

***State Collection of
Private Medical Information***

**Public Response to
Minnesota's Proposed Rule**

November 2002

Citizens' Council on Health Care

A free-market resource for designing the future of health care

Table of Contents

OVERVIEW 3

DATA TO BE COLLECTED..... 4

OFFICIAL DOCUMENTS..... 4

PUBLIC RESPONSE 4

 Number of Letters Received..... 4

 Letters of Full Support – Nearly Complete List..... 5

 Letters of Partial Support – Nearly Complete List..... 5

 Letters/Testimony of Opposition – Limited List..... 5

 Letters from Elected Officials..... 6

COMMENTS OF OPPOSITION – INDIVIDUALS 6

COMMENTS OF OPPOSITION – ORGANIZATIONS..... 12

 Citizens’ Council on Health Care..... 13

COMMENTS FROM ELECTED OFFICIALS..... 14

COMMENTS OF SUPPORT – INDIVIDUALS AND ORGANIZATIONS..... 16

PUBLIC SENTIMENT – SHORT TAKES..... 21

MN DEPARTMENT OF HEALTH: JUSTIFICATION FOR RULE..... 23

MN DEPARTMENT OF HEALTH: RESPONSE TO SPECIFIC CONCERNS..... 24

HISTORICAL TIME FRAME..... 25

SUMMARY 26

Compiled and Written by
Twila Brase, RN
President
Citizens’ Council on Health Care

State Collection of Private Medical Information

Public Response to Minnesota's Proposed Rule

Overview

On August 19, 2002, the Minnesota Department of Health (MDH) published in the State Register a proposed rule to require most hospitals and health insurers to collect and electronically transmit individually-identifiable medical record data to the department without patient consent: *Proposed Permanent Rule Regarding Administrative Billing Data, Minnesota Rules, chapter 4653*.

The announcement generated substantial opposition. With well over 25 letters requesting a hearing to be held, the health department was required to hold a hearing on October 4, 2002 before Administrative Law Judge, Allan W. Klein. About 100 people attended the hearing which lasted 4 1/2 hours. Health officials later responded to the public's comments by proposing various changes in a letter to the judge. The public responded back. A total of 1,086 letters from the public were received during public comment periods issued by MDH and the judge. Following state law, Judge Klein must issue a ruling on the proposed rule by December 2, 2002.

If the rule is approved, the collection of data begins January 1, 2003. On July 1, 2004, hospitals must begin annually submitting data to the health department on all patients, regardless of their insurance status. Following the same time frame, but only as soon as state funding permits, health plans and insurers must submit data on *fully-insured* individuals—those whose companies purchase insurance for them or who purchase their own insurance.

The fully-insured are 38.2 percent of the Minnesota population.¹ Because the State already collects data on the 23.7 percent whose health care is publicly subsidized, almost 62 percent of Minnesota citizens will have their private health information sent to the state government. The 29.8 percent who receive health coverage through self-insured companies—employers that use their own cash reserves to pay for employee health care expenses—and the 9.1 percent who are uninsured will not yet have their data collected or placed in a state database. The department has the legal authority to collect data on *all patients* from physicians and other health care professionals, but costs, physician acceptance, inadequate clinic data systems, and a federal law that doesn't require self-insured employers to follow certain benefits-related state laws likely led to the current proposal of using only insurers and hospitals, and tracking only the 62 percent.

According to the health department's Statement of Need and Reasonableness (SONAR), health officials intend to use these new data to supplement current data obtained from birth and death records, to track all services provided to a specific individual, to cross check data with existing disease surveillance systems, to supplement existing surveillance systems, to monitor hospitalization and age-related disease trends, to evaluate the use of antibiotics, to demonstrate that immunizations are economical, to strengthen immunization programs, to determine the cost of care for certain conditions, to evaluate disparities in provision of health care according to race and ethnicity, and to determine the severity of a diagnosis through use of pharmacy data.

If the judge *approves* the rule, the department cannot adopt it until five working days after receipt of the judge's report. However, the governor can veto the rule within 14 days after receiving a

¹ Percentages in this paragraph taken from the MDH report "62J Health Care Use and Outcomes Data and Research Initiatives," February 15, 2001, p. 6.

copy of the rule. If the judge *disapproves* the rule, the next steps depend on the context of the ruling. The department can opt to address the judge's concerns by changing the proposed rule, appealing the decision, or requesting legislative action to turn the rule into state law. According to Minnesota Rules 1400.2100, the judge may disapprove the rule if it exceeds statutory authority, does not comply with other Minnesota laws, is not rationally related to the agency's objective, has no demonstrated need or reasonableness, is unconstitutional or illegal, or, if after submitted changes by the department, is substantially different than the proposed rule.

This report details the public's response to the proposed rule as provided in public testimony or written in public comments and letters to the Minnesota Department of Health and Judge Klein. It also provides detail on the health department's stated justification for the rule and the department's written responses to the public's concerns.

Data To Be Collected

If the rule is approved, state health officials will collect and place into one or several databases nearly 100 data elements including: patient name, patient identification numbers, medical record numbers, address, date of birth, race, ethnic background, employment status, marital status, medical diagnoses, mental health diagnoses, procedures performed, treatments, medications prescribed, whether the prescription is a refill or first fill, health status, doctor's names, doctor's identification numbers, name of health insurer, name of hospital, dollar amount charged, total sum of medical bill, type of insurance, hospital discharge date, hospital admission date, cause of injury, date of onset of illness, date of onset of injury, date of onset of pregnancy, and relation of care to chemical dependency and mental health treatment.

Official Documents

Proposed Rule:

<http://www.comm.media.state.mn.us/bookstore/stateregister/stateregister/278.pdf>

MDH Statement of Need and Reasonableness (SONAR):

<http://www.health.state.mn.us/divs/hpsc/dap/encounter/sonaraug02.pdf>

Public Response

Letters, testimony, and email from members of the public, public officials, health officials, health insurers, corporations, various organizations and other state governments have been received by the MDH and the Office of Administrative Hearings during two separate comment periods. Letters express opposition, full support, or partial support. Judge Klein has in his possession all the public's comments for use in rendering a decision on the proposed rule.

Number of Letters Received

Letters <i>opposing</i> the rule:	1019	93.8%
Letters <i>supporting</i> the rule:	<u>67</u>	<u>6.2%</u>
Total Letters:	1086	100%

Letters of Full Support² – Nearly Complete List

Bloomington Public Health
Buyers Health Care Action Group
Dakota County Public Health Department
Environmental Impacts Analysis Unit, MDH
Harry Hull, State Epidemiologist, MDH
Hennepin Center for Diabetes & Endocrinology
Individual Citizens – *a few*
March of Dimes
Metro Public Health Planners
Minneapolis Department of Health and Family Support
Minnesota Cancer Surveillance System, MDH
Minnesota Department of Human Services
Minnesota Public Health Association
National Association of Health Data Organizations
Saint Paul – Ramsey County Department of Public Health
University of Minnesota, School of Public Health
University of Wisconsin, Centers for Health Systems Research and Analysis
Utah Department of Health

Letters of Partial Support³ – Nearly Complete List

Carlson Companies, Inc.
Employers Association, Inc.
Individual Citizens - *several*
Insurance Federation of Minnesota – *October 24, 2002 letter*
Minnesota Council of Health Plans
Minnesota Medical Association
UCare Minnesota
US Bank – *arrived late*⁴
Wells Fargo – *arrived late*

Letters/Testimony of Opposition – Limited List

American Family Insurance
Citizens Commission on Human Rights of Minnesota
Citizens' Council on Health Care
Federated Insurance
Individual Citizens – *hundreds*
Insurance Federation of Minnesota – *September 4, 2002 letter*
John Alden Life Insurance Company

² Full Supporters are defined as those individuals or organizations that wrote comments fully supportive of the rule, without any clear objections noted.

³ Partial Supporters are defined as those individuals or organizations that wrote comments which did not expressly oppose the entire rule, or oppose government collection of medical data without patient consent. However, such supporters opposed one or several or many sections of the rule.

⁴ Letters after the comment deadline are not considered by the judge, but were included in our letter count.

Lyme Disease Coalition of Minnesota
Members of Minnesota Health Information Management Association – *10 letters*
Miller Sellner Implements – *list of 20 names*
Minnesota Civil Liberties Union
Minnesota Family Council
Minnesota Physician-Patient Alliance
National Federation of Independent Business
State Farm Insurance Companies

Letters from Elected Officials

Attorney General of Minnesota, Mike Hatch
Board of Hennepin County Commissioners
Rep. Gregory Davids (R-Preston)
Rep. Bill Haas (R-Champlin)
Rep. Arlon Lindner (R-Corcoran)
Rep. Tom Rukavina (D-Virginia)
Sen. Twyla Ring (D-North Branch)
Rep. Alice Seagren (R-Bloomington)
Rep. Timothy Wilkin (R-Eagan)

Comments of Opposition - Individuals

- Citizens and Patients
- Data Professionals
- Health Care Professionals
- Legal/Research Professionals
- Out-of-State Citizens

Citizens and Patients

Action Plans

- “[T]his would be the same as if Mike Hatch and his department asked for all Attorney Records of their clients to make sure that services were available to all. Do you think the attorneys of this State would stand for that?...Quite frankly, I will instruct MY DOCTOR under threat of a law suit through patient confidentiality NOT TO AND TO NEVER release ANY information to the State of Minnesota. There might just be a revolt with this idea...and I’ll lead the charge.” - G.W., Bloomington
- “Just like telemarketers rent calling lists, I will rent my medical history to the state for a yearly fee.” – B.C.
- “The state will never get an accurate indication of disease because I personally will no longer go to a doctor in the state of Minnesota. I live in Hastings, a boarder [sic] city. I would have all my information transfered[sic] to a medical clinic in Prescott, Wisconsin. I believe that tens of thousands of people living along the borders would do the same.” – D.M.

Discrimination

- “[P]lease note not only the constitutional invasion of privacy it involves, but also that this proposed plan already discriminates against a group of citizens, those with medical conditions. Healthy persons who do not have to use state-regulated insurance plans will not have their private information (and misinformation) collected and analyzed.” – S.S., Slayton
- “[T]here is the real possibility of discrimination. This data could be available to a person’s employer, and used for unscrupulous and self-serving purposes. When a company downsizes, discriminatory information can be used as a means for determining which individuals should be laid off.” – G.G., Minneapolis
- “How are they doing[sic] to categorize ‘races,’ a term that’s practically irrelevant in a multicultural society. Plus, anthropologists argue that ‘race’ is a useless and often racist concept. Ethnicity and culture are too complicated to be identified by a check mark in a box.” – Mark Hochhauser, Ph.D, Readability Consultant, Golden Valley
- “I challenge anyone to define my race or ethnicity!” – Oral testimony, H.B., Cottage Grove

Patient Privacy and Cost

- “The bottom line is that *my* medical information is *my* concern and that of *my* healthcare provider. I believe that if MDH wanted to obtain this information from my home files, it would have to obtain a search warrant.” – N.W., Golden Valley
- “Are we looking for a way to track and monitor diseases or are we looking for a way to track and monitor people?” Oral testimony, Mary Tambornino, Hennepin County Commissioner
- “I’m sure this collection of information, cost of computer hardware and staff to keep it going will cost Minnesota Taxpayers a ton of money. And it will be not only a startup cost but a massive ongoing cost and we have other higher needs in this state...I don’t want to pay my taxes to support this endeavor.” – S.B.
- “This is another assault on privacy and certainly smacks of ‘big brother.’” - L.H., Hallock
- “Now, the government [is] trying to obtain my medical records and promising anonymity...It’s not like the government owned them, loaned them, and now wants them back. They never owned them. If the government is claiming public benefit, I would consider this a ‘taking’ of private property under the Fifth Amendment which would require just compensation.” – J.S., Bay City, Wisconsin
- “Isn’t there a Constitution that protects us? I think it has since it’s[sic] conception. It should still be good.” – M.L.
- “[I] sought mental health services for postpartum depression and that...diagnosis has consistently raised my insurance premiums to the highest level, despite the fact that the particular diagnosis was transient and related to the months following the birth of my first child. For my own protection, I have ceased to use my health insurance coverage when seeking follow-up appointments for the depression, as well as paying out of pocket for my

prescription medication despite the fact that I have insurance that would pay for those medications 100%. My husband...has also followed suit..." – Resident, Central Minnesota

- "I have been a diabetic for 50 years and have gotten along just fine without the government interfering with my health care...It's none of the government's damned business how many times I refill my prescriptions or what I take them for, who I am, or what diseases I have." – W.T.
- "We, the undersigned, do not believe the State of Minnesota should start collecting medical information on every patient in Minnesota. We have nothing to hide. We simply believe this to be very private information between his/her Doctor, Pharmacist, and insurance company." – signed by 10 citizens from West Minneapolis suburbs
- "If this data rule is passed, it would require a huge increase in the number of workers in the health department at a time when we already face a huge budget deficit." – J.A., Excelsior
- "If the records are kept at the Minnesota Department of Health, we are just one legislative action away from being public records. I cannot guarantee what a future legislative session will bring." – J.M., Lake City
- "As far as the constitutionality is concerned it seems like the greatest invasion of privacy there can be. What could be greater? Bedroom Police?" – G.W., Brandon
- "[T]he State of Minnesota, through the proposed rules, chooses to confiscate the privacy of every Minnesota citizen (or visiting citizen) on the vague assertion that this will somehow protect the public health. Worse yet, it places all medical information in one single database, thus simplifying access by a determined thief." – S.H., Apple Valley
- "Our individual rights MUST be honored over any 'perceived' benefits for the 'common good.' This is America, not the Soviet Union, or China, or any other socialistic or communistic country." – P.S., Eveleth
- "Please stop invading my privacy and spend your time doing something else that will be of value. There must be something." – D.W.

Public Health

- "While containment of communicable disease and prevention of chronic diseases caused by controllable external factors may normally fall within the purview of 'public health,' the long-term treatment of chronic diseases does not. The Minnesota Health Department is transgressing its limits with this proposal. The Department has not, to my knowledge, proposed any specific objectives or any scientific protocols by which the success of its projected program may be judged. – J.R., Ely
- "Improving public health is desirable, but the public would be a lot healthier of[sic] the state maintained and acted on a database of how many Twinkies, Big Mac's and beers I consume than what occurs between my doctor and me. It opens up a spectacular possibility for abuse...I will not accept being subject to the whim of a do-gooder, bigot, or activist whose agenda is different from what I find acceptable." – R.F., North Branch

- “I don’t think the health department is going to help anyone personally so why do they need all this medical data. It’s the physician who will be taking care of the patient, NOT the State of Minnesota.” F.G., White Bear Lake
- “Believe me, I understand the value of good government and the services that it can offer citizens. But the truth is, I don’t really care how the State Health Department would use this information. It doesn’t belong to them, and they have no right to it.” – L.A.

Data Professionals

“[S]everal states are now attempting to force central database reporting on insurance and administration companies. In all cases it involves encryption of individual names and the ‘secret’ to this encryption code is basically public knowledge, it’s openly published.” – B.S., Licensing Administrator

“I know a lot about database design because I am a programmer. There is no sure way to protect data for long. Just this year alone Microsoft has put out 57 bulletins of security problems with their system... Now since I program for Insurance companies I know they have been trying to get such [genetic] information for a long time. They want to use that information to start rating insurance policies based on some future genetic defect you and me might come down with. Just think of what they could do if they could combine that information from the Health Department’s database?” – L.W., Minneapolis

“I am a member of the Minnesota Health Information Management Association... I oppose the Department of Health’s efforts to collect individual healthcare data.” – R.G., RHIT, Hugo

“Anytime a database is created there is potential for misuse. Tracking every medical diagnosis seems Orwellian and very scary. Patients are becoming aware like never before of how their private medical information is being used and misused and the advent of HIPAA privacy is making them even more aware... It will be a huge invasion of medical privacy for health care organizations to be mandated to report every visit and release all the demographics, diagnosis, etc. for every patient for every visit. This proposed rule gives the state power as controller of all health information for all patients for all health care facilities.” – M.J., member of Minnesota Health Information Management Association

“I have spent much of my career working on privacy and encryption systems and ultimately the comment that I heard from a member of the National Security Administration rings the truest... [I]t does not matter how good or elaborate your protection system is, the place that creates the biggest breach of security is the person with the key.” – J.M., Minneapolis

“In the 1970’s I worked in hospital medical records, acquired a Medical Records Technician’s certification at which time I learned the guarantees of confidentiality of a patient’s medical records. Later in my career... I worked in the Commerce Dept. in the Census Bureau... Perhaps the most important thing I learned working in medical records is that the patient owns his/her medical records. The hospitals/doctor does not own the patient’s records! I believe the info needed could be accurately obtained in surveys, done by competent federal, state, or local canvassers who are well trained.” – J.M., Saint Paul

Health Care Professionals

“My patients already feel manipulated by their insurance carriers and gouged by the pharmaceutical companies. The prospect of their most confidential medical information being gathered and controlled by a state bureaucracy is perceived as the last and worst straw.” – P.B., medical doctor

“It just amazes me that the Department of Health, which is on our case constantly in the health field regarding patient confidentiality, would pull something like this!! Are they nuts?!...Please don't let this happen.” – K.G., registered nurse, New London

“The possibility of their entire chart being on file in a government agency is appalling.” – P.M., medical doctor, Dawson

“[C]entralizing data of individuals' health and mental health information records is simply centralizing power and should not be done. It tempts the blessed regardless of how lofty the goals are in reducing health care costs and identifying 'pockets of illness' that could be dealt with through preventative health measures. I am absolutely opposed to any system that would concentrate information in the hands of individuals who could never be trained, and who could never be in great enough number to accurately insure the privacy of the sweeping and comprehensive data that would need to be reported.” – S.S, psychologist, Mankato

“The intrusions on privacy already routinely practiced by the insurance industry are simultaneously vast and horrifying...[M]y clients who can afford it pay privately for their time with me, request I keep minimal records of our conversations and sign no releases of information, guaranteeing our private discussions remain private...To permit the State to gather private medical information which is linked with one's name, age, ethnicity and location for unstated, non-specific “research on health problems' makes my skin crawl.” – B.C., Licensed Psychologist

“[T]he MN Health Data Rule would be a means by which the government could develop and support policy that would ration health care for the citizens of this country. A concept that should not be tolerated in a democratic capitalistic nation.” – L.C., registered nurse, Blaine

“There is no way for us to know how this data may be used or by who, or for what purposes. This goes well beyond legitimate research, which can be conducted without identifying the patient and which I myself have participated in many times. It is one thing to give information voluntarily. It is quite another to have it confiscated from medical records without our consent.” – R.H., licensed practical nurse, Minneapolis

Legal/Research Professionals

“In my capacity as a prosecutor, I have also prosecuted employees of the State of Minnesota for embezzling from various departments. When asked why they stole from the State, the response is all too often ‘it was so easy, their bookkeeping, oversight and security systems are sloppy.’ If it is so easy to steal money from the State, it will be equally easy to sell private data to the highest bidder, just as it has happened in the financial and retail industry.” – H.B., Cottage Grove

“The Minnesota Supreme Court recently recognized a private right of action for invasion of privacy (ironically, a right that will not be available to patients for breaches of privacy by the

Health Department, its researchers or contractors). In so doing, the Court recognized the core nature of privacy to our humanity, in our society and in our form of government: ‘The right to privacy is an integral part of our humanity; one has a public persona, exposed and active, and a private persona, guarded and preserved. The heart of our liberty is choosing which parts of our lives shall become public and which parts we shall hold close.’ (*Lake v. Wal-Mart Stores, Inc.*, 582 N.W.2d 231, 235 (Minn.1998)” – Michael B. Rodning Bash, Attorney

“I am an attorney who advises clients about access to data under the Minnesota Government Data Practices Act. Under the Data Practices Act, the only data that may be collected is data that is necessary for the administration and management of programs specifically authorized by the legislature, local governing body, or federal government. The Minnesota Department of Health does not need patient-identifying data from all individuals obtaining health care in order to protect the ‘public health’...In addition, centralizing so much private and confidential data on individuals into one database system is fraught with danger. Recall years ago when the federal government sought to prevent criminals from breaking into pharmacies and stealing controlled substances which were mixed in among all of the other drugs. The federal government required all of the pharmacies to install specific safes to store the controlled substances. After the federal law passed, when the criminals broke into pharmacies, they knew exactly where to look for the controlled substances – in the safe. In the instant situation, persons interested in obtaining private and confidential information on individuals, including their health care information, will know where to look – the Minnesota Health Department’s Health Care Collection system.” – S.H. Apple Valley

“[N]o system is 100% secure. There is also the danger of legal evolutionary processes by corporate or governmental interests to eventually gain access. A notable historical example is the legal evolution of the Social Security number to a universal identification number: something the original proponents had assured the public would never happen. It did, although it took a generation.” – William W. Merrill, research scientist

“Confidential means confidential. And confidential does not mean that government has access except under very strict and unusual circumstances. I cannot believe that anyone of conscience would propose that health and medical information about an individual is legitimately information available to government entities for the purposes proposed.” – S.C., former professor of health care ethics.

“What the state is proposing essentially is a huge research project. I feel they need some form of Central IRB [Institutional Review Board] approval and also it should, like any other research project, be voluntary with written informed consent by the participant. I don’t mean a consent that is hidden in the release of information to the insurance company that is signed at the time of visit so the facility can receive reimbursement. It needs to be a separate written informed consent and should be on each episode of care...Without this process I feel this information gathering is an invasion of privacy and breach of medical provider/client confidentiality. – Margaret Brunner, R.N., Burn Center Clinical Educator, study site coordinator

Out-of-State Citizens

“Although I am not currently a Minnesota resident, my parents and other relatives still reside in Minnesota. Decades of my own health records are directly affected. The ‘family data’ provisions also tie my medical information to the disclosure provisions through the medical records of my parents.” – S.R., Hillsborough, NC

“I, myself am in a panic over this proposal. If your state passes this, my state, (Kentucky) may try to do the same.” – L.R., Kentucky

“While I may be a Wisconsin resident, I utilize doctors in Minnesota. The information is mine, after all. It is my right, and should remain my right, to disclose or not to disclose.” – W.D., Hudson, Wisconsin

Comments of Opposition – Organizations

Citizens Commission on Human Rights of Minnesota

“[T]he commitment law was passed in Minnesota lowering the standards for a person to be committed...[A] person can be committed if another person feels that some day, maybe down the road, this person may be dangerous to themselves or other. If someone really wants to abuse the system, they could have someone committed out of spite...So imagine if the Mental Health field would be allowed to look into anyone’s record.” – Brenda Glanzman

“[G]ive them an inch and they’ll take a mile. We’ve seen this time and again in our legislature. First a right is somewhat restricted, then, since a precedent in the area is set, the right gets somewhat more restricted. If we let the Health Department have personal and confidential information on individuals to conduct a study of health trends, what is to stop the corrections people from requesting mandatory collection of priest-penitent data from the clergy to see which areas of the state have the greatest potential for crimes?” – Nancy Schumacher, Exec. Director

Fortis Insurance Company

“Fortis Insurance Company is very concerned about the cost of complying with the expansive and complex data request for personally identifiable data required by the proposed rules... We believe these reporting requirements will present an undue, costly burden on our company. – Brian Fraley, Director, Government Relations

Health Insurance Association of America

“We are also concerned that the proposed rules may inadvertently require certain automobile and workers compensation carriers to comply with the data requests.” – Angela J. Franklin, Legislative Director and Counsel

Insurance Federation of Minnesota

“[O]ur members are very concerned about the significant cost of complying with the proposed rules. Minnesota citizens already have an extremely limited number of health insurers from which to choose. We do not think it is sound public policy to make it even more difficult for small companies to compete in this marketplace...we oppose the entire set of proposed rules. – Robyn Rowen, Vice President, September 4, 2002

John Alden Insurance Company

“While our market share is not large enough to include us in the initial group of health insurers required to submit data, that could change from year to year simply because yet another company has decided to stop writing health insurance in Minnesota. Therefore, John Alden opposes the entire set of proposed rules. – Shannon C. Krygiel, Associate Actuary

Minnesota Civil Liberties Union

“The MnCLU believes that the proposed rule should not be adopted on both legal and public policy grounds...The Minnesota Department of Health (MDH) has not made a sufficient showing that the need to gather such patient-specific data outweighs the patient’s constitutionally protected right to avoid disclosure of personal matter...The enabling statute requires the Commissioner to ‘establish specific public health goals’; however, no specific public health goal is addressed in the proposed rule. Moreover, §62J.311, subd. 5 requires data and research initiatives to “minimize any privacy impact on individuals.” By requiring a broad and expansive array of name-specific medical records, the proposed rule does exactly the opposite of what is required in the statute. Rather than relying on statistical sampling of anonymous health data, or seeking aggregate health data to address specific health issues, the proposed rule seeks to monitor every medical contact of every insured hospital patient.” – Charles Samuelson, Executive Director

Minnesota Family Council

“There are enormous personal privacy implications.” – Oral testimony, Tom Pritchard, Executive Director

Minnesota Physician-Patient Alliance

“If the new MDH rules are passed, medical ethics and basic human decency would require that physicians must first inform the patient that the privacy of the medical record can be compromised by state rules allowing open disclosure to the MDH of entries in the chart. This is the medical equivalent of the ‘Miranda Warning’ given to suspected criminals before police questioning. ‘Anything you say may be used against you.’...[We] therefore respectfully request that the proposed rules be rejected as overbroad, confusing, and an unnecessary threat to the effective operation of the health care system.” – Lee Beecher, M.D., President

Citizens’ Council on Health Care⁵

Lack of Proper Public Notice: “State officials have done their best to keep the proposal under wraps, outside public awareness. This speaks to a lack of integrity in the rulemaking process. First, the title of the proposed rule is deceptive. ‘Administrative billing data’ could pertain to special education or transportation or food stamps or anything else. Second, the department did not do a press release announcing the publication of the rule or the request for comments. Third, at about noon on September 18th, the last day of the comment period, there was no notice of the comment period on their home page. In fact, it was difficult to even find the page with the Internet links to the SONAR and the Rule.” – testimony

Poorly Written Rule: “The department’s definition of privacy and security are not defined...The department has not addressed access to data by vendors of their technology systems, or use of backup information systems and disaster recovery for identifiable data or encrypted and non-encrypted data...When individual clinics make errors in data about individuals, it is not clear how the state government will assure integrity of the data... Contractors and researchers, while required to treat the data according to department security and privacy specifications can duplicate, share or distribute data without ready detection...“Enhancements” to ongoing data collection is not defined...Variances to the entire rule can be granted...” – testimony

HIPAA Privacy Rule Violation: “The [federal] Privacy Rule...does not require covered entities ...to provide data to government agencies or other organizations for the purpose of public health research. It allows them to, but does not require them to do so. This rule requires covered entities

⁵ All comments/testimony provided by Twila Brase, RN, President, Citizens’ Council on Health Care.

to provide the data, and therefore does not follow the HIPAA standard for privacy.” – letter to the judge, October 31, 2002

Supreme Court Supports Privacy: “In *Ferguson v. City of Charleston*...the Supreme Court noted that, “[t]he reasonable expectation of privacy enjoyed by the typical patient undergoing diagnostic tests in a hospital is that the results of those tests will not be shared with nonmedical personnel without her consent.”...[T]he Court stated, “in fact, we have previously recognized that an intrusion on that expectation may have adverse consequences because it may deter patients from receiving needed medical care.”⁶ – testimony

Violation of Current Minnesota Law: “Section 62J.321...states that data collection must continue for a sufficient time to permit various activities. The proposed rule is a proposed permanent rule for unending data collection on the citizens of Minnesota.” – testimony

Constitutional Rights Violation: “The Minnesota Constitution and the Fourth Amendment to the U.S. constitution guarantee protection from unreasonable search and seizure of persons, papers, homes and effects without a specific and descriptive search warrant.” – testimony

Costs Borne by Patients and Taxpayers: “The department has left out an important element in the SONAR..[C]osts are always borne by the patients who use those systems and purchase their products. The consumer will bear the cost. In addition, the cost to the agency of \$1,000,000 per biennium will be borne by taxpayers, not the agency.” – letter to the judge, October 31, 2002

Nuremberg Code Violation: “Citizens have a right to not be included in medical research without their voluntary consent, according to the internationally-recognized Nuremberg Code...In the 1940’s, the Nuremberg Code resulted from the German government’s violation of individual patient rights. Privacy is a time-honored patient right which is severely violated when fully identified information that permits the creation of individual and family profiles is collected by the State. No citizen should be forced to become a research subject to receive medical care.” – testimony

Not in the Public’s Interest: “There is no ‘public good’ basis for this rule, despite arguments to the contrary. The Council contends instead that the public’s good and the public’s health is best served when the integrity of the health care system is preserved, the confidential contract between a patient and their doctors is honored, and the dignity and rights of patients are upheld...The sick, at the most vulnerable times in their lives, when they are least able to resist violation, will find themselves having to choose between health care and privacy. If the rule is approved, they cannot have both.” – testimony

Comments from Elected Officials

Minnesota Attorney General Mike Hatch

“This Office opposes the Proposed Rules because they require the collection of personal medical information about Minnesotans without their consent...This Office will continue to support efforts to repeal MDH’s authority to collect personal and medical information without patient consent. This Office’s opposition to the statutory authority and the Proposed Rules includes both

⁶ Taken from written testimony given by Deborah Peel, MD at a hearing on genetic privacy, the House Judiciary Subcommittee on the Constitution, Washington, D.C., September 12, 2002.

a fundamental objection to personal medical information being released without consent of individual patients, and a practical concern that this information could fall into the wrong hands, even if MDH takes the utmost in security precautions.”

“[U]nder the Proposed Rules, MDH is only obtaining patient data for the ‘fully-insured population’ of Minnesota. MDH’s own records indicate that only 36% of Minnesota’s population is fully-insured. It is questionable how MDH can claim that the collection of data will enable it to assess disparities in access to and the quality of care when little data pertaining to the population most likely to be denied access and receive less care – the uninsured – will be collected under the Proposed Rules. It is further unclear how any meaningful conclusions can be drawn from any analysis of the data to be collected since there is no evidence in the SONAR that the population covered by the Proposed Rules – the one-third of Minnesotans who are fully-insured – is representative of the entire population of Minnesota for purposes of health and health care assessments. The data proposed to be collected by MDH is simply too comprehensive on an individual basis and too narrow on a collective basis to serve the purported purposes identified by MDH.”

Board of Hennepin County Commissioners

“BE IT RESOLVED, that the Board requests the Commissioner of Health to re-examine the manner in which any such data will be collected to assure individual data is anonymous; and BE IT FURTHER RESOLVED, that the Hennepin County Board of Commissioners has great concerns with the MDH proposal to collect data on use of health care services by individual name and address; and BE IT FURTHER RESOLVED, that the Chair of the Board be authorized to send a letter to Administrative Law Judge Allan Klein forwarding this resolution.” (Resolution No. 02-10-720R1, 10/29/02)

Rep. Gregory Davids (R-Preston)

“I am very interested in trying to restore a competitive health insurance marketplace in Minnesota. I am concerned that the proposed rules will take us in the opposite direction by placing an undue burden on the small indemnity insurers.”

Rep. Bill Haas (R-Champlin)

“For the small indemnity insurers who write less than 2% of the market place, the cost of compliance is exceedingly burdensome relative to their size...Therefore I oppose the entire set of rules.”

Rep. Arlon Lindner (R-Corcoran)

“I oppose the entire set of proposed rules for Chapter 4653 regarding state collection of medical, health, race, ethnic, age, demographic, diagnosis, treatment, prescription, insurance enrollment and administrative billing data.”

Sen. Twyla Ring (D-North Branch)

“I am very concerned about the proposed rule for chapter 4653. It appears that private medical records are about to become public data without the consent of patients and parents, many of whom will have no idea that this is happening...Please enjoin the department from promulgating this rule until the 2003 legislature has the opportunity to carefully look at the law which has apparently permitted this rule to be written.”

Rep. Tom Rukavina (D-Virginia)

“I would like you to rule against the implementation of these procedures, so that they can be taken up by the Legislature next session...There are a number of concerns regarding the rules that

need to be further debated, so that they can be amended to ensure the possible benefits of the collection of this medical data is not overshadowed by the harm it causes to Minnesota citizens.”

Rep. Alice Seagren (R-Bloomington)

“I have grave concerns about this rule being proposed and the necessity for it. The Minnesota Department of Health should not be able to go forward with this far-reaching government intrusion into patients’ private medical records, unless consent is given by the patient to release their private information.”

Rep. Timothy Wilkin (R-Eagan)

“[The law] mandates that the commissioner require healthplans to use a standard patient identifier when reporting administrative billing data...If the legislature wanted the Department to have names of individuals in addition to their medical information there would have been no need for the patient identifier requirement in 62J. I also have questions about the health plans’ cost of compliance with the extensive data request contained the proposed rules. The necessary systems changes would seem to carry a hefty price tag. Are there any implications for health insurance premiums?...This could be enough to force [small] insurers to make the business decision to leave...I oppose the entire set of proposed rules.”

Comments of Support – Individuals and Organizations⁷

Buyers Health Care Action Group

“The employer members of the Buyers Health Care Action Group feel that the collection and dissemination of health data in a standardized manner is critical to health improvement in Minnesota. Employers who are paying a majority of the health care expense do not have access to information to help guide them in their purchasing decisions...Employers typically know what they are paying but they do not know what they are buying. How do the providers of care, doctors, clinics and hospitals re-engineer inefficient processes of care in the absense[sic] of data?” – Carolyn E. Pare, CEO

Carlson Companies, Inc.

“This letter is to reaffirm Carlson Companies’ general support of Minnesota Department of Health’s...proposed rules...relating to Administrative Billing Data...Carlson Companies continues to advocate that in order for employers, employees and their families to become better consumers of health care, they must first be provided the proper tools and information to make wise choices...[G]roup purchasers have a much more vested interest in the successful outcome of the Department’s initiative and can play a valuable role in its success. The purchasers of healthcare insurance (employers) need to be an integral part of this dialogue in order to continue to be engaged in important decisions about purchasing healthcare and advocate on behalf of their employees and their families, the beneficiaries of the information being collected.” - Charles F. Montreuil, V.P., Corporate Human Resources

Employers Association, Inc.

“This letter is to affirm the Employer Association’s general support of the state’s collection of patient encounter level data...The technical issues regarding privacy concerns are sobering. Also of concern is achieving a delicate balance that offers assurance to Minnesotans that the

⁷ Please see footnote numbers 2 and 3 for the definition of full and partial supporters of the rule. Many supporters of the rule express concerns about various sections of the rule.

Department has stayed within the boundaries of the enabling law that is the impetus for these proposed rules. However, our primary concern is with the make-up of the Data Use Committee... As currently drafted, the provision requires three health plan representatives and one representative of the Insurance Federation of Minnesota to sit on the Data Committee on behalf of group purchasers...It is inherently unfair to only allow our voice to be heard through third party vendor-payers who will have conflicting interests to those of employer group purchasers.” – Thomas A. Ebert, CEO

Environmental Impacts Analysis Unit, MDH

“Hospital discharge[sic] data, which includes identifiers, will be critical to effectively operating a statewide population based birth defects information system, including establishing prevalence and incidence, providing services, and targeting primary prevention activities to the greatest risk...We strongly support the proposed rules...” – Daniel Symonik, Supervisor

Former Legislator

“The Minnesota Department of Health is preparing to do exactly what the legislature authorized it to do...Without the ability to collect this data, there is no scientific way to determine quality of the services being provided. Without this data we cannot even be sure if adequate services are being provided to all parts of our population, including the frail elderly, people with disabilities, members of minority groups and poor children.” – Former Rep. Lee Greenfield (D-Mpls.)

HealthPartners

“First, privacy is a really significant concern for us...We are concerned about the repercussions for us if there is an inadvertent (or purposeful) release by the State or a subcontracting researcher of individually identifiable information that we provided. Is there anything that can be built into the rule that would provide us with some additional protection? For example, could you pick up the language from 62J that speaks to immunity from civil liability and criminal prosecution?”

“[U]nder HIPAA we MAY disclose to a public health authority but are not required to do so. Also under HIPAA we may disclose to a public health authority for the purpose of controlling or preventing disease, injury or disability, including, but not limited to, the reporting of disease, injury, vital events, and the conduct of public health surveillance, public health investigations, and public health interventions, however it does not mention Research. For us to disclose PHI [private health information] for research, we need an authorization or a waiver from the IRB. Has the rule committee considered this?” – Stephanie L Frost, Senior Policy Manager (7/31/02 email)

Hennepin Center for Diabetes & Endocrinology

“I am fully supportive of the concept of centralizing information regarding global aspects of health-care from a population perspective...this same information is essential in guiding rational, cost-effective decisions regarding use and distribution of scarce health care assets. Unfortunately, the processes for compiling population-based healthcare data and the perception of breach of individual patient rights to confidentiality is continually inappropriately portrayed and confused by privacy advocates, the media, and ultimately the population at large.” – John V. St. Peter, PharmD, BCPS

Individual Citizens

- “One of the essential elements of a free market is the ability of the purchaser to know, in advance, the price of the good or service and to have some knowledge of the relative utility of the goods or services under consideration...Collection of this data is critical to being able to

calculate the total cost of illness and to provide meaningful epidemiological analysis of disease patterns.” – M.C., Bloomington

- “I work in the microbiology lab at [a] Hospital in St. Paul...In order to stop epidemics, Minnesota needs a good public health system. MDH has risen to this challenge...I feel the benefit far outweighs the lack of privacy of the few. The only way to monitor infectious diseases in an area is to have a central log...If MDH only received zip codes or partial information about patients, it would take time (which costs taxpayers money) to track down all the information they need. When there is a crisis, time is critical.” – M.M., Roseville
- “The data needs to be gathered in a research methodology, which includes anonymity to all but the researchers and in our day and age specific safeguards against release to advertisers, sale for profit, etc. Medical researchers need to handle the data. I will certainly help in this task if paid enough and if there are State retirement benefits. – F.A., medical doctor, clinical associate professor, Golden Valley
- “Let us not get to[sic] overprotective of data. It is so obvious that data can be collected for statistics without narrowing in on specific personalities. I would suggest an Administrative Law Judge follow the data to see the benefits collected. As a Director of an Area Agency on Aging working with system change, is[sic] see the need to have a common sense approach to solve these issues or we will see a more fragmented, higher cost system of care. Neither do we want. – Maddy Forsberg

Insurance Federation of Minnesota

“I am writing this letter on behalf of the Insurance Federation and our members that write health insurance to state our intent to work with the Department of Health to determine whether there are means by which the small indemnity insurers can submit administrative billing data without imposing an undue burden on those insurers.” – Robyn Rowen, Vice President and Government Affairs Counsel, October 24, 2002

March of Dimes

“I am writing to support the proposed Permanent Rules Relating to Administrative Billing Data...We believe in a two-pronged approach to prevention: population based research to identify causes and prevention tools, and access to quality health care so women and children can benefit from existing medical knowledge. Obtaining sufficient data is the foundation on which population based research and prevention activities are based.” – Bob Gustafson, State Director

Minneapolis Department of Health and Family Support

“In Minnesota there has not been ongoing public health access to a data set that provides surveillance information about the many health issues affecting populations between the time they are born and when they die. The administrative data addressed in the proposed rule would fill this significant gap...It is [also] time to move forward with the collection of race/ethnicity data as part of an administrative data set that will augment current health surveillance capabilities” – Gretchen Musicant, RN, MPH, Director of Public Health Initiatives and Pat Harrison, Ph.D., Director of Research

Minnesota Cancer Surveillance System

“If the proposed Minnesota rules are adopted, there would be a tremendous ability to research whether there are differences in how early cancer is diagnosed among privately-insured, publicly-insured, and non-insured individuals, as well as how much cancer care costs, by type of cancer

and how advanced the cancer was at the time it was diagnosed. We could research the relationship between utilization of cancer screening and how early cancer is diagnosed, as well as with survival... The proposed rules, in my opinion, strike a good balance between protection of individuals' privacy and the protection and advancement of the health of Minnesotans. I support the collection of the identifiers (name, date of birth, social security number) of health insurance enrollees because the data are not very useful without them" – Sally Bushhouse, D.V.M., Director

Minnesota Council of Health Plans

Cost: "Several of the health plans have analyzed the costs of implementation. Smaller health plans have reported that their cost could be in the range of hundreds of thousands of dollars, and large health plans believe it may be as high as \$2 million. These costs include increasing capacity for data capture, data storage, operational costs, and costs of hardware. Added to these costs will be other administrative expenses as well..."

Data Collection: "[The rule] delays group purchasers' submission of data (but presumably not their collection of data), until the commissioner obtains funding to enable the collection and processing of administrative billing data. While we support a delay until funding is obtained, the delay should extend to data collection to avoid imposing burdensome data storage requirements upon group purchasers and the delay should continue until adequate funding is obtained..."

Distortion of Data: "[The rule] allows the group purchaser to limit diagnosis codes to five codes if the group purchaser does not store each diagnosis code listed on a claim or encounter. This has the potential for distorting the results of a data analysis. If a group purchaser retains 9 diagnosis codes, for example, and another group purchaser only retains 5 diagnosis codes, the group purchaser with 9 diagnosis codes may appear to have a higher prevalence for certain diseases..."

Privacy: "Requiring individually identifiable data without patient identifiers exceeds the scope of the statute and is contrary to the legislative intent... Consistent with state law, using unique identifiers allows the department to achieve its objectives while addressing data privacy concerns..."

Supersedes Federal Law: "During the rulemaking advisory committee meeting process, health plans understood that the rules would be consistent with the requirements under the federal Health Insurance Portability and Accountability Act (HIPAA). In other words, health plans would not be required to maintain or submit data that was not required under HIPAA... However, the definition of 'administrative billing data' includes any data submitted by a provider." – Kathryn Kmit, Director of Policy and Government Affairs

Minnesota Medical Association

"Many providing comments at the hearing expressed concern that the government is going to be involved in collecting patient data and feel threatened by the statute and rules that provide the department with the authority to conduct research. Therefore, how the department conducts research, what the department's role will be in research, and what topics the department will address in their research is of primary importance to the public and to the Minnesota Medical Association (MMA).

"The MMA recognizes that there are research projects appropriate for the department to undertake, for instance, disease surveillance, the assessment of regional health issues to target public health programs, identifying patterns of disease that may be associated with environmental concerns, and regional and geographic comparisons that will help in the development of

educational programs to improve public health. There are also research projects more appropriately undertaken by other entities such as academic health organizations...It seems unreasonable to the MMA that the department might choose to become involved in research that could be duplicative of research being done in an academic health organization. This duplication would also prove to be extremely costly...Nowhere in either the authorizing legislation or in the rules is a ‘research project proposal’ defined...We are [also] concerned about Part 4653.0700... that allow[s] the state to publish data and analyses identifying health care providers, including physicians...

“In closing, we want to reiterate that the MMA recognizes the value of good public health research and supports a strong health department that facilitates the health and safety of all Minnesotans...If the public health of Minnesotans is to be benefited by the department’s research, it will be critical that the department undertake only those research projects that are appropriate.”
– Paul S. Sanders, MD, CEO

Minnesota Department of Human Services

“The Department of Human Services purchases healthcare for more than 600,000 individuals each year. ..We are responsible for providing quality health care to this population. To accomplish this, we need to know as much as possible about our clients. Racial and ethnic data are essential information to consider in understanding the differences in disease incidence as well as variations in the course of many diseases.”

Minnesota Public Health Association

“The proposed rules offer an opportunity to link utilization data from health plans with public health data. A major advance in the ability to analyze and better understand trends in health status and access to care is to use traditional public health data sets, such as disease registries and health surveys to link to health care diagnoses and utilization data which are available from the standard health plan claims data. Although there could be a significant potential concern about infringement on the privacy of the individual, the proposed rules provide the appropriate balance between data privacy safeguards and useful access for assessment, evaluation and research.” –
Jaime Martinez, Co-president

National Association of Health Data Organizations

“NAHDO believes that patient consent for public health data reporting would have a negative impact on Minnesota’s ability to accurately measure health and health quality by: creating bias in the data that are collected...[and] adding an additional administrative burden on data providers and public health...Encounter level data are essential to the State and National quality agendas.” –
Denise Love, Executive Director, Utah

“Evidence-based medicine involves ‘the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.’ ..Is the Minnesota Department of Health (MDH) proposing to collect the best possible data? No. The best possible data would come directly from medical records. Unfortunately, that’s just not feasible today... Should there be concern about the collection of this kind of information? Yes. Everyone should be concerned...More importantly, there should be concern that these data go uncollected, untapped, unused — leaving a medical system akin to a marksman with bad eyesight.”– Michael Kassis, Vice Chair, Board of Directors, NAHDO, and Deputy Director, Healthcare Information Division, California Office of Statewide Health Planning and Development

State Epidemiologist, MDH

“One of the most urgent and important issues facing the State of Minnesota is the rising cost of health care. If health care costs are to be brought under control, then data is needed on how our health care dollars are being spent and the effectiveness of both prevention strategies and curative expenditures.” – Harry Hull, State Epidemiologist

UCare Minnesota

“UCare’s comments have two primary themes: (1) the rule could better clarify that it does not apply to data relating to services provided to individuals who are eligible for public programs; and (2) the rule’s reporting requirements should only apply to those health plans that will be able to provide the Department significant data on a consistent basis.” – Mark Traynor, Esq., General Counsel

University of Minnesota, School of Public Health

“I strongly support the statute permitting collection of such data...In order to evaluate public health problems, researchers need data on the ‘incidence’, or first occurrence, of various conditions. Incidence data can be used to identify trends in disease of public concern, groups at high risk for possible prevention or treatment, and geographic clustering of disease that might point to outbreaks...Certainly patient privacy is important. However, so is the prevention and control of public health threats. The data needed to control those threats require encounter level information.” – Aaron Folsom, MD, MPH, Professor of Epidemiology

University of Wisconsin, Center for Health Systems Research and Analysis, Madison

“The uses of healthcare data multiply as access increases. A website containing a query tool for the inpatient data has worldwide users...Has data transformed the market? We don’t know—but more and more requests come in for the data—we know it has value—public use file users purchase it and continue as users over time...While I understand that healthcare providers do not like to be ‘visible’—the visibility does drive quality improvement...Without this visibility, life goes on as usual. I urge you to re-consider the restrictions on provider identification in public use data. Please support the collection and release of information on health care....” – Barbara A. Rudolph, Ph.D., Associate Scientist

Utah Department of Health

“Public health is to a population as a doctor is to a patient. Before a doctor can treat a patient, he or she collects objective information about the patient’s condition, information such as temperature, blood pressure, and blood sugar level. In public health, we are required to develop public policy and population interventions...It is critical to have information about the health of the population of living persons, between the time they are born and the time they die – a lot can happen during the lifespan...In a democracy, we expect our leaders to make choices that are informed by accurate information. State policy-makers in all branches of government need accurate information about this very large economic sector.” – Lois Haggard, Ph.D., Director, Office of Public Health Assessment

Public Sentiment – Short Takes

- “positively revolting” – J.B., Shoreview
- “horrified and unaware” – J.A., Burnsville
- “vehemently opposed” – D.H., Minneapolis
- “mindboggling in its offensiveness” – R.G., Hackensack

“absolutely no right” – M.T.
 “I am outraged” – C.A., Prior Lake
 “way too scary” – P.H., Oakdale
 “Stop it” – M.S.
 “in SHOCK” – M.Z., Minneapolis
 “illegal and immoral” – D.E., Oakdale
 “disagree wholeheartedly” – K.S., Little Canada
 “ABSOLUTELY NO NO” – L.H., Bertha
 “violation of my rights” – M.H., Dexter
 “monumental intrusion” – M.B.
 “dismay” – P.L., Kandiyohi County
 “huge loss of privacy” – L.W., Burtrum
 “potentially dangerous incursion” – E.A.
 “government encroachment” – J.E., Rochester
 “strongly object” – T.P., Mound
 “stop this craziness” – K.M.
 “ridiculous proposal” – R.K., Grand Rapids
 “danger-ridden intrusion” – N.W., Golden Valley
 “misguided proposal” – J.W., Minneapolis
 “sweeping opportunities...for abuse” – M.T., Inver Grove Heights
 “chilling effect” – T.B.
 “absolutely wrong” – K.D.
 “fishing expedition” – M.B., M.Ed
 “gravely concerned” – M.H., St. Louis Park
 “severe infringement” – R.F., Plymouth
 “bothers me deeply” – S.G., Crystal
 “scares the hell out of me” – L.F., Richfield
 “abhor these changes” – J.S., Saint Paul
 “blatant disregard for our privacy” – A.V., Hills
 “just too scary” – J.D., Minneapolis
 “scary matter” – S.
 “EXTREME invasion of privacy” D.Z., Royalton
 “stealing the privacy” – S.F., Minneapolis
 “adamantly object” – J.L., White Bear Lake
 “slippery slope” – A.Z., Willmar
 “implore you to reject” – M.P., Eagan
 “robbed of any privacy” – H.B., St Louis Park
 “breach of ethics” – K.M.
 “unconstitutional” – S.M.
 “very detrimental” – P.K., Grey Eagle
 “violation of our civil rights” – C.B.
 “totally offensive” – KK
 “not acceptable” – J.F., Ramsey
 “strongly violates” – W.C., Roseville
 “furious” – T.S., Annandale
 “alarming” – K.K., Saint Paul
 “travesty of justice” – J.Y., Arden Hills

Minnesota Department of Health: Justification for Rule

Statute: “The Minnesota Legislature directed the Commissioner of Health to evaluate statewide health care access, quality, use, and cost, as part of the health care reform initiatives in the early 1990’s... specifically, Minnesota Statutes, sections 62J.301 – 62J.42 authorize the Commissioner to collect encounter level data to monitor and improve the effectiveness of health care in Minnesota. Administrative billing data are a subset of encounter level data.” (SONAR, p. 1)

Mission: “The charge of the Department of Health is to protect, maintain and improve the health of all Minnesotans. In order for MDH to be accountable for these goals, MDH needs to be able to assess the population’s health and monitor it over time. These billing data can help MDH monitor population health effectively, detect emerging disease or conditions earlier, and develop successful responses.” (MDH Fact Sheet, MDH Rules for Administrative Billing Data.)

Research: “Researchers will directly benefit from the proposed rule. For the first time, researchers will have rich data sets to support population based health research. The general public will benefit from the analysis researchers are able [to] conduct. MDH will use these data to support efforts to meet public health goals, such as reducing chronic disease and eliminating health disparities. MDH will be better able to answer legislative requests, such as providing information to inform debates on hospital moratorium issues.” (SONAR, pp 9-10)

“MDH must be able to identify all claims that belong to one individual. Most research does not depend on knowing the name of the covered individual but many kinds of research depend on being able to track all services provided to a specific individual for a particular condition. For example, to determine if hospitalizations for a chronic illness, such as asthma or diabetes, can be reduced or eliminated by ongoing outpatient care, a researcher must be able to track claims for both outpatient and inpatient services for specific individuals related to that chronic illness. Administrative billing data staff would use the name, date of birth, and gender to create an encrypted identifier. MDH researchers will see only the encrypted identifier. This would allow researchers to track individuals without seeing their names.” (SONAR, p. 29)

Race and Ethnic Data: “Collecting race/ethnic data could, in theory, result in race discrimination, but continuing the negative consequences of not collecting race/ethnicity data are far more likely...If it can be communicated to the public in an open and non-threatening way that the collection of this information is not prohibited by law, does not violate their civil rights, and is needed for improving health care, people will willingly provide the information” (SONAR, p. 30)

Pharmacy Data: “MDH plans to conduct public health studies on asthma, including analysis of the severity of the asthma. The only way to currently identify asthma severity in administrative claims data is to look at pharmacy utilization. This is because diagnostic coding for asthma in the current version of the ICD [diagnostic coding system] is very non specific about the nature and severity of the disease. If MDH did not know whether to expect pharmacy claims for an individual we could classify someone as not severely asthmatic when in fact they were.” (SONAR, p. 31)

Federal Initiatives: “At the national level, Congress has mandated that a National Report on Healthcare Quality be produced in 2003 that will include a broad set of performance measures that will be used to monitor the Nation’s progress toward improved health care quality...In addition, the security rules authorized by the Health Insurance Portability and Accountability Act

(HIPAA) specifically address the importance of allowing the collection and use of medical information. HIPAA specifically allows use of data without authorization for several national priority activities including: oversight of the health care system, including quality assurance activities, public health, research, and government health data systems” (Wendy Nelson, Draft Testimony emailed to CCHC, 10/1/02)

Other States Collect Data: “We are proposing to collect two different set of data. One set is data collected from hospitals and is the data most likely to be collected by other states. Many states have collected hospital discharge data for over 20 years and have been able to inform both the public and policymakers on quality, utilization, and access issues to allow decision making based on facts and not anecdotes...The other set of data is less likely to be collected by other states, but many, such as Wisc., are moving in that direction. That data is administrative data from health plans.” (Wendy Nelson, Draft Testimony emailed to CCHC, 10/1/02)

Able to Secure Data: “ • Personally identifying information will only exist on a physically-detached MDH computer during an interim step to unify the data. Then it is purged. • It is impossible to decipher a unique ID from a case number because the numbers are assigned randomly. A cross-reference table will exist, but only on the physically-detached computer server that is accessible by two staff members. The cross-reference table must exist because we need to unify data from subsequent data submissions. • It is impossible for hackers to gain access to a computer that is physically detached from a network. Again, this second server is also located behind two locked doors and the database is protected by several layers of security and passwords.” (Barbara Wills, Draft Testimony emailed to CCHC (*original had bullets*), 10/2/02)

Minnesota Department of Health: Response to Specific Concerns

Reported Privacy Breach by Health Department (letter to judge from parent who received information on someone else’s child from an MDH agency): “The reasons this occurred are being investigated and appropriate remedial action will be taken. In no way attempting to minimize the seriousness of this error, it is important to clarify that there has been no release of specific, personal financial or medical information to any unauthorized party.” (Letter, 10/31/02)

Non-Compliance with Minnesota’s Government Data Practices Act (Chapter 13): “The Department is proposing to collect data from hospitals and health plans, not directly from individuals. Section 13.04, subdivision 2, applies when data is collected directly from the individual. Since this data will not be collected directly from the individual, the requirements of section 13.04, subdivision 2, [informing individuals of use/purpose of data and right to refuse] do not apply. Further, Minnesota Statutes, section 144.335, subdivision 5a, requires the posting of a notice of data disclosures made without patient consent.” (Letter, 10/31/02)

Need for Additional Public Notice of State Data Collection: “The Department developed this notice [per MN Statutes, Sec. 144.335] in 1995 and it is posted in provider offices in Minnesota. The Department monitors changes to state law and will modify the notice as required by state law.” (Letter, 10/24/02) – See notice at: <http://www.health.state.mn.us/divs/hpsc/dap/records.htm>

Privacy Violation: “The Department of Health takes data security very seriously and has made every effort to balance the need to fully protect these sensitive data with the need to make the data available for use for important research and analyses.” (Letter, 10/24/02)

Violation of Constitutional Rights: “Government data collection, even the collection of personally identifiable data, does not infringe on rights protected by the fourth amendment. The fourth amendment does protect against unreasonable searches and seizures, but the requirement of a warrant to search is only necessary when there is suspicion of possible unlawful activity. In other words, a warrant is not necessary for the government to collect data because the individual has not engaged in suspicious or criminal activity to necessitate the issuance of a warrant.” (Letter, 10/24/02)

Need for Patient Consent: “Studies have shown that requiring consent results in substantial biases in studies on the effectiveness, quality and costs of patient care and treatments, as individuals with adverse outcomes or having more sensitive diseases or procedures are more likely to refuse authorization.” (Letter, 10/24/02)

No Compelling Reason to Collect Data: “The Department needs to be able to assess the population’s health and monitor it over time... These data are critical to successfully monitor and assure health care access... Health care costs continue to rise. Employers and consumers need to know what they are getting for their health care dollar. Lawmakers need to base their decisions about health care delivery systems on facts, not anecdotes... Concerns over the quality of medical care are on the rise. Quality issues that can be analyzed with administrative billing data include the efficacy and adequacy of medical treatment, as well as issues of patient safety.” (Letter, 10/24/02)

Violation of Nuremberg Code: “The Nuremberg Code applies to experimental clinical medical research on persons. The Nuremberg Code was a response to the Nazi medical experiments on persons during World War II. The Nuremberg Code does not apply to retrospective review of existing data.” (Letter, 10/24/02)

Limited State Financial Resources: “The Department has stated that the hospital discharge data collection can be accomplished with existing funding... [W]hen funding is secured for the group purchaser data, the Department will implement this part of the rule.” (Letter, 10/24/02)

Historical Time Frame

- 1992: The Minnesota legislature passed Health Right, a comprehensive health care cost containment law, later called MinnesotaCare. For the purpose of setting statewide health care spending limits, health officials were required to collect data on cost of health care. In addition, a data analysis unit was authorized to study specific health care conditions.
- 1993: The Minnesota legislature expanded data collection requirements, requiring insurers to send claim forms to the Minnesota Department of Health. The department issued an emergency rule requiring that the transmission begin.
- 1994: Data received by the health department was not uniform, and therefore difficult to use.
- 1995: The emergency rule was repealed, and the legislature authorized a pilot project for data collection. To help MDH create a uniform data set, two health plans, Medica and Blue Cross and Blue Shield of Minnesota, agree to send patient data to state health officials. The new law also created the Minnesota Health Data Institute to provide a mechanism for transmitting data to the health department, along with requirements for security and privacy of the data. The law also specified that patient consent was not required. And it

- made insurers and providers immune from civil liability and criminal prosecution for disclosing data.
- 1995: Several laws were repealed by the Minnesota legislature: the health department's data analysis unit, the large-scale database, and the statewide limits on health care spending.
- 1999: The health department's pilot project for data collection ended.
- 2001: The Minnesota Department of Health purchased five years of de-identified hospital data from the Minnesota Hospital and Healthcare Partnership.
- 2001: Public meetings on writing the rule for medical data collection began in October.
- 2002: Public meetings ended in June.
- 2002: The Minnesota Health Data Institute was dissolved for lack of legislative funding.
- August 19, 2002: The Minnesota Department of Health published a proposed rule to require hospitals and insurers to collect and transmit individually-identifiable medical data to the department without patient consent.
- August 29, 2002 As a result of an email alert from the Citizens' Council on Health Care MDH had received more than the 25 letters needed to require a hearing on the rule before an administrative law judge.
- September 18, 2002 Public comment period at Minnesota Department of Health ended.
- October 4, 2002 Administrative Law Judge Allan W. Klein held a hearing at the Minnesota Department of Health, which lasted 4 1/2 hours. At least 110 people attended, including the 18 individuals who testified, most in opposition to the rule. Additional comment period began.
- October 31, 2002 Official book on the hearing closed. No more comments were accepted.
- December 2, 2002 Date by which the judge must render a decision.

Summary

The Minnesota Department of Health has proposed to collect detailed individually-identifiable medical information without patient consent beginning on January 1, 2003. As a result of public comments, the MDH made changes but stated that these did not substantially change the rule. As rationale for this proposal, the department has used a nearly ten-year old state law, a federal rule, the mission of the department, and a federal health care quality initiative.

Nevertheless, the majority of over 1,000 commenters oppose the rule, questioning its legality, ethics and constitutionality. Members of the public and public officials have expressed concern or outright opposition to the rule, particularly related to the rights of individuals, the potential for future eliminations of any current restrictions on access to and use of the data, the patient-doctor relationship and the cost to taxpayers and the insured.

Even supporters of the rule express opposition to many and varied portions of the rule. Several express general support for state data collection—or do not expressly oppose it—but identify concerns regarding cost, duplication of research efforts, loss of competition in the insurance market, administrative burden, inadequate representation on the state's proposed data use

committee, vague inadequate definitions, unpromulgated rulemaking, or the broad reach of the rule. Only a few commenters, mostly health officials and public health researchers, have expressed support for the rule without reservation.

Until the judge issues a ruling on the proposed rule, the public, the health department, the Governor and the state legislature wait to determine what steps must next be taken.

Citizens' Council on Health Care

1954 University Ave. W., Suite 8

St. Paul, Minnesota 55104

651.646.8935p 651.646.0100 fx

info@cchconline.org

www.cchconline.org