programs
- Physician credential verification services
- Drug samples and pharmaceutical information
- Medical equipment and supplies
- Employment opportunities for health professionals
- General practice-related commercial offers of interest to physicians as consumers

The Masterfile is also used for important health and safety issues of interest to the entire medical community. For example, private industry and the government use the Masterfile to distribute drug recall and safety information.

Why does the AMA license the Masterfile?

In previous years, it was possible for the AMA to interact directly with commercial or government entities who utilized the Masterfile. However, as the physician population has increased and the information in the Masterfile has become more complex, it has become necessary to license this activity to experienced and reputable Database Licensee partners. In order to protect the viability of its information and the privacy of physicians, the use of AMA data by these partners is strictly monitored and governed by contractual agreements. Database Licensees may only release information for uses approved by the AMA. Subject to ongoing monitoring of their activities, the AMA Database Licensees employ a variety of means to disseminate information to physicians. These include *regular mail, phone,* or *FAX.*

What efforts has the AMA made towards ensuring data security?

Recognizing the need for enhanced security in the electronic age, in 2001 a leading auditing firm provided the Association with an assessment of its technical infrastructure. Basing its findings on years of experience in the security field for health care institutions and other industries, the firm characterized the AMA's overall security profile as meeting security standards. According to its assessment, the AMA's standardized policies and procedures minimize or eliminate external threats to its data. For example, the AMA's system prevents individual physicians and third party organizations from altering information by denying them read or write access to the Masterfile. In addition, all educational and licensure information changes require verification from a primary source before they are approved for inclusion in the Masterfile.

Does the AMA have a formal Physician Privacy Policy for the Masterfile?

YES. Physicians who choose NOT to receive information on the products and/or services offered through our Database Licensees may specify this preference as part of our *Do Not Release* policy. If you request this status, the AMA will prohibit the release of your Masterfile information to all entities and their direct affiliates outside the AMA except for national emergencies.

Specifically: The *Do Not Release* policy prohibits the AMA from releasing any Masterfile information on the physician. Thus, it is an all or nothing system. If a physician instructs the AMA to flag his/her record as *Do Not Release*, AMA Database Licensees will no longer have the right to use Masterfile information for the purpose of contacting the physician including health hazard warnings and drug recalls. The *Do Not Release* flag will also prohibit release of Masterfile information to State Licensing Boards and hospitals who use this information to verify credentials unless the AMA has written permission from the physician to release his/her Masterfile information to a specific organization.

As part of its efforts to protect the privacy of your data, the AMA also offers you a less stringent *No Contact* option.

The *No Contact* status on a physician's Masterfile record ensures that the physician's name will not be licensed for marketing purposes. You will still receive health hazard warnings, drug recalls, and AMA related information. Your information will be released to state licensing boards or hospitals to verify credentials. However, if a physician chooses *No Contact*, AMA Database Licensees will not be permitted to use his/her Masterfile information for purposes of distributing drug samples, journals or for other promotional purposes. A pharmaceutical representative may still contact a physician if using information from a source outside of the AMA.

If after careful consideration you decide to request a change, please choose one of the following methods to notify us:

For:	No Contact	Do Not Release
Email	nocontact@ama-assn.org	norelease@ama-assn.org
Call	800 621-8335	800 621-8335
Fax*	312 464-4880	312 464-4880
Mail*	Department of Data Collection American Medical Association 515 N. State St. Chicago, IL 60610	Department of Data Collection American Medical Association 515 N. State St. Chicago, IL 60610

***your signature is required, on your professional letterhead**

NOTE: Due to the advance purchase of lists, it may take 90 days or more for all end users to implement your *Do Not Release* or *No Contact* request and update their databases. The AMA, however, will process your request immediately upon receipt. Also, if at a later date you wish to re-instate a "release" or "contact" you may do so by contacting the AMA using one of the appropriate methods described above.

PDB-02-R02

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.

TESTIMONY

BY
CALVIN N. ROLFSON
ON BEHALF OF
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
(PhRMA)
IN OPPOSITION OF
HOUSE BILL NO. 1283

My name is Cal Rolfson, I am an attorney in Bismarck and am the legislative consultant for the Pharmaceutical Research and Manufacturers of America (PhRMA). I appear on PhRMA's behalf in opposition to House Bill No. 1283.

PhRMA represents the nation's leading research-based pharmaceutical and biotechnology companies, which discover and develop the majority of new medicines used in the United States and around the world. In 2001, PhRMA's member companies brought thirty-two new prescription drugs and biologics to market, including medicines for diseases that affect millions of patients, such as, Alzheimer's, AIDS, cancer, glaucoma, heart disease, and schizophrenia. Additionally, PhRMA's member companies invested more than $30 billion in research and development last year to create medicines that help combat diseases

that threaten the well-being of Americans and to help reduce the economic loss causes by an ailing workforce.

House Bill No. 1283 would limit the ability of pharmaceutical manufacturers ("manufacturers") to directly provide educational material to patient-consumers on issues pertaining to their health care needs. PhRMA supports the ability of all citizens to have access to the most recent medical information. House Bill 1283 would impede the ability of patients to have timely access to such information.

Overly restrictive limitations on access to and use of medical information by manufactures could impede the quality of health care available to patient-consumers and impede the effectiveness, including cost effectiveness, of the health care system. Manufacturers play an important and vital role in the dissemination of education material, including disease management information, to patient-consumers.

For example, by enabling a manufacturer to have direct contact with patient-consumer, especially in regard to disease-related education programs, manufacturers may utilize confidential information to ensure a patient consumer's access to effective health care treatment options, including prescription drugs.

Moreover, House Bill No. 1233 may have the effect of hindering a prescribing practitioner's ability to keep current on the newest and most effective drug therapy for a patient's needs.

Manufacturers provide to patients (either directly or indirectly) through physicians or pharmacists, brochures, newsletters, internet sites and other materials about their products. In its broad sense, this dissemination of information is referred to as direct-to-consumer ("DTC") advertising. The purpose of this patient information is to educate patient-consumers about diseases, the symptoms related to diseases, and the available methods of treatment.

Research indicates that DTC advertising is helpful in the following manner:

1. Educating patient-consumers about medical conditions and treatment options;
2. Encouraging dialogue between patients and physicians;
3. Prompting large numbers of Americans to discuss illnesses with their physicians for the first time; and
4. Improving compliance with physician-prescribed treatments.

A 1999 survey by *Prevention Magazine* found that consumers give high marks to pharmaceutical advertising. Of those surveyed, 76% felt that DTC

advertisements allowed them to become more involved in their own health care rather than have their physicians alone be the gate-keepers of their health information. The survey established that, "the benefits of DTC [direct-to-consumer] advertising could go far beyond simply selling prescription medicines: these advertisements play a very real role in enhancing the public health."[1]

In addition, House Bill 1283 poses extremely difficult challenges for national, let alone multinational, manufacturers. National consistency of rules relating to operations and marketing promotes efficiency and thereby helps keep drug costs down. By its nature, a manufacturer's internet/patient information needs uniform programs and messages. The restriction exemplified by House Bill No. 1283, will add to expenses for consultants, and add additional layers of processes to educate patient consumers. This will translate into additional cost for medications.

For these reasons, PhRMA opposes House Bill 1283

PhRMA will be pleased to work with the Bill sponsors and this Committee to find ways to modify this Bill to make it less restrictive and help continue the flow of valuable health care information to those who may need it.

---

[1]Year Two: A National Survey of Consumer Reactions to Direct-to-Consumer Advertising, Emmaus, PA, Rodale, 1999.

Thanks you for the privilege of being able to appear before you. May I respond to questions?

Calvin N. Rolfson
Legislative Counsel
PhRMA
(Lobbyist No. 144)

TESTIMONY OF THE OFFICE OF ATTORNEY GENERAL
ON HOUSE BILL 1283, REGARDING THE DISCLOSURE
OF HEALTH INFORMATION FOR MARKETING

BEFORE
SENATE HUMAN SERVICES COMMITTEE
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, who asked me to present testimony on House Bill 1283, which, in general, prohibits the use or disclosure of "individually identifiable health information" in connection with the marketing of pharmaceutical products or health services, unless an individual has authorized the use of their identifiable information for such a marketing campaign. Before I address the provisions of Senate Bill 1283, let me briefly outline the background and purpose of the federal HIPAA privacy rule regarding consent.

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) was promulgated by the Department of Health and Human Services (HHS) on December 28, 2000. [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, after extensive review of written comments, the final rule on the privacy of individually identifiable health information was published. (*To permit covered entities sufficient time to prepare for operations under the privacy rule, a "compliance date" allowing slightly more than two years to prepare for the rule was established.*)

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 rule difficult, on August 14, 2002, the Secretary of Health and Human Services made several changes to the rule. (Thus, the changes will be effective on the primary compliance date, April 14, 2003.) Among the most significant changes contained in the revised final privacy rule is removal of a requirement that a provider obtain "written consent" from a patient to "use or disclose" protected health information "for treatment, payment, or health care operations."

The Department of Health and Human Services had received numerous comments from health insurance companies, hospitals, pharmacists, emergency medical service providers, and other organizations that the consent requirement would impose substantial burdens, and in some situations delay or prohibit a health care provider from initiating treatment. In place of consent, the revised final rule requires a provider to make a good-faith effort to obtain an "acknowledgment" from a patient that the patient has received a copy of the provider's privacy policy, including information about a patient's rights regarding the privacy of health information.

Let me now turn to the substantive provisions of House Bill 1283.

House Bill 1283

Engrossed House Bill 1283, which would limit the disclosure of individually identifiable health information for marketing purposes, contains only one section. The bill would add a new section to chapter 43-15 of the North Dakota Century Code regulating pharmacies and pharmacists.

Under subsection 1 of the new section, unless a customer provides express authorization, "a pharmacist or pharmacy may not (a) disclose individually identifiable health information (which is a defined term in the federal privacy rule) to a third party for the purpose of marketing a product or service; or (b) participate in for-profit marketing of a product or service to a customer if the marketing to the customer is based upon identifying customer information." The limitation on marketing without a patient's "authorization" substantially overlaps the marketing restrictions contained in the federal HIPAA privacy rule. (The definition of "marketing," contained in 45 C.F.R. § 164.501, and

the requirement for the "authorization" of an individual in connection with marketing, which is contained in 45 C.F.R. § 164.508(a), are attached as Appendix A to this testimony.)

Subsection 2 provides that a pharmacist (or pharmacy) "may disclose identifying customer information to a business associate without the express authorization of the customer, if the disclosure is related to treatment or health care operations of the pharmacy and if the disclosure is not for marketing purposes." This section appears to be unnecessary because the HIPAA privacy rule permits the disclosure of protected health information to a business associate without the authorization of a customer (or patient), subject to the requirement that a health care provider, such as a pharmacist, may not disclose protected health information to a business associate for marketing purposes unless the pharmacist herself or himself would be permitted to make this disclosure without an authorization. 45 C.F.R. § 164.504(e)(2(i) ("The [business associate] contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of [the privacy rule], if done by the covered entity.")

Subsection 2 also provides that if protected health information is disclosed to a business associate, the business associate must keep that information confidential. This provision appears to be unnecessary because the HIPAA privacy rule already requires a business associate to maintain the confidentiality of information the associate receives from a covered entity, such as a health plan or a health care provider. 45 C.F.R. § 164.508(e)(2)(ii)(A) and (B) (a business associate may "[n]ot use or further disclose the information other than as permitted or required by the contract" and must "[u]se appropriate safeguards" to protect the confidentiality of the information).

Subsection 3 provides that an authorization "must include an expiration date; must clearly identify who will be provided the individually identifiable information; must clearly identify what the individually identifiable health information will be used for; must be in writing; and must be made knowingly by the customer." Each of these (and additional) requirements is required for a valid authorization under the HIPAA privacy rule. 45 C.F.R. § 164.508(c) (a valid authorization must contain six core elements, plus notice to the individual of their right to revoke the authorization).

Let me now address some of the legal-policy issues that are raised when this measure is viewed against the background of the HIPAA privacy rule.

Legal Issues: Giving Meaning to Every Word of a Statute, and Fair Notice

In enacting a statute, it is presumed that the entire statute is intended to be effective. N.D.C.C. § 1-02-38. In construing a statute, meaning must be given to every word, clause, and sentence, if possible. Fastow v. Burleigh County Water Resource District, 415 N.W.2d 505, 509-510 (N.D. 1987). Moreover, statutes are to be construed in a way that does not render them worthless because the law neither does nor requires idle acts nor will it be assumed that the Legislature intended that any sections be useless rhetoric. State v. Nordquist, 309 N.W.2d 109, 115 (N.D 1981).

In Gentile v. State Bar of Nevada, 501 U.S. 1030 (1991), the Supreme Court held that, as interpreted by the Nevada Supreme Court, a rule limiting out of court statements by lawyer was void for vagueness. Specifically, the rule failed to provide *fair notice* to those to whom it is directed and is so imprecise that discriminatory enforcement is a real possibility.

The "fair notice" rule is stated in Connally v. General Const. Co., 269 U.S. 385, 391, 46 S.Ct. 126, 127 (1926): "That the terms of a penal statute creating a new offense must be sufficiently explicit to inform those who are subject to it what conduct on their part will render them liable to its penalties is a well-recognized requirement, consonant alike with ordinary notions of fair play and the settled rules of law; and a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law." Another illustration of the rule is given by United States v. Capital Traction Co., 34 App. D. C. 592, 19 Ann. Cas. 68 (1910), which held that a statute making it an offense for any street railway company to run an insufficient number of cars to accommodate passengers "without crowding" was void for uncertainty.

These cases illustrate that in considering HB 1283, the Committee should carefully consider whether the measure merely mirrors the conduct prohibited under the HIPAA privacy rule, or if it prohibits additional conduct. And, if the latter result is intended, does the bill provide "fair notice" to pharmacies that must conform their conduct (and the pharmacists who must conform their conduct) to the requirements of this measure, what other conduct is prohibited.

Chairman Lee, thank you for providing me an opportunity to discuss the provisions of House Bill 1283 relating to the use of individually identifiable health information for marketing. I will be pleased to answer any questions you or other members of the committee have regarding the bill.

# # #

SECTION 164.501
HHS Final HIPAA Privacy Rules

HHS Regulations as Amended August 2002
Definitions - Marketing- 45 C.F.R. § 164.501

Marketing means:

1. To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

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

    ii. For the treatment of the individual; or

    iii. For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

2. An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

AUTHORIZATIONS FOR USES AND DISCLOSURES
SECTION 164.508(a)
HHS Final HIPAA Privacy Rules

HHS Regulations as Amended August 2002 Authorizations for Uses and Disclosures – 45 C.F.R. § 164.508(a)

Standard: authorizations for uses and disclosures

1. *Authorization required: general rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

***

3. *Authorization required: marketing.*

   i. Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

      1. A face-to-face communication made by a covered entity to an individual; or

      2. A promotional gift of nominal value provided by the covered entity.

If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state such remuneration is involved.

HB1283

DIRECT-TO-CONSUMER ADVERTISING *of* PRESCRIPTION MEDICINES

PHRMA

Jim M. Kasper

03/03/2003 01:57 PM

To: Judy E. Lee/NDLC/NoDak@NoDak, rlbrown@state.nd.us, Robert S. Erbele/NDLC/NoDak@NoDak, Tom L. Fischer/NDLC/NoDak@NoDak, April J. Fairfield/NDLC/NoDak@NoDak, Michael F. Polovitz/NDLC/NoDak@NoDak
cc: Jim M. Kasper/NDLC/NoDak@NoDak
Subject: HB 1283, PHARMACY AND PHARMACISTS PRIVACY REQUIREMENTS

Committee Members:

Thank you for the opportunity to testify this morning on the above bill, regarding pharmacists and pharmacy privacy laws for the state of North Dakota. As Yoggi Berra once said, "it was like deja' ve all over again" as I listened to the testimony of Mr. Rolfson.

What you heard in testimony from Mr. Rolfson was almost identical to the testimony the Banks gave, and arguments they used last session, to push through SB 2191. I'm sure you all remember the bank privacy vote here in the Legislature and more importantly, the vote of the people in June of last year, where they said by a 73% vote that they want their private and confidential information to remain private and confidential. That is what HB 1283 will do in the area of health pharmacy privacy.

You may have noticed as I was leaving the hearing room this morning, that I stopped to visit briefly with a gentleman who was in the room. He stopped me and introduced himself as Dr. Theodore W. Kleiman, MD. He is our doctor of the day and is employed by Dakota Clinic in their Pediatrics department in Fargo. He told me: "You are totally correct in your testimony and concerns. In fact, the problem is much bigger than you can possibly imagine. Please keep on working on this bill. It is very important to pass it."

His phone number in Fargo is 701-280-3491. I am sure he would welcome your phone calls to discuss his concerns and provide you with his input. I will be doing so tomorrow. His email address is "tkleiman@nnovishealth.com"

I would be very willing to participate in further discussions with Mike Mullen to address the HIPAA comments he made. Having said that, I believe that, regardless of HIPAA, it does no harm whatsoever, to codify North Dakota Pharmacy Privacy law, as HB 1283 will do. Remember, Federal law can always change and I do not feel it is good policy for the people of North Dakota to be at the mercy of, nor dependent upon, Federal law, for the protection of their personal, medical pharmacy information.

One other point. HB 1283 does not prohibit Direct to Consumer marketing. It simply requires the person's prior written consent before their personal information can be given to these pharmaceutical companies, or any other unknown entity.

Please feel free to contact me on this matter at any time. Thank you.

Rep. Jim Kasper

AMENDMENT TO HB 1283 **03-04-03**

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;"

ims

Use of Prescription Data & Protections for Physicians

Introduction. IMS HEALTH (IMS) is the world's leading provider of information, research, and analysis to the health care industry, with data collection and reporting activities in over 100 countries. Founded in 1954, the company receives and processes vast quantities of health care data. In the United States alone, the company collects information from over 250,000 sources: pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes over 72 million records each month (de-identified with respect to patient information).

IMS's business includes tracking patterns of disease and treatment, outcomes, and the prescriptions for and sales of pharmaceutical products. Almost all of the company's business is based on the receipt and analysis of patient-anonymized data. Using this data, we are able to assist the medical, scientific, pharmaceutical and health care management communities in conducting outcomes research, implementing best practices, and applying health economic analyses.

Prescription-Based Information Services in the U.S. The company's databases of patient de-identified prescription drug transactions are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, efficient pharmaceutical sales and marketing resource allocation, and assessment of drug utilization patterns (e.g., on- and off-label uses and regional variations in physician prescribing behavior).

American Medical Association Physician Data. IMS and its affiliated companies have licensed physician information from the AMA for more than thirty years. During that time, IMS has consistently used and distributed that information in accordance with AMA guidelines and restrictions. The use of the information by IMS, and the licensing and distribution of that information to others, is subject to detailed agreements which specify approved and restricted uses of the data.

How does IMS obtain and process prescription transaction data? IMS collects prescription transaction data from a variety of sources in the United States. After initial processing of the prescription data, IMS matches that data to a prescriber roster that is built largely from the AMA Masterfile. IMS, and the pharmaceutical industry, use this reference source for it consistency and accuracy, as well as for the data use safeguards and protections that are gained from operating within the AMA's framework.

What does IMS do with data after processing? IMS groups and aggregates prescription information at a number of different levels according to customer needs and demands. For example, IMS provides national-level projected data to illustrate trend and usage patterns for clients as diverse as pharmaceutical manufacturers, investment firms and governmental agencies. Also, territory-level aggregations are customized and prepared for pharmaceutical companies so their sales staffs can be accurately compensated.

Does IMS maintain and release prescriber-level information? Yes, under the terms of license agreements restricting unauthorized uses of the data. To ensure pharmaceutical manufacturers can transmit targeted promotional and educational information to the right prescribers in the most efficient manner, IMS provides information on the prescribing patterns of individual physicians. IMPORTANT: IMS information services are always subject to AMA guidelines and restrictions if individual physicians are identified.

What if a doctor has asked AMA to exercise the *'No Contact'* option? The American Medical Association provides IMS with frequently updated lists of physicians who have asked to be designated as "No Contact". IMS passes this information on to our customers, who are contractually bound to respect and abide by these doctors' wishes.

Additional Information. For more information regarding the AMA's "no contact" option, please contact the AMA' Dept. of Data Collection at (800) 621-8335. For more information regarding IMS's data practices, please visit our website at www.imshealth.com.

IMS: 03.16.2003

Proposed Amendment to HB 1283
Prepared by TaLisa Nemec, Legislative Intern at the request of the Senate Human Services Committee

Page 1, replace lines 7 through 24 with:

"Prohibited disclosures. A pharmacy shall not disclose to third parties information that identifies the prescriptive practices of practitioners. This prohibition applies to the pharmacist and any employee or agent of the pharmacy. As used in this section, "disclosure" is defined as the release or transfer of information, provision of access to information, or divulging information in any other manner." This prohibition does not apply to disclosures made:

a. within the pharmacy;
b. to the patient or the patients representative;
c. between the pharmacist or 'pharmacy employees and the practitioner or the practitioner's employees,
d. to other practitioners or facilities involved with the patient's care
e. to the North Dakota state board of pharmacy or to the North Dakota state board of medical examiners, as part of an inspection or investigation;
f. pursuant to an authorization by the practitioner; or
g. as otherwise authorized by law.

Page 2, remove lines 1 and 2

Renumber Accordingly