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2003 SENATE JUDICIARY

SB 2399

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2399

Senate Judiciary Committee

☐ Conference Committee

Hearing Date 02/12/03

Tape Number	Side A	Side B	Meter #
2	X		0.0 -35.0
Committee Clerk Signature	Maira L Salbey		

Minutes: **Senator Stanley W. Lyson, Vice Chairman,** called the meeting to order. Roll call was taken and not all committee members present. Sen. Lyson requested meeting starts with testimony on the bill:

Testimony Support of SB 2399

Sen. O'Connel - Introduced the bill (meter 0.1) Read Testimony - Attachment #8

Sen Fairfield - District 29 (meter 1.5) Went through Bill, Attachment #1a and Health Insurance Portability and Accountability Act of 1996 Summary of Administrative Provisions Attachment #1b.

Dave Peske - ND Medical Association. Discussed Section II (meter 8.8)

Senator Thomas L. Trenbeath discussed section II. Thinking Mr. Peske is not reading bill correctly. Senator Carolyn Nelson discussed the effect of Generic Drugs vs. Other's.

Testimony in Neutral of SB 2399

Michael J. Mullen - Asst. Attorney General (meter 14.0) Read Testimony - Attachment #2

Cal Rolifson - Attorney in Bismarck representing - Pharmaceutical Research and Manufactures of America (meter 32) $30 Billion of scientific health research for the US and World. My only concerns are the prohibition engaging in scientific medical research for the use of anonimized data discussed.

Testimony Oppose to SB 2399

Galen Jordre - Executive Vice President ND Pharmaceutical Association (meter 17) Read Testimony - Attachment #3, proposed an amendment - Attachment #4.

Senator Stanley W. Lyson, Vice Chairman discussed putting the whole bill into section 2 (meter 23.9)

Rolf Sletten - Executive Secretary ND State Board of Medical Examiners (meter 25.7) read testimony - Attachment #5

Rebecca Thiem - Attorney with Zuger, Kirmis and Smith, representing IMS Health (meter 27.5) Read Testimony - Attachment #6a. Submitted amendment - Attachment # 6b

Other Testimony submitted

Howard C. Anderson Jr, R.Ph., Executive Director of ND State Board of Pharmacy - Attachment #7

Guy Shanta, Pres., Midco Data Bismarck, Inc - Attachment # 9

Senator Stanley W. Lyson, Vice Chairman closed the hearing

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB2399

Senate Judiciary Committee

☐ Conference Committee

Hearing Date 02/18/03

Tape Number	Side A	Side B	Meter #
1	X		0.0 - End

Committee Clerk Signature Maria LaDalbury

Minutes: **Senator John T. Traynor, Chairman,** called the meeting to order. Roll call was taken and all committee members present. Sen. Traynor requested meeting starts with committee work on the bill:

Cal Rolfson - Bismarck Attorney representing Pharmaceutical Research and Manufacturers of America (PhRMA) Submitted Testimony - Attachment #1

Discussion on the three amendment submitted. Review work from 2/12.

Motion Made to DO NOT PASS SB 2399 by Senator Stanley W. Lyson, Vice Chairman and seconded by Senator Thomas L. Trenbeath

Roll Call Vote: 6 Yes. 0 No. 0 Absent

Motion Passed

Floor Assignment Senator Stanley W. Lyson, Vice Chairman

Senator John T. Traynor, Chairman closed the hearing

Date: February 18, 2003
Roll Call Vote #: 1

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2399

Senate **JUDICIARY** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken DO NOT PASS

Motion Made By Senator Stanley W. Lyson Seconded By Sen. Trenbeath

Senators	Yes	No	Senators	Yes	No
Sen. John T. Traynor - Chairman	X		Sen. Dennis Bercier	X	
Sen. Stanley. Lyson - Vice Chair	X		Sen. Carolyn Nelson	X	
Sen. Dick Dever	X				
Sen. Thomas L. Trenbeath	X				

Total (Yes) SIX (6) No ZERO (O)

Absent ZERO (0)

Floor Assignment Sen. Lyson

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

REPORT OF STANDING COMMITTEE (410)
February 18, 2003 11:49 a.m.

Module No: SR-31-3069
Carrier: Lyson
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

SB 2399: Judiciary Committee (Sen. Traynor, Chairman) recommends DO NOT PASS (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2399 was placed on the Eleventh order on the calendar.

2003 TESTIMONY

SB 2399

AH #1

TESTIMONY

BY
CALVIN N. ROLFSON
ON BEHALF OF
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
(PhRMA)
REGARDING
SENATE BILL NO. 2399

My name is Cal Rolfson, I am an attorney in Bismarck and the legislative counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA). I appear here as neutral on Senate Bill 2399, but to express PhRMA's concerns regarding this Bill. I have an amendment to propose to respond to our concerns.

PhRMA represents the nations leading research-based pharmaceutical and biotechnology companies that are devoted to inventing medicines that allow patients to live long, healthier and more product lives. The industry invested more than $30 billion during 2001 in discovery and developing new medicines. PhRMA companies are leading the way in the search for new cures. The vast majority (more than 70%) of all scientific research for the development of new drugs comes from private industries such as PhRMA companies.

While the concepts found in Senate Bill 2399 have a laudable basis behind them, PhRMA is concerned about possible restrictions that may be found or

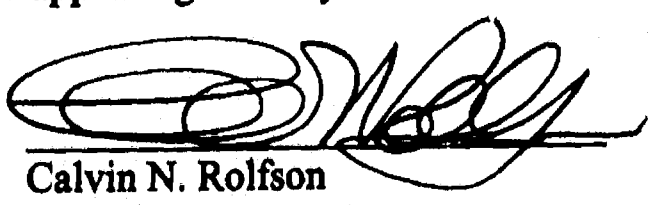
implied in the Bill that may prevent or restrict scientific medical research done by drug company researchers using anonymized or encoded data that does not identify individuals.

Attached to my testimony is a proposed amendment to Senate Bill 2399 that would ensure de-identified or encoded the right of any healthcare provider, pharmacy or other entity to provide anonymized data for medical and scientific healthcare research.

I also endorse the proposed amendments by the representative of North Dakota Board of Medical Examiners allowing the furnishing information to that Board, and I also recommend that you include the North Dakota Board of Nursing in those exceptions, since advanced practice nurses also are involved in writing prescriptions and the Board of Nursing would certainly need information of this type of investigate complaints and process administrative actions.

I will be pleased to work with the Committee and the Bill sponsors to provide whatever further amendments would be appropriate for this Bill to ensure that the furnishing of anonymized research data is not hampered either directly or by implication in this Bill.

Thank your for the privilege of appearing before your committee.



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

PROPOSED AMENDMENTS TO SENATE BILL NO. 2399

Page 2, after line 12, insert:

"4. This Act does not limit, qualify or restrict the disclosure by a pharmacy, healthcare provider, a person conducting health research, a health plan, a health oversight agency, a public health authority, an employer, a health or life insurer, or a school or university, from providing de-identified or encrypted health-related information to a pharmaceutical company or scientific and health research entity for the purpose of engaging in medical and scientific research."

Page 2, line 19, after the period, insert: "Nothing in this chapter shall limit, qualify or restrict the disclosure by a pharmacy, healthcare provider, a person conducting health research, a health plan, a health oversight agency, a public health authority, an employer, a health or life insurer, or a school or university, from providing de-identified or encrypted health-related information to a pharmaceutical company or scientific and health research entity for the purpose of engaging in medical and scientific research."

AH #1/a

SENATE JUDICIARY COMMITEE
TESTIMONY REGARDING SB 2399
SENATOR APRIL FAIRFIELD
February 12, 2003

Mr. Chairman, members of the Committee, for the record my name is April Fairfield and I am the Senator from District 29. I am a co-sponsor of SB 2399.

SB 2399 was introduced in response to an issue that was raised by one of my constituents, a medical provider. She informed me that it is a common practice for pharmaceutical company sales representatives to solicit information regarding the prescribing habits of physicians, physicians assistants and other health care providers from pharmacies.

Pharmaceutical sales representatives utilize that information to bring sales pressure to bear on prescribers. Hoping that they will prescribe their higher priced brand name drugs (as opposed to generic equivalents for example), increasing the pharmaceutical company's and representative's sales and profit margin. Higher profit margins are usually a good thing, but not when them come at the EXPENSE of the privacy and quality of life of the citizens of North Dakota, not to mention their pocketbooks.

Of course, this practice is not always or even usually of benefit to consumers. Moreover, health care professionals are not always pleased with this sort of marketing technique. Many health care professionals view their prescribing habits as private, professional information. With that in mind I worked with Senator O'Connell to have this bill drafted and introduced.

SB 2399 is about privacy. It protects the personal information of health care consumers and health care providers from the entities that wish to access that information only for the sake of selling as many of their branded, higher-cost prescription drugs as possible. Information about what medicines people take, why they take them and who prescribes them are important for medical professionals and pharmacies. These pieces of information are also of a sensitive nature and health care consumers deserve to have them treated as proprietary. In other words, exclusively owned by the consumer and absolutely private.

SB 2399 accomplishes two things:

- First, the bill closes a loophole in HIPAA (the federal Health Insurance Portability and Accountability Act) for "marketing" that allows a pharmacy, health care provider, insurance company, researcher, or other related individuals or institutions to forward marketing information from a pharmaceutical company to individuals. This "marketing" can be targeted to individuals based on their health status, prescription drug consumption or other factors.

This loophole was created by the pharmaceutical companies during the Congressional debate over HIPAA. By allowing these entities to "market" prescription drugs for them, these companies will be able to access the same personal information about individuals while still holding out the illusion that personal medical information will be kept private.

SB 2399 closes that loophole by prohibiting, under most circumstances, the entities identified in Section 1, subdivision 2 (page 1, lines 19-21) - pharmacies, health care professionals, health researchers, health insurance companies, etc. - from using individually identifiable health information in their possession to provide marketing services to any person.

The only exception to that section is that SB 2399 does allow health care entities to provide marketing services to a pharmaceutical company if they provide clear and conspicuous notice to the individual involved concerning the disclosure practices of the health care provider regarding all the personal medical information that they compile in the process. And if the provider of the marketing service obtains the expressed consent of the individual involved.

In other words, in order to "market" pharmaceuticals to us, health care providers would have to tell us how they will handle the information that they obtain in the process (their privacy policies) and allow for us to remain out of the "marketing" program unless we specifically "opt-in."

- Second, SB 2399 prohibits a pharmacist and any employee of a pharmacy disclosing to any third party any information about the prescriptive practices of a practitioner which identifies that individual medical professional. Of course, disclosures required by law and within the pharmacy for normal operations, or those disclosure consented to by the practitioner are allowed. This section (Section 2 - page 2, lines 15-19), protects the professional privacy of medical professionals.

I have also contacted several pharmacists in my district and have found that they are supportive of this legislation. I know that the board of pharmacists has amendments to offer to the bill that would essentially exempt them from first section of SB 2399. However, I have not found anything more than mild concern among pharmacists for the Section 1 of the bill and as for Section 2, at least one pharmacist in my district has unilaterally instituted the basic provisions of this section because of concerns about keeping personal and professional information private.

North Dakotans value their privacy. SB 2399 would protect one of the most personal areas of an individuals privacy. It would also protect the sanctity of one of the most sensitive professional relationships that most people ever form, namely our interactions with health care professionals. SB 2399 also preserves the privacy of medical professionals and prevents information about the prescribing and consumption of prescription drugs from being turned into a commodity.

I ask the committee for a Do Pass recommendation for SB 2399.

#16.

Health Insurance Portability and Accountability Act of 1996

Summary of Administrative Provisions

Standards for electronic health information transactions. Within 18 months of enactment, the Secretary of HHS is required to adopt standards from among those already approved by private standards developing organizations for certain electronic health transactions, including claims, enrollment, eligibility, payment, and coordination of benefits. These standards also must address the security of electronic health information systems.

Mandate on providers and health plans, and timetable. Providers and health plans are required to use the standards for the specified electronic transactions 24 months after they are adopted. Plans and providers may comply directly, or may use a health care clearinghouse. Certain health plans, in particular workers compensation, are not covered.

Privacy. The Secretary is required to recommend privacy standards for health information to Congress 12 months after enactment. If Congress does not enact privacy legislation within 3 years of enactment, the Secretary shall promulgate privacy regulations for individually identifiable electronic health information.

Preemption of State Law. The bill supersedes state laws, except where the Secretary determines that the State law is necessary to prevent fraud and abuse, to ensure appropriate state regulation of insurance or health plans, addresses controlled substances, or for other purposes. ***If the Secretary promulgates privacy regulations, those regulations do not pre-empt state laws that impose more stringent requirements. These provisions do not limit a State's ability to require health plan reporting or audits.***

Penalties. The bill imposes civil money penalties and prison for certain violations.

Att #2

TESTIMONY OF THE OFFICE OF ATTORNEY GENERAL
ON SENATE BILL 2399, REGARDING THE DISCLOSURE
OF HEALTH INFORMATION FOR MARKETING

BEFORE
SENATE JUDICIARY COMMITTEE
FEBRUARY 12, 2003

MICHAEL J. MULLEN
ASSISTANT ATTORNEY GENERAL

Chairman Traynor and Members of the Committee, I am pleased to be here on behalf of Attorney General Stenehjem, who asked me to present testimony on Senate Bill 2399, which, in general, prohibits the use or disclosure of "individually identifiable health information" in connection with the marketing of pharmaceutical products or other products or health services, unless an individual has authorized the use of identifiable information for such a marketing campaign. Before I address the provisions of Senate Bill 2399, 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 Senate Bill 2399.

Senate Bill 2399

As noted, section 1 of SB 2399 generally prohibits the use or disclosure of individually identifiable health information for the purpose of marketing products, such as pharmaceutical drugs, unless the individuals who are the recipients of the marketing materials have authorized the use or disclosure of their individually identifiable health information for such a marketing campaign. The limitations set forth in section 1 are similar to but slightly different than the restrictions on marketing under the 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.

The marketing restrictions in subsection 2 and subsection 3 of section 1 of SB 2399 apply to a health care provider, a pharmacy, a health plan, and a public health authority. In most situations, each of these organizations is likely to be a "covered entity" subject to the marketing limitations and other requirements of the HIPAA privacy rule. See 45 C.F.R.

§ 160.103 (defining a "covered entity" to include a "health plan" and any "health care provider" who transmits any health information in electronic form in connection with a standard transaction). Thus, the requirements of the privacy rule will, to some extent, overlap with the requirements of section 1 of SB 2399.

Section 2 of SB 2399 would restrict the disclosure of a physician's prescription drug profile, unless the physician authorized the disclosure of that information. Assuming that the prescription drug profile did not contain any individually identifiable patient information, section 2 is not in conflict with the HIPAA privacy rule.

* * *

Chairman Traynor, thank you for providing me an opportunity to discuss the provisions of Senate Bill 2399 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.

Appendix A

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 2002Authorizations 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.

Att #3

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 Senate Judiciary Committee
SB 2399
Wednesday, February 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 ~~support HB 1354.~~ opposition

We have seen a number of bills in this session that deal with privacy of health information. At the same time we are working with our members to get them into compliance with the privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA will impose sweeping new federal regulations on how all medical providers, health plans, and others will protect the health information of the patients and beneficiaries they serve. These provisions include the right for patients to have their information protected during routine health care and include additional safeguards related to marketing. The provisions of Section 1 of this Act would add conflicting terms and conditions related to marketing that would add to the implementation hurdles that our members are facing. We support HB 1438 that was prepared by health care groups and the state to resolve state law conflicts with HIPAA. In order to give our members and other providers sufficient time to implement HIPAA effectively, we would ask that Section 1 be deleted from this legislation.

Section 2 pertains directly to pharmacies and the disclosure of the prescriptive practices of a practitioner. 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 that claim and would then have to deny service to the patient who is receiving the prescription. These types of systems include the State Medicaid program and BlueCross BlueShield of North Dakota.

Another 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.

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.

AH #2

PROPOSED AMENDMENTS TO 2399

Page 1, remove lines 5-23

Page 2, remove lines 1-12

Page 2, line 18, insert immediately before "between" the word "disclosures"

Page 2, line 19, insert immediately after "staff; the word "disclosures"

Page 2, following line 19; insert new language " This section does not limit disclosures to the North Dakota State Board of Pharmacy or to the North Dakota State Board of Medical Examiners. This section does not limit disclosures made by a pharmacy necessary to receive payment for provision of prescription medications."

AH #5

North Dakota State
Board of Medical Examiners

ROLF P. SLETTEN
Executive Secretary and Treasurer

LYNETTE McDONALD
Administrative Assistant

TO: SENATE JUDICIARY COMMITTEE

FROM: ROLF SLETTEN, EXECUTIVE SECRETARY

RE: SB 2399

DATE: FEBRUARY 12, 2003

The North Dakota Board of Medical Examiners is charged with the responsibility of enforcing the Medical Practice Act. One vital aspect of that job is to ensure that the prescription writing practices of North Dakota physicians are within the parameters of good practice. Obviously it would be impossible for the Board to meet its obligation to the public if it could not determine what prescriptions are being written by individual physicians. The Board obtains that information from pharmacies and through the Board of Pharmacy.

This bill may have a devastating unintended consequence if it is not amended to clearly state that "this section does not limit disclosures to the North Dakota State Board of Pharmacy or to the North Dakota State Board of Medical Examiners".

That language is incorporated into the amendments being proposed by the State Board of Pharmacy. The Board of Medical Examiners supports the amendments proposed by the Pharmacy Board, however, it should be clearly understood that whatever the fate of the other proposed amendments may be, the language underscored above is essential to the functioning of the Board of Medical Examiners.

CITY CENTER PLAZA • 418 E. BROADWAY AVE., SUITE 12 • BISMARCK, NORTH DAKOTA 58501 • PHONE (701) 328-6500 • FAX (701) 328-6505
www.ndbomex.com

AH #6a

Testimony of Rebecca Thiem Before the Judiciary Committee

Requesting Amendment of Senate Bill 2399 to Delete Section 2

My name is Rebecca Thiem. I am an attorney with the law firm of Zuger Kirmis & Smith. I represent IMS HEALTH.

IMS HEALTH is the world's leading provider of information, research and analysis to the pharmaceutical and health care industries, with data collection activities in over 100 countries. Founded in 1954, IMS HEALTH operates throughout the United States. In the United States alone, it collects information from over 250,000 sources and processes over 72 billion records each month.

IMS HEALTH's business includes tracking diseases, treatments and their outcomes, a component of which includes measuring the prescription activities of physicians and the sale of pharmaceutical products.

Privacy is a priority for IMS and it has established privacy councils within the company, whose primary mission is to develop and disseminate comprehensive privacy principles and practices that reflect national and local regulations.

Protecting patient privacy is a priority to IMS. IMS requires that its data suppliers provide anonymized information, which has been stripped of all patient identifiers. In the few instances where patient identifiable information is required, IMS first obtains express prior consent of the patient.

For these reasons, IMS has no objection to Section 1 of SB 2399 which adds additional protection and privacy to identifiable health information in the marketing context. However, there is no similar public policy reason for protecting practitioner or provider-based identification information.

Using physician prescribing data obtained from pharmacies, IMS HEALTH is able to assist the medical, scientific, government, pharmaceutical, and health care management communities in conducting outcomes research, implementing best practices, and applying health economic analyses. IMS HEALTH has used the physician prescribing data it receives to provide information to the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the U.S. Department of Labor, and more recently the attorney general offices of various states in connection with their investigation of illegal prescribing practices for Oxycontin.

Similar legislation has been proposed in other states. However, to our knowledge, no state has adopted legislation which restricts access to provider information.

Individual physician concerns can be addressed through numerous mechanisms. Physician identifiable information obtained from pharmacies and used in IMS HEALTH reports is governed by agreements with the American Medical Association, the American Osteopathic Association, and others. These association agreements define permissible and impermissible uses of the information. In fact, the AMA agreement includes an opt-out provision which provides physicians with a method of placing additional restrictions on the use of information relating to a physician.

IMS HEALTH also does not believe that Section 2 of SB 2399 will achieve its purported purpose. Section 2 only seeks to protect the confidentiality by restricting disclosure of such information by pharmacists. Such information, however, is already available from a wide array of other sources. Moreover, Section 2 is overbroad in that it does not restrict disclosure only in the marketing context but for any valid reason including potentially the use of such information by third-party payers in adjudicating pharmacy claims.

Further, Section 2 of SB 2399 could be read to create a privacy right for practitioners, a right which would not be in the interests of either patients or the public. In a health care system where transparency is in the public interest, it is important to track and identify the quality of care and the efficiency of current practices. Providing for anonymity of health practitioners would jeopardize gains made in providing consumers with information about quality, price, and practices within the health care market.

Therefore, we urge that Section 2 of SB 2399 be deleted as against the best interests of the health care consumers in North Dakota.

Att 66.

PROPOSED AMENDMENT TO SENATE BILL 2399

Page 2, remove lines 13 through 19

Renumber accordingly

6c

IMS HEALTH POSITION PAPER ON SENATE BILL 2399
PROVIDER IDENTIFICATION
THE CASE FOR IDENTIFICATION AND DISCLOSURE

IMS HEALTH has no objection to Section 1 of Senate Bill 2399, but requests that SB 2399 be amended to delete Section 2. Section 2 prohibits disclosure by a pharmacist to a third person of "any information of a practitioner which identifies the practitioner."

SUMMARY

IMS HEALTH believes SB 2399 should be amended to delete Section 2 for the following reasons:

1. Section 2 of SB 2399 will disrupt many beneficial uses of physician prescribing data obtained from pharmacies (e.g., health care research, physician education, and increased drug samples available to consumers from their physicians).

2. A legislative solution is not necessary because other methods of addressing individual physician concerns exist.

3. Section 2 of SB 2399 will fail to achieve the desired objective of preventing distribution of physician prescriber information, because physician prescriber information is available from many sources beyond the pharmacy, including but not limited to pharmaceutical benefits managers, insurance companies, health care clearinghouses, and patients.

4. Section 2 of SB 2399 could be read as establishing a privacy right for physicians in their professional capacity (as compared with personal information), which privacy right is not in the best interests of the health care consumer.

IMS HEALTH – AN OVERVIEW

IMS HEALTH (www.imshealth.com) 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 billion records each month (de-identified with respect to patient information).

IMS HEALTH'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 de-identified data.

Using this data, IMS is able to assist the medical, scientific, pharmaceutical and health care management communities in conducting outcomes research, implementing best practices, and applying health economic analyses. 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).

Because the collection of health information touches on one of the most sensitive of all topics, IMS HEALTH has operated with long-standing and extensive practices to protect the privacy of individual patients and preserve the confidentiality of the information we collect. These practices include: requiring that transaction data not include identifiable patient information prior to being sent to IMS HEALTH; screening records before acceptance to ensure that they are patient de-identified; tightly controlling access to data; requiring informed patient consent before collecting individually identifiable patient information; restricting use of information; routinely auditing information practices; and entering into confidentiality agreements with data sources, employees, and clients. With significant business operations throughout the world, IMS HEALTH has addressed the requirements of country-specific data protection laws for many years, and with its enactment several years ago, has ensured compliance with the EU directive on privacy. In our 48 years of business, IMS has never had a complaint nor legal action due to mishandling of patient confidential information.

1. Section 2 of SB 2399 will disrupt many beneficial uses of physician prescribing data.

Using physician prescribing data obtained from pharmacies, IMS HEALTH is able to assist the medical, scientific, government, pharmaceutical and health care management communities in conducting outcomes research, implementing best practices, and applying health economic analyses. The company's databases of 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).

Customers for IMS HEALTH services include the U.S. Food & Drug Administration, the Centers for Disease Control and Prevention, and other government agencies. IMS HEALTH data is used by the U.S. Department of Labor to calculate the Consumer Price Index and the Producer Price Index. IMS HEALTH data has been used in connection with the resolution of dozens of

antitrust cases, including In re Brand Name Prescription Drug Litigation (Federal District Court, Northern District, Illinois). More recently, IMS HEALTH has been working with the Attorney General offices of a dozen states in connection with their investigation of illegal prescribing practices for Oxycontin.

In addition, IMS HEALTH data is used to conduct research and analyses on important health issues, such as over-prescribing of antibiotics. IMS HEALTH data also remains an important source of information for researchers in academia. IMS HEALTH needs physician-identifiable information to match prescriptions with other professional and practice information to conduct its analyses. Passage of Section 2 of SB 2399 will substantially increase the costs for IMS HEALTH to collect physician prescribing information, and will have an adverse impact on the quality of the information services available to IMS HEALTH customers.

2. A Legislative Solution is Not Necessary Because Other Methods of Addressing Individual Physician Concerns Exist.

IMS HEALTH clearly understands the need to balance the benefits of access to and use of physician prescribing information with its responsible use. IMS HEALTH has worked very closely with various professional organizations over the years to ensure the interests of physicians are reflected in the responsible use of physician prescribing information by IMS HEALTH and others. Physician-identifiable information obtained from pharmacies and used in IMS HEALTH reports is governed by agreements with the American Medical Association ("AMA"), the American Osteopathic Association and others. These association agreements define permissible and impermissible uses of this information. In addition, the AMA agreement includes an opt-out provision which provides physicians with a method of placing additional restrictions on the use of information relating to a physician (including physician prescribing information). IMS HEALTH has also worked with representatives of the American Medical Association and the pharmaceutical manufacturers to develop model guidelines in the use of physician prescribing information by pharmaceutical sales representatives.

In addition to the above, IMS HEALTH has worked directly with a small number of physicians over the years to address their concerns directly about the use of physician prescribing information. In its experience (in the United States and in other countries), only a small number of physicians have expressed concerns regarding the use of physician prescribing information, concerns which IMS endeavors to address in a prompt and responsible manner. IMS HEALTH will continue to address these concerns directly with physicians and indirectly through professional associations such as the American Medical Association.

3. **Section 2 of SB 2399 Will Fail to Achieve the Desired Objective of Preventing Distribution of Physician Prescriber Information Because Physician Prescriber Information is Available from Many Sources.**

Section 2 of SB 2399 intends to protect the confidentiality of physician prescribing information by restricting disclosure of such information by pharmacists (except for certain permitted releases). However, such information is available from a wide array of sources, including pharmacy benefits managers and other third party administrators, health plans (including health maintenance organizations, group health plans, and other insurers), claims processors and third party networks and switches. It is also well-recognized that patients are entitled to disclose physician-identifiable practice information relating to the patient's treatment without the consent of the physician. Creating confidential protection of physician prescribing information which only restricts pharmacists will have limited, if any, of the intended effect.

4. **Section 2 of SB 2399 could be read as establishing a privacy right for physicians in their professional capacity (as compared with personal information).**

The Supreme Court has recognized a constitutional right to privacy in several landmark cases such as Olmstead v. United States, 277 U.S. 438 (1928), Roe v. Wade, 410 U.S. 113 (1973), Whalen v. Roe, 429 U.S. 589 (1977), and Griswold v. Connecticut, 381 U.S. 479 (1965). These cases derive a privacy interest from the penumbra of rights enumerated in the 1st, 4th, 5th, 9th and 14th Amendments to the U.S. Constitution. The Supreme Court has set out two distinct privacy interests under the constitution: an individual interest in avoiding disclosure of personal matters, and an interest in independence in making certain kinds of important decisions. In the absence of these interests, any limitation on speech (on the basis of a privacy right) will generally be found to violate the first Amendment right to free speech. In fact, there has been no recognition of a privacy interest in professional or practice information. In a review of court decisions throughout the United States, physicians appear to have no reasonable expectation of privacy with respect to their patients' health care data. As a matter of first impression, Section 2 of SB 2399 could set a dangerous precedent in restricting access to this information.

On April 14, 2003, the final regulations containing the "Standards for Privacy of Individually Identifiable Health Information" issued by the U.S. Department of Health & Human Services will apply to health care providers (including pharmacists and pharmacies) and others (the "HIPAA regulations"). IMS HEALTH believes the HIPAA regulations give patients a system through which they can hold the health care system accountable for the proper use of their

private health information. Importantly, the use of physician-identifiable information is not restricted under the HIPAA regulations.

In addition to a review of case law and regulations, health privacy legislation introduced in Congress over the last several years has avoided any restrictions on "provider" or physician information from health care records. Examples of Federal legislation include: Senator Jefford's "Health Care Personal Information Nondisclosure Act" (S. 578), Senator Bennet's Medical Information Protection Act" (S. 881), and the "Medical Information Privacy and Security Act" introduced in the Senate as S. 573 by Sen. Leahy (Chair of the Senate Democratic Privacy Task Force) and in the House as H.R. 1057 by Rep. Ed Markey (Co-Chair of the Congressional Privacy Caucus).

The public policy reasons which require confidentiality of a patient's health care data do not apply in the provider context. In the health care system – where tracking and identifying poor quality care, fraud and inefficient practices are a critical function in both the private and public sectors – anonymity of health care providers would jeopardize the consuming public's right to know about quality, price, and practices within the health care market.

CONCLUSION

IMS urges the Senate Judiciary Committee to amend SB 2399 to delete Section 2 prohibiting disclosure by pharmacists of any practitioner-identifying information.

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Att # 7

BOARD OF PHARMACY
State of North Dakota

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Senate Bill 2399
Judiciary Committee
10:00 am on February 12, 2003

Chairman Traynor, members of the Judiciary Committee, for the record I am Howard C. Anderson, Jr, R.Ph., Executive Director of the North Dakota State Board of Pharmacy.

Thank you for the opportunity to submit written testimony. On behalf of the North Dakota Board of Pharmacy, we would first like to suggest combining all Senate bills related to patient privacy and disclosure issues in health care into one comprehensive bill. This will make it possible for health care providers, already struggling with HIPAA, to manage these issues without taking any more time away from patient care.

Pertaining to the bill at hand, the Board of Pharmacy along with the North Dakota Board of Medical Examiners have suggested an amendment to address some our concerns. The ability for disclosure of information regarding prescriptive practices to the Board of Pharmacy and the Board of Medical Examiners is necessary to facilitate the proper investigation into potentially suspicious and maybe even harmful prescribing practices. Without this ability, a pharmacist would be unable to report to either Board the name of a practitioner prescribing medications outside his or her scope of practice or prescribing large amounts of a medication that can potentially be used to cause harm. Both of these situations would be detrimental to safe and effective patient care.

Billing third party plans may also present a problem with the wording of the "Prohibited disclosures" portion starting on line 15 of the bill. Health insurance plans require pharmacies to submit all pertinent information including the practitioner's name to be eligible for payment. A further exception to the prohibited disclosures is needed to allow pharmacies to continue to be paid for dispensing services.

Drug companies do pay money for information which identifies how much of their drugs are being prescribed. They use this information to pay their salespersons based on commission and bonuses. This information sometimes comes from pharmacies that receive approximately twenty dollars a month for this information. Their computer vendor gathers this information and resells it to a company like IMS Health who in turn sells it to the drug company. We have one computer company in

North Dakota who receives significant revenue from this process. However, our pharmacies and computer vendor would be willing to forgo this amount of money. This would result in an increase for computer maintenance services from the computer company. However, once this information goes outside of the state for the adjudication of third party claims it gets into the hands of insurance companies, and their claims processors. Even Blue Cross Blue Shield uses an out-of-state claims processor for adjudication of their claims. These pharmacy benefit managers or switches that receive this information can capture it and in turn sell it to companies such as IMS. Our concern is that our local companies may lose revenue and those outside of the state will continue to sell the same data and the only thing that will change is that we will lose the revenue in North Dakota.

Even cash cards that are intended to give patients discounts when they do not have other insurance end up being vehicles for the capture of this information. The pharmacy ends up giving the patient a discount and the claims processor captures the information about the patient's prescriptions. This is a group of patients, typically Medicare patients with no prescription coverage, and the cash cards provide an easy mechanism to capture the drug utilization trends for these patients. Many of these patients are inadvertently, when they sign up for the discount card, agreeing to provide their information to the card sponsor.

Additionally, we have concern for pharmacies working with a health plan sponsor in an instance where a health plan has identified, for example, that ACE inhibitors, a blood pressure medication, may be underutilized in diabetic patients. This underutilization is a serious concern because ACE inhibitors have been shown to have a protective effect on the kidney in diabetic patients. Attempts to increase the utilization of those ACE inhibitors may realistically be compensated by the health plan or employer in the best interests of their employees. We are concerned that some of the language in this bill may prohibit those kinds of activities.

Thank you for your time.

Sincerely,

Howard C. Anderson R.Ph.

Howard C. Anderson, Jr, R.Ph., Executive Director

AH #8

SENATE JUDICIARY COMMITEE
TESTIMONY REGARDING SB 2399
SENATOR DAVID O'CONNELL
February 12, 2003

This legislation is about medical privacy. The bill keeps health care consumers' private information private and protects the people who prescribe the medicine we take.

SB 2399 has two sections:

- Section 1, restricts marketing of individually identifiable health information. Information that is specific to one health care consumer and can be used to identify an individual consumer. The section closes a loophole in federal law in the new HIPAA medical privacy law. The only exception to this section is allowed for marketing to individuals that specifically "opt-in" to a marketing program.

- Section 2, restricts that ability of pharmacists to reveal information about the prescriptive practices of medical professionals to third parties for the purpose of marketing. The bill recognizes that pharmacists must disclosure information about prescribers for other purposes, such as reimbursement by third party payers and to comply with certain laws and investigative bodies. Section 2 protects the professional privacy of health care providers.

Senator Fairfield will provide a more detailed description of the bill. Thank you for your consideration of this important matter and I ask that you give SB 2399 a Do Pass recommendation.

Att #9

To: Chairman John T. Traynor and Judiciary committee members

From: Guy Shanta, Pres., Midco Data Bismarck, Inc.

Re: SB#2399

Dear Chairman Traynor and committee members:

We are submitting this written testimony in opposition to SB#2399. We are a small North Dakota owned and operated company that supplies hardware, software and support services to Pharmacies across our state. We have recently completed extensive changes in our software to insure patient privacy in compliance with HIPPA regulations. We collect drug and physician data, no patient specific data, from our customers. The company we submit this data to then markets it to drug manufacturers. There are privacy contracts that the drug manufacturers and Midco Data have signed pertaining to this data. This data is used to calculate quotas and bonuses/commissions for the drug reps. All insurance companies require physician DEA/state code numbers to process prescriptions.

I do not believe this bill will improve healthcare for the patient.

Our pharmacies receive income for submitting this data, and so do we. Small businesses in North Dakota would lose approximately $123,000.00 in income if this bill passes.

We are the only pharmacy system vendor located in North Dakota, and of course would comply if this bill passes. How would all the other out of state system vendors be forced to comply? These out of state vendors do not support the North Dakota tax base, but may still be able to obtain income from North Dakota information.

If the drug manufacturers don't get physician specific data, will they continue to market their products in North Dakota? If they don't market their products here, the physician will not get personal detailing on new products, and the physician will not be sampled. This would be a negative for the patient because currently the physician can give them a sample to try to make sure it works for them before they have to purchase it.

I urge you to vote no on this bill.