Senate Counsel, Research, and Fiscal Analysis

G-17 State Capitol
75 Rev. Dr. Martin Luther King, Jr. Blvd.
St. Paul, MN 55155-1606
(651) 296-4791
FAX: (651) 296-7747
Jo Anne Zoff Sellner
Director

Senate

State of Minnesota

S.F. No. 3307 - Chemical Use Assessments and Chemical Health

Author: Senator Jane B. Ranum

Prepared by: Joan White, Senate Counsel (651/296-3814)

Date: March 27, 2006

S.F. 3307 resulted from the 2006 Office of the Legislative Auditors Report on Substance Abuse Treatment.

Section 1 amends the treatment for alcohol and drug abuse chapter of law.

Subdivision 1 clarifies chemical use assessments for a person who is arrested. For a person who is taken into custody outside the person's county of residence, the assessment must be completed by the person's county of residence no later than three weeks after the assessment is initially requested. If the assessment is not performed, the county where the person is to be sentenced must perform the assessment, and the county of financial responsibility must be determined under Minnesota Statutes, chapter 256G.

Subdivision 2 requires that the person's probation officer be contacted to verify or supplement information provided by the person.

Subdivision 3 prohibits the assessor from having any direct or shared financial interest or referral relationship resulting in financial gain with a treatment provider, except when a county contracts with an assessor and meets the documentation requirements under paragraph (b).

Section 2 requires the commissioner to perform the list of duties under this section of law, related to chemical health.

Section 3 requires the commissioner to report to the legislature by January 15, 2007, on recommendations which analyze the merits of changing statutory maintenance of effort provisions in the chemical dependency treatment fund.

Section 4 requires the commissioner to present a plan to the legislature by January 15, 2007, for improving the availability of community-based substance abuse treatment.

JW:mvm

Senators Ranum, Sams, Foley, Rosen and Koering introduced–

S.F. No. 3307: Referred to the Committee on Health and Family Security.

A bill for an act

relating to human services; modifying chemical use assessments; imposing duties on the commissioner of human services related to chemical health; proposing coding for new law in Minnesota Statutes, chapter 254A.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[254A.20] CHEMICAL USE ASSESSMENTS.**

Subdivision 1. **Persons arrested outside of home county.** When a chemical use assessment is required under Minnesota Rules, parts 9530.6600 to 9530.6655, for a person who is arrested and taken into custody by a peace officer outside of the person's county of residence, the assessment must be completed by the person's county of residence no later than three weeks after the assessment is initially requested. If the assessment is not performed within this time limit, the county where the person is to be sentenced shall perform the assessment. The county of financial responsibility must be determined under chapter 256G.

Subd. 2. **Probation officer as contact.** When a chemical use assessment is required under Minnesota Rules, parts 9530.6600 to 9530.6655, for a person who is on probation or under other correctional supervision, the assessor, either orally or in writing, shall contact the person's probation officer to verify or supplement the information provided by the person.

Subd. 3. **Financial conflicts of interest.** (a) Except as provided in paragraph (b), an assessor conducting a chemical use assessment under Minnesota Rules, parts 9530.6600 to 9530.6655, may not have any direct or shared financial interest or referral relationship resulting in shared financial gain with a treatment provider.

(b) A county may contract with an assessor having a conflict described in paragraph (a) if the county documents that:

(1) the assessor is employed by a culturally specific service provider or a service provider with a program designed to treat individuals of a specific age, sex, or sexual preference; or

(2) the county does not employ a sufficient number of qualified assessors and the only qualified assessors available in the county have a direct or shared financial interest or a referral relationship resulting in shared financial gain with a treatment provider.

An assessor under this paragraph may not place clients in treatment. The assessor shall gather required information and provide it to the county along with any required documentation. The county shall make all placement decisions for clients assessed by assessors under this paragraph.

EFFECTIVE DATE. This section is effective July 1, 2006, except for subdivision 3, which is effective July 1, 2008.

Sec. 2. **[254A.25] DUTIES OF COMMISSIONER RELATED TO CHEMICAL HEALTH.**

The commissioner shall:

(1) annually distribute information to chemical health assessors on best practices in assessments, including model instruments for adults and adolescents;

(2) monitor the compliance of local agencies with assessment and referral rules;

(3) develop a directory that identifies key characteristics of each licensed chemical dependency treatment program;

(4) work with the commissioner of health to develop guidelines and training materials for health care organizations on the use of brief interventions for alcohol abuse;

(5) provide local agencies with examples of best practices for addressing needs of persons being considered for repeat placements into publicly funded treatment;

(6) identify best practices to help local agencies monitor the progress of clients placed in treatment;

(7) periodically provide local agencies with statewide information on treatment outcomes; and

(8) post copies of state licensing reviews and treatment program peer reviews at an online location where they may be reviewed by agencies that make client placements.

Sec. 3. **RECOMMENDATIONS ON CHANGING THE CONSOLIDATED CHEMICAL DEPENDENCY TREATMENT FUND.**

The commissioner shall report to the legislature by January 15, 2007, on recommendations which analyze the merits of changing the statutory maintenance of effort provisions in the chemical dependency treatment fund.

Sec. 4. **PLAN FOR IMPROVING COMMUNITY-BASED SUBSTANCE ABUSE TREATMENT.**

The commissioner of human services shall present a plan to the legislature by January 15, 2007, for improving the availability of community-based substance abuse treatment.

Senator ..... moves to amend S.F. No. 3307 as follows:

Page 2, line 31, delete "and treatment program peer reviews"

Page 3, line 5, before the period, insert " and the feasibility of posting treatment program peer reviews at an online location where they can be viewed by agencies that make client placements"

Senate Counsel, Research,
and Fiscal Analysis

G-17 State Capitol
75 Rev. Dr. Martin Luther King, Jr. Blvd.
St. Paul, MN 55155-1606
(651) 296-4791
FAX: (651) 296-7747
Jo Anne Zoff Sellner
Director

Senate
State of Minnesota

S.F. No. 3342 - Disclosure of Information Regarding Clinical Trials (the A-1 Delete-Everything Amendment)

Author: Senator John Hottinger

Prepared by: David Giel, Senate Research (296-7178)

Date: March 23, 2006

S.F. No. 3342 requires drug manufacturers to disclose on the Internet certain information regarding clinical trials conducted or sponsored by the manufacturer. It establishes a fee on drug manufacturers to pay Minnesota Department of Health (MDH) costs. It directs the Attorney General to enforce the disclosure requirements.

Section 1 cites the disclosure requirements as the Patient Safety and Drug Review Transparency Act.

Section 2 (144.6601) establishes the purpose of the new requirements.

Section 3 (144.6602) defines terms.

Section 4 (144.6603) establishes disclosure requirements.

Subdivision 1 lists the kinds of information manufacturers must make publicly available regarding clinical trials.

Subdivision 2 applies the disclosure requirements to all clinical trials completed or terminated on or after January 1, 1990.

Subdivision 3 requires the information to be posted on the National Institutes of Health public Web site or on another publicly accessible Web site.

Subdivision 4 requires disclosure of clinical trials that are terminated prior to completion and specifies the information about them that must be disclosed.

Section 5 (144.6604) establishes an annual $1,000 fee on each manufacturer of drugs that are provided through the Medical Assistance program to pay MDH costs related to the disclosure requirements.

Section 6 (144.6605) establishes compliance dates. For trials on a drug that has been approved by the Food and Drug Administration (FDA), information must be posted within 90 days of completion or termination of the clinical trial or within 90 days of the effective date of this bill, whichever is later. For trials performed prior to FDA approval, information must be posted within 60 days after the date of FDA approval or within 90 days of the effective date of this bill, whichever is later.

Section 7 (144.6606) outlines requirements for public education, enforcement, and rulemaking.

Subdivision 1 directs MDH to conduct a public education initiative about clinical trials and drug safety.

Subdivision 2 requires the Attorney General to enforce disclosure requirements.

Subdivision 3 authorizes MDH to adopt rules to implement these requirements.

DG:rdr

Senators Hottinger, Lourey and Nienow introduced–

S.F. No. 3342: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; providing for clinical trial registration; providing civil penalties; proposing coding for new law in Minnesota Statutes, chapter 144.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[144.6601] CLINICAL TRIALS REGISTRATION.**

Subdivision 1. **Definitions.** For purposes of this section:

(1) "clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any experiment to test the safety or efficacy of a drug or biological product with one or more human subjects;

(2) "clinical trial registry" means a publicly available data bank;

(3) "institutional review board" means an independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of the human subjects involved in a clinical trial; and

(4) "sponsor" means:

(i) the manufacturer of a drug or biological product;

(ii) if the manufacturer provides no monetary support for the clinical trial, the person who provides the majority of monetary support; or

(iii) when the majority of monetary support comes from a state or federal agency, the principal investigator.

Subd. 2. **Requirements for institutional review board approval.** An institutional review board shall not approve any clinical trial unless the sponsor certifies in writing that:

(1) the clinical trial will be registered in a clinical trial registry at or before the time that patient enrollment begins;

(2) the clinical trial registry includes, at a minimum:

(i) a unique identifying number for each registered trial;

(ii) a statement of the interventions and comparisons studied;

(iii) a statement of the study hypothesis;

(iv) definitions of the primary and secondary outcome measures;

(v) eligibility criteria;

(vi) key trial dates;

(vii) the target number of subjects;

(viii) identification of the funding source; and

(ix) contact information for the sponsor;

(3) the clinical trial registry is accessible to the public at no charge, open to all prospective registrants, managed by a not-for-profit organization, and electronically searchable and contains a mechanism to ensure the validity of the registration data; and

(4) upon conclusion of the clinical trial, the results of the clinical trial will be published in a clinical trial registry that meets the requirements of clauses (2) and (3).

Subd. 3. **Review of prior approvals.** An institutional review board shall not approve any clinical trial if the sponsor failed to comply with subdivision 2 for a prior clinical trial that was approved by the same or another institutional review board under this section. Prior to approval, the institutional review board shall review the sponsor's record of compliance with subdivision 2 for prior clinical trials approved by the same or another institutional review board.

Subd. 4. **Penalties.** A sponsor in violation of this section is liable for a civil penalty of $20,000 per violation. Each day a sponsor is in violation is considered a separate violation. The attorney general or a district attorney, county attorney, or city attorney may bring an action against a sponsor for a violation of this section.

Senator ..... moves to amend S.F. No. 3342 as follows:

Delete everything after the enacting clause and insert:

"Section 1. **CITATION.**

Minnesota Statutes, sections 144.6601 to 144.6606, may be cited as the Patient Safety and Drug Review Transparency Act.

Sec. 2. **[144.6601] PURPOSE.**

The purpose of sections 144.6601 to 144.6606 is to disclose information regarding clinical trials of prescription drugs to the public, physicians, researchers, and state policymakers and administrators. Providing public access to information about drug trials and their results through a database accessible through the Internet is necessary to protect the public health and safety of the people of this state and to assure that the state, in its role as purchaser of prescription drugs and administrator of prescription drug programs, has the information necessary to appropriately administer those programs.

Sec. 3. **[144.6602] DEFINITIONS.**

Subdivision 1. **Scope of definitions.** The terms used in sections 144.6601 to 144.6606 have the following meanings, unless the context indicates otherwise.

Subd. 2. **Clinical trial.** "Clinical trial" means any pharmacological, pharmacokinetic, or other study of the safety or efficacy of a pharmaceutical drug, biological product, or vaccine, whether or not completed in full, including, but not limited to:

(1) a clinical investigation that involves any trial to test the safety or efficacy of a pharmaceutical drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of any application for a research or marketing permit or for any other type of application, permit, procedure, or requirement of the Food and Drug Administration, including, but not limited to, an abbreviated new drug application, an investigational new drug application, a new drug application, nonconfidential additions to the drug master file, postmarketing adverse events recording, and compliance with the electronic or paper common technical document; and

(2) any pharmacological study subsequent to initial approval for sale by the Food and Drug Administration, including studies assessing potential off-label applications, new therapies, new ways of using known treatments, and comparative drug trials assessing the efficacy or safety of a drug compared to other therapies.

Subd. 3. **Manufacturer.** "Manufacturer" means a manufacturer of prescription drugs or biological products or an affiliate of the manufacturer.

Sec. 4. **[144.6603] DISCLOSURE OF CLINICAL TRIALS OF PRESCRIPTION DRUGS.**

Subdivision 1. **Information to be disclosed.** A manufacturer of prescription drugs shall make publicly available in accordance with subdivision 3 the following information regarding clinical trials conducted or sponsored by the manufacturer, or any entity on its behalf, for each prescription drug the manufacturer sold, delivered, dispensed, offered for sale, or gave away in this state:

(1) the names of all participating organizations and funding sources of the clinical trial, including the name and contact information, including institutional affiliation, of all sponsors, cosponsors, and administrators, including the name of the principal investigators and study centers, of the clinical trial;

(2) a summary of the purpose of the clinical trial, including the name of the drug being tested and its active ingredients; overall design of the study, including statistical method to be employed; status or phase type of the trial; inclusion and exclusion criteria; treatment methods to be used; all hypotheses tested by the trial; the medical condition or conditions being studied; and outcomes that were evaluated;

(3) the dates during which the trial took place;

(4) information concerning the results and outcomes of the clinical trial, which shall include, but not be limited to, potential or actual adverse effects of the drug, including the frequency, severity, and nature of adverse events for any trial participant and the numbers of participants who discontinued participation in the trial and the reasons for their discontinuance; and

(5) any other information necessary to assure complete information about the safety of prescription drugs taken by residents of the state included in regulations adopted under section 144.6606.

Subd. 2. **Application.** The disclosure requirement in subdivision 1 shall apply to all clinical trials completed or terminated on or after January 1, 1990, including any clinical trials completed after a prescription drug has been approved for sale by the federal Food and Drug Administration.

Subd. 3. **Information to be posted.** The information required to be disclosed under subdivision 1 shall be posted on the publicly accessible Internet Web site of the federal National Institutes of Health or another publicly accessible Web site. In order to satisfy the requirements of this subdivision, the publicly accessible Web site and manner of posting must be acceptable to the commissioner and shall be a free, nonsubscription Web site that clearly indicates the location and instructions for downloading the files or information submitted under subdivision 1.

Subd. 4. **Disclosure of terminated trials.** Disclosure of clinical trials under subdivision 1 shall include clinical trials that the manufacturer, or an entity on its behalf, initiated but terminated prior to completion. For these trials, the manufacturer shall include an explanation for the termination of the trial, including, but not limited to, potential or actual adverse effects of the drug, including the frequency, severity, and nature of adverse events for any trial participant and numbers of participants who discontinued participation in the trial and the reasons for their discontinuance.

Sec. 5. **[144.6604] FEES.**

Beginning January 1, 2007, each manufacturer of prescription drugs that are provided to state residents through the medical assistance program shall pay a fee of $1,000 per calendar year to the commissioner. Fees collected under this section are appropriated to the commissioner to cover the cost of overseeing implementation of sections 144.6601 to 144.6606, including, but not limited to, maintaining links to publicly accessible Web sites to which manufacturers are posting clinical trial information under section 144.6603, and other relevant sites; assessing whether and the extent to which state residents have been harmed by the use of a particular drug; and undertaking the public education initiative under section 144.6606.

Sec. 6. **[144.6605] COMPLIANCE DATES.**

A manufacturer shall post the information required by section 144.6603 as follows:

(1) for a drug that has been approved for sale by the Food and Drug Administration, within 90 days after the completion or termination of the clinical trial, or within 90 days after the effective date of sections 144.6601 to 144.6606, whichever is later; or

(2) in the case of a clinical trial performed prior to approval for sale by the Food and Drug Administration, within 60 days after the date of approval for sale by the Food and Drug Administration, or within 90 days after the effective date of sections 144.6601 to 144.6606, whichever is later.

Sec. 7. **[144.6606] PUBLIC EDUCATION; ENFORCEMENT; RULEMAKING.**

Subdivision 1. **Public education initiative.** The commissioner shall conduct a public education initiative to inform state residents about clinical trials and drug safety information.

Subd. 2. **Enforcement.** Sections 144.6601 to 144.6606 shall be enforced by the attorney general under section 8.31. Each day a manufacturer is in violation of sections 144.6601 to 144.6606 shall be treated as a separate violation. Each clinical trial registration or clinical trial results disclosure that does not fully comply with the requirements of sections 144.6601 to 144.6606 shall be treated as a separate violation.

Subd. 3. **Rulemaking.** The commissioner may adopt rules to implement sections 144.6601 to 144.6606. These rules may eliminate or reduce the fee required under section 144.6604 for a manufacturer that provides only a small volume of prescription drugs through the state's medical assistance program. Rules may specify a template or other standardized reporting format for the information required in sections 144.6601 to 144.6606."

Amend the title accordingly

Consumers Union
Nonprofit Publisher of Consumer Reports

West Coast Office
1535 Mission Street
San Francisco, CA 94103
415-431-6747 (ph) 415-431-0906 (fax)
www.consumersunion.org

March 24, 2006

The Honorable Becky Lourey
Chair, Senate Health and Family Security Committee
State Capitol
75 Rev. Dr. Martin Luther King Jr. Blvd., Room G-24
St. Paul, MN 55155-1606

Re: Support for SF 3342 (Hottinger): Prescription drug clinical trial results
Hearing: Tuesday March 28, Senate Health & Family Security Committee

Dear Senator Lourey and Members of the Committee:

Consumers Union is the nonprofit publisher of *Consumer Reports* magazine and *Consumer Reports Online*, with approximately 5 million subscribers nationwide. Consumers Union's "Prescription for Change" Campaign (www.prescriptionforchange.org) works on prescription drug reform at the state and national levels. We strongly support SF 3342 which will give patients and medical professionals alike key information to help them weigh the benefits and risks of medicines, and not have to rely on one-sided information often promoted in prescription drug ads.

The Problem

Drug companies have powerful financial incentives to hide negative data turned up in clinical trials. They cannot be trusted to voluntarily give us complete and timely information about safety problems with their drugs, as the following examples demonstrate.

- Merck, the manufacturer of Vioxx, continued to heavily market the painkiller to doctors and patients for years after the company had substantial evidence that Vioxx significantly increased the risk of serious heart problems. When doctors started asking about safety studies, Merck sales reps were given a manual with a one-word instruction for responding – "DODGE!" FDA researchers estimate that, in less than 5 years, Vioxx may have caused as many as 139,000 heart attacks and strokes. Up to 40% of those patients – roughly 55,000 Americans – died from heart attacks and strokes caused by Vioxx.

- GlaxoSmithKline, the manufacturer of the anti-depressant Paxil, conducted

several studies showing that the drug was not effective at treating depression in children. As far back as 1997, the company had information that adolescent usage could actually increase the risk of suicidal behavior. Rather than revealing those tests to doctors and the public, the company continued to promote the drug's "remarkable efficacy and safety in the treatment of adolescent depression." The data eventually were made public in December 2004 not by the company but by ABC News. In the mean time, parents and insurers paid high prices for ineffective medication and children were needlessly exposed to a serious risk.

While these are two of the most public examples of the problem, data suppression and manipulation are all too commonplace within the industry.

The Solution

SF 3342 (Hottinger) requires drug companies to disclose information about all clinical trials they have sponsored for prescription drugs they sell in Minnesota. Publishing such information on the established and best-known federal clinical trials website makes it readily searchable by and accessible to doctors, patients and researchers alike. The American Medical Association and the American Pharmacists Association support public disclosure of clinical trial results.[1] SF 3342 is based on a law enacted last year in the state of Maine.

Thank you for your consideration of our views.

Sincerely,

Earl Lui
Senior Attorney
elui@consumer.org

[1] "AMA provides outline for developing national clinical trials registry," American Medical Association News Release, September 9, 2004; 2005 Action of the APhA House of Delegates, Orlando, Florida, April 2-5, 2005.

Why We Need Mandatory Disclosure of Clinical Trial Results

Drug companies have powerful financial incentives to hide negative data about their products. Unfortunately, they cannot be trusted to voluntarily give us complete and timely information about safety problems with their drugs, as the following examples demonstrate.

Rezulin

The FDA recalled Rezulin, a diabetes drug made by Warner-Lambert (now owned by Pfizer), on March 21, 2000. The drug was suspected of causing 391 deaths. The *Los Angeles Times* uncovered internal documents from the company and the FDA demonstrating Warner-Lambert knew about Rezulin's life-threatening risks as early as 1996, yet the company withheld this information from the FDA and instead continually assured it of its safety. (Willman, David. "Risk was Known as FDA OKd Fatal Drug." *Los Angeles Times*, March 11, 2001)

Vioxx

In 2004, Vioxx was withdrawn from the market based on a study showing that Vioxx increased heart attack risk. It appears that Merck was aware of the cardiovascular risk many years before Vioxx was withdrawn. The *New England Journal of Medicine* strongly criticized Merck for failing to disclose Vioxx's heart risks in an article published by the *Journal* in 2000. Documents uncovered in a Texas case where a jury found Merck liable for the death of a Vioxx patient revealed Merck's scientists were concerned about heart risks as early as 1997. Yet Merck trained its sales force to "dodge" doctors' concerns about the drug.

Antidepressants

Makers of antidepressants such as Paxil, Zoloft and Prozac failed to publish or publicize clinical trial results showing that their drugs increased suicide and were not effective in treating depression in teenagers and children. On September 13, 2004, FDA officials concluded after reviewing 15 clinical trials, "some of which were hidden for years from the public by the drug companies that sponsored them" that antidepressants were consistently linked to suicidal behavior in children and teenagers. (Harris, Gardner. "FDA Links Drugs to being Suicidal." *New York Times*, September 14, 2004)

At a congressional hearing a month later, House members discussed misleading drug company marketing materials. A GlaxoSmithKline marketing memorandum promoted the results of a Paxil study as showing effectiveness in treating depression when in fact the study failed to prove effectiveness. Forest Laboratories published a study showing positive results for Celexa, yet failed to mention or publish a second study showing no benefits from the drug.

Natrecor

Natrecor, made by a unit of Johnson & Johnson, is used for acutely-ill heart patients. The company admitted it failed to disclose two deaths from patients in a clinical trial of the drug to the FDA. The company also omitted the two deaths from a published report of the trial. (Saul,

For more information contact:
Earl Lui, Senior Attorney
Consumers Union, West Coast Office
1535 Mission Street San Francisco, CA 94103
415.431.6747
fax 415.431.0906
elui@consumer.org

Stephanie. "U.S Not Told of 2 Deaths During Study of Heart Drug." *New York Times*, January 4, 2006)

PPA

Phenylpropanolamline, known as PPA, was an active ingredient in many over-the-counter cold medicines. The FDA ordered PPA off the shelves in November 2000 because of increased risk of strokes. Yet studies showed the dangers of PPA as far back as 1982. In 1999, a landmark, long-term study of PPA designed by the industry and conducted by its handpicked researchers found a 50% higher risk of stroke in PPA patients. Despite this finding, the industry continued to resist a recall of PPA for another year. (Sack, Kevin & Mundy, Alice. "Over-the-Counter Peril; A Dose of Denial: How Drug Makers Sought to Keep Popular Cold and Diet Remedies on Store Shelves After their own Study Linked them to Strokes." *Los Angeles Times*, March 28, 2004)

For more information contact:
Earl Lui, Senior Attorney
Consumers Union, West Coast Office
1535 Mission Street San Francisco, CA 94103

415.431.6747
fax 415.431.0906
elui@consumer.org

To the Senate Health and Family Security Committee March 28, 20
re SF 3342 Clinical Trial data should be published.

Louise Bouta
Well Mind Association of Minnesota
6500 Woodlake Drive # 201
Richfield, MN 55423 Phone: 612-823-8249
wellmindmn@earthlink.net
www.wellmindminnesota.org

The legislation that Senator Hottinger proposes is long overdue, doesn
far enough, and only points to the tip of the iceberg of what is wrong wi
entire medical/industrial/health care system. The worst effects fall on th
people someone happens to designate as "mentally ill." This is easy to
here are no medical indications such as MRI, CAT scan, blood, hair nor urine nor any other kind of tests to define who is
ientally ill and who is not. In the commitment courts, people are taken out of their community, disrupting their livelihood and living situation, "branding" them for life, and pumping very addictive poisons into them, then they are asked, "Are you mentally ill? If the person says, "No," that is incontrovertible evidence that he/she is mentally ill. This is circular reasoning and foolish. Further, there is no way a person can prove he/she is not mentally ill. Any scientist can tell you that you can't prove a null hypothesis. This makes a mockery of the U.S. Justice system.

If mental illness were, indeed, a medical condition, then it would have some medical indications. It does no good to argue that mental illness is a physical disease like diabetes or Parkinson's because it has no medical markers as other medical diseases have.

If mental illness can not be shown to be a medical condition, then we do not have to hire police to pick up the customers and bring them in to the hospitals and treatment centers and pay for the court personnel to order them held. No other branch of medicine has their customers -- against their will -- brought to them. Then we do not have to disable millions of people with unneeded drugs.

Every person, not just the Senate Health and Family Security Committee, should have a chance to know the following:

PLoS Medicine (Public Library of Science) is an international, multidisciplinary medical journal that aims to promote translation of basic research into clinical ... www.plos.org/journals/index.html - 11k -

Volume 2 | Issue 8 | AUGUST 2005

Why Most Published Research Findings Are False John P. A. Ioannidis

Summary

There is increasing concern that most current published research findings are false. The probability that a research claim is true may depend on study power and bias, the number of other studies on the same question, and, importantly, the ratio of true to no relationships among the relationships probed in each scientific field. In this framework, a research finding is less likely to be true when the studies conducted in a field are smaller; when effect sizes are smaller; when there is a greater number and lesser preselection of tested relationships; where there is greater flexibility in designs, definitions, outcomes, and analytical modes; when there is greater financial and other interest and prejudice; and when more teams are involved in a scientific field in chase of statistical significance. Simulations show that for most study designs and settings, it is more likely for a research claim to be false than true. Moreover, for **many current scientific fields, claimed research findings may often be simply accurate measures of the prevailing bias.**

John P. A. Ioannidis is in the Department of Hygiene and Epidemiology, University of Ioannina School of Medicine, Ioannina, Greece, and Institute for Clinical Research and Health Policy Studies, Department of Medicine, Tufts-New England Medical Center, Tufts University School of Medicine, Boston, Massachusetts, United States of America. E-mail: jioannid@cc.uoi.gr

Corollary 5: The greater the financial and other interests and prejudices in a scientific field, the less likely the research findings are to be true. Conflicts of interest and prejudice may increase bias, *u*. Conflicts of interest are very common in biomedical research [26], and typically they are inadequately and sparsely reported [26,27]. Prejudice may not necessarily have financial roots. Scientists in a given field may be prejudiced purely because of their belief in a scientific theory or commitment to their own findings. Many otherwise seemingly independent, university-based studies may be conducted for no other reason than to give physicians and researchers qualifications for promotion or tenure. Such nonfinancial conflicts may also lead to distorted reported results and interpretations. Prestigious investigators may suppress via the peer review process the appearance and dissemination of findings that refute their findings, thus condemning their field to perpetuate false dogma. Empirical evidence on expert opinion shows that it is extremely unreliable [28].

Volume 2 | Issue 5 | MAY 2005

PLoS Medicine

Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies

Richard Smith

Richard Smith is Chief Executive of United Health Europe, London, United Kingdom. E-mail: richardswsmith@yahoo.co.uk

Competing Interests: RS was an editor for the *BMJ* for 25 years. For the last 13 of those years, he was the editor and chief executive of the BMJ Publishing Group, responsible for the profits of not only the *BMJ* but of the whole group, which published some 25 other

journals. He stepped down in July 2004. He is now a member of the board of the Public Library of Science, a position for which he is not paid.

"Journals have devolved into information laundering operations for the pharmaceutical industry", wrote Richard Horton, editor of the *Lancet*, in March 2004 [1]. In the same year, Marcia Angell, former editor of the *New England Journal of Medicine*, lambasted the industry for becoming "primarily a marketing machine" and co-opting "every institution that might stand in its way" [2]. Medical journals were conspicuously absent from her list of co-opted institutions, but she and Horton are not the only editors who have become increasingly queasy about the power and influence of the industry. Jerry Kassirer, another former editor of the *New England Journal of Medicine*, argues that the industry has deflected the moral compasses of many physicians [3], and the editors of *PLoS Medicine* have declared that they will not become "part of the cycle of dependency…between journals and the pharmaceutical industry" [4]. Something is clearly up.

The Problem: Less to Do with Advertising, More to Do with Sponsored Trials

The most conspicuous example of medical journals' dependence on the pharmaceutical industry is the substantial income from advertising, but this is, I suggest, the least corrupting form of dependence. The advertisements may often be misleading [5,6] and the profits worth millions, but the advertisements are there for all to see and criticize. Doctors may not be as uninfluenced by the advertisements as they would like to believe, but in every sphere, the public is used to discounting the claims of advertisers.

The much bigger problem lies with the original studies, particularly the clinical trials, published by journals. Far from discounting these, readers see randomized controlled trials as one of the highest forms of evidence. A large trial published in a major journal has the journal's stamp of approval (unlike the advertising), will be distributed around the world, and may well receive global media coverage, particularly if promoted simultaneously by press releases from both the journal and the expensive public-relations firm hired by the pharmaceutical company that sponsored the trial. For a drug company, a favourable trial is worth thousands of pages of advertising, which is why a company will sometimes spend upwards of a million dollars on reprints of the trial for worldwide distribution. The doctors receiving the reprints may not read them, but they will be impressed by the name of the journal from which they come. The quality of the journal will bless the quality of the drug.

Fortunately from the point of view of the companies funding these trials—but unfortunately for the credibility of the journals who publish them—these trials rarely produce results that are unfavourable to the companies' products [7,8]. Paula Rochon and others examined in 1994 all the trials funded by manufacturers of nonsteroidal anti-inflammatory drugs for arthritis that they could find [7]. They found 56 trials, and not one of the published trials presented results that were unfavourable to the company that sponsored the trial. Every trial showed the company's drug to be as good as or better than the comparison treatment.

By 2003 it was possible to do a systematic review of 30 studies comparing the outcomes of studies funded by the pharmaceutical industry with those of studies funded from other sources [8]. Some 16 of the studies looked at clinical trials or meta-analyses, and 13 had outcomes favourable to the sponsoring companies. Overall, studies funded by a company were four times more likely to have results favourable to the company than studies funded from other sources. In the case of the five studies that looked at economic evaluations, the results were favourable to the sponsoring company in every case.

The evidence is strong that companies are getting the results they want, and this is especially worrisome because between two-thirds and three-quarters of the trials published in the major journals—*Annals of Internal Medicine*, *JAMA*, *Lancet*, and *New England Journal of Medicine*—are funded by the industry [9]. For the *BMJ*, it's only one-third—partly, perhaps, because the journal has less influence than the others in North America, which is responsible for half of all the revenue of drug companies, and partly because the journal publishes more cluster-randomised trials (which are usually not drug trials) [9].

Why Do Pharmaceutical Companies Get the Results They Want?

Why are pharmaceutical companies getting the results they want? Why are the peer-review systems of journals not noticing what seem to be biased results? The systematic review of 2003 looked at the technical quality of the studies funded by the industry and found that it was as good—and often better—than that of studies funded by others [8]. This is not surprising as the companies have huge resources and are very familiar with conducting trials to the highest standards.

The companies seem to get the results they want not by fiddling the results, which would be far too crude and possibly detectable by peer review, but rather by asking the "right" questions—and there are many ways to do this [10]. Some of the methods for achieving favourable results are listed in the Sidebar, but there are many ways to hugely increase the chance of producing favourable results, and there are many hired guns who will think up new ways and stay one jump ahead of peer reviewers.

Then, various publishing strategies are available to ensure maximum exposure of positive results. Companies have resorted to trying to suppress negative studies [11,12], but this is a crude strategy—and one that should rarely be necessary if the company is asking the "right" questions. A much better strategy is to publish positive results more than once, often in supplements to journals, which are highly profitable to the publishers and shown to be of dubious quality [13,14]. Companies will usually conduct multicentre trials, and there is huge scope for publishing different results from different centres at different times in different journals. It's also possible to combine the results from different centres in multiple combinations.

These strategies have been exposed in the cases of risperidone [15] and odansetron [16], but it's a huge amount of work to discover

how many trials are truly independent and how many are simply the same results being published more than once. And usually it's impossible to tell from the published studies: it's necessary to go back to the authors and get data on individual patients.

Peer Review Doesn't Solve the Problem

Journal editors are becoming increasingly aware of how they are being manipulated and are fighting back [17,18], but I must confess that it took me almost a quarter of a century editing for the *BMJ* to wake up to what was happening. Editors work by considering the studies submitted to them. They ask the authors to send them any related studies, but editors have no other mechanism to know what other unpublished studies exist. It's hard even to know about related studies that are published, and it may be impossible to tell that studies are describing results from some of the same patients. Editors may thus be peer reviewing one piece of a gigantic and clever marketing jigsaw—and the piece they have is likely to be of high technical quality. It will probably pass peer review, a process that research has anyway shown to be an ineffective lottery prone to bias and abuse [19].

Furthermore, the editors are likely to favour randomised trials. Many journals publish few such trials and would like to publish more: they are, as I've said, a superior form of evidence. The trials are also likely to be clinically interesting. Other reasons for publishing are less worthy. Publishers know that pharmaceutical companies will often purchase thousands of dollars' worth of reprints, and the profit margin on reprints is likely to be 70%. Editors, too, know that publishing such studies is highly profitable, and editors are increasingly responsible for the budgets of their journals and for producing a profit for the owners. Many owners—including academic societies—depend on profits from their journals. An editor may thus face a frighteningly stark conflict of interest: publish a trial that will bring US$100 000 of profit or meet the end-of-year budget by firing an editor.

Journals Should Critique Trials, Not Publish Them

How might we prevent journals from being an extension of the marketing arm of pharmaceutical companies in publishing trials that favour their products? Editors can review protocols, insist on trials being registered, demand that the role of sponsors be made transparent, and decline to publish trials unless researchers control the decision to publish [17,18]. I doubt, however, that these steps will make much difference. Something more fundamental is needed.

Firstly, we need more public funding of trials, particularly of large head-to-head trials of all the treatments available for treating a condition. Secondly, journals should perhaps stop publishing trials. Instead, the protocols and results should be made available on regulated Web sites. Only such a radical step, I think, will stop journals from being beholden to companies. Instead of publishing trials, journals could concentrate on critically describing them.

Acknowledgments

This article is based on a talk that Richard Smith gave at the Medical Society of London in October 2004 when receiving the HealthWatch Award for 2004. The speech is reported in the January 2005 HealthWatch newsletter [20]. The article overlaps to a small extent with an article published in the BMJ *[21].*

Myth of a serotonin imbalance

"Biological psychiatrists have looked very closely for a serotonin imbalance or dysfunction in patients with depression or obsessive compulsive disorder and, to date, it has been elusive," says Dr. Wayne Goodman, Chair of the US Food and Drug Administration (FDA) Psychopharmacologic Drugs Advisory Committee.

Psychiatry's drug prescribing practices rest on a myth debunked by Jeffrey Lacasse and Jonathan Leo in their article in PLoS Medicine. Not a single representative of mainstream psychiatry has come forward to rebut them.

Lacasse and Leo lay out the case against psychiatry's bedrock justification for prescribing psychotropic drugs. For decades psychiatry's leadership and chorus of followers have claimed that depression is caused by a "chemical imbalance" in the brain, and that SSRI antidepressants normalize that "chemical imbalance."

But such claims have been overturned In the absence of evidence. As Lacasse and Leo have shown, not a single peer reviewed article validates the theory of a chemical or biological marker abnormality in persons diagnosed with depression--or, for that matter with any psychiatric disorder.

Thus, neurologist, Dr. Frederick Baughman argues, in the absence of a confirmed disease, no medical intervention is justified.

Evidence does exist showing that the drugs have serious adverse effects, which, for some individuals, cause permanent damage.

Furthermore, some of the prescribed drugs are controlled class II substances--which means they are highly addictive!

We are led to ask: What is the justification for giving psychiatrists a license to prescribe psychotropic drugs in the absence of evidence that:

1. A pathological abnormality is present;
2. The prescribed intervention (drug) is proven safe;
3. The intervention is proven effective to treat the pathology;

4. The benefit / risk ratio is favorable for those for whom it is prescribed.

See: Jeffrey R. Lacasse, Jonathan Leo. Serotonin and Depression: A Disconnect between the Advertisements and the Scientific Literature, PLoS Medicine, Dec 2005 at:
http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0020392

http://www.cmaj.ca/cgi/content/full/174/6/754-a
Canadian Medical Association Journal **NEWS** **SSRI ads questioned** **Colin Meek**
Wester Ross, Scotland

Claims in drug monographs and advertising that selective serotonin reuptake inhibitor (SSRI) antidepressants work by normalizing serotonin levels are not based on scientific evidence and should be prohibited, says a leading US psychiatrist.

"Biological psychiatrists have looked very closely for a serotonin imbalance or dysfunction in patients with depression or obsessive compulsive disorder and, to date, it has been elusive," says Dr. Wayne Goodman, Chair of the US Food and Drug Administration (FDA) Psychopharmacologic Drugs Advisory Committee. Although an SSRI may work well in an individual, this "doesn't prove that there is an underlying imbalance, defect or dysfunction in the person's serotonin system," he added.

Goodman was reacting to a recent article (December 2005, *PLoS Medicine*) about the growing body of medical literature that casts doubt on the "serotonin hypothesis." Co-author Jonathan Leo, associate professor of anatomy at Lake Erie College of Osteopathic Medicine, says the FDA should prohibit SSRI manufacturers from making these claims.

GlaxoSmith-Kline (GSK), for example, claims (www.paxil.com) that paroxetine (Paxil) can "help restore the balance of serotonin — which helps reduce the symptoms of anxiety and depression." GSK officials refused to comment.

In 2003, Ireland's drug regulator banned GSK from stating on its patient information leaflet that paroxetine "works by bringing serotonin levels back to normal." Officials stated that "There is no scientific investigation to measure what are normal serotonin levels in the human brain receptors. As such, claiming that a particular medicinal product works by bringing serotonin levels back to normal is not accurate."

The claims do not appear on Canadian product information, says Health Canada spokesperson Chris Williams. The Paxil monograph states it is "thought to work by increasing levels of serotonin in the brain."

There are laws against locking up people because of perceived mental illness:
The Minnesota Constitution does not allow anyone to be locked up without a trial by a jury, according to Amendment VII.

> "The next section of the article will review the Minnesota Supreme Court civil jury jurisprudence from 1860 to the present. [FN5] It will show that, for more than 140 years, the Minnesota Supreme Court has consistently held that the right to a jury that existed in the Minnesota Territory was part of the 1857 Constitution, and that this constitutional right to a jury trial cannot be altered by the Legislature or the courts. The article will then review the right to a jury in civil commitment proceedings in the Minnesota Territory by showing that the Territorial Probate Court, which had original jurisdiction over civil commitment proceedings, included the right to a jury. "

Appendix 1. Essay by Professor Peter Erlinder, William Mitchell Law Review, 2003, Westlaw 29. page 1269

But the Fort case has even more far-reaching implications.
In earlier cases, the court ruled that the Minnesota Constitution requires reasonable suspicion of crime to stop or hold someone [George(1997) /Blacksten(1993)] and that searches of cars also required reasonable suspicion of crime [Wiegand (2002)]. The requirement that police must have reasonable suspicion of crime before they can act also applies to other tactics such as roadblocks, which the court struck down nearly a decade ago. [Ascher (1994)].

Peter Erlinder Published May 12, 2003 ERL112 Star Tribune Peter Erlinder, professor at William Mitchell College of Law,St. P

The Fort case makes clear that the Minnesota Constitution requires police to leave people alone, unless police have evidence of suspected criminal activity to justify detentions or searches.
The Minnesota Constitution applies equally to everyone in our state: young and old, male and female, white and black, tall and short, citizens and noncitizens. This means that Minnesota law enforcement cannot seize or detain anyone for suspicion of activity that is not criminal . . . such as violation of civil laws or regulations, which would include questions of immigration status.

Seen in this light, the proposed Minneapolis ordinance is nothing more than a restatement of the rights that all people in Minnesota have to be left alone by police, unless they have committed acts that raise "reasonable suspicions of criminal activity." The ordinance is merely a restatement of the limited powers granted to local police by the Minnesota Constitution, and should not be very controversial

for either legal or budgetary...

Senate Counsel, Research, and Fiscal Analysis

G-17 State Capitol
75 Rev. Dr. Martin Luther King. Jr. Blvd.
St. Paul, MN 55155-1606
(651) 296-4791
FAX: (651) 296-7747
Jo Anne Zoff Sellner
Director

Senate

State of Minnesota

S.F. No. 3240 - Pharmacy Payment Reform Advisory Committee

Author: Senator Paul E. Koering

Prepared by: Katie Cavanor, Senate Counsel (651/296-3801) KC

Date: March 28, 2006

S.F. No. 3240 establishes the Pharmacy Payment Reform Advisory Committee to advise the Commissioner of Human Services and make recommendations to the Legislature in implementing federal charges.

Subdivision 1 defines the following terms: "department," "commissioner," "cost of dispensing," "additional costs," and "advisory committee."

Subdivision 2 establishes the advisory committee. Describes the makeup of the committee. States that the committee expires on January 31, 2008.

Subdivision 3 requires the commissioner to conduct a prescription drug cost of dispensing study to determine the average cost of dispensing prescriptions under the medical assistance program. Requires the commissioner to contract with an independent third party to conduct the study.

Subdivision 4 requires the study to determine the cost of dispensing the average prescription and any additional costs that may be incurred for dispensing prescriptions under the medical assistance program. Requires the study to include the current level of dispensing fees paid to providers and an estimate of revenues required to adequately adjust reimbursement to cover the cost to pharmacies.

Subdivision 5 requires the third-party entity to submit to the advisory committee the entity's proposed research methodology and publish the collected data to allow other researchers to validate the study results. States that any data published shall not identify the source of the data.

Subdivision 6 requires the advisory committee to use the information from the study and make recommendations to the commissioner on implementation of pharmacy reforms. Requires the commissioner to report the findings of the study and recommendations of the advisory committee to the Legislature by January 15, 2007. Requires the commissioner to conduct a cost of dispensing study every three years following the initial report. Requires the commissioner to make recommendations to the Legislature on how to adequately adjust reimbursement rates to pharmacies to cover the costs of dispensing and additional costs to pharmacies.

KC:ph

Senators Koering, Solon, Higgins, Sams and Berglin introduced–

S.F. No. 3240: Referred to the Committee on Health and Family Security.

A bill for an act

relating to human services; establishing a pharmacy payment reform advisory committee; providing for a study; requiring a report to the legislature.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **PHARMACY PAYMENT REFORM ADVISORY COMMITTEE.**

Subdivision 1. **Definitions.** For purposes of this section, the following words, terms, and phrases have the following meanings:

(a) "Department" means the Department of Human Services.

(b) "Commissioner" means the commissioner of the Department of Human Services.

(c) "Cost of dispensing" includes, but is not limited to, operational and overhead costs; professional counseling as required under the Omnibus Budget Reconciliation Act of 1990, excluding medication management services under Minnesota Statutes, section 256B.0625, subdivision 13h; salaries; and other associated administrative costs, as well as a reasonable return on investment. In addition, cost of dispensing includes expenses transferred by wholesale drug distributors to pharmacies as a result of the wholesale drug distributor tax under Minnesota Statutes, sections 295.52 to 295.582.

(d) "Additional costs" include, but are not limited to, costs relating to coordination of benefits, bad debt, uncollected co-pays, payment lag times, and high rate of rejected claims.

(e) "Advisory committee" means the Pharmacy Payment Reform Advisory Committee established by this section.

Subd. 2. **Advisory committee.** The Pharmacy Payment Reform Advisory Committee is established under the direction of the commissioner of human services. The commissioner, after receiving recommendations from the Minnesota Pharmacists Association, the Minnesota Retailers Association, the Minnesota Hospital Association,

and the Minnesota Wholesale Druggists Association, shall convene a pharmacy payment reform advisory committee to advise the commissioner and make recommendations to the legislature on implementation of pharmacy reforms contained in title VI, chapter IV, of the Deficit Reduction Act of 2005. The committee shall be comprised of three licensed pharmacists representing both independent and chain pharmacy entities, one of whom must have expertise in pharmacoeconomics, two individuals representing hospitals with outpatient pharmacies, and two individuals with expertise in wholesale drug distribution. The committee shall be staffed by an employee of the department who shall serve as an ex officio nonvoting member of the committee. The department's pharmacy program manager shall also serve as an ex officio, nonvoting member of the committee. The committee is governed by Minnesota Statutes, section 15.059, except that committee members do not receive compensation or reimbursement for expenses. The advisory committee members shall serve a two-year term and the advisory committee will expire on January 31, 2008.

Subd. 3. **Cost of dispensing study.** The department shall conduct a prescription drug cost of dispensing study to determine the average cost of dispensing Medicaid prescriptions in Minnesota. The department shall contract with an independent third party in the state that has experience conducting business cost allocation studies, such as an academic institution, to conduct a prescription drug cost of dispensing study. If no independent third-party entity exists in the state, the department may contract with an out-of-state entity. The cost of dispensing study shall be completed by an independent third party no later than October 1, 2006, and reported to the department and the advisory committee upon completion.

Subd. 4. **Content of study.** The study shall determine the cost of dispensing the average prescription and any additional costs that might be incurred for dispensing Medicaid prescriptions. The study shall include the current level of dispensing fees paid to providers and an estimate of revenues required to adequately adjust reimbursement to cover the cost to pharmacies.

Subd. 5. **Methodology of study and publishing requirement.** The independent third-party entity performing the cost of dispensing research shall submit to the advisory committee the entity's proposed research methodology and shall publish the collected data to allow other independent researchers to validate the study results. The data shall be published in a manner that does not identify the source of the data.

Subd. 6. **Recommendations.** The advisory committee shall use the information from the cost of dispensing study and make recommendations to the commissioner on implementation of pharmacy reforms contained in title VI, chapter IV, of the Deficit Reduction Act of 2005. The commissioner shall report the findings of the study and

the recommendations of the advisory committee to the legislature by January 15, 2007. The department shall conduct a cost of dispensing study every three years following the initial report. The commissioner, in consultation with the advisory committee, shall make recommendations to the legislature on how to adequately adjust reimbursement rates to pharmacies to cover the costs of dispensing and additional costs to pharmacies. Reports shall include the current level of dispensing fees paid to providers and an estimate of revenues required to adequately adjust reimbursement to ensure that:

(1) reimbursement is sufficient to enlist an adequate number of participating pharmacy providers so that pharmacy services are as available for Medicaid recipients under the program as for the state's general population;

(2) Medicaid dispensing fees are adequate to reimburse pharmacy providers for the costs of dispensing prescriptions under the Medicaid program;

(3) Medicaid pharmacy reimbursement for multiple-source drugs included on the federal upper reimbursement limit is set at the level established by the federal government under United States Code, title 42, section 1396r-8(e)(5);

(4) the combined Medicaid program reimbursement for prescription drug product and the dispensing fee provides a return adequate to provide a reasonable profit for the participating pharmacy; and

(5) the new payment system does not create disincentives for pharmacists to dispense generic drugs.

EFFECTIVE DATE. This section is effective the day following final enactment.

RESPONDING TO FEDERAL MEDICAID REFORMS: PHARMACY REIMBURSEMENT

MEDICAID PHARMACY REIMBURSEMENT

Minnesota has 1,586 pharmacies and roughly 485,400 people on Medicaid. Minnesota loses on average 12-13 pharmacies per year and has a shortage of approximately 400 pharmacists. Pharmacists in rural Minnesota also serve many nursing homes, hospitals and other entities by providing medication reviews for patients and ordering and delivering medications.

- FEDERAL CHANGES TO MEDICAID PHARMACY REIMBURSEMENT FORMULAS COULD UNINTENTIONALLY CREATE DISINCENTIVES FOR DISPENSING GENERIC DRUGS AND HARM PATIENTS' ACCESS TO MEDICATIONS AND ACCESS TO THE KNOWLEDGE OF A PHARMACIST. THIS IS PARTICULARLY LIKELY IF STATES DO NOT ADJUST REIMBURSEMENT TO ADDRESS STATE SPECIFIC CONDITIONS THAT ALTER THE COST OF DISPENSING.

  Average pharmacy profit margins are in the range of 1.8% - 2.2%. Further reductions in reimbursement will put pharmacists' profit margin below the cost of dispensing in many cases.

- IN ORDER TO ENSURE THAT THE FEDERAL REFORMS ARE IMPLEMENTED IN A WAY THAT DOES NOT BRING ABOUT THESE UNINTENDED CONSEQUENCES:
  - A study should be conducted to determine the cost of dispensing a prescription to Medicaid patients in Minnesota.
  - An advisory committee should be formed to review the new drug product reimbursement mechanism created and the cost of dispensing study results to make recommendations to the legislature on how to implement the federal reforms.
  - The cost of dispensing study must take state-specific policies that increase cost into consideration. For example expenses associated with the Minnesota Wholesale Drug Distributor Tax. **NO OTHER STATE HAS THIS TAX.**

MINNESOTA PHARMACISTS ASSOCIATION • 1935 West County Road B-2, Suite 165 • Roseville, MN 55113
651-697-1771 *metro* • 800-451-8349 *mn* • 651-697-1776 *fax* • Liz@mpha.org • Abbie@mpha.org

Rural Pharmacy In Minnesota

Rural Pharmacists Provide:

✔**Local and convenient access to medications and drug therapy.**
✔**Needed patient education about health conditions, medication use and side effects.**
✔**Management of drug safety and drug safety issues.**

- *Twenty-five percent of the U.S. population lives in rural areas, many are elderly. With the exponential increase in elderly people taking life-preserving medications for chronic disorders, pharmacists in rural areas provide an essential service.*

✔**Drug therapy knowledge to rural hospitals, clinics and long-term care facilities.**

- *Many pharmacists in small towns provide nursing home patients with medications. In addition, federal law requires monthly pharmacists' review of residents' medications.*
- *In the hospitals in these small towns, pharmacists oversee distribution of inpatient medications.*
- *Often, rural hospitals and nursing homes count on the local community pharmacist to provide these services.*

✔**Pharmacists are one of a limited number of health care providers serving in rural communities.**

- *The trusted expertise of pharmacists in medication management for patients cannot be provided through online or mail delivery of medications.*

✔**Access to over-the-counter medications, medical equipment and supplies, and flu and pneumococcal immunizations**

✔**Care for veterinary patients.**

Minnesota Rural Pharmacy Statistics:

There are 1,502 pharmacies in Minnesota; 641 of them (44%) are in rural Minnesota.

Rural Minnesota has lost 102 pharmacies since 1996, many of these closures resulted in communities having no access to a local pharmacy.

In Minnesota there are 126 towns with one pharmacy, the total number of residents/patients served by these small town pharmacies is more than 226,000.

In towns that have only one pharmacy, the nearest opportunity to obtain pharmacy services is, on average, at least 22 miles away.

The average age of a pharmacist in rural Minnesota is 50 years.

Solutions:

Pharmacists in rural areas are facing challenges in reimbursement, competition, covering staffing and meeting increased medication needs of patients.

As more rural pharmacists reach retirement age, the number of pharmacies *closing without replacement is likely to increase.*

To maintain pharmacy services in rural areas, pharmacists must be:

- Maintain Medicaid reimbursement at current levels.
- Conform Minnesota pharmacy access standards to match the Medicare standard.
- Assure provider tax relief for losses incurred as a result of the Medicare Part D Benefit.
- Support loan forgiveness for rural pharmacists.

References

1. www.nrhrural.org/page.file/different.html "What's Different About Rural Health Care."

2. "Profile of Pharmacies in Rural Minnesota," Office of Rural Health and Primary Care, MN Dept. of Health.

3. Unpublished research from the College of Pharmacy, University of Minnesota, data collected 2003.

Minnesota Pharmacists Association, 1935 West County Road B-2, Suite 165, Roseville, Minnesota 55113-2722
800-451-8349-MN ✧ 651-697-1771-Metro ✧ 651-697-1776-Fax ✧ Contacts: liz@mpha.org or abbie@mpha.org

Preliminary

NARRATIVE: HF 3590/SF 3240

Bill Description

This bill requires the commissioner to convene an advisory group that would, through a DHS funded study, identify the costs associated with filling a prescription in Minnesota. By January 15, 2006, the commissioner would report the committee's findings to the legislature.

Assumptions

If this bill is passed DHS will be responsible for the following:
1.) Begin meeting with committee members.
2.) Create an RFP for the cost study, distribute the RFP and select a vendor.
3.) Communicate vendor study methodology to the committee to obtain approval.
4.) Publish study data and findings for review by other researchers to validate findings.
5.) Communicate study results to committee by Oct 1, 2006.
6.) By January 15, 2007 the commissioner will report the findings and the committee recommendations to the legislature.
7.) This analysis addresses only the cost of the study, not the implementation of study results.

Expenditure and/or Revenue Formula

Study Cost = $100,000.00

Long-Term Fiscal Considerations
None

Local Government Costs
None

References/Sources

MPhA for cost of study.

Agency Contact Name: Steve Nelson 651-431-2202
FN Coord Signature: STEVE BARTA
Date: 03/28/06 Phone: 431-2916

Preliminary

Fiscal Note – 2005-06 Session

Bill #: H3590-0 **Complete Date:**

Chief Author: POWELL, DUKE

Title: PHARMACY PYMT REFORM ADVISORY COMM

Agency Name: Human Services Dept

Fiscal Impact	Yes	No
State	X	
Local		X
Fee/Departmental Earnings		X
Tax Revenue		X

This table reflects fiscal impact to state government. Local government impact is reflected in the narrative only.

Dollars (in thousands)	FY05	FY06	FY07	FY08	FY09
Expenditures					
General Fund		0	100	0	0
Less Agency Can Absorb					
-- No Impact --					
Net Expenditures					
General Fund		0	100	0	0
Revenues					
General Fund		0	40	0	0
Net Cost <Savings>					
General Fund		0	60	0	0
Total Cost <Savings> to the State		0	60	0	0

	FY05	FY06	FY07	FY08	FY09
Full Time Equivalents					
-- No Impact --					
Total FTE					

Senate Counsel, Research, and Fiscal Analysis

G-17 STATE CAPITOL
75 REV. DR. MARTIN LUTHER KING, JR. BLVD.
ST. PAUL, MN 55155-1606
(651) 296-4791
FAX: (651) 296-7747
JO ANNE ZOFF SELLNER
DIRECTOR

Senate
State of Minnesota

S.F. No. 1640 - Reporting and Review of Provider Expenditures (Delete-Everything Amendment)

Author: Senator Sheila M. Kiscaden

Prepared by: Katie Cavanor, Senate Counsel (651/296-3801) KTC

Date: March 27, 2006

S.F. No. 1640 requires providers to report certain expenditures in excess of $1 million to the Commissioner of Health; establishes a process for third parties to request a public meeting and hearing on certain expenditures over $2 million; and authorizes the Commissioner to audit the referral patterns of certain providers.

Section 1 (62J.17) modifies the definition of major spending commitment to mean expenditures in excess of $1 million but equal to or less than $2 million.

Section 2 (62J.18) establishes reporting requirements, public meeting procedures, and hearing procedures for expenditures over $2 million.

Subdivision 1 states that this section applies to providers and those who would be a provider upon making an expenditure in excess of $2 million and exempts hospital construction moratorium projects.

Subdivision 2, paragraph (a), requires a provider intending to make a major spending commitment of $2 million for the acquisition of a unit of medical equipment or in excess of $2 million for a single capital project for the purpose of providing health care services must file a report with the Commissioner of Health at least 60 days before making the expenditure.

Paragraph (b), the Commissioner must maintain a database to track reported expenditures.

Paragraph (c), the Commissioner must maintain a list of persons interested in receiving notice of a report filed under this section and provide notice to all persons on the list and by

publication in the *State Register* within 15 days of receiving the report. The notice must include a copy of the report or a description of the proposed expenditure.

Subdivision 3 exempts from the public meeting and hearing any expenditure:

(1) to replace existing equipment with comparable equipment;

(2) made by a research and teaching institution for purposes of conducting medical education, medical research, or clinical trials;

(3) to repair, remodel, or replace existing buildings or fixtures if it does not involve substantial expansion of service capacity or the nature of health services provided;

(4) for building maintenance;

(5) for activities not directly related to the delivery of patient care services; and

(6) for computer equipment or data systems not directly related to the delivery of patient care.

The exemption also does not apply to mergers, acquisitions, and other changes in ownership or control that do not involve substantial expansion of service capacity or substantial change in the services provided.

Subdivision 4 permits a third party to request a public meeting on projects that exceed $2 million in capital cost within 30 days of the filing of the report. The meeting is to be an informational forum for the provider to answer inquiries and must be arranged and coordinated by the Commissioner on an expedited basis. The requesting party is responsible for all costs related to the meeting.

Subdivision 5 permits a third party to request within 30 days from the date of the public meeting that the expenditure be the subject of a hearing before the Commissioner. The hearing must be public and on an expedited basis and the party requesting the hearing must pay the Commissioner for the cost of the hearing. Money received by the Commissioner must be appropriated to the Commissioner for administering this section. The hearing must proceed on an expedited basis.

Subdivision 6 describes the criteria that the Commissioner must consider: need and access; quality of health; cost of health care alternatives available to the provider; and other considerations. Permits the Commissioner to adopt rules to establish additional criteria. The commissioner is required to make: findings of fact as to whether the expenditure is needed to ensure quality of health care. If the Commissioner determines that the expenditure is not needed, the Commissioner shall obtain an injunction prohibiting the provider from making the expenditure. The final decision of the Commissioner is entitled to judicial review and,

if reviewed, each party must pay their respective cost unless the appeal is not successful, then the party bringing the appeal must pay all cost.

Subdivision 7 authorizes the Commissioner to enforce this section according to Minnesota Statutes, section 144.99, subdivision 8. Compliance is a condition of medical assistance reimbursement and to provide services to state employees. The Commissioner may also assess fines in an amount up to triple the amount of the expenditure.

Subdivision 8 requires the Commissioner to conduct a retrospective review on expenditures in excess of $2 million if a public meeting is not requested.

KC:ph

Senators Kiscaden and Lourey introduced--

S.F. No. 1640: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; modifying expenditure reporting requirements; establishing a separate reporting procedure for expenditures over $5,000,000; restricting certain medical referrals; appropriating money; amending Minnesota Statutes 2004, section 62J.17, subdivision 2; proposing coding for new law in Minnesota Statutes, chapter 62J.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2004, section 62J.17, subdivision 2, is amended to read:

Subd. 2. [DEFINITIONS.] For purposes of this section, the terms defined in this subdivision have the meanings given.

(a) "Access" means the financial, temporal, and geographic availability of health care to individuals who need it.

(b) "Capital expenditure" means an expenditure which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance.

(c) "Cost" means the amount paid by consumers or third party payers for health care services or products.

(d) "Date of the major spending commitment" means the date the provider formally obligated itself to the major spending commitment. The obligation may be incurred by entering into a contract, making a down payment, issuing bonds or entering a loan agreement to provide financing for the major spending commitment, or taking some other formal, tangible action evidencing the provider's intention to make the major spending

commitment.

(e) "Health care service" means:

(1) a service or item that would be covered by the medical assistance program under chapter 256B if provided in accordance with medical assistance requirements to an eligible medical assistance recipient; and

(2) a service or item that would be covered by medical assistance except that it is characterized as experimental, cosmetic, or voluntary.

"Health care service" does not include retail, over-the-counter sales of nonprescription drugs and other retail sales of health-related products that are not generally paid for by medical assistance and other third-party coverage.

(f) "Major spending commitment" means an expenditure in excess of $1,000,000<u>, but less than or equal to $5,000,000,</u> for:

(1) acquisition of a unit of medical equipment;

(2) a capital expenditure for a single project for the purposes of providing health care services, other than for the acquisition of medical equipment;

(3) offering a new specialized service not offered before;

(4) planning for an activity that would qualify as a major spending commitment under this paragraph; or

(5) a project involving a combination of two or more of the activities in clauses (1) to (4).

The cost of acquisition of medical equipment, and the amount of a capital expenditure, is the total cost to the provider regardless of whether the cost is distributed over time through a lease arrangement or other financing or payment mechanism.

(g) "Medical equipment" means fixed and movable equipment that is used by a provider in the provision of a health care service. "Medical equipment" includes, but is not limited to, the following:

(1) an extracorporeal shock wave lithotripter;

(2) a computerized axial tomography (CAT) scanner;

(3) a magnetic resonance imaging (MRI) unit;

(4) a positron emission tomography (PET) scanner; and

(5) emergency and nonemergency medical transportation equipment and vehicles.

(h) "New specialized service" means a specialized health care procedure or treatment regimen offered by a provider that was not previously offered by the provider, including, but not limited to:

(1) cardiac catheterization services involving high-risk patients as defined in the Guidelines for Coronary Angiography established by the American Heart Association and the American College of Cardiology;

(2) heart, heart-lung, liver, kidney, bowel, or pancreas transplantation service, or any other service for transplantation of any other organ;

(3) megavoltage radiation therapy;

(4) open heart surgery;

(5) neonatal intensive care services; and

(6) any new medical technology for which premarket approval has been granted by the United States Food and Drug Administration, excluding implantable and wearable devices.

Sec. 2. [62J.18] [PROVIDER REPORTING IN EXCESS OF $5,000,000.]

Subdivision 1. [APPLICABILITY; DEFINITIONS.] (a) This section applies to providers and to persons who would become providers after making the expenditures described in subdivision 2.

(b) For purposes of this section, the terms used have the meanings given in section 62J.17, subdivision 2, except that "major spending commitment" means an expenditure in excess of $5,000,000.

Subd. 2. [REPORTING REQUIREMENT.] (a) A provider that intends to make a major spending commitment in excess of $5,000,000 for the acquisition, by purchase or lease, of a unit of medical equipment or in excess of $5,000,000 for a single capital project for the purposes of providing health care services must file a report with the commissioner at least 60

days before committing to make the expenditure. The report must contain the information described in section 62J.17, subdivision 4a, paragraphs (b) and (c).

(b) The commissioner shall maintain a database to track expenditures reported under this subdivision.

(c) The commissioner shall maintain a list of all persons who have registered with the commissioner for the purpose of receiving notice by electronic mail of a report filed under this subdivision. The commissioner shall, within 15 days of receiving an expenditure report, provide notice of the report by electronic mail to all persons on the list and submit a summary of the report for publication in the State Register. The notice must include either the report or an easily understandable description of the proposed expenditure in the report. The publication in the State Register must include an easily understandable description of the proposed expenditure in the report and information on how to obtain a copy of the report. In addition, the commissioner shall make reasonable efforts to notify persons or classes of persons who may be significantly affected by the proposed expenditure in the report. The commissioner may recover the reasonable costs incurred in providing notice under this paragraph through costs paid by third parties involved in proceedings under this section.

(d) No provider may commit to making the expenditure until the procedures described in this section are completed.

Subd. 3. [PUBLIC MEETING.] (a) Within 30 days of the State Register publication under subdivision 2, a third party may request a public meeting on expenditures that exceed $5,000,000. The public meeting shall serve as an informational forum for the provider to answer inquiries of interested third parties.

(b) The commissioner shall arrange for and coordinate the meeting on an expedited basis. The party requesting the meeting shall pay the commissioner for the commissioner's cost of the meeting, as determined by the commissioner. Money received by the commissioner for reimbursement under this section is

appropriated to the commissioner for the purpose of administering this section.

Subd. 4. [PUBLIC MEETING EXCEPTIONS.] (a) Subdivisions 3, 5, and 6 do not apply to an expenditure:

(1) to replace existing equipment with comparable equipment used for direct patient care. Upgrades of equipment beyond the current model or comparable model are subject to subdivisions 3, 5, and 6;

(2) made by a research and teaching institution for purposes of conducting medical education, medical research supported or sponsored by a medical school or by a federal or foundation grant, or clinical trials;

(3) to repair, remodel, or replace existing buildings or fixtures if, in the judgment of the commissioner, the project does not involve a substantial expansion of service capacity or a substantial change in the nature of health care services provided;

(4) for building maintenance including heating, water, electricity, and other maintenance-related expenditures;

(5) for activities not directly related to the delivery of patient care services, including food service, laundry, housekeeping, and other service-related activities; and

(6) for computer equipment or data systems not directly related to the delivery of patient care services, including computer equipment or data systems related to medical record automation.

(b) In addition to the exceptions listed in paragraph (a), subdivisions 3, 5, and 6 do not apply to mergers, acquisitions, and other changes in ownership or control that, in the judgment of the commissioner, do not involve a substantial expansion of service capacity or a substantial change in the nature of health care services provided.

Subd. 5. [HEARING.] (a) Within 30 days from the date of a public meeting under subdivision 3, a third party may request that the planned expenditure be subject to a hearing before an administrative law judge. The hearing and review of the planned

expenditure shall be according to the relevant provisions of the Administrative Procedure Act, except as otherwise provided in this subdivision.

(b) A hearing under this subdivision is a public proceeding.

(c) A party to the hearing must pay for the party's representation before the administrative law judge. The party requesting the hearing shall pay the costs assessed by the chief administrative law judge according to section 14.53. Money received for services rendered by the Office of Administrative Hearings under this subdivision shall be deposited in the state Office of Administrative Hearings account and appropriated according to section 14.54.

(d) A hearing requested under this subdivision must proceed on an expedited basis.

Subd. 6. [HEARING CRITERIA; DECISION; RULES.] (a) The administrative law judge shall consider the following criteria:

(1) need and access, including, but not limited to:

(i) the need of the population served or to be served by the proposed health services for those services;

(ii) the project's contribution to meeting the needs of the medically underserved, including persons in rural areas, low-income persons, racial and ethnic minorities, persons with disabilities, and the elderly, as well as the extent to which medically underserved residents in the provider's service area are likely to have access to the proposed health service; and

(iii) the distance, convenience, cost of transportation, and accessibility to health services for those to be served by the proposed health services;

(2) quality of health care, including, but not limited to:

(i) the impact of the proposed service on the quality of health services available to those proposed to be served by the project; and

(ii) the impact of the proposed service on the quality of health services offered by other providers;

(3) cost of health care, including, but not limited to:

(i) the financial feasibility of the proposal;

(ii) probable impact of the proposal on the costs of and charges for health services provided by the person proposing the service;

(iii) probable impact of the proposal on the costs of and charges for health services provided by other providers;

(iv) probable impact of the proposal on reimbursement for the proposed services; and

(v) the relationship, including the organizational relationship, of the proposed health services to ancillary or support services;

(4) alternatives available to the provider, including, but not limited to:

(i) the availability of alternative, less costly, or more effective methods of providing the proposed health services;

(ii) the relationship of the proposed project to the long-range development plan, if any, of the person or entity providing or proposing the services; and

(iii) possible sharing or cooperative arrangements among existing facilities and providers; and

(5) other considerations, including, but not limited to:

(i) the best interests of the patients, including conflicts of interest that may be present in influencing the utilization of the services, facility, or equipment relating to the expenditures;

(ii) special needs and circumstances of those entities that provide a substantial portion of their services or resources, or both, to individuals not residing in the immediate geographic area in which the entities are located, which entities may include, but are not limited to, medical and other health professional schools, multidisciplinary clinics, and specialty centers;

(iii) the special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages; and

(iv) the impact of the proposed project on fostering competition between providers.

(b) The commissioner may adopt rules to establish additional hearing criteria.

(c) After applying the criteria under this subdivision, the administrative law judge shall make findings of fact as to whether the planned expenditure is needed to ensure quality health care. If the administrative law judge finds that the planned expenditure is not needed to ensure quality health care, the provider may not undertake the planned expenditure. The order of the administrative law judge constitutes the final decision in the case as applicable under section 14.62. A final decision in the case is entitled to judicial review under sections 14.63 to 14.69. In the event of an appeal, each party must pay the party's respective costs, except that the party bringing the appeal must pay all costs if the appeal is unsuccessful.

Subd. 7. [ENFORCEMENT.] The commissioner may enforce this section by denying or refusing to reissue the permit, license, registration, or certificate of a provider that does not comply with this section, according to section 144.99, subdivision 8. Compliance with this section is a condition of medical assistance reimbursement. The commissioner of employee relations shall not permit a provider that does not comply with this section to provide services to state employees. The commissioner may obtain an injunction prohibiting the provider from making the planned expenditure. In addition, the commissioner may assess fines against a provider that incurs an expenditure that is found by the commissioner as not needed to ensure quality health care according to this section in an amount up to triple the amount of the expenditure.

Subd. 8. [RETROSPECTIVE REVIEW.] Nothing in this section or section 62J.17 shall be construed to prohibit the commissioner from conducting a retrospective review of an expenditure in excess of $5,000,000 according to section 62J.17, subdivision 5a.

Sec. 3. [62J.24] [MEDICAL REFERRALS.]

(a) No individual physician or physician group engaged in a

solo or group practice, whether conducted for profit or not for profit and however organized, that is wholly owned and controlled by one or more of the physicians so associated, or, in the case of a not-for-profit organization, its only members are one or more of the physicians so associated, shall refer a patient for services to a health care entity that provides services through use of magnetic resonance imaging, positron emission tomography, linear accelerator equipment, or computerized axial tomography, if:

(1) the physician holds a direct or indirect ownership or investment interest in the entity;

(2) the physician's immediate family holds a direct or indirect ownership or investment interest in the entity; or

(3) the physician or member of the physician's immediate family has any direct or indirect arrangement involving compensation with the entity.

(b) For purposes of this section, the following definitions have the meanings given them:

(1) "control" means the ownership of at least 50 percent of the equity in an entity or the ability to appoint at least 50 percent of the members of the governing body of the entity;

(2) "health care entity" means an entity that provides health care-related testing, diagnosis, or treatment of individuals, but does not include a hospital, hospital affiliate, or a constituent of a hospital system;

(3) "hospital affiliate" means any entity that, directly or indirectly, is controlled by, controls, or is under common control with a hospital or a joint venture in which the hospital participates;

(4) "hospital system" means an organized group of health care providers in which at least one constituent is a not-for-profit hospital; and

(5) "investment interest" means an ownership or investment interest through equity, debt, leasehold interest, or other means, regardless of whether the interest is direct or indirect.

(c) The commissioner shall assess a fine against a person

who violates this section. The amount of the fine shall be not less than $25,000. Any continuing violation of this section is punishable by a fine of not less than $25,000 and not more than $100,000 per day of operation and by one or both of the following:

(1) referral of the physician to the Board of Medical Practice for appropriate disciplinary action; and

(2) revocation of the health care entity's license or registration.

(d) The attorney general may proceed on behalf of the state to enforce penalties that are due and payable under this section in any manner provided by law for the collection of debts and may bring other enforcement action, as described in section 144.991, subdivision 7.

Senator ..... moves to amend the delete-everything amendment (SCS1640A-1) to S.F. No. 1640 as follows:

Pages 1 to 6, delete sections 1 and 2 and insert:

"Section 1. **[62J.18] PROVIDER REPORTING IN EXCESS OF $5,000,000.**

Subdivision 1. **Applicability; definitions.** (a) For purposes of this section, the terms used have the meanings given in section 62J.17, subdivision 2, except that "major spending commitment" means an expenditure in excess of $5,000,000.

(b) This section applies to providers and to persons who would become providers after making the expenditures described in subdivision 2. This section does not apply to hospital construction projects subject to the hospital construction moratorium under section 144.551 or to the public interest review under section 144.552.

Subd. 2. **Reporting requirement.** (a) A provider that intends to make a major spending commitment in excess of $5,000,000 for an acquisition, by purchase or lease, of a unit of medical equipment or in excess of $5,000,000 for a single capital project for the purposes of providing health care services must file a report with the commissioner at least 60 days before committing to make the expenditure. The report must contain the information described in section 62J.17, subdivision 4a, paragraphs (b) and (c).

(b) The commissioner shall maintain a database to track expenditures reported under this subdivision.

(c) The commissioner shall maintain a list of all persons who have registered with the commissioner for the purpose of receiving notice by electronic mail of a report filed under this subdivision. The commissioner shall, within 15 days of receiving an expenditure report, provide notice of such report by electronic mail to all persons on its list, and by publication in the State Register. The notice must include either a copy of the report or an easily understandable description of the proposed expenditure in the report. The notice in the State Register must include a copy of the report, along with an easily understandable description of the proposed expenditure in the report. In addition, the commissioner shall make reasonable efforts to notify persons or classes of persons who may be significantly affected by the proposed expenditure in the report. The commissioner may recover the reasonable costs incurred in providing notice as required in this paragraph through costs paid by third parties involved in proceedings described in this section.

(d) No provider may commit to making the expenditure until the procedures described in this section are completed.

Subd. 3. **Exceptions.** (a) This section does not apply to an expenditure:

(1) to replace existing equipment with comparable equipment used for direct patient care. Upgrades of equipment beyond the current model or comparable model are subject to this section;

(2) made by a research and teaching institution for purposes of conducting medical education, medical research supported or sponsored by a medical school or by a federal or foundation grant, or clinical trials;

(3) to repair, remodel, or replace existing buildings or fixtures if, in the judgment of the commissioner, the project does not involve a substantial expansion of the service capacity or a substantial change in the nature of health care services provided;

(4) for building maintenance, including heating, water, electricity, and other maintenance-related expenditures;

(5) for activities not directly related to the delivery of patient care services, including food service, laundry, housekeeping, and other service-related activities; or

(6) for computer equipment or data systems not directly related to the delivery of patient care services, including computer equipment or data systems related to medical record automation.

(b) In addition to the exceptions listed in paragraph (a), this section does not apply to mergers, acquisitions, and other changes in ownership or control that, in the judgment of the commissioner, do not involve a substantial expansion of service capacity or a substantial change in the nature of health care services provided.

Subd. 4. **Public meeting.** (a) Within 30 days from the date the notice requirements of subdivision 2, paragraph (c), are satisfied, a third party may request a public meeting on expenditures that exceed $5,000,000. The public meeting shall serve as an informational forum for the provider to answer inquiries of interested third parties.

(b) The commissioner shall arrange for and coordinate the meeting on an expedited basis. The party requesting the meeting shall pay the commissioner for the commissioner's cost of the meeting, as determined by the commissioner. Money received by the commissioner for reimbursement under this section is appropriated to the commissioner for the purpose of administering this section.

Subd. 5. **Information required.** If a public meeting is requested, the provider shall provide the following information to be presented at the meeting:

(1) need and access, including, but not limited to:

(i) the need of the population served or to be served by the proposed health services for those services;

(ii) the project's contribution to meeting the needs of the medically underserved, including persons in rural areas, low-income persons, racial and ethnic minorities, persons

with disabilities, and the elderly, as well as the extent to which medically underserved residents in the provider's service area are likely to have access to the proposed health service; and

(iii) the distance, convenience, cost of transportation, and accessibility to health services for those to be served by the proposed health services;

(2) quality of health care, including, but not limited to:

(i) the impact of the proposed service on the quality of health services available to those proposed to be served by the project; and

(ii) the impact of the proposed service on the quality of health services offered by other providers;

(3) cost of health care, including, but not limited to:

(i) the financial feasibility of the proposal;

(ii) probable impact of the proposal on the costs of and charges for providing health services by the person proposing the service;

(iii) probable impact of the proposal on the costs of and charges for health services provided by other providers;

(iv) probable impact of the proposal on reimbursement for the proposed services; and

(v) the relationship, including the organizational relationship, of the proposed health services to ancillary or support services;

(4) alternatives available to the provider, including, but not limited to:

(i) the availability of alternative, less costly, or more effective methods of providing the proposed health services;

(ii) the relationship of the proposed project to the long-range development plan, if any, of the person or entity providing or proposing the services; and

(iii) possible sharing or cooperative arrangements among existing facilities and providers; and

(5) other considerations requested by the commissioner, including, but not limited to:

(i) the best interests of the patients, including conflicts of interest that may be present in influencing the utilization of the services, facility, or equipment relating to the expenditures;

(ii) special needs and circumstances of those entities that provide a substantial portion of their services or resources, or both, to individuals not residing in the immediate geographic area in which the entities are located, which entities may include, but are not limited to, medical and other health professional schools, multidisciplinary clinics, and specialty centers;

(iii) the special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages; and

(iv) the impact of the proposed project on fostering competition between providers.

Subd. 6. **Enforcement.** The commissioner may enforce this section by denying or refusing to reissue the permit, license, registration, or certificate of a provider that does not comply with this section, according to section 144.99, subdivision 8.

EFFECTIVE DATE. This section is effective the day following final enactment."

Renumber the sections in sequence and correct the internal references

Amend the title accordingly

Senate Counsel, Research, and Fiscal Analysis

G-17 STATE CAPITOL
75 REV. DR. MARTIN LUTHER KING, JR. BLVD.
ST. PAUL, MN 55155-1606
(651) 296-4791
FAX: (651) 296-7747
JO ANNE ZOFF SELLNER
DIRECTOR

Senate

State of Minnesota

S.F. No. 3223 – Special Transportation (the A-1 Delete-Everything Amendment)

Author: Senator Linda Higgins

Prepared by: David Giel, Senate Research (296-7178)

Date: March 24, 2006

S.F. No. 3223 increases Medical Assistance (MA) reimbursement rates for special transportation and delays full implementation of the use of a special transportation broker for one year.

Section 1 (256B.0625, subdivision 17) provides that residents of nursing facilities and persons being discharged from a hospital to a skilled nursing facility are eligible for driver-assisted service. It requires special transportation providers to transport recipients using the quickest route available, rather than the most direct route as required under current law. It increases the MA base rate by $1 and the per-mile rate by 50 cents for transport of recipients who need a wheelchair-accessible van and increases the base rate by 25 cents and the per-mile rate by five cents for transport of recipients who do not need an accessible van.

Section 2 delays for one year, until July 1, 2007, full implementation of the use of a broker to manage special transportation.

Section 3 is the effective date.

DG:rdr

Senators Higgins and Solon introduced–

S.F. No. 3223: Referred to the Committee on Health and Family Security.

A bill for an act

relating to human services; specifying criteria for coverage of medical assistance special transportation services; increasing special transportation reimbursement rates; extending the prohibition on the use of brokers or coordinators to manage special transportation services; amending Minnesota Statutes 2005 Supplement, section 256B.0625, subdivision 17; Laws 2003, First Special Session chapter 14, article 12, section 93, as amended.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2005 Supplement, section 256B.0625, subdivision 17, is amended to read:

Subd. 17. **Transportation costs.** (a) Medical assistance covers transportation costs incurred solely for obtaining emergency medical care or transportation costs incurred by eligible persons in obtaining emergency or nonemergency medical care when paid directly to an ambulance company, common carrier, or other recognized providers of transportation services.

(b) Medical assistance covers special transportation, as defined in Minnesota Rules, part 9505.0315, subpart 1, item F, if the recipient has a physical or mental impairment that would prohibit the recipient from safely accessing and using a bus, taxi, other commercial transportation, or private automobile. For purposes of this requirement, a recipient has a physical or mental impairment that would prohibit the recipient from safely accessing and using a bus, taxi, other commercial transportation, or private automobile if the recipient:

(1) lacks the upper body strength, lower body strength, or coordination to safely transfer from a wheelchair and position and secure their body in a prone or seated position in a vehicle; or

(2) is unable to safely walk or self-propel a wheelchair from the recipient's residence to a vehicle and from the vehicle through the outside door of the medical facility to the medical appointment.

The commissioner may use an order by the recipient's attending physician to certify that the recipient requires special transportation services. Special transportation includes driver-assisted service to eligible individuals, including, but not limited to, residents of a skilled nursing facility and individuals being discharged from a hospital to a skilled nursing facility. Driver-assisted service includes passenger pickup at and return to the individual's residence or place of business, assistance with admittance of the individual to the medical facility, and assistance in passenger securement or in securing of wheelchairs or stretchers in the vehicle. Special transportation providers must obtain written documentation from the health care service provider who is serving the recipient being transported, identifying the time that the recipient arrived. Special transportation providers may not bill for separate base rates for the continuation of a trip beyond the original destination. Special transportation providers must take recipients to the nearest appropriate health care provider, using the ~~most direct~~ quickest route available. The maximum medical assistance reimbursement rates for special transportation services are:

(1) ~~$17~~ $18 for the base rate and ~~$1.35~~ $1.85 per mile for services to eligible persons who need a wheelchair-accessible van;

(2) ~~$11.50~~ $11.75 for the base rate and ~~$1.30~~ $1.35 per mile for services to eligible persons who do not need a wheelchair-accessible van; and

(3) $60 for the base rate and $2.40 per mile, and an attendant rate of $9 per trip, for services to eligible persons who need a stretcher-accessible vehicle.

EFFECTIVE DATE. This section is effective July 1, 2006.

Sec. 2. Laws 2003, First Special Session chapter 14, article 12, section 93, as amended by Laws 2005, First Special Session chapter 4, article 8, section 80, is amended to read:

Sec. 93. **REVIEW OF SPECIAL TRANSPORTATION ELIGIBILITY CRITERIA AND POTENTIAL COST SAVINGS.**

The commissioner of human services, in consultation with the commissioner of transportation and special transportation service providers, shall review eligibility criteria for medical assistance special transportation services and shall evaluate whether the level of special transportation services provided should be based on the degree of impairment of

the client, as well as the medical diagnosis. The commissioner shall also evaluate methods for reducing the cost of special transportation services, including, but not limited to:

(1) requiring providers to maintain a daily log book confirming delivery of clients to medical facilities;

(2) requiring providers to implement commercially available computer mapping programs to calculate mileage for purposes of reimbursement;

(3) restricting special transportation service from being provided solely for trips to pharmacies;

(4) modifying eligibility for special transportation;

(5) expanding alternatives to the use of special transportation services;

(6) improving the process of certifying persons as eligible for special transportation services; and

(7) examining the feasibility and benefits of licensing special transportation providers.

The commissioner shall present recommendations for changes in the eligibility criteria and potential cost-savings for special transportation services to the chairs and ranking minority members of the house and senate committees having jurisdiction over health and human services spending by January 15, 2004. The commissioner is prohibited from using a broker or coordinator to manage special transportation services until July 1, ~~2006~~ 2009, except for the purposes of checking for recipient eligibility, authorizing recipients for appropriate level of transportation, and monitoring provider compliance with Minnesota Statutes, section 256B.0625, subdivision 17. The commissioner shall not amend the initial contract to broker or manage nonemergency medical transportation to extend beyond two consecutive years. The commissioner shall not enter into a broker or management contract for transportation services which denies a medical assistance recipient the free choice of health service provider, including a special transportation provider, as specified in Code of Federal Regulations, title 42, section 431.51. This prohibition ~~does not apply~~ also applies to the purchase or management of common carrier

transportation. The commissioner of human services is prohibited from using a broker or coordinator to manage common carrier transportation services until July 1, 2009, except for the purposes of checking for recipient eligibility, authorizing recipients for appropriate level of transportation, and monitoring provider compliance with Minnesota Statutes, section 256B.0625, subdivision 17.

EFFECTIVE DATE. This section is effective ~~the day following final enactment~~ July 1, 2006.

Senator ..... moves to amend S.F. No. 3223 as follows:

Delete everything after the enacting clause and insert:

"Section 1. Minnesota Statutes 2005 Supplement, section 256B.0625, subdivision 17, is amended to read:

Subd. 17. **Transportation costs.** (a) Medical assistance covers transportation costs incurred solely for obtaining emergency medical care or transportation costs incurred by eligible persons in obtaining emergency or nonemergency medical care when paid directly to an ambulance company, common carrier, or other recognized providers of transportation services.

(b) Medical assistance covers special transportation, as defined in Minnesota Rules, part 9505.0315, subpart 1, item F, if the recipient has a physical or mental impairment that would prohibit the recipient from safely accessing and using a bus, taxi, other commercial transportation, or private automobile.

The commissioner may use an order by the recipient's attending physician to certify that the recipient requires special transportation services. Special transportation includes driver-assisted service to eligible individuals, including, but not limited to, residents of a skilled nursing facility and individuals being discharged from a hospital to a skilled nursing facility. Driver-assisted service includes passenger pickup at and return to the individual's residence or place of business, assistance with admittance of the individual to the medical facility, and assistance in passenger securement or in securing of wheelchairs or stretchers in the vehicle. Special transportation providers must obtain written documentation from the health care service provider who is serving the recipient being transported, identifying the time that the recipient arrived. Special transportation providers may not bill for separate base rates for the continuation of a trip beyond the original destination. Special transportation providers must take recipients to the nearest appropriate health care provider, using the ~~most direct~~ quickest route available. The maximum medical assistance reimbursement rates for special transportation services are:

(1) ~~$17~~ $18 for the base rate and ~~$1.35~~ $1.85 per mile for services to eligible persons who need a wheelchair-accessible van;

(2) ~~$11.50~~ $11.75 for the base rate and ~~$1.30~~ $1.35 per mile for services to eligible persons who do not need a wheelchair-accessible van; and

(3) $60 for the base rate and $2.40 per mile, and an attendant rate of $9 per trip, for services to eligible persons who need a stretcher-accessible vehicle.

Sec. 2. Laws 2003, First Special Session chapter 14, article 12, section 93, as amended by Laws 2005, First Special Session chapter 4, article 8, section 80, is amended to read:

Sec. 93. **REVIEW OF SPECIAL TRANSPORTATION ELIGIBILITY CRITERIA AND POTENTIAL COST SAVINGS.**

The commissioner of human services, in consultation with the commissioner of transportation and special transportation service providers, shall review eligibility criteria for medical assistance special transportation services and shall evaluate whether the level of special transportation services provided should be based on the degree of impairment of the client, as well as the medical diagnosis. The commissioner shall also evaluate methods for reducing the cost of special transportation services, including, but not limited to:

(1) requiring providers to maintain a daily log book confirming delivery of clients to medical facilities;

(2) requiring providers to implement commercially available computer mapping programs to calculate mileage for purposes of reimbursement;

(3) restricting special transportation service from being provided solely for trips to pharmacies;

(4) modifying eligibility for special transportation;

(5) expanding alternatives to the use of special transportation services;

(6) improving the process of certifying persons as eligible for special transportation services; and

(7) examining the feasibility and benefits of licensing special transportation providers.

The commissioner shall present recommendations for changes in the eligibility criteria and potential cost-savings for special transportation services to the chairs and ranking minority members of the house and senate committees having jurisdiction over health and human services spending by January 15, 2004. The commissioner is prohibited from using a broker or coordinator to manage special transportation services until July 1, ~~2006~~ 2007, except for the purposes of checking for recipient eligibility, authorizing recipients for appropriate level of transportation, and monitoring provider compliance with Minnesota Statutes, section 256B.0625, subdivision 17. The commissioner shall not amend the initial contract to broker or manage nonemergency medical transportation to extend beyond two consecutive years. The commissioner shall not enter into a broker or management contract for transportation services which denies a medical assistance recipient the free choice of health service provider, including a special transportation provider, as specified in Code of Federal Regulations, title 42, section 431.51. This prohibition does not apply to the purchase or management of common carrier transportation.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 3. **EFFECTIVE DATE.**

Sections 1 and 2 are effective July 1, 2006."

Senate Counsel, Research, and Fiscal Analysis

G-17 STATE CAPITOL
75 REV. DR. MARTIN LUTHER KING, JR. BLVD.
ST. PAUL, MN 55155-1606
(651) 296-4791
FAX: (651) 296-7747
JO ANNE ZOFF SELLNER
DIRECTOR

Senate

State of Minnesota

S.F. No. 3221 - Lead Abatement (Delete-Everything Amendment)

Author: Senator Linda Higgins

Prepared by: Katie Cavanor, Senate Counsel (651/296-3801) KTC

Date: March 28, 2006

S.F. No. 3221 creates the elevated blood lead level prevention program, requires certain health care providers to screen children for elevated blood lead levels, prohibits the sale or distribution of lead jewelry, and transfers the authority for the lead abatement program from the Department of Education to the Department of Health.

Sections 1 and 2 (144.9501) make technical changes.

Section 3 (144.9501, subdivision 9a) defines an "eligible organization" in the Lead Poisoning Prevention Act.

Section 4 (144.9502, subdivision1) adds to the purpose of the lead surveillance system to ensure that children are screened.

Section 5 (144.9502, subdivision 9) permits the data collected by the Commissioner of Health about persons with blood lead levels to be used by a public health organization that has entered into a data sharing agreement with the commissioner as part of the lead level prevention program.

Section 6 (144.9503, subdivision 3) requires the primary prevention lead education strategy to provide lead education material to the general public that includes information on the dangers and hazards of jewelry containing lead.

Section 7 (144.9512) transfers the lead abatement program to the Department of Health's statutes.

Section 8 (144.9513) establishes the elevated blood lead level prevention program.

Subdivision 1 requires the commissioner to provide a grant to a public health organization to establish an elevated blood lead level prevention program.

Subdivision 2 requires the commissioner and the public health organization to enter into a data sharing agreement that provides the organization with the names of children found to have blood lead levels of more than five micrograms of lead per deciliter of whole blood. Requires the commissioner and the organization to enter into a data privacy agreement that ensure that data remains private.

Subdivision 3 states that the program is to operate from January 1, 2007, to January 1, 2010, and provide the following services:

(1) education and information services that inform parents about the risk of elevated blood lead levels and the importance of prevention;

(2) assessments that identify possible sources of lead in or around homes;

(3) referrals to and assistance in accessing lead abatement services when appropriate;

(4) assistance in ensuring that all children in the program receive lead testing every three months;

(5) consultation services with physicians about prevention;

(6) health education and information services; and

(7) case coordination services.

Subdivision 4 requires the Commissioner of Health to submit a report to the Legislature by February 15, 2009, on the impact of the program and recommendations on whether the program should be continued.

Section 9 (144.9514) requires a health care provider who provides primary health care services to children to screen, or refer for screening, all children at age 12 months and 24 months for elevated blood lead levels unless the provider makes an affirmative determination that there is no risk of an elevation of blood lead levels. If the child has a blood lead level of at least ten micrograms per deciliter of whole blood, the provider is required to follow the Centers for Disease Control and Prevention guidelines for follow-up.

Section 10 (325F.385) prohibits the sale or distribution of jewelry that contains more than 600 parts per million of lead on or after July 1, 2006, and the sale or distribution of jewelry that contains more than 200 parts per million of lead on or after January 1, 2008. Defines "jewelry."

Section 11 appropriates money from the general fund in fiscal year 2007 to the Commissioner of Health for the elevated blood lead level prevention program.

Section 12 instructs the Revisor of Statutes to change references.

Section 13 repeals the lead abatement program in the Department of Education statutes.

KC:ph

Senator ..... moves to amend S.F. No. 3221 as follows:

Delete everything after the enacting clause and insert:

"Section 1. Minnesota Statutes 2004, section 144.9501, subdivision 1, is amended to read:

Subdivision 1. **Citation.** Sections 144.9501 to ~~144.9509~~ 144.9513 ~~144.9514~~ may be cited as the "Lead Poisoning Prevention Act."

Sec. 2. Minnesota Statutes 2004, section 144.9501, subdivision 2, is amended to read:

Subd. 2. **Applicability.** The definitions in this section apply to sections 144.9501 to ~~144.9509~~ 144.9513 ~~144.9514~~.

Sec. 3. Minnesota Statutes 2004, section 144.9501, is amended by adding a subdivision to read:

Subd. 9a. **Eligible organization.** "Eligible organization" means a city, board of health, community health department, community action agency, nonprofit organization, or community development corporation.

Sec. 4. Minnesota Statutes 2004, section 144.9502, subdivision 1, is amended to read:

Subdivision 1. **Surveillance.** The commissioner of health shall establish a statewide lead surveillance system. The purpose of this system is to:

(a) monitor blood lead levels in children and adults to identify trends and populations at high risk for elevated blood lead levels;

(b) ensure that children are screened as required under section ~~144.9514~~ 144.9513;

~~(b)~~ (c) ensure that screening services are provided to populations at high risk for elevated blood lead levels;

~~(c)~~ (d) ensure that medical and environmental follow-up services for children with elevated blood lead levels are provided; and

~~(d)~~ (e) provide accurate and complete data for planning and implementing primary prevention programs that focus on the populations at high risk for elevated blood lead levels.

Sec. 5. Minnesota Statutes 2004, section 144.9502, subdivision 9, is amended to read:

Subd. 9. **Classification of data.** Notwithstanding any law to the contrary, including section 13.05, subdivision 9, data collected by the commissioner of health about persons with blood lead levels, including analytic results from samples of paint, soil, dust, and drinking water taken from the individual's home and immediate property, shall be private and may only be used by the commissioner of health, the commissioner of labor and industry, authorized agents of Indian tribes, ~~and~~ authorized employees of local boards of health for the purposes set forth in this section, and a public health organization that has

entered into a data sharing agreement with the commissioner of health under section 144.9513, subdivision 2.

Sec. 6. Minnesota Statutes 2004, section 144.9503, subdivision 3, is amended to read:

Subd. 3. **Primary prevention lead education strategy.** The commissioner of health shall develop and maintain a primary prevention lead education strategy to prevent lead exposure. The strategy includes:

(1) lead education materials that describe the health effects of lead exposure, safety measures, and methods to be used in the lead hazard reduction process;

(2) providing lead education materials to the general public including, but not limited to, information on the dangers and hazards of jewelry containing lead;

(3) providing lead education materials to property owners, landlords, and tenants by swab team workers and public health professionals, such as nurses, sanitarians, health educators, nonprofit organizations working on lead issues, and other public health professionals in areas at high risk for toxic lead exposure; and

(4) promoting awareness of community, legal, and housing resources.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 7. **[144.9512] LEAD ABATEMENT PROGRAM.**

Subdivision 1. **Grants; administration.** Within the limits of the available appropriation, the commissioner may make grants to eligible organizations to train workers to provide swab team services for residential property. Grants may be awarded to eligible organizations to provide technical assistance and training to ensure quality and consistency within the statewide program.

Subd. 2. **Applicants.** (a) Interested eligible organizations may apply to the commissioner for grants under this section. Two or more eligible organizations may jointly apply for a grant. Priority shall be given to community action agencies in greater Minnesota and to either community action agencies or neighborhood based nonprofit organizations in cities of the first class. Of the total annual appropriation, 12.5 percent may be used for administrative purposes. The commissioner may deviate from this percentage if a grantee can justify the need for a larger administrative allowance. Of this amount, up to five percent may be used by the commissioner for state administrative purposes. Applications must provide information requested by the commissioner, including at least the information required to assess the factors listed in paragraph (d).

(b) The commissioner must consult with boards of health to provide swab team services for purposes of secondary prevention. The priority for swab teams created by grants to eligible organizations under this section must be work assigned by the

commissioner, or by a board of health if so designated by the commissioner, to provide secondary prevention swab team services to fulfill the requirements of section 144.9504, subdivision 6, in response to a lead order. Swab teams assigned work under this section by the commissioner, that are not engaged daily in fulfilling the requirements of section 144.9504, subdivision 6, must deliver swab team services in response to elevated blood lead levels as defined in section 144.9501, subdivision 9, where lead orders were not issued, and for purposes of primary prevention in census tracts known to be in areas at high risk for toxic lead exposure as described in section 144.9503, subdivision 2.

(c) Any additional money must be used for grants to establish swab teams for primary prevention under section 144.9503, in census tracts in areas at high risk for toxic lead exposure as determined under section 144.9503, subdivision 2.

(d) In evaluating grant applications, the commissioner must consider the following criteria:

(1) plans for the provision of swab team services for primary and secondary prevention;

(2) plans for resident and property owner education on lead safety;

(3) measures of program effectiveness;

(4) coordination of program activities with other federal, state, and local public health and housing renovation programs; and

(5) prior experience in providing swab team services.

Subd. 3. **Eligible grant activities.** An eligible organization receiving a grant under this section must ensure that all participating lead supervisors or certified firms are licensed and that all swab team workers are certified by the Department of Health under section 144.9505. Eligible organizations may participate in the program by:

(1) providing on-the-job training for swab team workers;

(2) providing swab team services to meet the requirements of sections 144.9503, subdivision 4, and 144.9504, subdivision 6;

(3) providing lead hazard reduction to meet the requirements of section 144.9501, subdivision 17;

(4) providing lead dust clean-up equipment and materials, as described in section 144.9503, subdivision 1, to residents; or

(5) having a swab team worker instruct residents and property owners on appropriate lead control techniques, including the lead-safe directives developed by the commissioner.

Subd. 4. **Swab team workers.** Each worker engaged in swab team services established under this section must have blood lead concentrations below 15 micrograms of lead per deciliter of whole blood as determined by a baseline blood lead screening. Any

organization receiving a grant under this section is responsible for lead screening and must assure that all swab team workers meet the standards established in this subdivision. Grantees must use appropriate workplace procedures including following the lead-safe directives developed by the commissioner to reduce risk of elevated blood lead levels. Grantees and participating contractors must report all employee blood lead levels that exceed 15 micrograms of lead per deciliter of whole blood to the commissioner.

Subd. 5. **Program benefits.** As a condition of providing swab team services under this section, an organization may require a property owner to not increase rents on a property solely as a result of a substantial improvement made with public funds under the programs in this section.

Subd. 6. **Requirements of organizations receiving grants.** An eligible organization that is awarded a grant under this section must prepare and submit a quarterly progress report to the commissioner beginning three months after receipt of the grant.

Sec. 8. **[144.9513] ELEVATED BLOOD LEAD LEVEL PREVENTION PROGRAM.**

Subdivision 1. **Program established.** The commissioner of health shall provide a grant to a public health organization with expertise in lead poisoning prevention for the purpose of establishing an elevated blood lead level prevention program. The program shall assist families of children at risk for elevated blood lead levels to prevent their children's blood lead levels from rising to 10 micrograms of lead per deciliter of whole blood.

Subd. 2. **Data.** The commissioner of health and the public health organization shall enter into a data sharing agreement that provides the organization with the names of children found to have blood lead levels of more than five micrograms of lead per deciliter of whole blood. The commissioner of health and the organization shall enter into a data privacy agreement that ensures that data on children with elevated blood lead levels remains private as required under section 144.9502, subdivision 9.

Subd. 3. **Program requirements.** The program shall operate from January 1, 2007, to January 1, 2010, and offer the following services:

(1) education and information services that inform parents about the risk of elevated blood lead levels and the importance of prevention;

(2) assessments that identify possible sources of lead in and around homes, such as home lead tests;

(3) referrals to and assistance in accessing lead abatement services when appropriate;

(4) assistance in ensuring that all children in the program receive lead testing every three months;

(5) consultation services with physicians about prevention issues;

(6) health education and information services including information on diet and health practices that prevent further increases in blood lead levels; and

(7) case coordination services.

Subd. 4. **Report required.** The commissioner of health shall submit a report to the legislature by February 15, 2009, that contains information on the impact of the program and recommendations on whether or not the program should be continued, and if so, any changes that should be made to the program. The public health organization shall provide the commissioner of health with all the data necessary to complete the report.

144.9513

Sec. 9. **[144.9514] REQUIRED LEAD SCREENING OF CHILDREN.**

A health care provider providing primary health care services to children shall screen, or refer for screening, all children at age 12 months and 24 months for elevated blood lead levels~~, unless the provider makes an affirmative determination that there is no risk for an elevation of blood lead levels~~. If a child who is screened under this section has a blood lead level of at least ten micrograms per deciliter of whole blood, the health care provider shall follow the follow-up care guidelines for children with elevated blood lead levels established by the Centers for Disease Control and Prevention.

Sec. 10. **[325E.385] SALE OF JEWELRY CONTAINING LEAD PROHIBITED.**

Subdivision 1. **Definition.** For the purposes of this section "jewelry" means: (1) an ornament worn by a person on the body or on clothing, including, but not limited to, a necklace, bracelet, anklet, earring, locket, pendant, charm bracelet, ring, pinky ring, chain, broach, pin, lapel pin, headband, watchband; or (2) any pendant, bead, chain, link, or other component of such an ornament.

Subd. 2. **Sale prohibited.** (a) On or after July 1, 2006, no person in this state shall sell, offer for sale, or distribute free of charge any jewelry that contains more than 600 parts per million of lead.

(b) On or after January 1, 2008, no person in this state shall sell, offer for sale, or distribute free of charge any jewelry that contains more than 200 parts per million of lead.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 11. **APPROPRIATION.**

$..... is appropriated from the general fund in fiscal year 2007 to the commissioner of health to be used for a grant to a public health organization with expertise in lead

poisoning prevention for the purpose of establishing an elevated blood lead level prevention program under Minnesota Statutes, section 144.9513. The grant may be used in combination with existing public and private funds.

Sec. 12. **REVISOR'S INSTRUCTION.**

The revisor of statutes shall change the range reference "144.9501 to 144.9509" to "144.9501 to ~~144.9512~~ 144.9513" wherever the reference appears in Minnesota Statutes and Minnesota Rules.

Sec. 13. **REPEALER.**

Minnesota Statutes 2004, section 119A.46, subdivisions 4, 5, 6, 7, 9, and 10, and Minnesota Statutes 2005 Supplement, section 119A.46, subdivisions 1, 2, 3, and 8, are repealed."

Amend the title accordingly

Senator Higgins introduced--

S.F. No. 2055: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; requiring medical assistance to cover environmental investigations for children with elevated blood lead levels; amending Minnesota Statutes 2004, section 256B.0625, subdivision 14.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2004, section 256B.0625, subdivision 14, is amended to read:

Subd. 14. [DIAGNOSTIC, SCREENING, AND PREVENTIVE SERVICES.] (a) Medical assistance covers diagnostic, screening, and preventive services.

(b) "Preventive services" include services related to pregnancy, including:

(1) services for those conditions which may complicate a pregnancy and which may be available to a pregnant woman determined to be at risk of poor pregnancy outcome;

(2) prenatal HIV risk assessment, education, counseling, and testing; and

(3) alcohol abuse assessment, education, and counseling on the effects of alcohol usage while pregnant. Preventive services available to a woman at risk of poor pregnancy outcome may differ in an amount, duration, or scope from those available to other individuals eligible for medical assistance.

(c) "Screening services" include, but are not limited to, blood lead tests. <u>Screening services also include, for children</u>

with blood lead levels equal to or greater than ten micrograms of lead per deciliter of whole blood, environmental investigations to determine the source of lead exposure. Reimbursement is limited to a health professional's time and activities during an on-site investigation of a child's home or primary residence.

Senator Higgins introduced--

S.F. No. 2055: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; requiring medical assistance to cover environmental investigations for children with elevated blood lead levels; amending Minnesota Statutes 2004, section 256B.0625, subdivision 14.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2004, section 256B.0625, subdivision 14, is amended to read:

Subd. 14. [DIAGNOSTIC, SCREENING, AND PREVENTIVE SERVICES.] (a) Medical assistance covers diagnostic, screening, and preventive services.

(b) "Preventive services" include services related to pregnancy, including:

(1) services for those conditions which may complicate a pregnancy and which may be available to a pregnant woman determined to be at risk of poor pregnancy outcome;

(2) prenatal HIV risk assessment, education, counseling, and testing; and

(3) alcohol abuse assessment, education, and counseling on the effects of alcohol usage while pregnant. Preventive services available to a woman at risk of poor pregnancy outcome may differ in an amount, duration, or scope from those available to other individuals eligible for medical assistance.

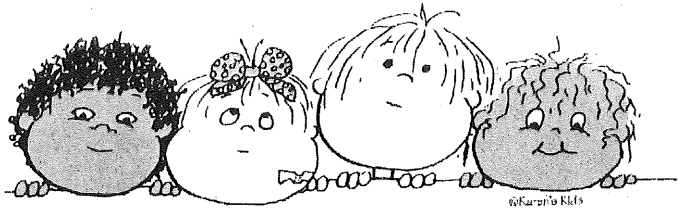
(c) "Screening services" include, but are not limited to, blood lead tests. <u>Screening services also include, for children</u>

with blood lead levels equal to or greater than ten micrograms of lead per deciliter of whole blood, environmental investigations to determine the source of lead exposure. Reimbursement is limited to a health professional's time and activities during an on-site investigation of a child's home or primary residence.

Lead Hurts Kids!

Sustainable Resources Center
Lead Poisoning Prevention Program
Local Lead Testing Initiatives
612-872-3282

To Be Their Best, Kids Need A LEAD Test!



If you have children, you need to know...

The only way to know if you or your child has been exposed to lead is to receive a blood lead test. The Minnesota Department of Health recommends that children be tested at ages 12 and 24 months. Children ages 6 years and under who have never been tested should also receive a blood lead test. Pregnant women who may have been exposed to lead should also be tested.

Even at low levels, lead poisoning affects a child's ability to learn and function.

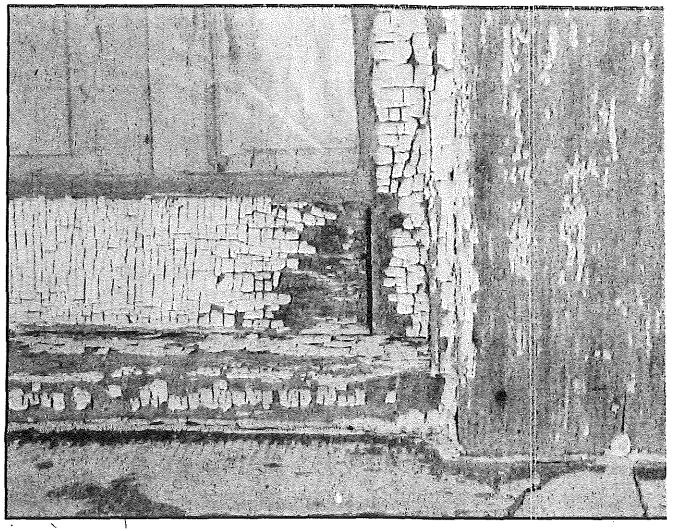
Some effects from exposure may include:

Brain Damage
Loss of IQ
Headaches
Learning Difficulties
Hyperactivity
Hearing Problems
Irritability & Vomiting

REMEMBER... Many children never exhibit any signs or symptoms of lead poisoning. The only way to know for sure if your child has lead in his/her blood is through a blood test!

During a blood lead test, a small amount of blood will be obtained from your child's finger. Please be aware that if your child's blood test comes back high, your local health professional may ask you to bring your child in for a follow-up venous test. The results are then reported as micrograms of lead per deciliter of blood (ug/dL).

Higher numbers indicate higher concentration of lead in the body.



GET THE LEAD OUT!

Chipping and peeling paint from houses and apartment buildings built before 1978 may contain LEAD.

LEAD is a heavy metal that makes kids sick.

Deteroriated LEAD based paint on windows poses the biggest threat to children.

Lead Safe Work Practices need to be followed to ensure your family's safety. Ask a professional before renovating, remodeling, painting, scraping or doing any other project that may disturb LEAD based paint.

Contacts:

The LEAD LINE: 612-870-4937

Sustainable Resources Center
1916 Second Avenue South
Minneapolis, MN 55403
612-872-3282
www.src-mn.org

SUSTAINABLE RESOURCES CENTER

CLEARCorps Minnesota
612-872-3287

Protecting children from lead poisoning

Minnesota Department of Health
Lead Program
651-215-0890
1-800-657-3908
TTY 651-215-0707

Does Your Child Need A Blood Lead Test?

YES! At 1 and 2 years of age if the child lives in Minneapolis or St. Paul

YES! If the child is under the age of six and has never been tested.

YES! If the child has recently moved from another major metropolitan area or another country within the last 12 months.

YES! If the child has regularly visited a home built before 1978 with recent or ongoing repair, remodeling or damage (such as water and/or chipping and peeling paint).

YES! If the child has lived in or regularly visited a home, child care facility or other building built before 1950.

YES! If the child or his/her sibling or playmate had an elevated blood lead level.

YES! If the child receives services from Minnesota Care (MnCare) or Medical Assistance (MA) which includes the Prepaid Medical Assistance Program (PMAP).

Looking for a primary care clinic? Wondering about medical insurance? Need a lead safe contractor? Call the LEAD LINE at 612-870-4937 for clinic referrals and more information on how to keep kids safe from lead.

Together We Can Keep Kids LEAD Safe!

Policy Position

Minnesota Department of Health February 2006

Swab-Team Grant Housekeeping

Problem Statement

In the 2005 Legislative Session, the swab-team grant program was transferred from the Minnesota Department of Education (MDE) to the MDH. The responsibility for administering this grant program was changed to MDH from the Dept of Education, but the statutory language remains in the Education laws, M.S. §119A.46. Because of this separation from the Lead Poisoning Prevention Act (M.S. §144.9501-9509), some of the language is outdated because the law was updated in 2003.

The grant process as currently defined is unnecessarily cumbersome and needs to be streamlined.

How does this legislation address the problem?

This proposal is housekeeping in nature to move the swab-team grant language to the LPPA and to streamline the administration of the grant process. The bill streamlines the grant requirements for a grant of this size. These changes will bring the grant language more in line with the current grant administrative authority for the lead safe housing grants in M.S. §144.9507.

What is a "swab team"?

In the LPPA, Swab team services are defined as activities that provide protection from lead hazards primarily through the use of interim controls, such as:
(1) removing lead dust by washing, vacuuming with high efficiency particle accumulator (HEPA) or wet vacuum cleaners, and cleaning the interior of residential property;
(2) removing loose paint and paint chips and repainting or installing guards to protect intact paint;
(3) covering or replacing bare soil that has a lead concentration of 100 parts per million or more;
(4) health education;
(5) advice and assistance to help residents locate and move to a temporary residence while lead hazard reduction is being completed; or
(6) any other assistance necessary to meet the resident's immediate needs as a result of the relocation.

Legislative & Funding History

This grant program originated as a jobs and training program. It has moved from Economic Security to the Department of Children, Families and Learning that changed back to the MDE in 2003. In 2005 it was moved to MDH where the Lead Poisoning Prevention program is operated. Because of this transition, MDH does not have past funding history. The funding (currently $100K per year) was transferred administratively and not by legislative action.

Who is affected?

The MDE awarded these funds annually to the Sustainable Resources Center (SRC), a nonprofit organization. SRC uses the funds to match federal funding of their CLEARCorps program. CLEARCorps recruits and trains AmeriCorps volunteers to work intensively with families whose children are at risk of lead poisoning. Corps members provide family-centered education, training, and lead hazard control services.

What are the consequences if this legislation does not pass?

MDH will continue to administer the swab-team grant according to the current language.

MINNESOTA MDH DEPARTMENT OF HEALTH
Freeman Building
625 Robert Street N.
P.O. Box 64975
St. Paul, MN 55164-0975
(651) 201-5000
www.health.state.mn.us

Senators Kelley, Berglin, Michel, Sams and Lourey introduced–

S.F. No. 3444: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; modifying the nursing home construction moratorium by creating an additional exception for a new facility for persons with eating disorders to be located in Hennepin or Dakota County; amending Minnesota Statutes 2004, section 144A.071, subdivision 3.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2004, section 144A.071, subdivision 3, is amended to read:

Subd. 3. **Exceptions authorizing an increase in beds.** (a) The commissioner of health, in coordination with the commissioner of human services, may approve the addition of a new certified bed or the addition of a new licensed nursing home bed, under the following conditions:

~~(a)~~ (1) to license or certify a new bed in place of one decertified after July 1, 1993, as long as the number of certified plus newly certified or recertified beds does not exceed the number of beds licensed or certified on July 1, 1993, or to address an extreme hardship situation, in a particular county that, together with all contiguous Minnesota counties, has fewer nursing home beds per 1,000 elderly than the number that is ten percent higher than the national average of nursing home beds per 1,000 elderly individuals. For the purposes of this section, the national average of nursing home beds shall be the most recent figure that can be supplied by the federal Centers for Medicare and Medicaid Services and the number of elderly in the county or the nation shall be determined by the most recent federal census or the most recent estimate of the state demographer as of July 1, of each year of persons age 65 and older, whichever is the most recent at the time of the request for replacement. An extreme hardship situation can only be found after the county documents the existence of unmet medical needs that cannot be addressed by any other alternatives;

~~(b)~~ (2) to certify or license new beds in a new facility that is to be operated by the commissioner of veterans affairs or when the costs of constructing and operating the new beds are to be reimbursed by the commissioner of veterans affairs or the United States Veterans Administration;

~~(c)~~ (3) to license or certify beds in a facility that has been involuntarily delicensed or decertified for participation in the medical assistance program, provided that an application for relicensure or recertification is submitted to the commissioner within 120 days after delicensure or decertification;

~~(d)~~ (4) to certify two existing beds in a facility with 66 licensed beds on January 1, 1994, that had an average occupancy rate of 98 percent or higher in both calendar years 1992 and 1993, and which began construction of four attached assisted living units in April 1993; ~~or~~

~~(e)~~ (5) to certify four existing beds in a facility in Winona with 139 beds, of which 129 beds are certified~~.~~; or

(6) to approve a project involving the establishment of a new facility in Hennepin or Dakota County that the legislature hereby determines to be uniquely and urgently needed and feasible and that is demonstrated by the project applicant to meet the following criteria:

(i) the facility will operate primarily to serve persons with eating disorders;

(ii) the facility will be licensed and certified for no more than 30 beds;

(iii) the facility will be owned either by a nonprofit corporation that is exempt from income tax pursuant to United States Code, title 26, section 501(c)(3) or by an entity that is a related organization of a nonprofit corporation exempt from income tax pursuant to United States Code, section 501(c)(3);

(iv) the entity owning the facility, or a related organization of the entity, operates a hospital located in Hennepin County; and

(v) the entity owning the facility, or a related organization of the entity, will furnish a continuum of services to persons with eating disorders, including acute inpatient hospital and ambulatory services.

(b) The exception available under paragraph (a), clause (6), is limited to the establishment of one new facility. Between June 30 and September 30 of each year until the commissioner issues an order approving an application under this paragraph, any entity that:

(i) has a plan for a new facility; and

(ii) desires to establish a new facility must submit an application to the commissioner for an exception to subdivision 2 according to paragraph (a), clause (6). The application must contain the plan and any additional relevant evidence not contained in the plan

that is supportive of the application and demonstrates evidence of compliance with the criteria specified in paragraph (a), clause (6).

(c) If there is only one applicant, the commissioner shall review the application to determine compliance with the criteria. If the commissioner determines that the application complies with the criteria, the commissioner shall issue an order approving the application. An applicant aggrieved by an order issued by the commissioner concerning the applicant's application may request that the commissioner initiate a contested case proceeding under sections 14.57 to 14.62. Judicial review of the final decision of the commissioner shall be governed by chapter 14.

(d) If there is more than one applicant during any period between June 30 and September 30, the commissioner shall determine which applications comply with the criteria. If more than one application complies with the criteria, the commissioner shall determine which applicant would best satisfy the criteria established in paragraph (a), clause (6). The commissioner shall make this determination by order following a hearing as provided in this paragraph. This hearing shall not constitute or be considered a contested case hearing under chapter 14 and shall be conducted solely under the procedures specified in this paragraph. The hearing shall commence after 90 days' notice to the applicants is given by the commissioner. The hearing may be conducted by the commissioner or by a person designated by the commissioner, who may be an administrative law judge. The purpose of the hearing shall be to receive evidence to assist the commissioner in determining which applicant best meets the criteria in paragraph (a), clause (6), item (ii). The parties to the hearing shall consist only of those applicants who have submitted a completed application that the commissioner has determined would be in the public interest. Each applicant shall have the right to be represented by counsel, to present evidence deemed relevant by the commissioner, and to examine and cross-examine witnesses. Persons who are not parties to the proceeding but who wish to present comments or submit information may do so in the manner determined by the commissioner or the commissioner's designee. Any person who is not a party shall have no right to examine or cross-examine witnesses. The commissioner shall issue an order approving an application within 30 days following the closing of the record of the hearing. The commissioner's order shall include a statement of the reasons the application best meets the criteria of paragraph (a), clause (6). Any applicant aggrieved by an order issued by the commissioner under this paragraph may seek judicial review of the final decision of the commissioner under sections 14.63 to 14.68.

Senate Counsel, Research, and Fiscal Analysis

G-17 STATE CAPITOL
75 REV. DR. MARTIN LUTHER KING, JR. BLVD.
ST. PAUL, MN 55155-1606
(651) 296-4791
FAX: (651) 296-7747
JO ANNE ZOFF SELLNER
DIRECTOR

Senate

State of Minnesota

S.F. No. 3399 - Medical Assistance Services to Persons With Disabilities (the A-2 Delete-Everything Amendment)

Author: Senator Becky Lourey

Prepared by: David Giel, Senate Research (296-7178)

Date: March 28, 2006

Section 1 (256B.69, subdivision 9) modifies the reporting requirements of health plans participating in Medical Assistance (MA). This section defines the following as public data that the Department of Human Services (DHS) must publicize: nonpersonally identifiable health plan encounter data, aggregate spending data, and criteria for service authorization and service use. This section also requires health plans and county-based purchasing plans to provide this data to DHS.

Section 2 (256B.69, subdivision 23) allows DHS to contract with Medicare-approved special needs plans to provide MA services to the elderly and persons with disabilities. This section also modifies the language governing expansion of the Minnesota Disability Health Options (MnDHO) Program. Until 2008, expansion for MnDHO projects that include home and community-based services is limited to the two projects currently in place. Enrollment in them must remain voluntary. MnDHO costs for home and community-based services must not exceed fee-for-service costs. In planning expansion of integrated programs, the commissioner must consult the stakeholder group established in section 3. Plans for further MnDHO expansion must be presented to the Legislature in 2007.

Section 3 (256B.69, subdivision 28) authorizes DHS to contract with Medicare-approved special needs plans to provide MA basic health care services to persons with disabilities. "Basic health care services" are defined. Unless a person is otherwise required to enroll in managed care, enrollment in these plans must be voluntary. Automatic enrollment with an option to opt out is not considered voluntary. Beginning in 2007, DHS may contract with special needs plans to provide MA basic health care services to persons who are dually eligible for Medicare and MA, and to Social Security beneficiaries who are eligible for MA but in the waiting period for Medicare. Beginning in 2008, DHS may expand contracting to all persons with disabilities not otherwise required to enroll in managed care. This section also requires establishment of a state-level stakeholder group to advise the department on managed care programs for persons with disabilities. Each health plan under

contract to provide MA basic health care services must establish a local or regional stakeholder group.

Section 4 requires DHS to establish one or more stakeholder groups to provide information and advice on the development of any proposals to modify MA as authorized by the recent federal Deficit Reduction Act (DEFRA).

Section 5 requires MA changes proposed as a result of DEFRA to be approved by law prior to implementation or submission to the Centers for Medicare and Medicaid Services.

Section 6 is an appropriation.

DG:rdr

Senators Lourey and Koering introduced–

S.F. No. 3399: Referred to the Committee on Health and Family Security.

A bill for an act

relating to human services; allowing the commissioner of human services to contract with Medicare-approved Special Needs Plans to provide medical assistance services to persons with disabilities; amending Minnesota Statutes 2005 Supplement, section 256B.69, subdivision 23.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2005 Supplement, section 256B.69, subdivision 23, is amended to read:

Subd. 23. **Alternative services; elderly and disabled persons.** (a) The commissioner may implement demonstration projects to create alternative integrated delivery systems for acute and long-term care services to elderly persons and persons with disabilities as defined in section 256B.77, subdivision 7a, that provide increased coordination, improve access to quality services, and mitigate future cost increases. The commissioner may seek federal authority to combine Medicare and Medicaid capitation payments for the purpose of such demonstrations and may contract with Medicare-approved Special Needs Plans to provide Medicaid services. Medicare funds and services shall be administered according to the terms and conditions of the federal ~~waiver~~ contract and demonstration provisions. For the purpose of administering medical assistance funds, demonstrations under this subdivision are subject to subdivisions 1 to 22. The provisions of Minnesota Rules, parts 9500.1450 to 9500.1464, apply to these demonstrations, with the exceptions of parts 9500.1452, subpart 2, item B; and 9500.1457, subpart 1, items B and C, which do not apply to persons enrolling in demonstrations under this section. An initial open enrollment period may be provided. Persons who disenroll from demonstrations under this subdivision remain subject to Minnesota Rules, parts 9500.1450 to 9500.1464. When a person is enrolled in a health plan under these

demonstrations and the health plan's participation is subsequently terminated for any reason, the person shall be provided an opportunity to select a new health plan and shall have the right to change health plans within the first 60 days of enrollment in the second health plan. Persons required to participate in health plans under this section who fail to make a choice of health plan shall not be randomly assigned to health plans under these demonstrations. Notwithstanding section 256L.12, subdivision 5, and Minnesota Rules, part 9505.5220, subpart 1, item A, if adopted, for the purpose of demonstrations under this subdivision, the commissioner may contract with managed care organizations, including counties, to serve only elderly persons eligible for medical assistance, elderly and disabled persons, or disabled persons only. For persons with primary diagnoses of mental retardation or a related condition, serious and persistent mental illness, or serious emotional disturbance, the commissioner must ensure that the county authority has approved the demonstration and contracting design. Enrollment in these projects for persons with disabilities shall be voluntary. The commissioner shall not implement any demonstration project under this subdivision for persons with primary diagnoses of mental retardation or a related condition, serious and persistent mental illness, or serious emotional disturbance, without approval of the county board of the county in which the demonstration is being implemented.

(b) Notwithstanding chapter 245B, sections 252.40 to 252.46, 256B.092, 256B.501 to 256B.5015, and Minnesota Rules, parts 9525.0004 to 9525.0036, 9525.1200 to 9525.1330, 9525.1580, and 9525.1800 to 9525.1930, the commissioner may implement under this section projects for persons with developmental disabilities. The commissioner may capitate payments for ICF/MR services, waivered services for mental retardation or related conditions, including case management services, day training and habilitation and alternative active treatment services, and other services as approved by the state and by the federal government. Case management and active treatment must be individualized and developed in accordance with a person-centered plan. Costs under these projects may not exceed costs that would have been incurred under fee-for-service. ~~Beginning July 1, 2003, and until two years after the pilot project implementation date, subcontractor participation in the long-term care developmental disability pilot is limited to a nonprofit long-term care system providing ICF/MR services, home and community-based waiver services, and in-home services to no more than 120 consumers with developmental disabilities in Carver, Hennepin, and Scott Counties. The commissioner shall report to the legislature prior to expansion of the developmental disability pilot project. This paragraph expires two years after the implementation date of the pilot project.~~

(c) Before implementation of a demonstration project for disabled persons, the commissioner must provide information to appropriate committees of the house of representatives and senate and must involve representatives of affected disability groups in the design of the demonstration projects.

(d) A nursing facility reimbursed under the alternative reimbursement methodology in section 256B.434 may, in collaboration with a hospital, clinic, or other health care entity provide services under paragraph (a). The commissioner shall amend the state plan and seek any federal waivers necessary to implement this paragraph.

(e) The commissioner, in consultation with the commissioners of commerce and health, may approve and implement programs for all-inclusive care for the elderly (PACE) according to federal laws and regulations governing that program and state laws or rules applicable to participating providers. The process for approval of these programs shall begin only after the commissioner receives grant money in an amount sufficient to cover the state share of the administrative and actuarial costs to implement the programs during state fiscal years 2006 and 2007. Grant amounts for this purpose shall be deposited in an account in the special revenue fund and are appropriated to the commissioner to be used solely for the purpose of PACE administrative and actuarial costs. A PACE provider is not required to be licensed or certified as a health plan company as defined in section 62Q.01, subdivision 4. Persons age 55 and older who have been screened by the county and found to be eligible for services under the elderly waiver or community alternatives for disabled individuals or who are already eligible for Medicaid but meet level of care criteria for receipt of waiver services may choose to enroll in the PACE program. Medicare and Medicaid services will be provided according to this subdivision and federal Medicare and Medicaid requirements governing PACE providers and programs. PACE enrollees will receive Medicaid home and community-based services through the PACE provider as an alternative to services for which they would otherwise be eligible through home and community-based waiver programs and Medicaid State Plan Services. The commissioner shall establish Medicaid rates for PACE providers that do not exceed costs that would have been incurred under fee-for-service or other relevant managed care programs operated by the state.

(f) The commissioner shall seek federal approval to expand the Minnesota disability health options (MnDHO) program established under this subdivision in stages, first to regional population centers outside the seven-county metro area and then to all areas of the state.

(g) Notwithstanding section 256B.0261, health plans providing services under this section are responsible for home care targeted case management and relocation targeted

case management. Services must be provided according to the terms of the waivers and contracts approved by the federal government.

Senator ..... moves to amend S.F. No. 3399 as follows:

Delete everything after the enacting clause and insert:

"Section 1. Minnesota Statutes 2004, section 256B.69, subdivision 9, is amended to read:

Subd. 9. **Reporting.** (a) Each demonstration provider shall submit information as required by the commissioner, including data required for assessing client satisfaction, quality of care, cost, and utilization of services for purposes of project evaluation. The commissioner shall also develop methods of data reporting and collection ~~from county advocacy activities~~ in order to provide aggregate enrollee information on encounters and outcomes to determine access and quality assurance. Required information shall be specified before the commissioner contracts with a demonstration provider.

(b) Nonpersonally identifiable health plan encounter data, aggregate spending data, and criteria for service authorization and service use are public data that the commissioner shall make available and use in public reports. The commissioner shall require each health plan and county-based purchasing plan to provide:

(1) encounter data for each service provided, using standard codes and unit of service definitions set by the commissioner, in a form that the commissioner can report by age, eligibility groups, and health plan;

(2) total aggregate medical assistance spending for major categories of service as reported to the commissioner of commerce under section 62D.08, subdivision 3, paragraph (a), in a form that the commissioner can report by age, eligibility group, and health plan; and

(3) criteria, written policies, and procedures required to be disclosed under section 62M.10, subdivision 7, and Code of Federal Regulations, title 42, part 438.210(b)(1), used for each type of service for which authorization is required.

Sec. 2. Minnesota Statutes 2005 Supplement, section 256B.69, subdivision 23, is amended to read:

Subd. 23. **Alternative services; elderly and disabled persons.** (a) The commissioner may implement demonstration projects to create alternative integrated delivery systems for acute and long-term care services to elderly persons and persons with disabilities as defined in section 256B.77, subdivision 7a, that provide increased coordination, improve access to quality services, and mitigate future cost increases. The commissioner may seek federal authority to combine Medicare and Medicaid capitation payments for the purpose of such demonstrations and may contract with Medicare-approved special needs plans to provide Medicaid services. Medicare funds and services shall be administered according to the terms and conditions of the federal waiver

and demonstration provisions. For the purpose of administering medical assistance funds, demonstrations under this subdivision are subject to subdivisions 1 to 22. The provisions of Minnesota Rules, parts 9500.1450 to 9500.1464, apply to these demonstrations, with the exceptions of parts 9500.1452, subpart 2, item B; and 9500.1457, subpart 1, items B and C, which do not apply to persons enrolling in demonstrations under this section. An initial open enrollment period may be provided. Persons who disenroll from demonstrations under this subdivision remain subject to Minnesota Rules, parts 9500.1450 to 9500.1464. When a person is enrolled in a health plan under these demonstrations and the health plan's participation is subsequently terminated for any reason, the person shall be provided an opportunity to select a new health plan and shall have the right to change health plans within the first 60 days of enrollment in the second health plan. Persons required to participate in health plans under this section who fail to make a choice of health plan shall not be randomly assigned to health plans under these demonstrations. Notwithstanding section 256L.12, subdivision 5, and Minnesota Rules, part 9505.5220, subpart 1, item A, if adopted, for the purpose of demonstrations under this subdivision, the commissioner may contract with managed care organizations, including counties, to serve only elderly persons eligible for medical assistance, elderly and disabled persons, or disabled persons only. For persons with primary diagnoses of mental retardation or a related condition, serious and persistent mental illness, or serious emotional disturbance, the commissioner must ensure that the county authority has approved the demonstration and contracting design. Enrollment in these projects for persons with disabilities shall be voluntary. The commissioner shall not implement any demonstration project under this subdivision for persons with primary diagnoses of mental retardation or a related condition, serious and persistent mental illness, or serious emotional disturbance, without approval of the county board of the county in which the demonstration is being implemented.

(b) Notwithstanding chapter 245B, sections 252.40 to 252.46, 256B.092, 256B.501 to 256B.5015, and Minnesota Rules, parts 9525.0004 to 9525.0036, 9525.1200 to 9525.1330, 9525.1580, and 9525.1800 to 9525.1930, the commissioner may implement under this section projects for persons with developmental disabilities. The commissioner may capitate payments for ICF/MR services, waivered services for mental retardation or related conditions, including case management services, day training and habilitation and alternative active treatment services, and other services as approved by the state and by the federal government. Case management and active treatment must be individualized and developed in accordance with a person-centered plan. Costs under these projects may not exceed costs that would have been incurred under fee-for-service. Beginning July 1, 2003, and until two years after the pilot project implementation date, subcontractor participation

in the long-term care developmental disability pilot is limited to a nonprofit long-term care system providing ICF/MR services, home and community-based waiver services, and in-home services to no more than 120 consumers with developmental disabilities in Carver, Hennepin, and Scott Counties. The commissioner shall report to the legislature prior to expansion of the developmental disability pilot project. This paragraph expires two years after the implementation date of the pilot project.

(c) Before implementation of a demonstration project for disabled persons, the commissioner must provide information to appropriate committees of the house of representatives and senate and must involve representatives of affected disability groups in the design of the demonstration projects.

(d) A nursing facility reimbursed under the alternative reimbursement methodology in section 256B.434 may, in collaboration with a hospital, clinic, or other health care entity provide services under paragraph (a). The commissioner shall amend the state plan and seek any federal waivers necessary to implement this paragraph.

(e) The commissioner, in consultation with the commissioners of commerce and health, may approve and implement programs for all-inclusive care for the elderly (PACE) according to federal laws and regulations governing that program and state laws or rules applicable to participating providers. The process for approval of these programs shall begin only after the commissioner receives grant money in an amount sufficient to cover the state share of the administrative and actuarial costs to implement the programs during state fiscal years 2006 and 2007. Grant amounts for this purpose shall be deposited in an account in the special revenue fund and are appropriated to the commissioner to be used solely for the purpose of PACE administrative and actuarial costs. A PACE provider is not required to be licensed or certified as a health plan company as defined in section 62Q.01, subdivision 4. Persons age 55 and older who have been screened by the county and found to be eligible for services under the elderly waiver or community alternatives for disabled individuals or who are already eligible for Medicaid but meet level of care criteria for receipt of waiver services may choose to enroll in the PACE program. Medicare and Medicaid services will be provided according to this subdivision and federal Medicare and Medicaid requirements governing PACE providers and programs. PACE enrollees will receive Medicaid home and community-based services through the PACE provider as an alternative to services for which they would otherwise be eligible through home and community-based waiver programs and Medicaid State Plan Services. The commissioner shall establish Medicaid rates for PACE providers that do not exceed costs that would have been incurred under fee-for-service or other relevant managed care programs operated by the state.

(f) The commissioner shall seek federal approval to expand the Minnesota disability health options (MnDHO) program established under this subdivision in stages, first to regional population centers outside the seven-county metro area and then to all areas of the state. Until January 1, 2008, expansion for MnDHO projects that include home and community-based services is limited to the two projects and service areas in effect on March 1, 2006. Enrollment in integrated MnDHO programs that include home and community-based services shall remain voluntary. Costs for home and community-based services included under MnDHO must not exceed costs that would have been incurred under the fee-for-service program. In developing program specifications for expansion of integrated programs, the commissioner shall involve and consult the state-level stakeholder group established in subdivision 28, paragraph (d), including consultation on whether and how to include home and community-based waiver programs. Plans for further expansion of MnDHO projects shall be presented to the chairs of the house and senate committees with jurisdiction over health and human services policy and finance by February 1, 2007.

(g) Notwithstanding section 256B.0261, health plans providing services under this section are responsible for home care targeted case management and relocation targeted case management. Services must be provided according to the terms of the waivers and contracts approved by the federal government.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 3. Minnesota Statutes 2004, section 256B.69, is amended by adding a subdivision to read:

Subd. 28. **Medicare special needs plans and medical assistance basic health care for persons with disabilities.** (a) The commissioner may contract with qualified Medicare-approved special needs plans to provide medical assistance basic health care services to persons with disabilities, including those with developmental disabilities. Basic health care services include:

(1) those services covered by the medical assistance state plan except for ICF/MR services, home and community-based waiver services, case management for persons with developmental disabilities under section 256B.0625, subdivision 20a, and personal care and certain home care services defined by the commissioner in consultation with the stakeholder group established under paragraph (c);

(2) basic health care services may also include risk for up to 100 days of nursing facility services for persons who reside in a noninstitutional setting and home health services related to rehabilitation as defined by the commissioner after consultation with the stakeholder group; and

(3) the commissioner may exclude other medical assistance services from the basic health care benefit set. Enrollees in these plans can access any excluded services on the same basis as other medical assistance recipients who have not enrolled.

Unless a person is otherwise required to enroll in managed care, enrollment in these plans for Medicaid services must be voluntary. For purposes of this subdivision, automatic enrollment with an option to opt out is not voluntary enrollment.

(b) Beginning January 1, 2007, the commissioner may contract with qualified Medicare special needs plans to provide basic health care services under medical assistance to persons who are dually eligible for both Medicare and Medicaid and those Social Security beneficiaries eligible for Medicaid but in the waiting period for Medicare. The commissioner shall consult with the stakeholder group under paragraph (c) in developing program specifications for these services. The commissioner shall report to the chairs of the house and senate committees with jurisdiction over health and human services policy and finance by February 1, 2007, on implementation of these programs and the need for increased funding for the ombudsman for managed care and other consumer assistance and protections needed due to enrollment in managed care of persons with disabilities.

(c) Beginning January 1, 2008, the commissioner may expand contracting under this subdivision to all persons with disabilities not otherwise required to enroll in managed care.

(d) The commissioner shall establish a state-level stakeholder group to provide advice on managed care programs for persons with disabilities, including both MnDHO and contracts with special needs plans that provide basic health care services as described in paragraphs (a) and (b). The stakeholder group shall provide advice on program expansions under this subdivision and subdivision 23, including:

(1) implementation efforts;

(2) consumer protections; and

(3) program specifications such as quality assurance measures, data collection and reporting, and evaluation of costs, quality, and results.

(e) Each plan under contract to provide medical assistance basic health care services shall establish a local or regional stakeholder group, including representatives of the counties covered by the plan, members, consumer advocates, and providers, for advice on issues that arise in the local or regional area.

Sec. 4. **STAKEHOLDER PARTICIPATION.**

The commissioner of human services shall establish one or more stakeholder groups of interested persons, including representatives of recipients, advocacy groups, counties, providers, and health plans to provide information and advice on the development of any

proposals for changes in the medical assistance program authorized by the federal Deficit Reduction Act of 2005, Public Law 109-171.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 5. **LEGISLATIVE AUTHORIZATION REQUIRED.**

Any changes to the medical assistance program proposed as a result of the federal Deficit Reduction Act of 2005, Public Law 109-171, which affect cost sharing, co-payments, premiums, eligibility, covered services, service limitations, or benefit set changes, must receive legislative approval prior to being implemented or submitted to the Centers for Medicare and Medicaid Services.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 6. **APPROPRIATION; OMBUDSMAN FOR MANAGED CARE.**

$200,000 is appropriated from the general fund to the commissioner of human services in fiscal year 2007 to increase staff for the development and management of contract requirements associated with enrolling persons with disabilities in managed care and for the ombudsman for managed care office in order to assist persons with disabilities on issues involving health coverage under Minnesota Statutes, section 256B.69, subdivision 28."

Request for Expansion of Integrated Disability Care Projects

S.F. No. 3399 (Lourey)/H.F. No. 3591 (Finstad)

PrimeWest Health System and South Country Health Alliance

About PrimeWest and South Country.

- PrimeWest Health System and South Country Health Alliance are county-based purchasing health plans that provide health coverage to persons residing in their participating counties who are eligible for government health care programs, including:
  - Persons who receive their Medical Assistance or General Assistance Medical Care coverage through Minnesota's Prepaid Medical Assistance Program (PMAP);
  - Seniors who receive both Medicare and Medicaid coverage, including Medicare Part D benefits, through Minnesota Senior Health Options (MSHO);
  - Seniors who receive their Medical Assistance and Elderly Waiver Home and Community-Based Services coverage through Minnesota Senior Care.
- PrimeWest also will and South Country has begun to serve Medicare enrollees with disabilities as a Medicare-approved "Special Needs Plan" (SNPs).
- PrimeWest serves Big Stone, Douglas, Grant, McLeod, Meeker, Pipestone, Pope, Renville, Stevens and Traverse counties.
- South Country Health Alliance serves Brown, Dodge, Freeborn, Goodhue, Kanabec, Sibley, Steele, Wabasha and Waseca counties.

Request to Serve Persons with Disabilities.

- Current state law exempts people with disabilities from participating in PMAP, with the exception of two Twin Cities-based pilot projects: one for persons with a physical disability; and another for persons with a developmental disability.
- The pilot projects are known as "MnDHO" (Minnesota Disability Health Options) and provide integrated health coverage to persons eligible for both Medicare and Medical Assistance.
- The Twin Cities integrated disability care pilot projects have been successful and are popular with consumers:
  - Creates locally based, integrated coverage -- consumers can receive all their health care and social services from a single source and the services are well coordinated
  - Offers greater flexibility than the traditional Medical Assistance fee-for-service program
  - Consumers receive personalized care coordination help and can receive some types of equipment and services that are not covered under the Medical Assistance programs
  - Results in fewer emergency room visits and hospitalizations
- Because of the success of MnDHO and its popularity with consumers, PrimeWest and South Country request the authority to offer this option in rural communities, too.

Reasons to Permit Rural Communities to Establish a MnDHO Program:

- Fewer health care resources in rural areas require an individualized, local care coordination approach to assist consumers in finding and accessing appropriate care in a timely manner
- This option will likely result in higher reimbursement for providers than traditional Medical Assistance
- When provided through a county-based purchasing approach, this model will improve access to care and effectiveness of care through *community-based* coordination of local health and social services around the individual's needs
- PrimeWest and South Country have been highly successful in serving PMAP participants and cost-effectively managing the Medical Assistance resource for the State at the local level
- This approach caps the state's financial liability under the Medical Assistance program

We urge you to support S.F. No. 3399 and H.F. No. 3591