Senate Counsel & Research

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. 22 - Prescription Drug Bulk Purchasing Program

Author: Senator Yvonne Prettner Solon

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

Date: January 18, 2005

S.F. No. 22 requires the Commissioner of Human Services to establish prescription drug bulk purchasing programs if it is determined to result in significant state savings.

Subdivision 1 directs the Commissioner of Human Services to establish and administer an intrastate prescription drug bulk purchasing program. Requires the Commissioner to consolidate drug purchasing by the prescription drug program, the state hospitals and other health care facilities, state educational facilities, the State Health Plan, and other state and local government entities and programs that purchase significant quantities of prescription drugs that wish to participate. Requires the Department of Administration to negotiate the prices of the prescription drugs purchased under this program unless negotiated by an agent of an interstate prescription drug bulk purchasing program.

Subdivision 2 directs the Commissioner of Human Services to establish or join an existing interstate prescription drug bulk purchasing program with other interested states. Requires the program to select an agent to negotiate prices for the states in the program and requires the Commissioner to administer the state's participation in the program.

Subdivision 3 requires the Commissioner of Human Services to direct the Department of Administration to negotiate with state-approved Canadian pharmacies or wholesalers the prices to be charged to Minnesota residents who purchase their prescription drugs from Canada pursuant to the state's prescription drug importation

program. Requires the Commissioner to determine whether there would be a savings if the state's intrastate prescription drug bulk purchasing program purchased some or all of the prescription drugs from Canada and to make such purchases if it would result in significant savings. Requires the Commissioner to encourage the interstate bulk purchasing program to purchase prescription drugs from Canada if the result would be significant savings.

Subdivision 4 requires the Commissioner to establish and administer a public/private intrastate prescription drug bulk purchasing alliance in order to consolidate their drug purchasing. Requires the Department of Administration to negotiate the prices of prescription drugs purchased through the alliance. States that participation by private entities would be voluntary.

Subdivision 5 states that the commissioner is not required to establish or administer any of the bulk purchasing programs if the commissioner determines that the program would not result in significant savings. States that the MA program, MinnesotaCare program, or the Department of Corrections shall not be included in the bulk purchasing program unless it is determined to be beneficial to the state and would result in significant savings.

Subdivision 6 requires any drugs purchased by the state or local government entities or consumers through the bulk purchaser program to be distributed through Minnesota pharmacies unless an alternative distributing system is selected.

KC:ph

Senator Solon introduced--

S.F. No. 22: Referred to the Committee on Health and Family Security.

A bill for an act

relating to human services; providing for prescription drug bulk purchasing; proposing coding for new law in Minnesota Statutes, chapter 256.

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

Section 1. [256.9551] [PRESCRIPTION DRUG BULK PURCHASING PROGRAMS.]

Subdivision 1. [INTRASTATE PRESCRIPTION DRUG BULK PURCHASING PROGRAM.] The commissioner of human services is directed to establish and administer an intrastate prescription drug bulk purchasing program in order to try to save money for the state, its agencies, and local governments in regard to the cost of the prescription drugs they purchase. Under the program, the Department of Human Services will consolidate drug purchasing by the state prescription drug program, state hospitals and other health care facilities, state educational facilities, the State Health Plan, and other state and local government entities and programs that purchase significant quantities of prescription drugs and wish to participate in the intrastate bulk purchasing program. The Department of Administration will negotiate the prices of the prescription drugs purchased under this program unless the prices of some or all of the purchased drugs are negotiated by an agent of an interstate prescription drug bulk purchasing program described in subdivision 2.

Subd. 2. [INTERSTATE PRESCRIPTION DRUG BULK PURCHASING PROGRAM.] The commissioner of human services is directed to establish or join an existing interstate prescription drug bulk purchasing program with other interested states. The program will select an agent to negotiate prices for the states in the program. The department shall administer the state's participation in the program.

Subd. 3. [NEGOTIATION OF CANADIAN PRESCRIPTION DRUG PRICES.] The commissioner of human services shall request the Department of Administration to negotiate with state-approved Canadian pharmacies or wholesalers the prices to be charged to Minnesota residents who purchase their prescription drugs from Canada pursuant to the state's prescription drug importation program. The commissioner shall also determine whether it would save money for the state's intrastate prescription drug bulk purchasing program to purchase some or all of the prescription drugs from Canada and will make such purchases if it would result in significant savings. The commissioner shall also encourage the members of the state's interstate prescription drug bulk purchasing program to purchase some or all of the necessary prescription drugs in Canada if it would result in significant savings.

Subd. 4. [PUBLIC/PRIVATE INTRASTATE PRESCRIPTION DRUG BULK PURCHASING ALLIANCE.] The commissioner shall establish and administer a public/private intrastate prescription drug bulk purchasing alliance under which the state and interested private entities can consolidate their drug purchasing to save money. The participation of private entities in this alliance is voluntary. The Department of Administration will negotiate the prices of prescription drugs purchased through the alliance.

Subd. 5. [COMMISSIONER DISCRETION.] The commissioner of human services is not required to establish or administer any of the bulk purchasing programs in subdivisions 1 to 4 if the commissioner determines that any such program would not result in significant savings to the state. The commissioner shall not include the state Medicaid program, MinnesotaCare program, or

Department of Corrections in the bulk purchasing programs in subdivisions 1 to 4. These programs may later be included in any or all of the bulk purchasing programs in subdivisions 1 to 4 if the commissioner deems those bulk purchasing programs to be beneficial to the state and that the inclusion of the state Medicaid program, MinnesotaCare, and the Department of Corrections in a bulk purchasing program would result in savings to the state.

Subd. 6. [PHARMACY PARTICIPATION.] Any pharmaceuticals purchased by state or local government entities or Minnesota consumers pursuant to the bulk purchasing programs identified in subdivisions 1 to 4 shall be distributed through Minnesota pharmacies, unless the commissioner or the state or local government entities select an alternate distribution system.

Senator Hoggan moves to amend S.F. No. 22 as follows:

Page 2, line 8, after "CANADIAN" insert "OR EUROPEAN"

Page 2, line 11, after "Canadian" insert "or European"

Page 2, lines 13, 17, and 21, after "Canada" insert "or Europe"

Page 2, line 29, delete "will" and insert "shall"

HHS Importation Task Force finds Importation and Department of Commerce finds Government Price Controls Bad Medicine for Patients

"When a drug comes in from Canada, I want to make sure it cures you and doesn't kill you. And that's why the FDA and...the Surgeon General are looking very carefully to make sure it can be done in a safe way." President Bush, Second Presidential Debate, October 8, 2004.

HHS Study

HHS' Drug Importation Task Force's recent study found that it costs too much to safely import prescription drugs. Chaired by the U.S. Surgeon General, the task force warns that buying prescription drugs from Canada presents "significant risk" without cost savings.

The study confirms:

- "Foreign governments have little incentive and limited resources to ensure the safety of drugs exported from their countries, particularly when those drugs are transshipped or are not intended for import;"
- It would be "extraordinarily difficult" to ensure the safety of personally imported drugs;
- The overall cost savings from drug importation would likely be small and, historically, a large portion of any savings would be retained by middlemen, not consumers; and
- Legalized importation would reduce R&D into new drugs, likely reducing the number of new therapies by as many as 18 new medicines per decade.

Commerce Report

The Department of Commerce's recently-released "Pharmaceutical Price Controls in OECD Countries" provides evidence that government price controls on medicines are the wrong prescription for patients. The report shows that such price controls in Europe and elsewhere inhibit R&D, thereby denying access to drug therapy.

Drug importation is tantamount to importing a foreign government's price controls on American patients. The U.S. now develops most of the world's new drugs. Patients all over the world would lose if government price controls harmed U.S. drug research.

Key report findings include:

Bob Vanasek

- That "the price controls maintained by the OECD countries in the study...reduce the amount of global pharmaceutical R&D below what it would otherwise be under market conditions similar to those in the United States."

- "The study estimates that this reduction falls in the range of $5 billion to $8 billion annually, once prices were fully adjusted. This represents between 11 and 16 percent of current private worldwide R&D...;" and

- That this reduction in global R&D means that three to four fewer new medicines are launched each year, thus reducing patient access to innovative drug therapy.

Safe, Affordable and Legal Medicine Solutions Already Exist

- Drug makers' patient assistance programs last year alone provided over 18 million free or reduced needed prescriptions to patients in the U.S.

- Generic drugs, as explained in the HHS study, are up to 50% cheaper in the U.S. compared to international prices for similar drugs.

- The Medicare prescription drug benefit (beginning January 2006) will contain costs through private sector competition, making medicines more accessible and affordable.

- Today, eligible patients can receive up to $600 in transitional prescription drug assistance under the current Medicare drug discount card.

EXECUTIVE SUMMARY

HHS REPORT ON PRESCRIPTION DRUG IMPORTATION

OVERVIEW

Introduction

In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173 (Medicare Modernization Act or MMA), which for the first time provided a prescription drug benefit for seniors and people with disabilities. The MMA also contained provisions that would permit the importation of prescription drugs into the U.S. if the Secretary of the Department of Health and Human Services (HHS) certifies that drugs imported from Canada pose no additional risk to public health and safety and that such imports would provide significant cost savings to American consumers. The MMA also requires the Secretary to conduct a study on the importation of drugs. The conference agreement for MMA included eleven issues for consideration. The Surgeon General of the U.S. Public Health Service, Dr. Richard H. Carmona, was charged with leading a task force of senior executives across the Federal government to conduct the analysis required by the MMA. The Task Force met with key constituencies numerous times throughout 2004 in public forums, received testimony from over one hundred presenters from around the world with all types of backgrounds, and received over one hundred written comments providing insight into these issues. This report is a summary of what the Task Force reviewed from the testimony and written comments for the specific questions posed in the MMA conference agreement and their findings based on this evaluation.

Background

In the early years of the twentieth century, pharmaceuticals in the U.S. were characterized by a large number of ineffective, often dangerous, compounds, the principal ingredient of which was often alcohol. The invention of penicillin in the 1930s marked the beginning of the modern era of drug

development, when scientists were able to create powerful new chemicals that were safe and effective in killing bacteria. Since then, the world's investment in research and development (R&D) has produced many more safe and effective treatments to reduce pain and inflammation, regulate the cardiovascular system, impede the growth of cancer cells, and provide a host of other effective therapies for disease. The resulting discovery of new medications has enabled doctors to offer comfort for the sick and to prescribe from an extensive array of drugs to treat most human afflictions.

As this innovation began in the 1930s, Congress recognized the need for a strong oversight body to ensure that drugs were properly tested before being given to patients. The manufacturing of drugs needed equally rigorous oversight to ensure that drugs were made in a safe and consistent way. The Federal Food, Drug, and Cosmetic (FD&C) Act of 1938 and its 1962 amendments provided that oversight, by requiring that the U.S. Food and Drug Administration (FDA) approve each new drug as safe and effective before marketing and authorizing FDA to oversee the production of drugs, whether manufactured in a U.S. facility or imported from abroad.

By the 1980s, Congress recognized that some entities not subject to U.S. law were importing counterfeit drugs as well as improperly handled and stored drugs. For example, at that time, counterfeit birth control pills found their way into the U.S. drug distribution system. These types of activities posed significant risks to American consumers. Therefore, in 1987, Congress passed the Prescription Drug Marketing Act (PDMA), which, among other things, strengthened oversight of domestic wholesalers and added the "American goods returned" provision to the FD&C Act, which prohibits anyone except a drug's manufacturer from importing into the U.S. a prescription drug that was originally manufactured in the U.S. and then sent abroad.

We recognize that there are different categories of "imported drugs" that potentially have different levels of associated risk. Currently, the only types of legally imported drugs are: 1) those that are manufactured in foreign FDA-inspected facilities and

adhere to FDA-approval standards, or 2) those that are U.S.-approved and manufactured in the U.S., sent abroad, then imported back into the U.S. by the manufacturer under proper controls and in compliance with the FD&C Act. This latter category includes products that are truly re-imported. In both cases, the manufacturing process is subject to direct FDA oversight and the drug distribution system is "closed," and the manufacturer complies with FDA and other regulations to assure that the drug delivered to the pharmacy is of high quality.

Another category of imported drugs are those that are manufactured in a foreign facility that also manufactures the U.S.-approved version. In such a case, FDA would have inspected the U.S.-approved manufacturing process, but not the unapproved production lines; in this case, the foreign version may differ in certain respects from the U.S.-approved version. Although there may be significant similarities between the two versions, because of the potential differences and the fact that only the U.S.-approved drugs have been shown to meet U.S standards enforced by FDA, the foreign version cannot necessarily be considered equivalent to the U.S.-approved version.

A final category of imported drugs are unapproved drugs that are produced in foreign facilities that FDA has not inspected and, therefore, has no knowledge of, or experience with, the facility. Consequently, the safety and effectiveness of these drugs and the safety and security of their distribution systems are unknown. These drugs pose the greatest level of concern because they are not regulated within the U.S. drug safety system and little is known to U.S. regulators about the specifications to which they are made, the processes used to ensure their safety, and the integrity of their distribution. As the report describes, there is ample evidence that these are the types of drugs that consumers have received when they order prescription drugs from some international sources over the internet.

When a drug is imported into the U.S., FDA inspectors are required to confirm that the drug meets the necessary approval requirements. Such review of imported drugs is limited by the amount of resources available, given the substantial amount of legal and illegal

prescription drugs that are imported daily. If there is a question of whether the drug can legally be imported and, thus, raises safety questions, FDA has the authority to detain the product and gives the importer several days to demonstrate the drug's acceptability (or, failing that, the drug is either refused admission and returned to its foreign source, if known, or destroyed.)

The conclusion of Congress reflected in current law is that the safety and effectiveness of imported drugs can only be assured for drugs legally imported into the U.S., as described above. In these cases, the chain of custody is known for a U.S.-approved drug manufactured in an FDA-inspected facility using FDA approved methods as it travels through the U.S. distribution system. Much of the current public debate about the safety of broader importation comes down to issues regarding the additional oversight authorities, resources, and foreign government support that would be needed to assure the safety and effectiveness of other types of drugs, principally foreign drug purchases from international internet operations that are not subject to FDA's regulatory oversight.

Since the FD&C Act's passage in 1938, American citizens returning from overseas with foreign drugs have been advised that most of these drugs are not legal, but, as a matter of enforcement discretion, FDA has generally allowed those citizens to bring in small quantities for their personal use and advised them to consult with their physician. FDA created this enforcement discretion policy to allow American residents who became ill in another country to continue the treatment prescribed by a foreign healthcare practitioner until they could receive medical attention back home. That policy was not controversial until the latter part of the 1990's, when some citizens began traveling regularly to other countries to fill their prescriptions, and especially when more Americans began ordering drugs via internet pharmacies located in other countries.

The Task Force understands what motivates more and more Americans to import drugs. Access to affordable prescription drugs, many of which are needed to treat life-threatening and serious conditions, is a daily concern and challenge for many Americans. As there has been a significant increase in drug utilization and

in list prices for drugs in the U.S. over the last few years, spending by American consumers on prescription drugs has risen significantly. Over 40 percent of Americans take at least one prescription drug and, in an effort to lower their prescription drug bill, a relatively small but increasing number have turned to importing drugs.

Consequently, the Task Force believes that access to drugs that are safe and effective, as well as affordable, is a critical policy goal, and that all approaches to achieving this challenging goal should be explored thoroughly. Drugs that are affordable, but not safe and effective, could be more harmful to patients than not having the drugs at all. The difficult balance between the need for affordable prescription drugs and concerns over potential safety hazards that many imported drugs may pose is reflected in the public debate and controversies regarding drug importation policy in the U.S. The Task Force report presents a comprehensive overview of the evidence related to this balance, as well as a number of other critical issues, as requested by Congress, on the subject of prescription drug importation.

THE REPORT IN BRIEF

Chapter 1 –Scope, volume, and safety of unapproved drugs

The number of unapproved prescription drug products entering the U.S. is now very large. Nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately $700 million, entered the U.S. from Canada alone in 2003, via internet sales and travel to Canada by American consumers. This report estimates that an equivalent amount of prescription drugs are currently coming in from the rest of the world, mostly through the mail and courier services.

Imported drugs are arriving from all corners of the world, including developed and emerging countries. Their scope is broad and includes tablets, capsules, inhalants, injectables, biologics, generics, brand name drugs, and controlled substances. Some of the arriving products appear to have been made in the U.S.; however, many are not. The majority of these currently imported drugs are unapproved by FDA and do not appear to conform in many aspects to the properly

approved and manufactured products available in American pharmacies.

Numerous comments submitted to the Task Force described the current practice of internet purchases by American consumers who seek lower-priced drugs. Many state-licensed internet pharmacies provide a legitimate means for consumers to access safe and effective medicines, but others raise significant safety concerns.

Most of these drugs are purchased by individual consumers via internet, phone, or fax, from entities that focus on providing drugs to Americans and other long-distance purchasers. These entities generally are cross-border foreign pharmacies that may not primarily serve the citizens of the country in which they are located, and their methods for providing drug products may not be subject to the same oversight that foreign governments provide for drugs and pharmacies serving their own citizens. When consumers order prescription drugs over the internet from international sources, they generally receive drugs that do not have regulatory assurances of equivalence to U.S. products or of safety and security in the distribution process.

Some sellers of imported drugs are "rogue" internet pharmacies that pretend to be legitimate and operate behind facades. Many of the drugs sold over the internet claim to be interchangeable with the approved U.S. drug, but are not. Imported drugs include those that pose special concerns, such as drugs that require special handling, drugs with high abuse potential, drugs that should be sterile, counterfeit drugs, improperly packaged drugs shipped loose in sandwich bags and envelopes, and drugs from countries that have differing and sometimes more limited regulatory authority to assure the safety of pharmaceuticals manufactured and exported from those countries. In sum, this report finds that American consumers currently purchasing drugs from overseas are generally doing so at significant risk.

Chapter 2 – Limits on resources and authorities

The Federal law governing drug safety in the U.S. establishes the standards by which FDA determines whether a prescription drug is "safe and effective" for sale in the U.S. These standards govern the way in

which prescription drugs are manufactured, packaged, labeled, held, and shipped. Many of the prescription drugs that are imported into the U.S. now by individual citizens, via mail and courier services, fail to comply with some or all of these Federal standards. To ensure that imported prescription drugs are as safe as those that are legally sold in the U.S., an importation program for U.S.-approved drugs would have to ensure that the imported drugs meet the current (or equivalent) Federal standards. This report determines that it would be extraordinarily difficult to ensure that drugs personally imported by individual consumers could meet the necessary standards for a certification of safety to be made, especially if consumers continue to import prescription drugs in the same or increased numbers. Meanwhile, a commercial importation program could be feasible but would require new legal authorities, substantial additional resources and significant restrictions on the type of drugs that could be imported, which could increase the costs of imported drugs.

Chapter 3 – Impact on the pharmaceutical distribution system

The drug distribution network for legal prescription drugs in the U.S. is a "closed" system that involves several players (e.g., manufacturers, wholesalers, pharmacies) who move drug products from the point of manufacture to the end user, and provides the American public with multiple levels of protection against receiving unsafe, ineffective, or poor quality medications. This system evolved as a result of legislative requirements that drugs be treated as potentially dangerous consumer goods that require professional oversight to protect the public health. The result has been a level of safety for drug products that is widely recognized as the world's "gold standard." Legalized importation of drugs in such a way that creates an opening in the "closed" system will likely result in some increase in risk, as the evidence shows that weaknesses in the oversight of drug regulation and the distribution system have been exploited. For example, doing so would increase the opportunity for counterfeit and other substandard drugs to enter and be dispersed into the U.S. drug distribution system.

Chapter 4 – Role of new technologies

There are a number of anti-counterfeiting technologies that show potential for effectively assuring the authenticity of drugs and, thus, for combating the counterfeiting of drugs. Some examples include holograms, color shifting inks, and watermarks currently employed for U.S. currency. So-called "track and trace" technologies, such as radio-frequency identification (RFID) and sophisticated bar coding, can provide effective monitoring of a drug's movement from the point of manufacture and through the U.S. distribution chain. Although these new and emerging technologies are promising, until they are fully adopted internationally they cannot be adequately relied upon to secure the safety, efficacy, and integrity of the global market to safely import prescription drugs into the U.S.

Chapter 5 – Agency resources associated with drug importation activities

FDA currently has about 3,800 employees assigned to field activities (e.g., inspections) involved in protecting the many thousands of products that make up the Nation's food, drug, biologic, medical device, and veterinary drug supply. Of the 3,800 field staff, 450 are involved in investigative import activities. Only a limited number of FDA inspectors are available to staff the 14 international mail facilities in the U.S., where they historically have had to inspect a small number of large commercial pharmaceutical imports. FDA managers have repeatedly noted that the large number of personal drug shipments coming into the international mail and courier facilities is overwhelming the available staff.

This report finds that despite significant efforts, including joint efforts with CBP and import alerts/bulletins, FDA currently does not have sufficient resources to ensure adequate inspection of current levels and categories of personal shipments of prescription drugs entering the U.S. With respect to commercial shipments, based on the information presented to the Task Force, FDA would need a meaningful investment, among other things, in new information technology and personnel, as well as appropriate standards to ensure adequate

inspection of commercial quantities of drug products, if importation were legalized.

Chapter 6 – Role of foreign health agencies

Just as the U.S. is responsible for the safety and effectiveness of drugs made available to its citizens, foreign governments give priority to ensuring the safety of drugs used by their citizens. Foreign governments have little incentive and limited resources to ensure the safety of drugs exported from their countries, particularly when those drugs are transshipped or are not intended for import. No country expressed any interest or willingness to ensure the safety and effectiveness of drugs exported from their country in any expansion of legal U.S. importation. Although we specifically solicited them, few comments were submitted by foreign governments, and none outlined a specific strategy for new steps to collaborate with the U.S. government on the effective oversight of importation, suggesting that they are not willing or do not have the means to ensure the safety of exported products and that the primary safety responsibilities would have to remain with the U.S.

Chapter 7 – Effects of importation on prices and consumer savings

Consumers seek to import prescription drugs from other countries in part because they believe they can save money if they purchase their drugs from outside the U.S. In many instances, U.S. consumers have been able to purchase from abroad foreign versions of U.S.-approved brand name drugs at lower prices. However, based on an analysis of actual data on drug prices and volumes, this report finds that total savings to consumers from legalized importation under a commercial system would be a small percentage relative to total drug spending in the U.S. (about one to two percent). These savings are much smaller than some specific international comparisons of retail prices for certain drugs might suggest. Under any safe, legalized commercial importation program, when the scope is limited, intermediaries would likely capture a large part of the price differences. (This is based on evidence from European countries where some form of importation is legal.)

This report also finds that generic drugs are often

cheaper in the U.S. compared to international prices for similar drugs. Other, independent studies have reached similar conclusions. The prices foreigners pay for generic drugs are on average 50 percent greater than the prices Americans pay for generic drugs. Furthermore, there is evidence that greater use of U.S.-approved generic drugs by Americans could reduce drug spending by billions of dollars annually. In addition, to the extent that prescription drugs are eligible for importation from the same company at a lower price than in the U.S., potential quantity constraints imposed by manufacturers or foreign governments would limit the eligible supply and the benefits to U.S. consumers.

Chapter 8 – Impact of importation on research and development and consumer welfare

One of the most frequently debated issues surrounding drug importation is whether the legalization of importation would reduce research and development (R&D), including spending on discovery, development, and launching of new drugs. Based on both an empirical analysis of drug data and a review of previous studies, this report finds that, by shifting sales to countries with price controls for new drugs, importation would reduce overall U.S. pharmaceutical industry revenues. Since revenues would fall without a reduction in the cost to produce new medicines, profits would likely fall, as well as spending on R&D. Consequently, legalized importation would likely adversely affect incentives for R&D, thereby slowing the flow of new drugs. This report also finds that since annual R&D spending would drop, importation could result in between four to eighteen fewer new drugs being introduced per decade at a substantial cost to society. Furthermore, if there were a likely reduction in innovative new drugs, then the foregone consumer benefits associated with loss or delay in new therapies may significantly offset any anticipated savings from legalized importation, depending on uncertainties.

Chapter 9 – Impact on intellectual property rights

Intellectual property rights have evolved over many

years to strike a balance between, on the one hand, providing incentives for innovation through grants of exclusive rights over new ideas or products and, on the other hand, ensuring that knowledge and products are widely disseminated and accessible to provide the maximum benefit to society now and in the future. As with most new ideas and products, inventors of pharmaceuticals may obtain patents and other intellectual property protections for their products that provide certain exclusive rights. The challenge policymakers face is to ensure that intellectual property protection for pharmaceuticals provides adequate economic incentives to develop new drugs while facilitating access to affordable medicines. An exhaustive legal analysis of the implications of allowing importation of patented pharmaceuticals to which intellectual property protections apply would require further study. However, it is clear that importation could impact the intellectual property rights of developers of pharmaceutical products and could be subject to challenge under domestic law, including possibly the U.S. Constitution, and international intellectual property rules.

Chapter 10 – Liability issues related to importation

This report identifies the liability issues raised if importation is legalized for entities within the pharmaceutical distribution system. This report notes that allowing prescription drug importation would have uncertain effects on the litigation exposure of manufacturers, distributors, doctors, and pharmacists. To deal with these likely increased risks, entities in the pharmaceutical distribution chain may take additional costly defensive actions. Perhaps the largest source of additional liability and/or litigation risk under a drug importation system would be an increase in the number of injuries and poor disease outcomes if imported drugs are, as a class, less safe and effective.

KEY FINDINGS

This report details the diverse opinions expressed, the data collected, and Task Force findings based on the information presented. Some of the key findings of the Task Force are:

1) **The current system of drug regulation in the U.S. has been very effective in protecting public safety, but is facing new threats. It should be modified only with great care to ensure continued high standards of safety and effectiveness of the U.S. drug supply.** Americans have the benefit of one of the safest drug supplies in the world and generally have first access to the newest breakthrough drug treatments. Any legislation to permit the importation of foreign drugs should only be done in a way that provides the statutory authority and substantial resources needed to effectively regulate imported drugs and, most importantly, protect the public health by providing the same level of safety assurances available for drugs sold in the U.S.

2) **There are significant risks associated with the way individuals are currently importing drugs.** While some means of drug importation (e.g., traveling to Canada for certain brand name drugs available in both countries) may be relatively safe in specific instances, this is not the only way "importation" into the U.S. is occurring today. Many transactions are occurring via poorly-regulated and occasionally bogus internet operations that have been documented in some cases to provide consumers with inferior products that are not the same as the U.S.-approved versions. Also, treatment failures, which are not obvious adverse events, are a real concern with substandard drug products.

3) **It would be extraordinarily difficult and costly for "personal" importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.** While wholesalers and pharmacists purchase, transport, and dispense imported drugs within our regulatory framework, American consumers making individual purchases from foreign sources outside our regulatory system, in particular those making long-distance purchases from internet

sites or by fax or phone, face safety hazards that would be extraordinarily difficult to effectively address and prevent.

4) **Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.** The public rightly expects that, under any legal importation program, the imported drugs will be safe and effective. To accomplish this, additional safety protections would need to be added that would increase the costs of the program in an additive way as more safety measures are put in place. Substantial resources would also be needed to ensure adequate inspection of imported drug products. In addition to other factors that are likely to reduce potential consumer savings, these increased regulatory and program costs will also impact potential savings to consumers. Furthermore, intermediaries will likely capture at least half of any savings between the U.S. and price-controlled countries and potential quantity constraints imposed by foreign governments and manufacturers will likely further limit the supply of these drugs to U.S. consumers.

5) **The public expectation that most imported drugs are less expensive than American drugs is not generally true.** Generic drugs account for most prescription drugs used in the U.S. and are usually less expensive in the U.S. than abroad. Shopping around for price comparisons, asking a doctor or pharmacist for a generic alternative to a prescribed brand name drug, or using a Medicare or other prescription drug discount card is a proven method to save American consumers money on domestic prescription drugs while retaining the protections of a comprehensive safety regime.

6) **Legalized importation will likely adversely affect the future development of**

new drugs for American consumers. This report estimates that R&D incentives will be lowered by legalized importation, resulting in roughly between four and eighteen fewer new drugs introduced per decade.

7) **The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.** A host of legal and constitutional challenges are probable, and the effects on enforcement of intellectual property rights and on agreements with foreign countries are likely to be problematic. These effects could create additional disincentives to develop breakthrough medicines and further limit any potential savings that might have been realized.

8) **Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.** Consumers harmed by imported drugs may not have legal recourse against foreign pharmacies, distributors, or others suppliers. Entities in the pharmaceutical supply chain may take actions to protect themselves from liability that could ultimately raise the cost of drugs.

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75 REV. DR. MARTIN LUTHER KING JR. BLVD.
ST. PAUL, MN 55155-1606
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JO ANNE ZOFF SELLNER
DIRECTOR

Senate
State of Minnesota

S.F. No. 23 - Pharmaceutical Pricing Disclosure

Author: Senator Yvonne Prettner Solon

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

Date: January 18, 2005

S.F. No. 23 requires drug manufacturers to disclose certain pharmaceutical pricing to the Board of Pharmacy and to the Commissioner of Human Services as a requirement for licensure under Minnesota Statutes, chapter 151.

Section 1 (151.47, subdivision 1) requires drug manufacturers to on a quarterly basis report to the Board of Pharmacy and to the Commissioner of Human Services the following pharmaceutical pricing criteria for each of their drugs: average wholesale price (AWP); wholesale acquisition cost (WAC); average manufacturer price (AMP) as defined under federal law; and best price as defined under federal law. Describes the calculation to be used to determine the AWP and WAC. Requires a detailed description of the methodology used to calculate the reported AWP, WAC, AMP, and best price be included in the report. Requires the president or chief executive officer of the manufacturer to certify to the medical assistance program on a form provided by the Commissioner of Human Services that the reported prices are accurate. States that any information reported shall be classified as nonpublic data under section 13.02, subdivision 9, but authorizes the attorney general's office or another law enforcement agency to access and obtain copies of th data and use it for law enforcement purposes.

Section 2 (151.45, subdivision 3) authorizes the attorney general to pursue penalties and remedies available under section 8.31 against any manufacturer who violates **section 1.**

KC:ph

Senator Solon introduced--

S.F. No. 23: Referred to the Committee on Health and Family Security.

A bill for an act

relating to pharmacy; modifying wholesale drug distributor requirements; amending Minnesota Statutes 2004, section 151.47, subdivision 1, by adding a subdivision.

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

Section 1. Minnesota Statutes 2004, section 151.47, subdivision 1, is amended to read:

Subdivision 1. [REQUIREMENTS.] All wholesale drug distributors are subject to the requirements in paragraphs (a) to ~~(f)~~ (g).

(a) No person or distribution outlet shall act as a wholesale drug distributor without first obtaining a license from the board and paying the required fee.

(b) No license shall be issued or renewed for a wholesale drug distributor to operate unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board.

(c) The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within the state, or for a parent entity with divisions, subsidiaries, or affiliate companies within the state, when operations are conducted at more than one location and joint ownership and control exists among all the entities.

(d) As a condition for receiving and retaining a wholesale

drug distributor license issued under sections 151.42 to 151.51, an applicant shall satisfy the board that it has complied with paragraph (g) and that it has and will continuously maintain:

(1) adequate storage conditions and facilities;

(2) minimum liability and other insurance as may be required under any applicable federal or state law;

(3) a viable security system that includes an after hours central alarm, or comparable entry detection capability; restricted access to the premises; comprehensive employment applicant screening; and safeguards against all forms of employee theft;

(4) a system of records describing all wholesale drug distributor activities set forth in section 151.44 for at least the most recent two-year period, which shall be reasonably accessible as defined by board regulations in any inspection authorized by the board;

(5) principals and persons, including officers, directors, primary shareholders, and key management executives, who must at all times demonstrate and maintain their capability of conducting business in conformity with sound financial practices as well as state and federal law;

(6) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, about each wholesale drug distributor to be licensed, including all pertinent corporate licensee information, if applicable, or other ownership, principal, key personnel, and facilities information found to be necessary by the board;

(7) written policies and procedures that assure reasonable wholesale drug distributor preparation for, protection against, and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized product control, appropriate disposition of returned goods, and product recalls;

(8) sufficient inspection procedures for all incoming and

outgoing product shipments; and

(9) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(e) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section.

(f) A wholesale drug distributor shall file with the board an annual report, in a form and on the date prescribed by the board, identifying all payments, honoraria, reimbursement or other compensation authorized under section 151.461, clauses (3) to (5), paid to practitioners in Minnesota during the preceding calendar year. The report shall identify the nature and value of any payments totaling $100 or more, to a particular practitioner during the year, and shall identify the practitioner. Reports filed under this provision are public data.

(g) Manufacturers shall, on a quarterly basis, report by National Drug Code the following pharmaceutical pricing criteria to the commissioner of human services for each of their drugs: average wholesale price, wholesale acquisition cost, average manufacturer price as defined in United States Code, title 42, chapter 7, subchapter XIX, section 1396r-8(k), and best price as defined in United States Code, title 42, chapter 7, subchapter XIX, section 1396r-8(c)(1)(C). The calculation of average wholesale price and wholesale acquisition cost shall be the net of all volume discounts, prompt payment discounts, chargebacks, short-dated product discounts, cash discounts, free goods, rebates, and all other price concessions or incentives provided to a purchaser that result in a reduction in the ultimate cost to the purchaser. When reporting average wholesale price, wholesale acquisition cost, average manufacturer price, and best price, manufacturers shall also include a detailed description of the methodology by which the prices were calculated. When a manufacturer reports average wholesale price, wholesale acquisition cost, average manufacturer price, or best price, the president or chief executive officer of the manufacturer shall certify to the Medicaid program, on a form provided by the

commissioner of human services, that the reported prices are accurate. Any information reported under this paragraph shall be classified as nonpublic data under section 13.02, subdivision 9. Notwithstanding the classification of data in this paragraph and subdivision 2, the Minnesota Attorney General's Office or another law enforcement agency may access and obtain copies of the data required under this paragraph and use that data for law enforcement purposes.

Sec. 2. Minnesota Statutes 2004, section 151.47, is amended by adding a subdivision to read:

Subd. 3. [PENALTIES AND REMEDIES.] The attorney general may pursue the penalties and remedies available to the attorney general under section 8.31 against any manufacturer who violates subdivision 1, paragraph (g).

SF 23

Barr Laboratories, Inc.

Suite 722, 444 North Capitol Street, NW, Washington, DC 20001

January 20, 2005

Senator Yvonne Prettner Solon
303 State Capitol
St. Paul, Minnesota 55155

Dear Senator Solon:

Barr Laboratories, Inc. is a leading generic pharmaceutical company, currently manufacturing and distributing nearly 100 pharmaceutical products in therapeutic categories including female healthcare, cardiovascular, oncology, anti-infective and psychotherapeutics. We are a part of the generic pharmaceutical manufacturing industry that is providing massive savings to all Minnesotans as well as to the state through Medical Assistance and the other state pharmacy assistance programs. Generic pharmaceuticals offer the same safety and effectiveness as the brand counterparts, saving consumers more than $10 billion a year nationally. We share your concerns regarding the high cost of drugs and are doing our best to provide lower cost generic alternatives as soon as possible when a patent expires.

I am writing to you regarding SF 23, the legislation you are authoring requiring pharmaceutical manufacturers to report various pricing structures of each drug to the Minnesota Department of Human Services and to provide certification by the company president or CEO. We have a number of concerns with this legislation and encourage you to reconsider whether it will accomplish the intended purpose.

We recognize that many policy-makers find the current pricing structure of pharmaceuticals very complicated and confusing. This is an issue at the federal level; Congress and Centers for Medicaid & Medicare Services (CMS) are currently working towards developing greater consistency in drug pricing nationally. CMS is weighing many options including moving toward an Average Sales Price reporting system, and the House Energy and Commerce Committee held a hearing last month to discuss fixing the price reporting system as a part of Medicaid reform this year. The administration has made it a top priority a well. We believe that it is most appropriate for this issue to be addressed at the federal level and have been cooperating fully and eagerly with CMS, Congress and the Bush Administration in their efforts.

Despite the goal of trying to assist your Department of Human Services in identifying potentially inflated prices for rebate purposes, this legislation will instead be a reporting procedure that either a) unnecessarily duplicates federal reporting requirements, or b) creates a cumbersome price reporting system for each drug in each form and strength that identifies the price to each customer. Either scenario raises serious concerns regarding the confidentiality of our pricing among customers that

goes well beyond the needs of the Department of Human Services for identifying potential Medicaid fraud.

We are concerned that this legislation requires far more than is currently required to be reported federally. The federal reporting is not vendor specific and is not public data. This legislation does not specify whether our highly sensitive pricing data will remain completely confidential. Please keep in mind that the generic industry is a competitive marketplace. In most instances, there are multiple generic manufacturers for each drug. Consumers do not request our drugs by name – we compete based on the price we offer to our customers (such as the local pharmacies). This individual pricing information is proprietary and should remain proprietary and not be publicly available from the state. Similar concerns have been raised with the Texas law by the Generic Pharmaceutical Manufacturers Association (GPHA).

One element of your proposed legislation that does not exist federally or in any other state is the "certification" by the company president or CEO. This is not part of the federal price reporting requirements and seems to be a highly extraordinary step. Barr Laboratories, Inc., as a corporation, is diligent in reporting the required pricing information to the Federal and State governments. As an entity, we are responsible to give accurate and timely reports; a requirement for certification by our CEO is burdensome and unnecessary.

Finally, in a time of budget deficit experienced by your state, managing this information is a significant task for your Department of Human Services. In Texas, the agency hired many new staff people to administer a similar program and sort through thousands of reporting forms. We believe that there are more cost effective means to achieve your goals that will not interfere with critical program needs in the state.

In conclusion, we respect your goals but oppose state-by-state efforts for price reporting and instead support federal initiatives on price reporting and in reforming the AWP pricing system. We also have serious concerns about the competitive implications for generics if the pricing information we must report to the state is not private and confidential.

I appreciate your consideration of the concerns we have raised regarding SF 23.

Sincerely,

Jake Hansen

Jake Hansen
Vice President, Government Affairs

FAEGRE & BENSON LLP

2200 WELLS FARGO CENTER, 90 SOUTH SEVENTH STREET
MINNEAPOLIS, MINNESOTA 55402-3901
TELEPHONE 612.766.7000
FACSIMILE 612.766.1600
www.faegre.com

Kerry Bundy

January 18, 2005

Pharmaceutical Manufacturers' Pricing Information Is a Protectible Trade Secret

Under Minnesota law, the existence of a trade secret is established by demonstrating that the owner: (1) has knowledge or information that derives independent economic value from not being generally known or readily ascertainable, and (2) has taken reasonable efforts to maintain the secrecy of the knowledge or information. Minn. Stat. § 325C.01, subd. 5.

Pharmaceutical manufacturers' pricing, rebate and cost information typically qualify as trade secrets. The pricing, rebate and cost information derive independent economic value from not being generally known. With respect to reasonable efforts, pharmaceutical companies take appropriate steps to prevent the disclosure of their pricing information by employees and third parties. For example, pharmaceutical companies protect the secrecy of their pricing information internally by limiting access to those employees with a need-to-know and by requiring employees to sign nondisclosure agreements. *See Surgidev Corp. v. Eye Technology, Inc,* 828 F.2d 452, 455 (8th Cir. 1987) (under Minnesota Uniform Trade Secrets Act, employee nondisclosure agreements are sufficient protection of secrecy). Pharmaceutical companies also protect the secrecy of their pricing information by contractually prohibiting their customers from disclosing this information. *C & F Packing Co., Inc. v. IBP, Inc.,* 1998 WL 1147139 (N.D. Ill. Mar 16, 1998) (disclosure to outsiders for particular purpose under confidentiality agreement preserves trade secret status).

Courts routinely hold that manufacturers' pricing, rebate and cost information are protectible trade secrets. *See EFCO Corp. v. Symons Corp.*, 219 F.3d 734 (8th Cir. 2000) (manufacturer's pricing and cost or marketing data constituted trade secrets, so long as manufacturer received value from keeping the information secret and made attempts to keep it secret); *Pharmaceutical Care Management Assoc. v. Rowe*, 307 F. Supp.2d 164, 177 (D. Me. 2004) (terms of rebates and "financial and utilization" information constituted trade secrets for purposes of preliminary injunction motion); *Pharmaceutical Care Management Assoc. v. District of Columbia,* Civ. No. 04-1082 (D.D.C. December 21, 2004) (net cost information, including rebate and discount information, constitutes protectible trade secret); *Whyte v. Schlage Lock Co.*, 101 Cal.App.4th 1443, 1454 (Cal. App. 4th Dist. 2002) (pricing, profit margins, promotional discounts, and pricing concessions can be trade secrets).

Legislative or Regulatory Requirements that Require the Disclosure of Trade-Secret Pricing Information without Just Compensation Violate the Takings Clause

The Takings Clause to the United States Constitution provides: "nor shall private property be taken for public use, without just compensation." U.S. Const. Amend. V. The Fifth Amendment applies to the States through the Fourteenth Amendment. Trade secrets are considered property rights and therefore are protected by the Takings Clause. *Ruckelhaus v. Monsanto Co.*, 467 U.S. 986, 1003-4 (1984). Legislative or regulatory requirements that obligate pharmaceutical manufacturers to disclose their trade secrets without just compensation violate the Takings Clause.

The Takings Clause prohibits physical and regulatory takings. *Philip Morris, Inc. v. Reilly,* 312 F.3d 24, 33 (1st Cir. 2002). A "physical taking" is when there is a condemnation or physical appropriation of property. *Id.* A physical taking results in the permanent physical occupation of property or the denial to an owner of all economically beneficial use of his or her property. *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1015 (1992). In these instances, known as *per se* takings, just compensation is required, no matter how minor the invasion or how great the public purpose served by the regulation. *Id.* A "regulatory taking" is when some significant restriction is placed upon an owner's use of property for which "justice and fairness" require that compensation be given. *Reilly,* 312 F.3d at 33. The three-part test for whether certain actions involving trade secrets constitute a regulatory taking is found in *Penn Central Trans Company v. City of New York*, 438 U.S. 104 (1978). The *Penn Central* analysis considers: (1) the plaintiff's reasonable, investment-backed expectations; (2) the economic impact of disclosure of the plaintiff's trade secret; and (3) the character of the government action.

A legislative or regulatory mandate that requires pharmaceutical manufacturers to disclose their trade secrets constitutes both a physical and regulatory taking. First, such legislation or regulations allow for broadly-construed, contemplated use of that trade secret information. This results in an unconstitutional physical taking because the pharmaceutical companies effectively lose their ability to exclude others from their property. *See Kaiser Aetna v. United States*, 444 U.S. 164 (1979) (physical takings where U.S. required the builder of a private marina to provide open access to all individuals who had access to public waters).

In addition, legislation or a regulation that requires pharmaceutical manufacturers to disclose their trade secrets creates a regulatory taking. Pharmaceutical manufacturers have reasonable, investment-backed expectations that their trade secrets will remain confidential. The pharmaceutical pricing information has not been regulated by Minnesota in the past. The manufacturers operate in Minnesota under the protection of the Minnesota Uniform Trade Secret Act, which – as discussed above - protects their pricing information as trade secrets. The direct economic impact of any legislation or regulation that requires disclosure of the pharmaceutical manufacturers' trade secrets severely diminishes the value of the

manufacturer's property. The consequential economic impact of disclosure would also be great because of the increased costs associated with reporting. Further, legislative or regulatory directives that require disclosure of trade secrets without expressing the purpose for the disclosure, a convincing public policy reason to justify the disclosure, and a description of how the disclosure bears any relationship to the purpose of the proposed legislative or regulatory directive are insufficient to justify the taking of trade secret pricing information.

The fact that the proposed legislation or regulation requiring disclosure of pricing information designates the information "nonpublic" does not mean that the statute passes constitutional muster. Instead, a federal court recently addressed a very similar situation and held that regardless of the protection offered against further disclosure, if the statute requires a disclosure that threatens the value of the trade secret information, the disclosure is an unconstitutional taking. *Pharmaceutical Care Management Assoc. v. Maine Attorney General*, 324 F.Supp.2d 74 (D. Me. 2004) ("*Pharmaceutical Care II*").

In addition, if the legislation or regulation has exceptions to keeping the trade secret information "nonpublic," the exceptions may be so broad and undefined that it is possible, if not likely, that the trade secret information will be publicly disclosed. Broad exceptions that provide no protection from public disclosure are invalid because they create an unconstitutional taking. See *Philip Morris Inc. v. Reilly*, 314 F.3d 24 (2002) (invalidated Massachusetts law that required tobacco manufacturers to disclosure their secret ingredients because it created an unconstitutional taking; Massachusetts law promised confidentiality until Massachusetts found that disclosure "could reduce risk to public health" and the Massachusetts Attorney General had found that such disclosure would not be an unconstitutional taking). See also, *Pharmaceutical Care Management Assoc. v. District of Columbia,* Civ. No. 04-1082 (D.D.C. December 21, 2004) (preliminarily enjoined enforcement of disclosure statute because, even though statute allowed disclosed information to be designated confidential, information could still be used in a manner that destroyed the trade secrets' value).

Requiring Disclosure of Trade Secret Pricing Information Without Pre-Deprivation Notice Violates the Due Process Clause

The Due Process Clause of the Fourteenth Amendment imposes procedural constraints on state decisions that deprive individuals of property interests. Fundamentally, the Due Process Clause requires that "a person in jeopardy of serious loss [be given] notice of the case against him and the opportunity to meet it." *Mathews v. Eldridge*, 424 U.S. 319, 348 (U.S. 1976) (citations omitted).

Legislative or regulatory requirements that allow disclosure of trade secret information without a prior meaningful opportunity to be heard violate the affected discloser's due process rights. See *Phillip Morris, Inc. v. Reilly*, 113 F.Supp.2d 129, 145-46

(D. Mass. 2000) (tobacco disclosure act violated Due Process because it did not provide affected manufacturer with meaningful opportunity to argue against publication prior to public disclosure of trade secrets), *reversed*, *Philip Morris, Inc. v. Reilly,* 267 F.3d 45 (1st Cir. 2001), rehearing en banc, *Philip Morris Inc. v. Reilly*, 314 F.3d 24 (2002) (no need to examine Due Process argument since Act held an unconstitutional taking).

Conclusion

In sum, pharmaceutical manufacturers' rebate, cost and pricing information are valuable trade secrets, which are property interests protected under state and federal law. Any legislative or regulatory enactment that requires disclosure of this trade secret information without just compensation constitutes an unconstitutional taking. The statute or regulation may violate the Takings Clause even if it intends to categorize the disclosed information as nonpublic, particularly if the exceptions to keeping the trade secret information nonpublic are broad and undefined. Further, any statute or regulation that allows for disclosure of trade secret information without giving the affected discloser pre-deprivation notice and an opportunity to be heard violates the Due Process Clause.

Senate Counsel & Research

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. 227 - Cancer Drug Repository Program

Author: Senator Yvonne Prettner Solon

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

Date: January 18, 2005

Section 1 (144.707) establishes the cancer drug repository program.

Subdivision 1 defines the following terms: "cancer drug," "dispense," "medical facility," "medical supplies," "pharmacist," "pharmacy," "practitioner," and "prescription drug."

Subdivision 2 requires the Commissioner of Health to establish and maintain a cancer drug repository program. Under the program, a person may donate a cancer or medical supply for use by an individual who meets the eligibility requirements established by the Commissioner. Donations may be made to a medical facility or a pharmacy that elects to participate in the program and meets the requirements specified by the Commissioner. These donations may be dispensed to an eligible individual or distributed to another participating medical facility or pharmacy.

Subdivision3 establishes requirements that must be met before a cancer drug or medical supply can be accepted and dispensed under this program. These requirements are that the drug or supply must:

(1) be in its original, unopened, sealed, and tamper-evident unit dose packaging, or, if packaged in single-unit-doses, unopened;

(2) bear an expiration date that is later than six months after the date the drug was donated;

(3) not be adulterated or misbranded, as determined by a pharmacist who has inspected the drug or supply before it is dispensed; and

(4) be prescribed by a practitioner for use by an eligible individual and be dispensed to that individual by a pharmacist.

Subdivision 4 states that no cancer drug or medical supply donated to this program may be resold. The medical facility or pharmacy may charge a handling fee to the individual who receives the drug or supply that does not exceed an amount specified by the Commissioner.

Subdivision 5 states that a medical facility or pharmacy is not required to participate in this program.

Subdivision 6, paragraph (a), states that the manufacturer of a drug or supply is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the manufacturer's drug or supply that is donated to the program. This includes immunity from liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or supply. This immunity does not apply if the manufacturer of a drug or supply exercises bad faith.

Paragraph (b) provides that a medical facility, pharmacist, pharmacy or practitioner participating in the program are immune from civil liability for injury to or the death of the individual to whom the drug or supply is dispensed and may not be disciplined for unprofessional conduct for their acts or omissions relating to donating, accepting, distributing, or dispensing a cancer drug or supply under this program. This immunity does not apply if the act or omission involves reckless, wanton, or intentional misconduct.

Subdivision 7 requires the Commissioner to promulgate rules on the following:

(1) requirements for medical facilities and pharmacies to accept, distribute and dispense donated cancer drugs and supplies;

(2) eligibility criteria for individuals to receive donated cancer drugs or supplies;

(3) a maximum handling fee that a medical facility or pharmacy may charge; and

(4) a list of cancer drugs and supplies that will and will not be accepted under the program.

KC:ph

Senators Solon, Berglin, Kiscaden, Lourey and Rosen introduced--
S.F. No. 227: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; establishing a cancer drug repository program; requiring rulemaking; proposing coding for new law in Minnesota Statutes, chapter 144.

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

Section 1. [144.707] [CANCER DRUG REPOSITORY PROGRAM.]

Subdivision 1. [DEFINITIONS.] (a) For the purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Cancer drug" means a prescription drug that is used to treat:

(1) cancer or the side effects of cancer; or

(2) the side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(c) "Dispense" has the meaning given in section 151.01, subdivision 30.

(d) "Medical facility" means an institution defined in section 144.50, subdivision 2.

(e) "Medical supplies" means any medical supply needed to administer a cancer drug.

(f) "Pharmacist" has the meaning given in section 151.01, subdivision 3.

(g) "Pharmacy" means any pharmacy registered with the Board of Pharmacy according to section 151.19, subdivision 1.

(h) "Practitioner" has the meaning given in section 151.01,

subdivision 23.

(i) "Prescription drug" means a legend drug as defined in section 151.01, subdivision 17.

Subd. 2. [ESTABLISHMENT.] The commissioner of health shall establish and maintain a cancer drug repository program, under which any person may donate a cancer drug or medical supply for use by an individual who meets eligibility criteria specified by rule. Under the program, donations may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements specified by rule. A medical facility or pharmacy that accepts a donated cancer drug or supply may dispense the drug or supply to an eligible individual or may distribute the cancer drug or supply to another participating medical facility or pharmacy.

Subd. 3. [REQUIREMENTS TO BE MET.] A cancer drug or medical supply may be accepted and dispensed as part of this program only if the following requirements are met:

(1) the cancer drug or medical supply is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened;

(2) the cancer drug bears an expiration date that is later than six months after the date that the drug is donated;

(3) the cancer drug or supply is not adulterated or misbranded, as determined by a pharmacist employed by, or under contract with, the medical facility or pharmacy accepting the donation. The pharmacist shall inspect the drug or supply before the drug or supply is dispensed; and

(4) the cancer drug or supply is prescribed by a practitioner for use by an eligible individual and is dispensed to that individual by a pharmacist.

Subd. 4. [ADMINISTRATION COST.] No cancer drug or supply that is donated for use under this section shall be resold. The medical facility or pharmacy may charge the individual who receives a cancer drug or supply under the program a handling fee that may not exceed an amount specified by the commissioner.

Subd. 5. [PARTICIPATION.] Nothing in this section requires that a medical facility, pharmacy, pharmacist, or practitioner participate in the program.

Subd. 6. [LIABILITY.] (a) Unless a manufacturer of a drug or supply exercises bad faith, the manufacturer is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a cancer drug or supply manufactured by the manufacturer that is donated by any individual under this section, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated cancer drug or supply.

(b) A medical facility, pharmacy, pharmacist, or practitioner participating in the program is immune from civil liability for injury to or for the death of an individual to whom the cancer drug or supply is dispensed and no disciplinary action shall be taken for unprofessional conduct for acts or omissions related to donating, accepting, distributing, or dispensing a cancer drug or supply under this section, unless the act or omission involves reckless, wanton, or intentional misconduct.

Subd. 7. [RULES.] The commissioner shall adopt rules to implement the program, including:

(1) requirements for medical facilities and pharmacies to accept, distribute, and dispense donated cancer drugs and supplies under this section, including:

(i) eligibility criteria;

(ii) standards and procedures for accepting, safely storing, and dispensing donated cancer drugs and supplies;

(iii) standards and procedures for inspecting donated cancer drugs and supplies to determine if the cancer drug or supply is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened; and

(iv) standards and procedures for inspecting donated cancer drugs and supplies to determine that the cancer drug or supply

is not adulterated or misbranded;

(2) eligibility criteria for individuals to receive donated cancer drugs or supplies under the program. The standards shall prioritize dispensation to individuals who are uninsured or indigent but must permit dispensation to others if an uninsured or indigent individual is unavailable;

(3) a maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated cancer drugs or supplies; and

(4) a list of cancer drugs and supplies arranged by category or by individual cancer drug or supply that will be accepted under the program and a list of cancer drugs and supplies that will not be accepted under the program. The list shall include a statement that specifies the reason that a cancer drug or supply is ineligible for donation.

Senate Counsel & Research

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. 99 - Conformity to Federal Health Savings Accounts

Author: Senator Brian LeClair

Prepared by: Patricia A. Lien, Senate Counsel (651/296-0558)

Date: January 18, 2005

The Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173, created an income tax deduction for amounts paid into health savings accounts (HSA). HSA provisions are contained in section 223 of the Internal Revenue Code. HSA's are tax-exempt accounts created exclusively to pay for the qualified medical expenses of the account holder, a spouse, and dependents. An eligible individual may deduct contributions, earn interest on the account tax-free, and make tax-exempt withdrawals to pay for qualified medical expenses. Employers may deduct contributions into an HSA for employees, and may exclude the contributions from "wages" for employment tax purposes.

Individuals eligible for HSA's are individuals covered by a high deductible health plan. Individuals are not eligible if they are entitled to Medicare benefits or may be claimed as a dependent on another person's tax return. A high deductible health plan is a health plan that has a deductible that is at least $1,000 for single coverage and has an out-of-pocket expense limit that does not exceed $5,000, or a deductible that is at least $2,000 for family coverage with an out-of-pocket expense limit that is no more than $10,000.

The maximum amount of the deduction for contributions into an HSA for an individual is the lesser of: (1) the annual deductible under the health plan; or (2) $2,250. The maximum amount of the deduction for family coverage is the lesser of: (1) the annual deductible under the health plan; or (2) $4,500. The amount of the deduction is increased for individuals who are age 55 or older by $500 in tax year

2004, and by an additional $100 each year until 2009. The HSA deduction is reduced by contributions into other tax preference medical savings accounts.

"Qualified medical expenses" paid from an HSA include amounts paid for medical care for the individual, spouse, and dependents to the extent that the amounts are not compensated by insurance or otherwise. Generally, insurance premiums are not "qualified medical expenses," however, premiums for insurance are qualified expenses under an HSA under the following circumstances: (1) continuation of insurance when required under Federal law; (2) when the individual is receiving unemployment benefits; (3) when the individual is receiving Social Security and the policy is not a Medicare supplemental policy; or (4) premiums for qualified long-term care insurance.

Section 1. Health Savings Accounts. Amends Minnesota Statutes, section 290.01, subdivision 19, to adopt the health savings account provisions of section 1201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, effective at the same time the provisions are effective for federal tax purposes, taxable years beginning after December 31, 2003. The retroactive effective date allows taxpayers who established an HSA during tax year 2004 to claim the deduction on their 2004 income tax returns. If this provision is not adopted, Minnesota taxpayers will need to continue to adjust the computation of net income by adding back any deduction taken on their federal return for an HSA.

Section 2. Internal Revenue Code. Amends Minnesota Statutes, section 290.01, subdivision 31, to update the reference to the Internal Revenue Code to include the provisions relating to the deduction for HSA's.

PAL:dv

Senator LeClair introduced--

S.F. No. 99: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; conforming to federal tax changes to encourage consumer-driven health plans; amending Minnesota Statutes 2004, section 290.01, subdivisions 19, 31.

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

Section 1. Minnesota Statutes 2004, section 290.01, subdivision 19, is amended to read:

Subd. 19. [NET INCOME.] The term "net income" means the federal taxable income, as defined in section 63 of the Internal Revenue Code of 1986, as amended through the date named in this subdivision, incorporating any elections made by the taxpayer in accordance with the Internal Revenue Code in determining federal taxable income for federal income tax purposes, and with the modifications provided in subdivisions 19a to 19f.

In the case of a regulated investment company or a fund thereof, as defined in section 851(a) or 851(g) of the Internal Revenue Code, federal taxable income means investment company taxable income as defined in section 852(b)(2) of the Internal Revenue Code, except that:

(1) the exclusion of net capital gain provided in section 852(b)(2)(A) of the Internal Revenue Code does not apply;

(2) the deduction for dividends paid under section 852(b)(2)(D) of the Internal Revenue Code must be applied by allowing a deduction for capital gain dividends and

exempt-interest dividends as defined in sections 852(b)(3)(C) and 852(b)(5) of the Internal Revenue Code; and

(3) the deduction for dividends paid must also be applied in the amount of any undistributed capital gains which the regulated investment company elects to have treated as provided in section 852(b)(3)(D) of the Internal Revenue Code.

The net income of a real estate investment trust as defined and limited by section 856(a), (b), and (c) of the Internal Revenue Code means the real estate investment trust taxable income as defined in section 857(b)(2) of the Internal Revenue Code.

The net income of a designated settlement fund as defined in section 468B(d) of the Internal Revenue Code means the gross income as defined in section 468B(b) of the Internal Revenue Code.

The provisions of sections 1113(a), 1117, 1206(a), 1313(a), 1402(a), 1403(a), 1443, 1450, 1501(a), 1605, 1611(a), 1612, 1616, 1617, 1704(l), and 1704(m) of the Small Business Job Protection Act, Public Law 104-188, the provisions of Public Law 104-117, the provisions of sections 313(a) and (b)(1), 602(a), 913(b), 941, 961, 971, 1001(a) and (b), 1002, 1003, 1012, 1013, 1014, 1061, 1062, 1081, 1084(b), 1086, 1087, 1111(a), 1131(b) and (c), 1211(b), 1213, 1530(c)(2), 1601(f)(5) and (h), and 1604(d)(1) of the Taxpayer Relief Act of 1997, Public Law 105-34, the provisions of section 6010 of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105-206, the provisions of section 4003 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Public Law 105-277, and the provisions of section 318 of the Consolidated Appropriation Act of 2001, Public Law 106-554, shall become effective at the time they become effective for federal purposes.

The Internal Revenue Code of 1986, as amended through December 31, 1996, shall be in effect for taxable years beginning after December 31, 1996.

The provisions of sections 202(a) and (b), 221(a), 225,

312, 313, 913(a), 934, 962, 1004, 1005, 1052, 1063, 1084(a) and (c), 1089, 1112, 1171, 1204, 1271(a) and (b), 1305(a), 1306, 1307, 1308, 1309, 1501(b), 1502(b), 1504(a), 1505, 1527, 1528, 1530, 1601(d), (e), (f), and (i) and 1602(a), (b), (c), and (e) of the Taxpayer Relief Act of 1997, Public Law 105-34, the provisions of sections 6004, 6005, 6012, 6013, 6015, 6016, 7002, and 7003 of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105-206, the provisions of section 3001 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Public Law 105-277, the provisions of section 3001 of the Miscellaneous Trade and Technical Corrections Act of 1999, Public Law 106-36, and the provisions of section 316 of the Consolidated Appropriation Act of 2001, Public Law 106-554, shall become effective at the time they become effective for federal purposes.

The Internal Revenue Code of 1986, as amended through December 31, 1997, shall be in effect for taxable years beginning after December 31, 1997.

The provisions of sections 5002, 6009, 6011, and 7001 of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105-206, the provisions of section 9010 of the Transportation Equity Act for the 21st Century, Public Law 105-178, the provisions of sections 1004, 4002, and 5301 of the Omnibus Consolidation and Emergency Supplemental Appropriations Act, 1999, Public Law 105-277, the provision of section 303 of the Ricky Ray Hemophilia Relief Fund Act of 1998, Public Law 105-369, the provisions of sections 532, 534, 536, 537, and 538 of the Ticket to Work and Work Incentives Improvement Act of 1999, Public Law 106-170, the provisions of the Installment Tax Correction Act of 2000, Public Law 106-573, and the provisions of section 309 of the Consolidated Appropriation Act of 2001, Public Law 106-554, shall become effective at the time they become effective for federal purposes.

The Internal Revenue Code of 1986, as amended through December 31, 1998, shall be in effect for taxable years beginning after December 31, 1998.

The provisions of the FSC Repeal and Extraterritorial Income Exclusion Act of 2000, Public Law 106-519, and the provision of section 412 of the Job Creation and Worker Assistance Act of 2002, Public Law 107-147, shall become effective at the time it became effective for federal purposes.

The Internal Revenue Code of 1986, as amended through December 31, 1999, shall be in effect for taxable years beginning after December 31, 1999. The provisions of sections 306 and 401 of the Consolidated Appropriation Act of 2001, Public Law 106-554, and the provision of section 632(b)(2)(A) of the Economic Growth and Tax Relief Reconciliation Act of 2001, Public Law 107-16, and provisions of sections 101 and 402 of the Job Creation and Worker Assistance Act of 2002, Public Law 107-147, shall become effective at the same time it became effective for federal purposes.

The Internal Revenue Code of 1986, as amended through December 31, 2000, shall be in effect for taxable years beginning after December 31, 2000. The provisions of sections 659a and 671 of the Economic Growth and Tax Relief Reconciliation Act of 2001, Public Law 107-16, the provisions of sections 104, 105, and 111 of the Victims of Terrorism Tax Relief Act of 2001, Public Law 107-134, and the provisions of sections 201, 403, 413, and 606 of the Job Creation and Worker Assistance Act of 2002, Public Law 107-147, shall become effective at the same time it became effective for federal purposes.

The Internal Revenue Code of 1986, as amended through March 15, 2002, shall be in effect for taxable years beginning after December 31, 2001.

The provisions of sections 101 and 102 of the Victims of Terrorism Tax Relief Act of 2001, Public Law 107-134, shall become effective at the same time it becomes effective for federal purposes.

The Internal Revenue Code of 1986, as amended through June 15, 2003, shall be in effect for taxable years beginning after December 31, 2002. The provisions of section 201 of the Jobs

and Growth Tax Relief and Reconciliation Act of 2003, H.R. 2, if it is enacted into law, are effective at the same time it became effective for federal purposes.

Section 1201 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173, relating to health savings accounts, is effective at the same time it became effective for federal purposes.

Except as otherwise provided, references to the Internal Revenue Code in subdivisions 19a to 19g mean the code in effect for purposes of determining net income for the applicable year.

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

Sec. 2. Minnesota Statutes 2004, section 290.01, subdivision 31, is amended to read:

Subd. 31. [INTERNAL REVENUE CODE.] Unless specifically defined otherwise, "Internal Revenue Code" means the Internal Revenue Code of 1986, as amended through June 15, 2003, and as amended by section 1201 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173, relating to health savings accounts.

[EFFECTIVE DATE.] This section is effective for tax years beginning after December 31, 2003.

Senator LeClair
S.F. 99

Committee on Ways and Means

Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Health Savings Accounts (HSAs)
Lifetime Savings for Health Care

Working Years:
Tax-Free Asset Accumulation and Meeting Health Care Needs

- Workers under the age of 65 can accumulate tax-free savings for lifetime health care needs if they have qualified health plans.
    - A qualified health plan has a minimum deductible of $1,000 with a $5,000 cap on out-of-pocket expenses for self-only policies. These amounts are doubled for family policies.
    - Preventive care services are not subject to the deductible.
- Individuals can make pre-tax contributions of up to 100% of the health plan deductible. The maximum annual contribution is $2,600 for individuals with self-only policies and $5,150 for families (indexed annually for inflation).
- Pre-tax contributions can be made by individuals, their employers and family members.
- Individuals age 55 - 65 can make additional pre-tax "catch-up" contributions of up to $1,000 annually (phased in).
- Tax-free distributions are allowed for health care needs not covered by the insurance policy. Tax-free distributions can also be made for continuation coverage required by Federal law (i.e., COBRA), health insurance for the unemployed, and long-term care insurance.
- The individual owns the account. The savings follow the individual from job to job and into retirement.

Retirement Years:
Meeting Retiree Health Needs

- HSA savings can be drawn down to pay for retiree health care once an individual reaches Medicare eligibility age.

- Catch-up contributions during peak saving years allow individuals to build a nest egg to pay for retiree health needs. Catch-up contributions allow a married couple to save an additional $2,000 annually (once fully phased in) if both spouses are at least 55.

- Tax-free distributions can be used to pay for retiree health insurance (with no minimum deductible requirements), Medicare expenses, prescription drugs, and long-term care services, among other retiree health care expenses.

- Upon death, HSA ownership may be transferred to the spouse on a tax-free basis.

Benefits:

- *Contain rising medical costs* – HSAs will encourage individuals to buy health plans that better suit their needs so that insurance kicks in only when it is truly needed. Moreover, individuals will make cost-conscious decisions if they are spending their own money rather than someone else's.

- *Tax-free asset accumulation* – Contributions are pre-tax, earnings are tax-free, and distributions are tax-free if used to pay for qualified medical expenses.

- *Portability* – Assets belong to the individual; they can be carried from job to job and into retirement.

- *Benefits for Medicare beneficiaries* – HSAs can be used during retirement to pay for retiree health care, Medicare expenses and prescription drugs. HSAs will provide the most benefit to seniors who are unlikely to have employer-provided health care during retirement. During their peak saving years, individuals can make pre-tax catch-up contribution

Senator LeClair
S.F. 99

WSJ.com THE WALL STREET JOURNAL. ONLINE
January 19, 2004

COMMENTARY

Health and Taxes

By Martin Feldstein

The Health Savings Accounts that President Bush recently signed into law may well be the most important piece of legislation of 2003. These new tax and medical insurance rules have the potential to transform health-care finances, bringing costs under control and making health care reflect what patients and their doctors really want. It is remarkable that this legislation has received so little public attention.

Today's high cost of health care reflects the way that the tax law has subsidized the use of insurance to pay for health care. Private insurance now pays 70% of all nongovernment health-care costs and more than 90% of nongovernment hospital costs. Because out-of-pocket payments at the time of care are only a small fraction of the total cost of producing that care, individuals naturally want "the best care" that medical science can provide. And the demand for that high-tech care drives medical innovation toward new and more expensive modes of treatment.

The demand for the typical health-insurance policy reflects the tax provision that allows employees to exclude payments for health insurance from their taxable income. Since the annual premium for a family may be as much as $10,000, the resulting tax saving is a very large subsidy for the purchase of the kind of comprehensive, low-deductible insurance policy that drives up health-care costs and that has led to the imposition of controls on patient choice. In the aggregate, this exclusion reduces Federal income-tax collections by $120 billion a year, essentially a $120 billion subsidy for purchasing the wrong kind of insurance.

Although HMOs and other forms of managed care that aim at controlling health costs have become increasingly common in recent years, health costs continue to take a growing share of GDP. And neither patients nor doctors are happy when HMOs restrict the health care that can be given, or limit the time that doctors can spend with each patient, or appear to deny patients information about the care that might benefit them.

The new HSA law (a part of the recent Medicare reform bill) eliminates the preferential subsidy for comprehensive insurance by giving the same tax treatment to individuals who set aside income to pay cash for a larger share of their own health care. Anyone under the age of 65 can establish a Health Savings Account if they have a "qualified" health-insurance plan. A "qualified" plan is an insurance policy that has a minimum deductible of $2,000 for a family and a $10,000 limit on the family's annual out-of-pocket expenses. The deductible is designed to make individuals more cost-conscious in their consumption

of health care, and the annual limit on out-of-pocket expenses is there to prevent financial hardship or a lack of care because of an inability to pay. Individuals or their employers can make annual pretax contributions to Health Savings Accounts of up to 100% of the health-plan deductible, with a maximum of $5,150 in 2004.

An individual can withdraw funds from his HSA without paying tax if the money is used for any kind of health bills, including prescription drugs, dental care and long-term care. Any funds not used in one year are automatically carried forward to the future. Individuals can also withdraw funds from these Health Savings Accounts for nonmedical expenses by paying tax as they would for any IRA withdrawal. And the individual pays no tax on the interest, dividends or capital gains earned on the HSA investment.

Here's an example of how such a "qualified plan" and an HSA can substantially reduce costs for a family without increasing its financial risk. California Blue Cross now offers a traditional low-deductible plan (a deductible of $500 per family member, up to a maximum of two) with an annual premium of $8,460. It also offers a high-deductible plan that is similar except that the deductible is $2,500 per family member, also up to a maximum of two. The annual premium for the high-deductible plan is only $3,936, a premium saving of $4,524. The premium saving is so large that it actually exceeds the maximum additional out-of-pocket cost that the family would face if it reached the maximum deductible for both individuals!

The traditional tax rules are the only reason why someone in the past would have chosen the low deductible policy. A family that earns $50,000 faces a marginal tax rate of about 45% (a 27% federal income tax rate, 15% payroll tax rate and a state income tax rate of about 5%). If the $4,524 premium saving was turned into taxable salary, the individual's net income would rise by only 55% of $4,524, or $2,488. But when the saving of $4,524 is put into a Health Savings Account, there is no tax to pay and the funds can accumulate tax-free.

High-deductible policies give individuals and their doctors an incentive to avoid wasteful health spending. When spending comes from the individuals' own Health Savings Accounts, individuals and their doctors have a strong reason to balance the costs of medical procedures against the potential favorable impact on health. The same incentive can influence the choice among hospitals and among different prescription drugs. And because these cost incentives reduce the need for HMO rules that limit the availability of care, individuals can have greater scope for choosing the care that they want.

In short, the new HSA tax and insurance rules can be the beginning of successfully controlling medical spending and bringing it in line with what patients and their doctors really think is best.

Mr. Feldstein, chairman of the Council of Economic Advisers under President Reagan, is an economics professor at Harvard and a member of the Journal's Board of Contributors.

Sen Le Clair

AHIP
Center for Policy and Research

HEALTH SAVINGS ACCOUNTS OFF TO A FAST START IN THE INDIVIDUAL MARKET

Preliminary data from AHIP members show 438,000 people covered by September 2004

By Teresa Chovan and Hannah Yoo[1]

Health Savings Accounts (HSAs) are designed to give consumers financial incentives and information to choose their health care providers and manage their own health expenses. HSAs were created in December 2003 as part of the Medicare Modernization Act of 2003, and regulatory guidance was released by the Internal Revenue Service mid-year 2004. Modeled after Archer Medical Savings Accounts (MSAs), individuals' HSAs must be coupled with a High Deductible Health Plan (HDHP) to cover current and future health care costs.

AHIP has embarked on an ongoing project to monitor and report on the emerging HSA/HDHP health insurance market through a series of member surveys. This report contains data from the first two surveys conducted in June and September 2004, containing data from 29 companies. The next survey will be conducted in March of 2005.

Market Overview

According to responding companies, HSA/HDHP products covered 438,000 people by the third quarter of 2004. By comparison, the initial take up for MSAs was roughly 40,000 by 1997, 60,000 by 1998 and 90,000 in 1999.[2]

Table 1. HSA/HDHP Sales as of 3rd Quarter 2004

	Total Covered Lives
Individual Market	346,000
Small Group Market	79,000
Large Group Market	13,000
Total	438,000

The individual market appears to have adopted HSA/HDHP coverage more rapidly than either the small group or large group markets. As of September 2004, AHIP member companies had 346,000 covered lives in the individual market. In the small-group market, 79,000 people were covered by

[1] The authors are with the Center for Policy and Research at America's Health Insurance Plans.
[2] Internal Revenue Service, Individual Master File System. Data reported are for "tax units" as counted by the IRS, which may include more than one individual.

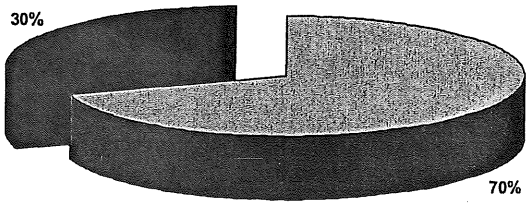
HSAs/HDHPs, and in the large-group market, the number of covered persons was about 13,000. Table 1 shows the total number of covered lives as reported in the survey.

In general, preliminary data suggest that HSA/HDHP coverage is not limited to a single age or gender. Consumers over age 40 represent nearly half of the market.

Individual Market

Responding companies reported a total of 346,000 people covered by individually purchased HSA/HDHPs in September 2004. A subgroup of companies reported the percentage of policies that were sold to previously uninsured people, compared to those that were replacement policies. For those providing this data[3], the survey showed that 30% of policies were purchased by individuals who previously did not have coverage. (Figure 1)

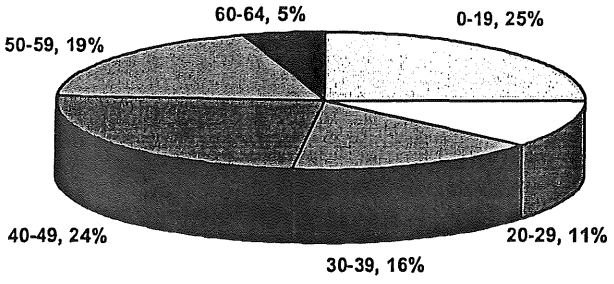
Figure 1. 30% of HSA/HDHP policies sold in the individual market were purchased by persons previously uninsured.



AHIP. Data as of 3rd Q 2004, weighted by covered lives

The age distribution of people covered by HSA/HDHPs in the individual market appears to be evenly allocated among major age groups: 25% of covered people are younger than 20 years of age, 27% are between ages 20 and 39, 24% are between ages 40 and 49 years, and 24% are between ages 50 and 64. (Figure 2) Fifty-one percent of people covered were male; 49% were female.

Figure 2. Age Distribution of Covered Lives Individual Market for HSA/HDHP Products



AHIP. Data as of 3rd Q 2004, weighted by covered lives

AHIP asked companies to report sales figures for all HSA products, and also for their best selling HSA product. In the individual market, 58% of policies sold were for the companies' most popular product.

[3] Companies responding to this question reported HSA/HDHP enrollment of 132,000 in the individual market.

Table 2 provides information on deductibles, out-of-pocket limits and maximum lifetime benefits for the individual market.

Table 2. Description of HSA/HDHP Policies Individual Market – Best Selling Product		
	Single	Family
Average Annual Deductible	$2,856	$5,425
Average Annual Out-Of-Pocket Limit	$3,068	$5,781
Average Lifetime Maximum Benefit	$3.8 Million	$3.8 Million

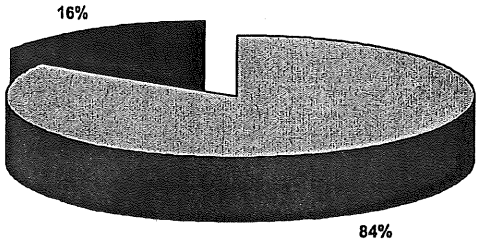
Premiums for best selling policies in the individual market, by age group, are provided in Table 3.

Table 3. Average Premiums of HSA/HDHP Policies, by Age Group Individual Market – Best Selling Product				
	Age 0-19	Age 20-29	Age 30-54	Age 55-64
Average Annual Premium, Single Policy	$1,013	$978	$1,902	$3,440
Average Annual Premium, Family Policy	$1,310	$1,515	$2,641	$4,581

Employer Market: Small Group Policies

The small group insurance market was defined as serving firms with up to 50 employees. AHIP members selling HSA/HDHP products reported enrollment of 79,000 people in the small group market as of September 2004. Sixteen percent of small group policies (1,900) were sold to employers that previously offered no health care coverage to their workforce prior to the HSA/HDHP policy, and these "new" policies covered 22,000 employees. (Figure 3)

Figure 3. 16% of Small Group HSA/HDHP policies were sold to employers that previously offered no health care coverage.



America's Health Insurance Plans
Data as of 3rd Q 2004

The age distribution for covered lives in the small group market is similar to that seen in the individual market. In the small group market 47% of individuals covered by an HSA/HDHP are age 40 or older; 52% are male and 48% are female.

Average deductibles for the best-selling HSA/HDHPs in the small group market were lower than those in the individual market, as were the average annual out-of-pocket limits. The average lifetime maximum benefit for small group policies was in the $4 million range.

Data regarding deductibles, out-of-pocket limits and lifetime maximum benefits for the small group market, as well as average annual premiums, are provided in Table 4.

Table 4. Description of HSA/HDHP Policies Small Group Market – Best Selling Product		
	Single	Family
Average Annual Deductible	$1,850	$4,007
Average Annual Out-of-Pocket Limit	$2,207	$4,793
Average Lifetime Maximum Benefit	$4.1 Million	$4.4 Million
Average Annual Premium	$2,224	$5,496

Employer Market: Large Group Policies

Data reported on the large group market – defined as having more than 50 employees - were quite limited and do not allow for extensive reporting. Even though 54% of responding companies currently selling HSA/HDHP coverage were in the large group market as of September 2004, only a few were able to provide data. According to the survey, large group policies cover approximately 13,000 people. The lack of data on policies in the large group market may be attributed to the fact that HSAs were created in December 2003 – too late to be incorporated in most companies' open enrollment policies for employees' coverage in 2004.

Table 5 provides the average annual deductibles, out-of-pocket limits, and lifetime maximum benefits for single and family policies in the large group market.

Table 5. Description of HSA/HDHP Policies Large Group Market – Best Selling Product		
	Single	Family
Average Annual Deductible	$1,607	$3,000
Average Annual Out-of-Pocket Limit	$2,550	$4,736
Average Lifetime Maximum Benefit	$3.2 million	$4.8 million

Many large employers may currently offer Health Reimbursement Arrangements (HRA) plans, which have features similar to HSAs and have been available since 2002. This survey focused on the HSA product only and does not take into account HRA enrollment.

Looking Ahead

Many companies responding to the survey stated they intend to offer HSA/HDHP coverage in the individual and employer markets in 2005. As the market matures over the next six to twelve months and more insurers and health plans introduce HSA products, additional data will become available through AHIP's Center for Policy and Research, www.ahipresearch.org.

For further information on HSAs visit www.HSADecisions.org, AHIP's new clearinghouse of information for consumers and small businesses, cosponsored by the U.S. Small Business Association.

America's Health Insurance Plans
601 Pennsylvania Ave., NW
Suite 500
Washington, DC 20004

202.778.3200
www.ahip.org

MINNESOTA
MDH
DEPARTMENT OF HEALTH

Sen. Kelly

Protecting, maintaining and improving the health of all Minnesotans

January 2005

Dear Colleague:

It has been five years since the Institute of Medicine (IOM) released its landmark report "To Err is Human". This report introduced many Americans to the idea that medical errors in hospitals kill between 44,000 and 98,000 people each year, making medical errors the 8th leading cause of death in this country. The report helped to confirm that most of these errors resulted from a failure of the complex systems and processes in health care.

In Minnesota our health care leaders and policy makers embraced the notion that one serious medical error is one too many and that broad system changes were needed to make health care safer. With that conviction in mind, legislation creating Minnesota's Adverse Health Event Reporting Law was proposed and passed during the 2003 legislative session. This law requires that hospitals disclose the occurrence of any of the 27 serious events defined in the law and requires the Minnesota Department of Health (MDH) to publish reports of the events by facility, along with a summary of the corrections implemented by hospitals.

MDH is pleased to provide you with the first annual public report on preventable adverse events in Minnesota hospitals*. This report summarizes completed event reports that hospitals have submitted during the transition period of the law, from July 2003 to October 2004. This report includes, background information on the Minnesota reporting law, safety tips and resources for patients and consumers, information about the reported events for each hospital, and a summary of the actions put in place by hospitals to prevent future events.

Reducing medical errors and preventing harm to patients requires more than just counting events. Disseminating the best practices about patient safety, implementing these changes and sustaining them over time is critical if we want to see reduced harm to patients from medical errors. This is the goal of the Minnesota Department of Health as we move forward with this new initiative. Questions and comments on the report can be directed to Marie Dotseth, Senior Policy Advisor for Patient Safety at (651) 297-7733.

Sincerely,

Dianne Mandernach

Dianne M. Mandernach
Commissioner
P.O. Box 64882
St. Paul, MN 55164-0882

* This public report provides the information required for the January 2005 legislative report. One report has been prepared for both purposes. The incremental cost of the legislative report was negligible.

Background Information

Minnesota Department of Health January 2005

Adverse Health Events Reporting in Minnesota: First Annual Public Report

Background

It has been five years since the Institute of Medicine (IOM) released its landmark report "To Err is Human". This report introduced many Americans to the idea that medical errors in hospitals kill between 44,000 and 98,000 people each year, making medical errors the 8th leading cause of death in this country.

The report helped to confirm that most of the medical errors were not the result of the actions of any one provider of care, but that most of these errors resulted from a failure of the complex systems and processes in health care.

In Minnesota our health care leaders embraced the notion that one serious medical error is one too many and that broad system changes were needed to make health care safer. With that conviction in mind, a coalition of Minnesota hospitals, doctors, nurses and patient advocates supported the legislation creating Minnesota's Adverse Health Event Reporting Law during the 2003 legislative session.

This law requires that hospitals disclose when any of the 27 serious events defined in the law occur and requires the Minnesota Department of Health (MDH) to publish reports of the events by facility, along with a summary of the corrections implemented by hospitals.

MDH has released the first annual public report on preventable adverse events in Minnesota hospitals. This report summarizes completed event reports that hospitals have submitted during the transition period of the law, from July 2003 to October 2004.

What is included in the report?

- Background information on the Minnesota reporting law,
- Safety tips and resources for patients and consumers,
- Information about the reported events for each hospital, and
- A summary of the actions put in place by hospitals to prevent future events.

Summary of reported events:

99 events were reported by hospitals during the transition period from July 1, 2003 through October 6, 2004. These events are categorized as follows:

Surgical – 52 events

Product or device – 4 events

Patient Protection – 2 events

Care Management – 31 events

Environmental – 9 events

Criminal – 1 event

Which serious events are reportable?

Examples of incidents that must be reported include wrong-site surgery, retention of a foreign object in a patient after surgery, and death or serious disability associated with medication error. A full list of the 27 reportable events is included in the report.

MINNESOTA MDH DEPARTMENT OF HEALTH

Commissioner's Office
85 East Seventh Place, Suite 400
P.O. Box 64882
St. Paul, MN 550164-0882
(651) 215-1300
www.health.state.mn.us

Adverse Health Events Reporting in Minnesota: First Annual Public Report -- page 2

Why these events?

One of the principle recommendations in the original IOM report was to create a mandatory reporting system for the most serious errors. In response to the IOM's recommendation, a national health policy group, the National Quality Forum (NQF), developed a broad consensus around a specific, targeted list of events that should never happen to patients in hospitals. This list, which started as the "never events" list, evolved into the 27 Serious Reportable Events in Healthcare published by NQF in 2002. Minnesota is the first state to fully adopt the standards established by NQF for reporting medical errors.

What is being done about the events included in this report?

Minnesota's hospitals are already implementing a variety of proven strategies for preventing many types of errors. Such strategies include developing new ways to track objects used in surgical procedures, improving how patients are assessed for the risk of falling, regularly re-positioning patients at risk of pressure sores, and adding special labels to high-risk medications.

The law requires hospitals to do a detailed analysis of why an event occurred and to report the findings of this analysis (called a "root cause analysis") into the electronic registry. In addition, hospitals must report the actions that were put in place to prevent future events.

The full report includes summaries of the corrective actions individual hospitals have implemented along with some collaborative initiatives designed for broad implementation at several hospitals.

How should consumers use this report?

This report should be used as a guide to increase awareness of safety issues. Patients and families should ask questions and take action based on issues of concern to them. If hospitals have implemented corrective actions and prevention strategies regarding adverse events, patients and families should ask how they can support and reinforce these efforts.

The events listed in this report represent a very small fraction of all of the procedures and admissions in Minnesota's hospitals. With relatively low occurrence of these serious events, it is important to be aware that differences in reports between facilities can come from differences in reporting procedures or differences in interpretation or understanding of the law as much as from differences in the quality or safety of a hospital.

What about the other regulatory responsibilities of MDH?

The adverse event reporting law is an added requirement above and beyond the existing state and federal regulatory requirements for health care facilities. Patients and families may always contact MDH regarding concerns with facilities and file complaints. Reports to provider-licensing boards will be acted on according to the laws regulating providers in Minnesota. The events that are categorized under the criminal section of the adverse events reporting law must be reported to the appropriate authorities in addition to the adverse event report.

The new adverse event reporting law and existing regulatory processes function in a complementary manner to provide patients and families with a system for accountability and a system for learning and prevention.

For more information:

The full report can be found on the internet at: www.minnesotahealthinfo.org

Marie Dotseth,
Senior Policy Advisor for Patient Safety
Minnesota Department of Health
651-297-7733
marie.dotseth@health.state.mn.us

JANUARY 2005

ADVERSE HEALTH EVENTS IN MINNESOTA HOSPITALS

FIRST ANNUAL PUBLIC REPORT

MINNESOTA MDH DEPARTMENT OF HEALTH

ADVERSE HEALTH EVENTS IN MINNESOTA HOSPITALS

MDH | 2005

TABLE OF CONTENTS

BACKGROUND	2
HOW TO USE THIS REPORT	3
SELECTED SAFETY TIPS FROM AHRQ	5
SUMMARY OF REPORTABLE EVENTS	6
EVENTS REPORTED BETWEEN JULY 1, 2003 – OCTOBER 6, 2004	7
OVERVIEW OF ROOT CAUSE ANALYSES AND ACTION PLANS	7
TABLES	10
APPENDICES	45

This report can be found on the internet at: **www.minnesotahealthinfo.org**

For More Information Contact:
Marie Dotseth
Senior Policy Advisor for Patient Safety
Minnesota Department of Health
651-297-7733
marie.dotseth@health.state.mn.us

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ADVERSE HEALTH EVENTS IN MINNESOTA HOSPITALS

First Annual Report • January 2005

Includes Hospital Events Reported: July 2003 — October 2004

"People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer."
– The Institute of Medicine, "To Err Is Human"

The landmark IOM Report, "To Err Is Human," estimated that the overall cost of preventable adverse events was between $17 and $29 billion. Half of this was direct health care costs.

Assuming the IOM numbers would apply in Minnesota today for our population, the estimated direct health care cost of all preventable adverse events in Minnesota is nearly $200 million per year.

BACKGROUND

It has been five years since the Institute of Medicine (IOM) released its landmark report "To Err is Human." This report introduced many Americans to the idea that medical errors in hospitals kill between 44,000 and 98,000 people each year, making medical errors the 8th leading cause of death in this country.[1] This problem was not a new one for health professionals, but the IOM report helped to focus the efforts of many in health care to address the systemic causes of medical errors.

The report helped to confirm that most of the medical errors were not the result of the actions of any one provider of care, but that most of these errors resulted from a failure of the complex systems and processes in health care. According to the report, "People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer."[2] Recognizing that entire systems of care were in need of redesign and that one of the most effective ways to accomplish this was to know more about preventable adverse events, the IOM recommended a mandatory reporting system where the most serious events would be reported, persistent safety problems would be identified and action would be taken to prevent these errors.[3]

In response to the IOM's recommendation, a national health policy group, the National Quality Forum (NQF), and their expert panel representing a broad range of health care stakeholders developed a consensus list of specific events that should never happen to patients in health facilities. This list, which became known as the "never events" list, evolved into the 27 Serious Reportable Events in Healthcare published by the NQF in 2002.[4]

In some states there was considerable debate about the accuracy of the numbers in the IOM report or the best approach among the different solutions proposed by the IOM and others. In Minnesota our health care leaders embraced the notion that one serious medical error is one too many. And with that conviction in mind, a coalition of Minnesota hospitals, doctors, nurses and patient advocates supported the legislation creating Minnesota's Adverse Health Event Reporting Law during the 2003 legislative session. With Sen. Steve Kelley and Rep. Lynda Boudreau as chief authors, the law had broad bipartisan legislative support and support from Governor Pawlenty and the Minnesota Department of Health (MDH). This law mandated the reporting of the "never events" as developed by the National Quality Forum. (For more information on the National Quality Forum and their work on the list of "Serious Reportable Events," see Appendix C.)

The law directed that non-state funds were to be used to implement the law and required a transition period prior to full implementation. The transition period was needed to work through some of the reporting requirements and data needs as well as to identify and secure funding for the start-up period. A broad group of stakeholders contributed $250,000 in the first two years to get the process started.[5] It is a tribute to the strong collaborative relationships in Minnesota's health care community and the dedication to improving patient safety that significant funds were contributed and work was able to proceed rapidly.

[1] Institute of Medicine, To Err is Human: Building a Safer Health System. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds. Washington, D.C.: National Academy Press, 2000
[2] Ibid
[3] Ibid
[4] National Quality Forum, Serious Reportable Events in Healthcare. Washington D.C., 2002.
[5] The Minnesota Hospital Association worked with MDH to raise the necessary funds. Major donors include Stratis Health, Blue Cross Blue Shield of Minnesota, Midwest Medical Insurance Company and the Buyers Health Care Action Group. Funds were also contributed by the St. Jude Medical Foundation and the Pharmaceutical Research Manufacturers of America.

During the transition period, Minnesota hospitals began electronically reporting the adverse events as required on July 1, 2003, through the Minnesota Hospital Association's Patient Safety Registry. Hospitals are required to post information on the registry about the 27 reportable events, along with their determination of why the event happened and what is being done to prevent the event from happening again. With this web-based system and the analysis and feedback provided in the law, hospitals are able to learn from the experiences of other hospitals.

Full implementation, with reports coming to MDH, began on December 6, 2004. MDH has implemented the adverse events law as a quality improvement initiative, not as a regulatory enforcement tool and has non-regulatory staff processing and analyzing adverse event reports. MDH is required to execute a number of activities related to the adverse event reports including:

- Tracking, assessing and analyzing the incoming reports, findings and corrective action plans,
- Determining patterns of failure, if any, and successful methods to correct system problems,
- Sharing findings with individual facilities, providing follow-up and feedback as needed,
- Educating facilities across the state regarding best safety practices,
- Monitoring national efforts and those in other states to ensure consistency and best practice in the Minnesota law and proposing modifications to the law based on this analysis, and;
- Publishing an annual report of events and corrective actions and communicating with purchasers and the public about lessons learned to improve health care quality.

The analysis and feedback process has just begun with the full implementation of the law. Much work lies ahead; however, early results suggest that the law has already demonstrated success in the ongoing goals of quality improvement and accountability. Hospitals have initiated specific safety improvement strategies with measurable results (for selected examples refer to the "Corrective Actions" section of this report on page 7). The Minnesota Department of Health and provider licensing boards are working together under the adverse events reporting law to identify opportunities for learning and prevention. And Minnesota hospital leaders have remained committed to transparency, encouraging the publication of the data collected during the transition period as soon as possible.

This report summarizes completed event reports Minnesota hospitals have reported during the transition period of the law; from July 2003 to October 2004. Tables with the overall, state-wide information begin on page 11. Hospital-specific data follows, beginning on page 15. Outpatient surgical centers were added as reporting facilities under modifications made to the law in the 2004 legislative session and began reporting events on December 6, 2004. Surgical center events will be included in the next annual report.

HOW TO USE THIS REPORT

Consumers and patients should know that events listed in this report represent a very small fraction of all of the procedures and admissions in Minnesota's hospitals, but that patient awareness is important to help prevent these relatively rare events.

With relatively low occurrence of these serious events, it is important to be aware that differences in reports between facilities can come from differences in reporting procedures or differences in interpretation or understanding of the law as much as from differences in the quality or safety of a hospital. As clearly and concisely as the Minnesota Adverse Health Event Reporting Law is written, there will still be variation in what gets reported based on interpretation of which events are

THE INFORMATION IN THIS REPORT SHOULD NOT BE USED TO COMPARE THE SAFETY OR QUALITY OF FACILITIES. THE NUMBER OF REPORTED EVENTS CAN VARY BASED ON MANY FACTORS OTHER THAN DIFFERENCES IN THE SAFETY OF CARE, INCLUDING:

- *THE SIZE OF THE FACILITY.*
- *DIFFERENCES IN INTERPRETATION ON WHICH EVENTS QUALIFY AS REPORTABLE.*
- *STAFF AWARENESS OF SITUATIONS REQUIRING REPORTING.*

IT IS ALSO IMPORTANT TO REMEMBER THAT THE SCOPE OF PATIENT SAFETY IS MUCH BROADER THAN WHAT IS REPRESENTED WITH THESE 27 REPORTABLE EVENTS.

Because it is difficult to know which of the many factors may be influencing the number of reported events for any hospital, it is best to use this report as a guide to increase awareness of safety issues. Prepared with this information, consumers should ask questions and take action based on what is important to them. If hospitals have implemented corrective actions and prevention strategies regarding adverse events, patients and families should ask how they can support and reinforce these efforts.

reportable or the awareness of the staff to identifying potentially harmful situations and reporting events. MDH, hospitals and other patient safety stakeholders continue work to reduce this variation in understanding and application of the law.

The fact that health care providers in Minnesota's hospitals are looking for potentially dangerous situations and reporting them with the intention to learn and prevent harm to patients is a major step forward in patient safety. Consumers should use this report to identify situations of interest to them and then ask their hospital or health care provider what is being done in their facility to prevent this type of event from occurring.

Patients and families are a vital part of the health care team and play an important role in ensuring safe health care. Many resources are available for patients interested in what they can do to help make their health care safer. One such resource is the Federal Agency for Health Research and Quality (AHRQ). AHRQ has pulled together the best research on patient safety and has developed many tips for patients that can be found at www.ahrq.gov. Some of these tips are highlighted on the following page.

SELECTED SAFETY TIPS FROM THE AGENCY FOR HEALTH QUALITY AND RESEARCH[6]

Be Involved in Your Health Care

1. The single most important way you can help to prevent errors is to be an active member of your health care team. That means taking part in every decision about your health care. Research shows that patients who are more involved with their care tend to get better results.

Hospital Stays

2. If you have a choice, choose a hospital at which many patients have the procedure or surgery you need. Research shows that patients tend to have better results when they are treated in hospitals that have a great deal of experience with their condition.

3. If you are in a hospital, consider asking all health care workers who have direct contact with you whether they have washed their hands. Hand washing is an important way to prevent the spread of infections in hospitals. Yet, it is not done regularly or thoroughly enough. A recent study found that when patients checked whether health care workers washed their hands, the workers washed their hands more often and used more soap.

4. When you are being discharged from the hospital, ask your doctor to explain the treatment plan you will use at home. This includes learning about your medicines and finding out when you can get back to your regular activities. Research shows that at discharge time, doctors think their patients understand more than they really do about what they should or should not do when they return home.

Surgery

5. If you are having surgery, make sure that you, your doctor, and your surgeon all agree and are clear on exactly what will be done. Doing surgery at the wrong site (for example, operating on the left knee instead of the right) is rare. But even once is too often. The good news is that wrong-site surgery is 100 percent preventable. The American Academy of Orthopaedic Surgeons urges its members to sign their initials directly on the site to be operated on before the surgery.

Other Steps You Can Take

6. Speak up if you have questions or concerns. You have a right to question anyone who is involved with your care.

7. Make sure that someone, such as your personal doctor, is in charge of your care. This is especially important if you have many health problems or are in a hospital.

8. Make sure that all health professionals involved in your care have important health information about you. Do not assume that everyone knows everything they need to.

9. Ask a family member or friend to be there with you and to be your advocate (someone who can help get things done and speak up for you if you can't). Even if you think you don't need help now, you might need it later.

10. Know that "more" is not always better. It is a good idea to find out why a test or treatment is needed and how it can help you. You could be better off without it.

11. If you have a test, don't assume that no news is good news. Ask about the results.

12. Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources.[7]

[6] Agency for Health Quality and Research, Patient Fact Sheet: 20 Tips to Help Prevent Medical Errors Online. Available: http://www.ahrq.gov/consumer/ [Accessed January 2005]

[7] A number of good sources are available both nationally and locally on the best available healthcare treatments. For example nationally, treatment recommendations based on the latest scientific evidence are available from the National Guidelines Clearinghouse at www.guideline.gov. Local examples of information resources on evidence based health care include the Institute Clinical Systems Improvement at www.icsi.org. Ask your doctor if your treatment is based on the latest evidence.

CATEGORIES OF REPORTABLE EVENTS AS DEFINED BY LAW

Detailed definitions are included in Appendix B.

SURGICAL EVENTS

- Surgery performed on a wrong body part;
- Surgery performed on the wrong patient;
- The wrong surgical procedure performed on a patient;
- Foreign objects left in a patient after surgery; or
- Death during or immediately after surgery of a normal, healthy patient.

ENVIRONMENTAL EVENTS

Patient death or serious disability associated with:

- An electric shock;
- A burn incurred while being cared for in a facility;
- A fall while being cared for in a facility;
- The use of or lack of restraints or bedrails while being cared for in a facility;. and
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.

PATIENT PROTECTION EVENTS

- An infant discharged to the wrong person;
- Patient death or serious disability associated with patient disappearance; and
- Patient suicide or attempted suicide resulting in serious disability.

CARE MANAGEMENT EVENTS

Patient death or serious disability:

- Associated with a medication error;
- Associated with a reaction due to incompatible blood or blood products;
- Associated with labor or delivery in a low-risk pregnancy;
- Directly related to hypoglycemia (low blood sugar);
- In newborn infants during the first 28 days of life;
- Due to spinal manipulative therapy; and
- Stage 3 or 4 ulcers (very serious pressure sores) acquired after admission to a facility.

PRODUCT OR DEVICE EVENTS

Patient death or serious disability associated with:

- The use of contaminated drugs, devices, or biologics;
- The use or malfunction of a device in patient care; and
- An intravascular air embolism.

CRIMINAL EVENTS

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;
- Abduction of a patient of any age;
- Sexual assault on a patient within or on the grounds of a facility; and
- Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

EVENTS REPORTED BETWEEN JULY 1, 2003 – OCTOBER 6, 2004[8]

Detailed information is provided in the tables beginning on page 10.

The purpose of the law is to learn from serious events so that harm to patients can be prevented.

Early Findings:

- *The most frequently reported events were foreign objects left in patients after surgery.*
- *The next most frequently reported event was stage 3 or 4 pressure ulcers.*
- *Almost a third of the "Wrong Body Part Surgery" reports occurred in spine surgeries.*

For the period covered in this report, 99 events were reported into the web-based registry. These events are categorized as follows:

Surgical	**52 events**
Product or device	**4 events**
Patient Protection	**2 events**
Care Management	**31 events**
Environmental	**9 events**
Criminal	**1 event**

OVERVIEW OF ROOT CAUSE ANALYSES AND ACTION PLANS

Hospitals have put in place procedures for determining the underlying causes of adverse events in their facilities. This process is called a "root cause analysis" or an "RCA." The process of completing a root cause analysis helps a hospital determine exactly what happened and why it happened. Once the findings from an RCA are known, the hospital may then put actions in place to prevent future adverse events. These actions are called "corrective action plans."

The new Adverse Health Event Reporting law requires hospitals to submit the findings from their root cause analyses and corrective action plans whenever events are reported. These findings are an important part of the reporting process. Information from the RCAs and correction action plans will foster learning among facilities and help spread preventive actions across the state of Minnesota.

RCAs REPORTED DURING THE TRANSITION PERIOD

On an individual level, hospitals have been conducting RCAs and implementing a number of actions to reduce the harm from events and to prevent future adverse events. This work is typically conducted by teams within the facilities. These teams develop actions that will range from effective, yet simple quick "fixes" to significant changes that require more time and resources to implement.

The RCA information that has been reported during the transition period has varied from a minimum amount of reported information — sometimes only a couple of sentences — to very detailed reports of the RCA team findings. One of the challenges for future reporting will be to work with the facilities to determine what level of information is most useful to report in order to help other facilities learn from the work that has been completed. MDH will work with the facilities over the next year to help ensure that the RCA processes are consistently high quality and thorough across all facilities in the state.

CORRECTIVE ACTION PLANS DURING THE REPORTING PERIOD

The findings from the RCAs have led to a number of different action plans within the individual hospitals. These actions are a direct result of the reporting law. The majority of the planned actions have fallen under three main categories: providing care in a consistent manner; adopting practices that have been shown to improve patient safety; and restructuring of the hospital environment.

Examples of action plans that have been submitted for the most frequently reported adverse event types include:

Surgical

- Developing new ways to track objects used in surgical procedures
- Purchasing surgical sponges and other materials that are easier to track and count
- Making sure that surgery teams are pausing before surgery to review patient information

[8] This represents all event reports completed during the transition, or start-up period of the law.

- Marking the surgical site prior to surgery
- Increasing the use of x-rays in the operating room to identify the correct surgery site

Patient Falls

- Providing tools and processes to consistently assess patients at risk for falls
- Designing new processes for toileting patients at risk for falls
- Trialing different types of slippers

Pressure Ulcers (Bed Sores)

- Providing tools and methods to consistently assess patients at risk for pressure ulcers
- Purchasing special equipment to use for patients at risk for pressure ulcers
- Set up physician orders to make sure patients at risk for pressure ulcers are re-positioned on a regular basis
- Increasing the involvement of staff that specialize in wound care

Medication Errors

- Adding special labels to high risk medications
- Purchasing medications that are pre-packaged and pre-labeled
- Evaluating different types of pumps to deliver medications

COLLABORATIVE EFFORTS TO PREVENT ADVERSE EVENTS:

In addition to the work individual hospitals are doing to make improvements through their root cause analyses and corrective action plans, hospitals are taking several collaborative steps that are worth noting.

- The Minnesota Hospital Association formed a Registry Advisory Council, made up of patient safety professionals from member hospitals, to review the information being reported. The council looks for trends, identifies the need for safety alerts and develops recommendations for acting on data and sharing what has been learned. The first safety alert was issued in April 2004. This alert identified the relatively high number of surgical events and pressure ulcers reported. Some of the specific hospital actions as well as the actions of the Minnesota Alliance for Patient Safety and Safest in America (below) were taken based on the information in this alert.

- The Minnesota Alliance for Patient Safety (MAPS), which was co-founded by the Minnesota Department of Health, the Minnesota Hospital Association and the Minnesota Medical Association, has formed a MAPS Best Practices Subcommittee to research and promote best practices around prevention and treatment of reportable events. The subcommittee is focusing on identifying and highlighting best practices for implementing pressure ulcer assessments and treatments that have led to a successful reduction in pressure ulcers. There are many guidelines and tools that already exist, however the challenge is implementing and sustaining them. MAPS will be identifying barriers to implementing existing tools and educating health care professionals, patients and families on how to successfully implement a pressure ulcer reduction program. MAPS plans to apply for a federal AHRQ grant to assist in the dissemination of tools and methods to prevent pressure ulcers and to measure the effectiveness of different approaches.

- Safest in America — Safest in America is a collaboration of 10 hospital systems in the Twin Cities and Rochester that are committed to working together to improve patient care. In 2002 the group issued a protocol to standardize surgical site marking practices at the participating hospitals. The group has begun using information reported into the adverse health event system, reviewing each surgical event from their hospitals that involved a wrong body part, wrong patient or wrong procedure. This careful analysis has led Safest in America to revise its surgical site marking protocol. For example, the protocol now says that imaging (such as CT scans) should be done during spinal surgery to confirm that a procedure is being done at the correct position on the spine. In addition, Safest in America has taken further steps to ensure providers are adhering to the surgical marking protocol.

  In 2005 Safest in America will work to standardize steps hospitals can take to prevent patients from developing serious bed sores.

CONCLUSION

Reducing medical errors and preventing harm to patients requires more than just counting events. Disseminating the evidence-based best practices about patient safety, implementing these changes and sustaining them over time is critical if we want to see reduced harm to patients from medical errors. Leveraging the improvements directly resulting from the implementation of this law and sustaining them is the goal of the Minnesota Department of Health and its partners as we move forward. The specific activities listed on page 3 will be accomplished in the next phase, events from outpatient surgical centers will be reported and progress in patient safety improvements will be tracked. Generalized findings from the reports will be shared with the hospitals and surgical centers throughout the year and all of the activities for the year will be summarized in the next annual public report.

There is still much work to be done to improve patient safety. Comprehensive efforts to reduce adverse events are underway nationally and here in Minnesota. Initiatives like the adverse health events reporting law help to focus attention and energy on preventing the most serious adverse events and harm to patients. It is important to remember, however, that this reporting system is just one component of broader patient safety improvement strategies in Minnesota. Consumers and patients should use reports like this one to increase their awareness of patient safety issues and let their health providers know that patient safety and adverse event prevention strategies are a priority for them. This awareness and attention will help ensure that patient safety will continue to be a priority for hospitals and health providers in Minnesota.

TABLES AND DETAILED INFORMATION

TABLE 1:
Overall State-Wide Report **page 11**

This table describes the total number of reported events for the state during the transition period from July 1, 2003 through October 6, 2004. The events are grouped under the six major categories of events. The severity details are also included for the events reported, indicating if the result was death, serious disability or if the outcome was neither death nor serious disability.

TABLE 2:
State-wide Report by Event Category **pages 12 – 14**

This table also provides overall information for the state, but shows each type of reportable event within each of the six major categories.

TABLE 3.1 – 3.30:
Hospital-Specific Events **pages 15 – 44**

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

HOW TO READ HOSPITAL-SPECIFIC TABLES

Information on the size of the facility is presented on each hospital table. This information is given in two ways:

1) **Number of beds:** This is a common measure of the size of a hospital and provides a sense of the maximum number of patients who could stay at the facility at any one time. In Minnesota, hospitals range in size from 10 to 1,700 beds.

2) **Patient Days:** This measure represents how busy the hospital was over the reporting time period. It is a measure of the number of days that inpatients are hospitalized. Patient days were adjusted to account for inpatient and outpatient services.

- Hospitals are listed in alphabetical order.
- If there is no table for a hospital, it means that hospital did not report any events.

The Minnesota Hospital Association worked with each of its member hospitals to verify the accuracy of the reported events and, in cases where there were no events reported, asked hospitals to verify that they had no events.

TABLE 1
OVERALL STATE-WIDE REPORT

Reported adverse health events: **ALL EVENTS** (July 1, 2003- October 6, 2004)

	CATEGORY OF EVENTS						
	SURGICAL	PRODUCTS OR DEVICES	PATIENT PROTECTION	CARE MANAGEMENT	ENVIRONMENTAL	CRIMINAL	TOTAL
ALL HOSPITALS	52 Events	4 Events	2 Events	31 Events	9 Events	1 Event	99 Events
SEVERITY DETAILS	Serious Disability: 0 Death: 2 Neither: 50	Serious Disability: 0 Death: 4	Serious Disability: 2 Death: 0	Serious Disability: 2 Death: 5 Neither: 24	Serious Disability: 0 Death: 9	Serious Disability: 0 Death: 0 Neither: 1	Serious Disability: 4 Death: 20 Neither: 75

TABLE 2
STATE-WIDE REPORTS BY CATEGORY

Details by Category: **SURGICAL** (July 1, 2003- October 6, 2004)

	TYPES OF EVENTS					
	1. WRONG BODY PART	2. WRONG PATIENT	3. WRONG PROCEDURE	4. FOREIGN OBJECT	5. INTRA/POST-OP DEATH	TOTAL
ALL HOSPITALS	13 Events	1 Event	5 Events	31 Events	2 Events	52 Events
SEVERITY DETAILS	Serious Disability: 0 Death: 0 Neither: 13	Serious Disability: 0 Death: 0 Neither: 1	Serious Disability: 0 Death: 0 Neither: 5	Serious Disability: 0 Death: 0 Neither: 31	Serious Disability: 0 Death: 2 Neither: 0	Serious Disability: 0 Death: 2 Neither: 50

Details by Category: **PRODUCTS OR DEVICES** (July 1, 2003- October 6, 2004)

	TYPES OF EVENTS			
	6. CONTAMINATED DRUGS, DEVICES OR BIOLOGICS	7. MISUSE OR MALFUNCTION OF DEVICE	8. INTRAVASCULAR AIR EMBOLISM	TOTAL FOR PRODUCTS OR DEVICES
ALL HOSPITALS	0 Events	4 Events	0 Events	4 Events
SEVERITY DETAILS		Serious Disability: 0 Death: 4		Serious Disability: 0 Death: 4

Details by Category: **PATIENT PROTECTION** (July 1, 2003- October 6, 2004)

	TYPES OF EVENTS			
	9. WRONG DISCHARGE OF INFANT	10. PATIENT DISAPPEARANCE	11. SUICIDE OR ATTEMPTED SUICIDE	TOTAL FOR PATIENT PROTECTION
ALL HOSPITALS	0 Events	0 Events	2 Events	2 Events
SEVERITY DETAILS			Serious Disability: 2 Death: 0	Serious Disability: 2 Death: 0

TABLE 2 (CONTINUED)

Details by Category: **CARE MANAGEMENT** (July 1, 2003- October 6, 2004)

	TYPES OF EVENTS							
	12. DEATH OR DISABILITY DUE TO MEDICATION ERROR	13. DEATH OR DISABILITY DUE TO HEMOLYTIC REACTION	14. DEATH OR DISABILITY DURING LOW-RISK PREGNANCY LABOR OR DELIVERY	15. DEATH OR DISABILITY ASSOCIATED WITH HYPO-GLYCEMIA	16. DEATH OR DISABILITY ASSOCIATED WITH FAILURE TO TREAT HYPER-BILIRUBI-NEMIA	17. STAGE 3 OR 4 PRESSURE ULCERS ACQUIRED AFTER ADMISSION	18. DEATH OR DISABILITY DUE TO SPINAL MANIPULA-TION	TOTAL FOR CARE MANAGE-MENT
ALL HOSPITALS	6 Events	0 Events	0 Events	1 Event	0 Events	24 Events	0 Events	31 Events
SEVERITY DETAILS	Serious Disability: 2 Death: 4 Neither: 0			Serious Disability: 0 Death: 1 Neither: 0		Serious Disability: 0 Death: 0 Neither: 24		Serious Disability: 2 Death: 5 Neither: 24

Details by Category: **ENVIRONMENTAL** (July 1, 2003- October 6, 2004)

	TYPES OF EVENTS					
	19. DEATH OR DISABILITY ASSOCIATED WITH AN ELECTRIC SHOCK	20. WRONG GAS OR CONTAMINA-TION IN PATIENT GAS LINE	21. DEATH OR DISABILITY ASSOCIATED WITH A BURN	22. DEATH ASSOCIATED WITH A FALL	23. DEATH OR DISABILITY ASSOCIATED WITH RESTRAINTS	TOTAL FOR ENVIRON-MENTAL
ALL HOSPITALS	0 Events	0 Events	1 Event	8 Events	0 Events	9 Events
SEVERITY DETAILS			Serious Disability: 0 Death: 1	Death: 8	Serious Disability: 0 Death: 0	Serious Disability: 0 Death: 9

TABLE 2 (CONTINUED)

Details by Category: **CRIMINAL** (July 1, 2003- October 6, 2004)

	TYPES OF EVENTS				
	24. CARE ORDERED BY SOMEONE IMPERSONATING A PHYSICIAN, NURSE OR OTHER PROVIDER	25. ABDUC-TION OF PATIENT	26. SEXUAL ASSAULT OF A PATIENT	27. DEATH OR INJURY OF PATIENT OR STAFF FROM PHYSICAL ASSAULT	TOTAL FOR CRIMINAL
ALL HOSPITALS	0 Events	0 Events	0 Events	1 Event	1 Event
SEVERITY DETAILS				Serious Disability: 0 Death: 0 Neither: 1	Serious Disability: 0 Death: 0 Neither: 1

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.1

ABBOTT NORTHWESTERN HOSPITAL

Address: 800 East 28th Street Minneapolis, MN 55407
Website: www.allina.com/patientsafety
Phone number: 612-775-9762
Number of beds: 926

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**36,537 surgeries were performed at this facility during this time period**
Surgery performed on wrong patient	1	Deaths: 0; Serious Disability: 0; Neither: 1
Wrong surgical procedure performed	2	Deaths: 0; Serious Disability: 0; Neither: 2
Retention of a foreign object in a patient after surgery or other procedure	3	Deaths: 0; Serious Disability: 0; Neither: 3
Patient Protection Events		**There were 288,326 patient days at this facility during this time period**
Patient suicide or attempted suicide resulting in serious disability	1	Deaths: 0; Serious Disability: 1; Neither: 0
Care Management		**There were 288,326 patient days at this facility during this time period**
Hypoglycemia	1	Deaths: 1; Serious Disability: 0; Neither: 0
Environmental Events		**There were 288,326 patient days at this facility during this time period**
A fall while being cared for in a facility	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	9	Deaths: 2; Serious Disability: 1; Neither: 6

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.2

ALBERT LEA MEDICAL CENTER – MAYO HEALTH SYSTEM

Address: 404 West Fountain Street Albert Lea, MN 56007
Website: www.almedcenter.org
Phone number: 507-373-2384
Number of beds: 219

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**4,054 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 0; Serious Disability: 0; Neither: 1

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.3

BETHESDA REHABILITATION HOSPITAL

Address: 559 Capitol Boulevard St Paul, MN 55103
Website: www.healtheast.org/patientsafety
Phone number: 651-326-2273
Number of beds: 264

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Care Management		**There were 58,710 patient days at this facility during this time period**
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	2	Deaths: 0; Serious Disability: 0; Neither: 2
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 0; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.4

FAIRVIEW LAKES REGIONAL MEDICAL CENTER

Address: 5200 Fairview Boulevard Wyoming, MN 55092-8013
Website: www.fairview.org
Phone number: 651-982-7835
Number of beds: 70

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**4,687 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 0; Serious Disability: 0; Neither: 1

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.5

FAIRVIEW NORTHLAND REGIONAL HOSPITAL

Address: 911 Northland Drive Princeton, MN 55371
Website: www.fairview.org
Phone number: 763-389-6305
Number of beds: 41

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Product or Device Events		**There were 27,614 patient days at this facility during this time period**
The use or malfunction of a device in patient care	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 1; Serious Disability: 0; Neither: 0

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.6

FAIRVIEW RED WING MEDICAL CENTER

Address: 701 Fairview Blvd. Red Wing, MN 55066
Website: www.fairview.org
Phone number: 651-267-5757
Number of beds: 57

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**3,840 surgeries were performed at this facility during this time period**
Wrong surgical procedure performed	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 0; Serious Disability: 0; Neither: 1

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.7

FAIRVIEW RIDGES HOSPITAL

Address: 201 East Nicollet Boulevard Burnsville, MN 55337
Website: www.fairview.org
Phone number: 952-892-2262
Number of beds: 150

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**12,611 surgeries were performed at this facility during this time period**
Wrong surgical procedure performed	1	Deaths: 0; Serious Disability: 0; Neither: 1
Retention of a foreign object in a patient after surgery or other procedure	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 0; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.8

FAIRVIEW SOUTHDALE HOSPITAL

Address: 6401 France Avenue South Edina, MN 55435
Website: www.fairview.org
Phone number: 952-924-5161
Number of beds: 390

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**23,744 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	1	Deaths: 0; Serious Disability: 0; Neither: 1
Product or Device Events		**There were 131,466 patient days at this facility during this time period**
The use or malfunction of a device in patient care	1	Deaths: 1; Serious Disability: 0; Neither: 0
Environmental Events		**There were 131,466 patient days at this facility during this time period**
A fall while being cared for in a facility	2	Deaths: 2; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	4	Deaths: 3; Serious Disability: 0; Neither: 1

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.9

FAIRVIEW-UNIVERSITY MEDICAL CENTER

Address: 2450 Riverside Avenue Minneapolis, MN 55454
Website: www.fairview.org
Phone number: 612-672-6396
Number of beds: 1700

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**26,310 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	6	Deaths: 0; Serious Disability: 0; Neither: 6
Product or Device Events		**There were 362,802 patient days at this facility during this time period**
The use or malfunction of a device in patient care	1	Deaths: 1; Serious Disability: 0; Neither: 0
Care Management		**There were 362,802 patient days at this facility during this time period**
A medication error	1	Deaths: 0; Serious Disability: 1; Neither: 0
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	5	Deaths: 0; Serious Disability: 0; Neither: 5
TOTAL EVENTS FOR THIS FACILITY	13	Deaths: 1; Serious Disability: 1; Neither: 11

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.10

GILLETTE CHILDREN'S SPECIALTY HEALTHCARE

Address: 200 East University Avenue St. Paul, MN 55101
Website: www.gillettechildrens.org
Phone number: 651-229-1723
Number of beds: 60

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**3,470 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	1	Deaths: 0; Serious Disability: 0; Neither: 1
Retention of a foreign object in a patient after surgery or other procedure	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 0; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.11

GRANITE FALLS MUNICIPAL HOSPITAL AND MANOR

Address: 345 Tenth Ave. Granite Falls, MN 56241-1442
Website: www.gfmhm.com
Phone number: 320-564-3111
Number of beds: 30

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Environmental Events		**There were 13,222 patient days at this facility during this time period**
A fall while being cared for in a facility	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 1; Serious Disability: 0; Neither: 0

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.12

HENNEPIN COUNTY MEDICAL CENTER

Address: 701 Park Ave S Minneapolis, MN 55145-1829
Website: www.hcmc.org/patients/patientsafety
Phone number: 612-873-2338
Number of beds: 910

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**11,139 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	1	Deaths: 0; Serious Disability: 0; Neither: 1
Patient Protection Events		**There were 215,174 patient days at this facility during this time period**
Patient suicide or attempted suicide resulting in serious disability	1	Deaths: 0; Serious Disability: 1; Neither: 0
Care Management		**There were 215,174 patient days at this facility during this time period**
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	3	Deaths: 0; Serious Disability: 0; Neither: 3
Criminal Events		**There were 215,174 patient days at this facility during this time period**
Death or significant injury of patient or staff from physical assault	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	6	Deaths: 0; Serious Disability: 1; Neither: 5

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.13

IMMANUEL ST JOSEPH'S – MAYO HEALTH SYSTEM

Address: 1025 Marsh Street Mankato, MN 56001
Website: www.isj-mhs.org
Phone number: 507-345-2646
Number of beds: 272

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**8,338 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	1	Deaths: 0; Serious Disability: 0; Neither: 1
Death of a normal, healthy patient during or immediately after surgery	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 1; Serious Disability: 0; Neither: 1

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.14

METHODIST HOSPITAL PARK NICOLLET HEALTH SERVICES

Address: 6500 Excelsior Blvd. St Louis, MN 55426
Website: www.parknicollet.com/methodist/patients-visitors/patient_safety.cfm
Phone number: 952-993-5114
Number of beds: 426

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**25,860 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	6	Deaths: 0; Serious Disability: 0; Neither: 6
TOTAL EVENTS FOR THIS FACILITY	6	Deaths: 0; Serious Disability: 0; Neither: 6

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.15

NORTH COUNTRY HEALTH SERVICES

Address: 1300 Anne St. N.W. Bemidji, MN 56601-5103
Website: www.nchs.com/ptsafe.htm
Phone number: 218-333-5760
Number of beds: 98

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Care Management		**There were 49,582 patient days at this facility during this time period**
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	2	Deaths: 0; Serious Disability: 0; Neither: 2
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 0; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.16

NORTH MEMORIAL MEDICAL CENTER

Address: 3300 Oakdale Avenue North Robbinsdale, MN 55422
Website: www.northmemorial.com
Phone number: 763-520-5183
Number of beds: 518

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**23,637 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	3	Deaths: 0; Serious Disability: 0; Neither: 3
Care Management		**There were 202,022 patient days at this facility during this time period**
A medication error	1	Deaths: 1; Serious Disability: 0; Neither: 0
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	3	Deaths: 0; Serious Disability: 0; Neither: 3
TOTAL EVENTS FOR THIS FACILITY	7	Deaths: 1; Serious Disability: 0; Neither: 6

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.17

REGIONS HOSPITAL

Address: 640 Jackson Street St Paul MN 55101
Website: www.regionshospital.com
Phone number: 651-254-4725
Number of beds: 427

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**19,854 surgeries were performed at this facility during this time period**
Wrong surgical procedure performed	1	Deaths: 0; Serious Disability: 0; Neither: 1
Retention of a foreign object in a patient after surgery or other procedure	1	Deaths: 0; Serious Disability: 0; Neither: 1
Care Management		**There were 197,500 patient days at this facility during this time period**
A medication error	1	Deaths: 0; Serious Disability: 1; Neither: 0
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	1	Deaths: 0; Serious Disability: 0; Neither: 1
Environmental Events		**There were 197,500 patient days at this facility during this time period**
A fall while being cared for in a facility	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	5	Deaths: 1; Serious Disability: 1; Neither: 3

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.18

RIVERVIEW HEALTHCARE ASSOCIATION

Address: 323 S. Minnesota St. Crookston, MN 56716-1601
Website: www.riverviewhealth.org
Phone number: 612-775-9762
Number of beds: 49

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**2,871 surgeries were performed at this facility during this time period**
Death of a normal, healthy patient during or immediately after surgery	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 1; Serious Disability: 0; Neither: 0

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.19

ROCHESTER METHODIST HOSPITAL

Address: 201 West Center Street Rochester, MN 55902
Website: www.mayoclinic.org/event-reporting
Phone number: 507-284-5005
Number of beds: 794

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003–OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**28,438 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 0; Serious Disability: 0; Neither: 1

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.20

SAINT MARYS HOSPITAL

Address: 1216 Second Street SW Rochester, MN 55902
Website: www.mayoclinic.org/event-reporting
Phone number: 507-284-5005
Number of beds: 1157

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**38,259 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	1	Deaths: 0; Serious Disability: 0; Neither: 1
Retention of a foreign object in a patient after surgery or other procedure	2	Deaths: 0; Serious Disability: 0; Neither: 2
Care Management		**There were 485,961 patient days at this facility during this time period**
A medication error	2	Deaths: 2; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	5	Deaths: 2; Serious Disability: 0; Neither: 3

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.21

ST. CLOUD HOSPITAL

Address: 1406 Sixth Avenue North St. Cloud, MN 56303
Website: www.centracare.com
Phone number: 320-251-2700 ext 54100
Number of beds: 489

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**17,641 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	2	Deaths: 0; Serious Disability: 0; Neither: 2
Care Management		**There were 205,813 patient days at this facility during this time period**
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	2	Deaths: 0; Serious Disability: 0; Neither: 2
TOTAL EVENTS FOR THIS FACILITY	4	Deaths: 0; Serious Disability: 0; Neither: 4

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.22

ST. FRANCIS REGIONAL MEDICAL CENTER

Address: 1455 St. Francis Avenue Shakopee, MN 55379
Website: www.allina.com/patientsafety
Phone number: 612-775-9762
Number of beds: 70

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**5,440 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 0; Serious Disability: 0; Neither: 1

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.23

ST. JOHN'S HOSPITAL

Address: 1575 Beam Avenue Maplewood, MN 55109
Website: www.healtheast.org/patientsafety
Phone number: 651-326-2273
Number of beds: 184

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**8,198 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	2	Deaths: 0; Serious Disability: 0; Neither: 2
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 0; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.24

ST. JOSEPH'S HOSPITAL

Address: 69 West Exchange Street St. Paul, MN 55102
Website: www.healtheast.org/patientsafety
Phone number: 651-326-2273
Number of beds: 401

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**7,352 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	2	Deaths: 0; Serious Disability: 0; Neither: 2
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 0; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.25

ST. JOSEPH'S MEDICAL CENTER

Address: 523 North Third Street Brainerd, MN 56401
Website: www.sjmcmn.org
Phone number: 218-828-7339
Number of beds: 162

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Care Management		**There were 75,795 patient days at this facility during this time period**
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	2	Deaths: 0; Serious Disability: 0; Neither: 2
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 0; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.26

ST. LUKE'S HOSPITAL

Address: 915 East First Street Duluth, MN 55805
Website: www.slhduluth.com
Phone number: 218-249-5359, 218-249-5389
Number of beds: 267

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**12,790 surgeries were performed at this facility during this time period**
Retention of a foreign object in a patient after surgery or other procedure	2	Deaths: 0; Serious Disability: 0; Neither: 2
Product or Device Events		**There were 129,283 patient days at this facility during this time period**
The use or malfunction of a device in patient care	1	Deaths: 1; Serious Disability: 0; Neither: 0
Care Management		**There were 129,283 patient days at this facility during this time period**
A medication error	1	Deaths: 1; Serious Disability: 0; Neither: 0
Environmental Events		**There were 129,283 patient days at this facility during this time period**
A burn received while being cared for in a facility	1	Deaths: 1; Serious Disability: 0; Neither: 0
A fall while being cared for in a facility	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	6	Deaths: 4; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.27

ST. MARY'S MEDICAL CENTER

Address: 407 East Third Street Duluth, MN 55805
Website: www.smdc.org/customer_serv_patient_rep.cfm
Phone number: 218-786-3827
Number of beds: 380

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Care Management		**There were 133,523 patient days at this facility during this time period**
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	2	Deaths: 0; Serious Disability: 0; Neither: 2
Environmental Events		**There were 133,523 patient days at this facility during this time period**
A fall while being cared for in a facility	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	3	Deaths: 1; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.28

UNITED HOSPITAL

Address: 333 North Smith Avenue St. Paul, MN 55102
Website: www.allina.com/patientsafety
Phone number: 612-775-9762
Number of beds: 556

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**19,978 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	1	Deaths: 0; Serious Disability: 0; Neither: 1
Care Management		**There were 198,887 patient days at this facility during this time period**
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	2	Deaths: 0; Serious Disability: 0; Neither: 2

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.29

UNITY HOSPITAL

Address: 550 Osborne Road N.E. Fridley, MN 55432-2718
Website: www.allina.com/patientsafety
Phone number: 612-775-9762
Number of beds: 275

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Surgical Events		**11,046 surgeries were performed at this facility during this time period**
Surgery performed on wrong body part	2	Deaths: 0; Serious Disability: 0; Neither: 2
Retention of a foreign object in a patient after surgery or other procedure	1	Deaths: 0; Serious Disability: 0; Neither: 1
Environmental Events		**There were 98,412 patient days at this facility during this time period**
A fall while being cared for in a facility	1	Deaths: 1; Serious Disability: 0; Neither: 0
TOTAL EVENTS FOR THIS FACILITY	4	Deaths: 1; Serious Disability: 0; Neither: 3

TABLE 3: HOSPITAL-SPECIFIC DATA

TABLE 3.30

VALLEY HOSPITAL AT HIDDEN LAKES*

Address: 1300 Hidden Lakes Parkway Golden Valley, MN 55422
Website: www.regencyhospital.com
Phone number: 763-588-2750
Number of beds: 92

HOW TO READ THESE TABLES

These tables show the number of events reported at each hospital. They include the reported number for each of the 27 event types, organized under six categories. Categories and event types are not shown if no events were reported.

	REPORTED ADVERSE HEALTH EVENTS (JULY 1, 2003-OCTOBER 6, 2004)	
CATEGORY AND TYPE	NUMBER	BACKGROUND
Care Management		**There were 3,611 patient days at this facility during this time period**
Stage 3 or 4 pressure ulcers (with or without death or serious disability)	1	Deaths: 0; Serious Disability: 0; Neither: 1
TOTAL EVENTS FOR THIS FACILITY	1	Deaths: 0; Serious Disability: 0; Neither: 1

* Valley Hospital at Hidden Lakes was purchased by Regency Hospital Company after the reporting period and has been renamed Regency Hospital of Minneapolis.

APPENDIX A:
Definitions

ACTION PLAN
The product of the root cause analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, timelines, and strategies for measuring the effectiveness of the actions.[9]

ADVERSE EVENT
An untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.[10]

ERROR
Error is the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning). [11]

PATIENT SAFETY
Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur.[12]

ROOT CAUSE ANALYSIS
Root cause analysis is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist.[13]

SERIOUS DISABILITY [14]
(1) A physical or mental impairment that substantially limits one or more of the major life activities of an individual,
(2) A loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or
(3) Loss of a body part.

[9] Joint Commission on Accreditation of Healthcare Organizations, Sentinel Event Glossary of Terms, Online. Available at: http://www.jcaho.org/accredited+organizations/sentinel+event/glossary.htm. [Accessed January 2005]
[10] Ibid.
[11] National Quality Forum, Serious Reportable Events in Healthcare. Washington D.C., 2002.
[12] Institute of Medicine, To Err is Human: Building a Safer Health System. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds. Washington, D.C.: National Academy Press, 2000
[13] Joint Commission on Accreditation of Healthcare Organizations, Sentinel Event Glossary of Terms, Online. Available at: http://www.jcaho.org/accredited+organizations/sentinel+event/glossary.htm. [Accessed January 2005]
[14] Minnesota statutes 144.7065

APPENDIX B:
Reportable events as defined in the law

Below are the events that must be reported under the law. This language is taken directly from Minnesota statutes 144.7065.

SURGICAL EVENTS

1. Surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

2. Surgery performed on the wrong patient;

3. The wrong surgical procedure performed on a patient that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

4. Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained; and

5. Death during or immediately after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

PRODUCT OR DEVICE EVENTS

6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product;

7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Device includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators; and

8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

PATIENT PROTECTION EVENTS

9. An infant discharged to the wrong person;

10. Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have decision-making capacity; and

11. Patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

CARE MANAGEMENT EVENTS

12. Patient death or serious disability associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose;

13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products;

14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy;

APPENDIX B: (CONTINUED)
Reportable events as defined in the law

15. Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a facility;

16. Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. "Hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter;

17. Stage 3 or 4 ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission; and

18. Patient death or serious disability due to spinal manipulative therapy.

ENVIRONMENTAL EVENTS

19. Patient death or serious disability associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock;

20. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;

21. Patient death or serious disability associated with a burn incurred from any source while being cared for in a facility;

22. Patient death associated with a fall while being cared for in a facility; and

23. Patient death or serious disability associated with the use of or lack of restraints or bedrails while being cared for in a facility.

CRIMINAL EVENTS

24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;

25. Abduction of a patient of any age;

26. Sexual assault on a patient within or on the grounds of a facility; and

27. Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

APPENDIX C:
Background Information on the National Quality Forum and the "Serious Reportable Events"

NQF
NATIONAL QUALITY FORUM

MINNESOTA'S ADVERSE EVENT REPORTING LAW
by Kenneth W. Kizer, MD, MPH

The people of Minnesota today benefit from the release of "Adverse Health Events in Minnesota Hospitals," which details the most serious medical care errors that have occurred in Minnesota hospitals in the past year. Publication of this document demonstrates that Minnesota is in the vanguard of public reporting of medical errors.

Under state law, Minnesota hospitals must report the occurrence of any of the 27 so-called "never events" that are described in the National Quality Forum's report, Serious Reportable Events in Healthcare. This 2002 report presents a consensus list of harmful events that everyone agrees should never happen; they're known as "never events" because all stakeholders agree that these things should never happen in any care setting.

The objective of NQF's Serious Reportable Events project, which was undertaken at the request of the federal government, was to establish agreement among consumers, providers, purchasers, researchers and other healthcare stakeholders about those preventable adverse events that should never occur and to define them in a way that should they occur it would be clear what had to be reported to the authorities. The goal was to bring order to the chaos that typifies adverse event reporting in most of the relatively few states that have adverse event reporting laws.

Minnesota was the first state to require reporting of the entire NQF list of Serious Reportable Events. It has since been joined by Connecticut and New Jersey, and a number of other states are considering doing the same thing. Our hope is that before long all states will collect and publicly report data on the occurrence of these events, forming a national system for tracking the worst kinds of medical mishaps.

Why these events in particular? This was the set of events about which a diverse array of healthcare stakeholders were able to achieve consensus that the evidence was clear that the occurrence of these things was under the control of the healthcare facilities and the events simply should never happen. This consensus is very important. Getting the disparate groups of people with their divergent interests to agree on anything was a challenge; however, without such consensus there is not sufficient focus to get anything done. Indeed, that has been the experience of states having less clear reporting laws. To fix a problem there must be a common ground to which limited resources can be directed. The NQF list of "never events" provides that common ground.

The events on this list are clearly identifiable and measurable, and thus feasible to expect compliance with in a reporting system; and they are events for which the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility. The nature of these events is unambiguous, and they are usually preventable.

There is no question that lapses in patient safety are a major healthcare quality problem; that the occurrence of patient harm due to such lapses is too common; and that a large majority of these lapses are preventable. In the literature review, we learned that these lapses are rarely the result of professional misconduct or criminal acts, despite headlines that sometimes suggest the contrary. Instead, we found that the overwhelming majority of these lapses are unintended consequences of an exceedingly complex and imperfect healthcare delivery system.

The public expects healthcare professionals to go to great lengths to ensure that care is safe, and to the government and other oversight authorities to make sure that this is done. Part of providing oversight is collecting data and investigating serious adverse events. With the new law and its clearly defined list of adverse healthcare events, Minnesota's state government is now able to provide more effective oversight and to make healthcare safer.

Kenneth W. Kizer, MD, MPH, is President and CEO of the National Quality Forum, Washington, DC.

APPENDIX D:
Links and Other Resources

- Full text of Minnesota's Adverse Health Care Events Reporting Law can be found at: www.revisor.leg.state.mn.us/stats/144/ sections 144.706 through 144.7069

- Additional background information on the law can be found at: www.health.state.mn.us/patientsafety

- The Minnesota Alliance for Patient Safety (MAPS) was established in 2000 as a partnership between the Minnesota Hospital Association, Minnesota Medical Association, Minnesota Department of Health and more than 50 other public-private health care organizations working together to improve patient safety. More information about Minnesota's patient safety coalition can be found at: www.mnpatientsafety.org

- The federal Agency for Healthcare Research and Quality's (AHRQ) provides a number of safety and quality tips for consumers. The mission of AHRQ is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Information from AHRQ's research helps people make more informed decisions and improve the quality of health care services. The AHRQ tips for consumers can be found at: www.ahrq.gov/consumer/

- The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program, and works in partnership with the states to administer Medicaid and the State Children's Health Insurance Program (SCHIP). CMS has developed a number of quality improvement initiatives that can be found at: www.cms.hhs.gov/quality/

- Institute for Safe Medication Practices (ISMP) Alerts for Patients page containing a listing of frequent medication errors and how to avoid them, general information and advice on medication safety for consumers. The web address for this page is: www.ismp.org/Pages/Consumer.html

- The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) evaluates and accredits more than 15,000 health care organizations and programs in the United States. JCAHO's mission is to continuously improve the safety and quality of care provided to the public. JCAHO provides a number of patient safety tips for patients and consumers. This information can be found at: www.jcaho.org/general+public/index.htm

- Consumers Advancing Patient Safety (CAPS) is a consumer-led nonprofit organization, formed to be a collective voice for individuals, families and healers who wish to prevent harm in healthcare encounters through partnership and collaboration. CAPS envisions creating a healthcare system that is safe, compassionate and just. In addition to the CAPS resources available on their web site, this site also provides several links to other patient safety web sites of interest to consumers. www.patientsafety.org

- The National Academy for State Health Policy (NASHP) is a non-profit, non-partisan organization dedicated to helping states achieve excellence in health policy and practice. NASHP provides resources to compare patient safety initiatives and approaches across the states. www.nashp.org

- The Leapfrog Group is an initiative driven by organizations that buy health care who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans. The Leapfrog website provides quality and safety information about hospitals that consumers can search. www.leapfroggroup.org

This list represents only a small fraction of the resources available on patient safety. The web sites listed here provide an example of the types of information available. There are additional local and national resources on patient safety that can provide valuable information for patients, consumers, purchasers and policy-makers.

GOLDEN RULE BUILDING
85 EAST SEVENTH PLACE, SUITE 400
P.O. BOX 64882
ST. PAUL, MN 55164-0882
651-215-5800

WWW.HEALTH.STATE.MN.US

Recommendations on Systems Improvements to Advance Evidence-Based Health Care

Report to the Legislature

Minnesota Department of Health

January 2005

MINNESOTA MDH DEPARTMENT OF HEALTH

Commissioner's Office
85 East Seventh Place, Suite 400
P.O. Box 64882
St. Paul, MN 55164-0882
(651) 215-1300
www.health.state.mn.us

Dear Colleague:

Physicians and researchers have been working over the course of the past several decades to objectively and scientifically examine which care delivery models and methods work best for certain types of conditions and for the average patient under normal circumstances. The more widespread use of "evidence-based medicine" and the acceleration in the use of "best clinical practice" can improve patient care, provide better patient outcomes, and has the potential of lowering health care costs.

In September 2004, a distinguished panel of health experts was formed to advise on how best to encourage the use of evidence-based guidelines by providers and consumers. Representation on this panel include: Dr. Gordon Mosser, Institute for Clinical Systems Improvement; Dr. Patricia Lindholm, MN Medical Assn.; Dr. Brian Anderson, MN Hospital Assn.; Dr. John St. Peter, MN Pharmacists Assn.; Kathi Koehn, MN Nurses Assn.; Carolyn Jones, Chamber of Commerce; Carolyn Pare, Buyers Health Care Action Group; Dr. Charlie Fazio, MN Council of Health Plans; and Co-Chairs Dr. Mac Baird, University of MN and Patsy Riley, Stratis Health.

On behalf of the experts listed above, we are pleased to provide you with a copy of *Recommendations on Systems Improvements to Advance Evidence-Based Health Care: A Report to the Legislature.* As required by 2004 Minn. Laws Chapter 288, Article 7, Section 2, this report provides an update to the legislature on the implementation of current and ongoing activities in the areas of evidence-based guidelines.

This status report discusses the panel's recommendations to use a series of linked strategies that promote timely access to and appropriate use of evidence-based health care guidelines in systems that are designed to continually improve outcomes. The strategies outlined are focused in the following five areas: develop and assure access to evidence-based guidelines; build systems improvements; measure and publicly report health care performance; align incentives and reward for improvement; and utilize government to facilitate and collaborate in the pursuit of the four strategies above.

Questions and comments on the report can be directed to Lin Nelson 651/215-5816 or Shawn Holmes at 651/215-8987.

Sincerely,

Dr. Macaran Baird, Co-Chair
University of Minnesota

Patsy Riley, Co-Chair
Stratis Health

Dianne Mandernach
Commissioner
MN Department of Health

Executive Summary

The Minnesota Legislature, recognizing the important role that the appropriate use of high quality scientific evidence can play in improving the quality of care and decreasing costs in Minnesota's healthcare system, passed legislation in May 2004, directing Minnesota's state agencies to "encourage the adoption of best practice guidelines and participation in best practice activities by physicians, other health care providers and health plan companies." The legislation further directed the Commissioner of Health to "facilitate access to best practice guidelines and quality of care measurement information for providers, purchasers, and consumers …"

This report provides an update to the legislature on the implementation of current and ongoing activities in the areas of evidence-based health care guidelines. The work of a distinguished panel of health experts – who serve as the project ad hoc steering committee – is the first phase of an effort to improve the quality of health care in Minnesota by encouraging clinicians to adopt best practices or evidence-based health care guidelines (EBHCG). The steering committee's charge was to advise the Governor's Health Care Cabinet on how to best meet the mandate of the legislature (see Appendix A) and to advise on how to best encourage the use of EBHCG by providers and consumers.

The following are actions taken by the Health Care Cabinet in recent months:

- Created an ad hoc group to provide them with recommendations regarding the issues and legislation on evidence-based health care guidelines, which encompasses the body of this report.
- Adopted an initial list of five health issues to be addressed by the ad hoc group mentioned above – asthma, diabetes, hypertension, back pain and depression. These health issues were identified as priority areas due to their high volume of health care costs generated annually and the high-level quality work already completed by national and state health organizations in researching evidence-based health care guidelines used in assessing and treating these conditions.
- Endorsed the work of the MN Community Measurement Project as a good first step to empowering consumers with easy access information (www.mnhealthcare.org). The Community Measurement Project measures the quality of care patients receive in comparison to the physician-designed standards recommended by the Institute of Clinical Systems Improvement (ICSI). (www.icsi.org).
- Developed a new health information website (www.minnesotahealthinfo.org) sponsored by the Minnesota Department of Health to provide consumers and purchasers with access to standardized, easy-to understand information about health care costs and quality.
- Formed the Smart Buy Alliance to adopt and utilize uniform measures of quality and results and will purchase health care based upon those measurements. To the extent procedures are used as a basis for payment, procedures that have demonstrated the best results will be featured and rewarded.

The ad hoc group supports the action taken by the Governor's Health Care Cabinet as they should facilitate the use of evidence-based health care guidelines. Furthermore, the group recommends a series of linked strategies that promote evidence-based health care guidelines (EBHCG) in systems of care designed to continually improve outcomes. These are:

- **Develop and Assure Access to Evidence-based Guidelines**
- **Build Systems Improvements**
- **Measure and Publicly Report Health Care Performance**
- **Align Incentives and Reward for Improvement**
- **Utilize Government to Facilitate and Collaborate in the Pursuit of the Four Strategies Noted Above.**

Table of Contents

Introduction 4

Background 5

- Evidence-based Health Care Guidelines & the Six Aims for Improvement 6
- Barriers & Challenges 7

Methodology 7

Develop & Assure Access to Evidence-based Guidelines 8

Build Systems Improvements 8

Measure & Publicly Report Health Care Performance 11

Align Incentives & Reward for Improvement 12

Utilize Government to Facilitate & Collaborate in the Pursuit of the Four Strategies Noted Above 12

Appendices 14

- Appendix A – Legislation 15
- Appendix B – Health Care Guidelines Work Group Membership 18
- Appendix C – Guidelines References 19
- Appendix D – Description of Evidence-based Health Care Guidelines For Asthma, Diabetes & Hypertension 21

Introduction

While Minnesota and the United States have committed health care professionals who deliver excellent care under most circumstances, there is widespread evidence that there is substantial room for improvement in the delivery of health care services. This is especially important in terms of reducing medical errors, improving health care outcomes, and decreasing costs. Efforts should focus on building a health care system that is safer and at the same time more effective and efficient in terms of cost, quality, and timeliness.

The evidence from scientific study shows that there is wide variation on the care delivered to patients[1]. Patients may receive different treatments for the same condition depending on which part of the country they live in, if they live in an urban or outstate area, which provider they see, and even their racial or ethnic background plays a role in the type of treatment they may receive. Too often patients receive care that is not the best that medicine has to offer for their condition.

The variation in care described above is not the result of providers not trying hard enough or being smart enough. Our health care system has become so complex and the volume of new information increases so quickly that unless systems of support are rapidly put in place to help clinicians provide consistently high quality care, we run the risk of overwhelming the clinicians and further compromising the quality of clinical care. These systems are so complicated that identifying specific guidelines is not enough.

Another major factor in this variation is due to patients' choices and available community factors that support healthy choices. Patients often desire the heavily advertised medications or technical interventions, even though less expensive and more scientifically supported choices are recommended by "best evidence". Similarly, patients' economic and community resources vary widely and may directly influence factors important to improved health such as exercise, a healthy diet, meaningful daily tasks, and positive reinforcement for changing to a healthier behavior pattern.

Physicians and researchers have been working over the course of the past several decades to objectively and scientifically examine which care delivery models and methods work best for certain types of conditions and for the average patient under normal circumstances.

The more widespread use of "evidence-based medicine" and the acceleration in the use of "best clinical practice" can improve patient care, provide better patient outcomes, and has the potential of lowering health care costs.

Minnesotans spend nearly $23 billion annually on health care services, 1/8 of our entire Minnesota economy, yet we have very little information on how effectively that money is spent. The cost of poor health goes beyond that when we look at societal impact. By incorporating information gained from scientific study of health care outcomes, providers can ensure that their patients are receiving the best quality care for their condition.

The Minnesota Legislature, recognizing the important role that the appropriate use of scientific evidence can play in potentially improving the quality of care and decreasing costs in Minnesota's healthcare system, passed legislation in May 2004, directing Minnesota's state agencies to "encourage the adoption of best practice guidelines and participation in best practice activities by

[1] McGlynn, et.al, "The Quality of Health Care delivered to Adults in the United States" N Engl J Med 2003; 349:1866-1868, Nov 6, 2003

physicians, other health care providers and health plan companies." The legislature further directed the Commissioner of Health to "facilitate access to providers, purchasers, and consumers by…"

This report provides an update on the implementation of current and ongoing activities in the areas of evidence-based health care guidelines (EBHCG). The work of a distinguished panel of health experts – who serve as the project ad hoc steering committee – is the first phase of an effort to improve the quality of health care in Minnesota by encouraging clinicians to adopt best practices or EBHCG. The ad hoc group's charge was to advise the Governor's Health Care Cabinet on how to best meet the mandate of the legislature (see Appendix A) and to advise on how to best encourage the use of EBHCG by providers and consumers.

Background

In February 2004, Governor Tim Pawlenty announced the formation of a Health Care Cabinet to begin the implementation of many of the recommendations made by the Minnesota Citizens Forum on Health Care Costs and to consider other administrative and legislative reform ideas. The Forum, led by former U.S. Senator Dave Durenberger, was appointed by the governor in the fall of 2003 to develop recommendations for improving the cost and quality of health care in Minnesota.

In May, legislation passed by the Minnesota Legislature, signed into law by Governor Pawlenty and being coordinated by the Minnesota Department of Health, has the potential to improve health care outcomes while also reducing the cost of care for Minnesotans.

The Health Care Cabinet formed an ad hoc group of health experts to pursue discussions on the adoption of evidence-based health care guidelines for specific health issues in Minnesota. An initial list of five health issues was chosen – asthma, diabetes, hypertension, back pain and depression. These issues have been identified as priority areas due to their prevalence and high volume of health care costs generated annually and the high-level quality work already completed by national and state health organizations in researching evidence-based practices to be used in treating these conditions.

The ad hoc steering committee is comprised of representatives from the MN Pharmacists Association, MN Medical Association, MN Nurses Association, MN Hospital Association, University of Minnesota, Stratis Health, Institute for Clinical Systems Improvement, MN Council of Health Plans, MN Chamber of Commerce and the Buyers Health Care Action Group. Dr. Macaran Baird with the University of Minnesota and Patsy Riley with Stratis Health are co-chairing this effort. (See Appendix B for complete membership list.)

The work group met six times since September 2004. Numerous presentations have been made during these meetings including:

- Community Measurement Project
- Institute for Clinical Systems Improvement (ICSI) Health Care Guidelines Development
- DOQ-IT – Doctor's Office Quality – Information Technology
- MN Diabetes Program
- MN Asthma Plan
- Heart Disease and Stroke Plan 2004-2010

For the purposes of this report, the ad hoc committee will concentrate their discussion on asthma, diabetes and hypertension. These are three of the five health topic areas originally identified by the Health Care Cabinet.

Evidence-based Health Care Guidelines and the "Six Aims for Improvement"

The Institute of Medicine (IOM) recently published the report, *Crossing the Quality Chasm*, in which it issued a challenge to all sectors of health care to "adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States."[2,3] The IOM contended that while medical science and technology have achieved rapid advancements, the health care delivery system has been unable to translate this scientific progress into high quality care for all Americans. The Institute of Medicine has stated the lag between the discovery of more effective forms of treatment and their incorporation into routine patient care averages 17 years. The IOM proposed six "aims for improvement" - dimensions in which the current health care systems function below optimal levels. A health care system that achieves major gains in these six dimensions will provide better patient care that represents a substantial improvement over today's system. Many of the principles addressed in six aims for health care improvement are embodied within the practice of evidence-based health care guidelines. The IOM report defines "evidenced based practice" as:

Six Guiding Aims of Health Care Should Be:

Safe *Avoid injuries to patients from care that is intended to help them.*

Effective *Provide services based on scientific knowledge to all who could benefit; refrain from providing services to those unlikely to benefit (avoid underuse and overuse, respectively).*

Patient-centered *Provide care that is respectful of and responsive to individual patient preferences, needs, values; ensure that patient values guide all clinical decisions.*

Timely *Reduce waits and potentially harmful delays for both those who receive and those who give care.*

Efficient *Avoid waste of equipment, supplies, ideas, and energy.*

Equitable *Provide care that does not vary in quality because of personal characteristics such as gender, ethnicity, geography, or socioeconomic status.*

> "Evidence-based practice is the integration of best research evidence with clinical expertise and patient values. *Best research evidence* refers to clinically relevant research, often from the basic health and medical sciences, but especially from patient-centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination); the power of prognostic markers; and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. *Clinical expertise* means the ability to use clinical skills and past experience to rapidly identify each patient's unique health state and diagnosis, individual risks and benefits of potential interventions, and personal values and expectations. *Patient values* refers to the unique preferences, concerns, and expectations that each patient brings to a clinical encounter and that must be integrated into clinical decisions if they are to serve the patient."

The ad hoc group's definition of an evidence-based health care guideline is in strong alignment with the IOM's six aims: **"an evidence-based statement of how to prevent or manage a particular symptom or disease for an individual patient under normal circumstances, taking into account the preferences of the patient or his or her family."**[4] Evidence-based health care guidelines can play an active role in helping achieve the six aims of the IOM report.

[2] Crossing the Quality Chasm. 2003 National Academy of Sciences http://books.nap.edu/catalog/10027.html

[3] Berwick DM. A user's manual for the IOM's 'Quality Chasm' report. Health Affairs 2002;21(3):80-90

[4] The ad hoc group recommended that this definition, which is based on the ICSI definition, be used for the purposes of this report.

Barriers/Challenges
Implementation of evidence into practice has been incomplete due to the lack of organization systems support to effectively utilize the volume of information and the lack of rapid feedback of outcomes measures.

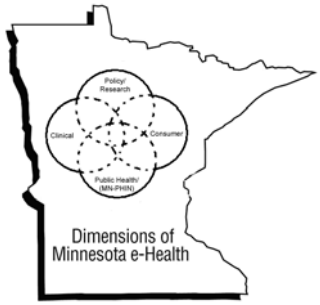


Figure 1. Four Dimensions of Minnesota's e-Health Initiative
Minnesota e-Health is a statewide public-private collaboration to accelerate the use of health information technology in Minnesota. Its goal is to make the information needed for good health decisions available whenever and wherever health decisions are made. It encompasses four dimensions representing users of health information: Public Health (state and local), Clinical (health care providers and health plans), Consumers (all of us), and Policy and Research (health education and research institutions). The maximum value is realized for all of us when we share information across all four dimensions.

Electronic decision support systems are a valuable tool that should be used to accelerate access to high-quality evidence-based health care guidelines. They can make a difference to the quality of health care – by giving clinicians and consumers access to relevant, evidence-based information at the point of care. **However, for these electronic decision support arrangements to be effective, it is essential that there is a nationally coordinated approach in their development and that a state/national governance structure is in place to provide direction and coordination.** An integral part of this group's work has been to recommend a way for ensuring a national approach to the development of electronic decision support systems, including governance arrangements, priorities, timetables and cost implications. The work of the MN e-Health Steering Committee will be an important component to ensure the development of sustainable, nationally integrated, electronic decision support systems. In Minnesota, the e-Health Initiative, a partnership of MDH and healthcare organizations, is poised to ride this wave of support. They have four strategic goals: inform clinical practice, interconnect clinicians, personalize care, and improve population health.

Methodology

The ad hoc committee recommends a series of linked strategies that promote timely access to and appropriate use of evidence-based health care guidelines in systems that are designed to continually improve outcomes. These recommendations and strategies are organized in the following areas throughout the remainder of this report:

- Develop and Assure Access to Evidence-based Guidelines
- Build Systems Improvements
- Measure and Publicly Report Health Care Performance
- Align Incentives and Reward for Improvement
- Utilize Government to Facilitate and Collaborate in the Pursuit of the Four Strategies Noted Above.

Develop and Assure Access to Evidence-based Guidelines

The committee agreed that many versions of evidence-based health care guidelines are available and utilized by providers and agreed that the following criteria should be met when selecting a guideline:

1. Scope and application are clear.
2. Authorship is stated, and any conflicts of interest are disclosed.
3. Authors represent all pertinent clinical fields (or other means of input have been used).
4. The development process is explicitly stated.
5. The guideline is grounded in evidence.
6. The evidence is cited and graded.
7. The document itself is clear and practical.
8. The document is flexible in use; i.e. exceptions are noted or provided for with general statements.
9. Measures are included for use in systems improvement.
10. Scheduled review and updating are provided for.

The ad hoc committee reviewed several guidelines that are referenced in Appendix C. After careful consideration, they agreed that the guidelines in Appendices C and D meet the above list of criteria. Among the recommended guidelines are those adopted by ICSI, which is a homegrown Minnesota organization. ICSI's presence in Minnesota demonstrates 80 percent consensus on adopted guidelines by clinicians. This is accomplished by involving stakeholders in the region to participate in reviewing national guidelines and achieving consensus on guidelines adopted and used in the provider community. ICSI is a collaboration of 50 medical groups and hospital systems and is sponsored by six health plans. Membership includes 55 hospitals and medical practices totaling 7400 physicians. ICSI is a notable example of systems improvement collaboration in Minnesota

Recommendation: The above criteria should be evaluated when utilizing any EBHCG. In addition, the guideline information for asthma, diabetes and hypertension in Appendix D should be included on the MDH website www.minnesotahealthinfo.org. **These guidelines have broad support in MN, meet the criteria listed above and, if posted on the website, will be disseminated in a way that is useable and attractive.**

Build Systems Improvements

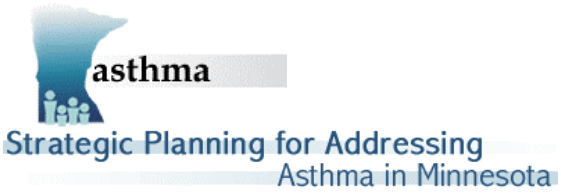
The view of quality should be shifted from something produced by one clinician working by him or herself to the view that quality is predominantly a manifestation of the system in which clinicians work. The ad hoc committee acknowledges that many organizations have assumed leadership positions in the three health issues of focus. The committee reviewed the work of the asthma, diabetes, and heart disease programs at the Minnesota Department of Health (MDH). In addition, they discussed the Stratis Health collaborative on congestive heart failure and diabetes; ICSI's training and collaborative efforts throughout the state; and various other endeavors in Minnesota that focus on organization system improvements that support better health outcomes. The clinical indications of asthma, diabetes and hypertension involve care provided in multiple health care settings and organizations, care funded both privately and publicly, and care provided by a variety of health care professionals. Patients, clinicians and families should fully understand the purpose of guidelines, how to use them properly, what their limitations are, and how they relate to other therapies. The ad hoc group expressed the importance of providing consumer-based information and incentives to influence patients to engage in self-management activities, such as attending group

classes and self-monitoring glucose levels from home. It is extremely important that this information meets the needs of our diverse populations. Self-management and self-management support are not only desirable but also necessary to bridge the quality chasm.

Knowing that diabetes, heart attack and stroke are largely preventable, a comprehensive approach is needed to institute positive change. Research has shown that health is related to both the physical and social environment. Culture, environments, social norms, policies, regulations, and laws impact behaviors of individuals. These social and environmental elements can promote, support, and reinforce healthy behaviors and contribute to the reduction of diabetes, heart disease and stroke.[5]

The ad hoc group utilized the comprehensive structure of the socio-economic approach in the development of their recommendations. The work cited below has completed significant work based on that approach.

Asthma



To reduce asthma's burden, the public, individuals with asthma, their families, caregivers, health systems, health care providers, schools, employers, childcare providers, community groups and others must all work together in a coordinated approach. The Minnesota Asthma Plan addresses recommendations in the areas of:

- Awareness
- Education
- Public Policy
- Data & Surveillance

The Minnesota Department of Health's Asthma Program is implementing several of the recommendations in the Strategic Plan for Addressing Asthma in MN. The plan was developed through a broad-based stakeholder group and can be seen at http://www.health.state.mn.us/divs/hpcd/cdee/asthma/StatePlan.html. Key plan recommendations include ensuring that providers are aware of and follow, to the extent possible, asthma guidelines in managing asthma - National Institutes of Health - National Heart, Lung, and Blood Institute (NIH-NHLBI). These recommendations, coupled with community collaboration, are seen as mechanisms for accelerating system-level change toward eliminating or drastically reducing asthma-related emergency department visits or hospitalizations.

[5] Minnesota Cardiovascular Health Steering Committee and Minnesota Department of Health. (2004***) Minnesota Heart Disease and Stroke Prevention Plan 2004-2010***. St. Paul, Minnesota: Minnesota Department of Health.

Diabetes

MINNESOTA DIABETES PROGRAM

The Minnesota Diabetes Program is dedicated to improving the health of all Minnesota's by reducing the impact of diabetes. To achieve this we…

- Facilitate partnerships with health systems, communities and other stakeholders,
- Convene forums to identify common interests and foster action,
- Translate health research and information into practice,
- Promote and develop innovative, effective and culturally appropriate health promotion strategies,
- Focus on populations.

Since 1980, the Minnesota Diabetes Program (MDP) has provided strong leadership to engage stakeholders in working together to improve the quality of life for Minnesotans with diabetes and to reduce the human and economic burden of diabetes for all Minnesotans. The MDP has a long history of partnership that includes: working with the Minnesota Diabetes Steering Committee to develop and implement the statewide diabetes plan, *Minnesota Diabetes Plan 2010: Creating a Healthier Future for All People in Minnesota (the Plan)*; working with the Minnesota Diabetes Surveillance and Data Review Advisory Committee to create the *Diabetes in Minnesota* data report; establishing and monitoring statewide diabetes public health objectives, including preventive care practices; developing and implementing programs to eliminate health disparities such as the annual *Changing Faces of Diabetes* conference for health professionals serving Minnesota's populations of color; and, since the mid-1980s, developing and implementing clinical and community-based diabetes quality improvement programs such as Project IDEAL, a randomized control study, conducted with Health Partners, to evaluate the effectiveness of a diabetes primary care quality improvement intervention. In addition, the MDP has recently conducted an initiative to determine the appropriate strategies for diabetes prevention in Minnesota. The MDP is primarily a CDC-funded program and more information can be found at www.health.state.mn.us/diabetes.

Hypertension

The ***Minnesota Heart Disease and Stroke Prevention Plan 2004-2010*** provides a blueprint and call to action for individuals, communities, and organizations to collaborate to reduce the incidence, complications and mortality rates of heart disease and stroke. Many can and need to be involved by taking action and implementing the recommended strategies in the document.

The Minnesota Heart Disease and Stroke Prevention (HDSP) Program at the Minnesota Department of Health is leading the implementation of the Minnesota Heart Disease and Stroke Prevention Plan 2004-2010. This strategic plan was developed by a diverse group of stakeholders across the state – in healthcare, worksite, schools, community, land planning and transportation settings. Hypertension control is a key objective in this plan and priority area for the HDSP Program. One key strategy that the program has implemented was to offer training to professionals on the current guidelines for hypertension treatment and standardized blood pressure measurements. Several strategies address behavior changes, such as increasing physical activity and improving eating habits. Other key strategies include improving disease-management in the health care system and promoting hypertension screening in high-risk populations. The plan can be seen at http://www.health.state.mn.us/cvhplan.

Recommendation: Support for these programs should continue as they leverage federal funding to provide a systems approach in facilitating the use of evidence-based health care guidelines to a multi-disciplined team of providers, communities, schools and others necessary in providing tools to inform clinicians and consumers. In addition, state agencies should proactively engage the private sector delivery systems, providers and public health resources in these collaborative efforts. Active participation by professional societies should be solicited.

Key strategies are needed to coordinate the many efforts to make better use of all members of the health care team and catalyze the diffusion of consumer education for self-management and self-management support for these conditions. **Strategies aimed to improve organizational systems of care needed to improve consumer outcomes and thereby improve consumer satisfaction include:**

- **Develop and maintain tailored learning mechanisms for providers and consumers.**
- **Provide access to technical support for implementation, including a tool kit to support providers.**
- **Assure support at the organizational level for implementation.**
- **Provide feedback on evaluation results to providers.**
- **Provide mechanisms for dialogue between physician champions and practitioners who are reluctant adopters.**
- **Implement information technologies to facilitate adoption and implementation of evidence-based health care guidelines.**
    - **Decision support – integration of evidence-based guidelines into daily practice.**
    - **Clinical information systems – reminder and feedback systems for clinicians and the tools to plan care for both individuals and whole populations of patients.**
- **Incorporate and reimburse the use of case-managers into the care process.**
- **Identify and disseminate evidence-based self-management practices.**
- **Recognize the centrality of self-management to good patient care, and incorporate this recognition into the health care culture.**
- **Develop self-management programs and tools that are applicable to diverse populations.**

Measure and Publicly Report Health Care Performance

To provide information to consumers, clinicians and other stakeholders, a multifaceted evaluation and measurement approach is considered necessary. One firmly grounded in practice, focused upon both outcome and process measurements and appropriately adjusted for difference in patient populations and other factors outside the control of the health care system. The newly developed MN Community Measurement Project (CMP) (www.mnhealthcare.org) measures the quality of care patients receive in comparison to the physician-designed standards recommended by the Institute of Clinical Systems Improvement (ICSI). ICSI considers both scientific evidence and local physician expertise as it develops evidence-based health care guidelines for treating various conditions and diseases. These guidelines are available to all providers. The recent CMP report results show that as expected, there is variation in care among providers and across all measures. No provider group has the highest or lowest rate across all measures. The Minnesota CMP is an attempt to help consumers decide where to get the best care. This privately sponsored enterprise is a first step and its effectiveness should be evaluated to determine its utility for continued development.

Recommendation:

- **Collaborate in measurement activities to increase efficiency, minimize any data burden and avoid duplication.**
- **Ensure utility of measurement to provide timely, valid and useful information at the point of need.**
- **Develop a standard measurement process across the state to assist in determining root causes of why outcomes are not being met.**

Align Incentives and Reward for Improvement

A system of incentives and rewards for excellence are positive motivators to clinicians and/or organizations to perform at a higher level. Successful facilitation of EBHCG must include buy-in from stakeholders – clinicians, patients, advocacy groups, payers, and academic researchers at both the broad state and local level. Structured mechanisms must be available to provide clinicians with information, updates, and logistical support, as well as immediate (i.e., "bedside") assistance with difficult or complex cases. Achieving this buy-in requires the appropriate incentives and rewards. Certain direct financial, indirect financial and non-financial incentives may accelerate and promote guideline adoption. Identifying the benefits of evidence-based health care guidelines to consumers, clinicians and provider organizations is essential, for example: usage leads to more cost-effective practice (so that there is less requirement to subsidize ineffective practice); and measurable improved quality of performance.

Recommendations:

- **Provide incentives for the appropriate use of self-management support integrated into the delivery of health care.**
- **Define an appropriate mix of financial solutions—focused not only on health insurance, but also on such alternatives as schools, community health foundations, and state health departments—to effectively deliver a package of evidence-based chronic disease management and community services. These resources would be linked to communitywide aims established through a process of community activation, such as a multi-stakeholder coalition.**
- **Align financial incentives at the hospital and system levels. An immediate effort to reward providers for building systems improvements to improve quality of care is essential as a means to hasten the implementation of well-established evidence-based health care guidelines (electronic health records, computerized prescription writing, etc.)**

Utilize Government to Facilitate and Collaborate in the Pursuit of the Four Strategies Noted Above

This was discussed throughout the development of the recommendations and strategies in the previous categories. The group agreed that government had a unique role in disseminating information to consumers, clinicians and various stakeholders.

Recommendations that government should:

- **Continue to address the high cost - high volume health issues.**
- **Commit to rational purchasing strategies as agreed in the Smart Buy Alliance.**
- **Support efforts to develop more effective dissemination methods and tailored learning approaches to guidelines through various state programs (i.e. asthma, diabetes, and hypertension) to increase visibility at all levels of the community and permeate messages.**

- **Ensure synergy between public and private sector, i.e. continued support for the Community Measurement Project and proactively engaging in public-private partnerships.**
- **Reinforce infrastructure for effective care coordination, measurement and outreach.**
- **Develop small-scale demonstration projects and multilevel collaborations across health systems with the emphasis on outcomes, such as patients being healthier and more satisfied with their care. These demonstration projects could include more flexibility to cover treatment modalities using the telephone or e-mail follow-up with patients.**
- **Consider revising the enacting legislation. The current language in statute is misleading and may be misinterpreted. The group has developed specific language changes that are attached in Appendix A, Part2.**
- **Facilitate discussions and advice from stakeholders when choosing to collaborate with a quality improvement organization.**
- **Avoid punitive endeavors aimed at rooting out and punishing individual bad actors – efforts of this kind destroy openness about systems faults and undermine collaboration for systems improvement.**

Recommendations that government should not:

- **The legislature should not adopt as statute any specific evidence-based health care guideline as it would be a detriment to the ever expanding body of knowledge and ability to remain fluid in implementation.**

Appendices

- **Appendix A – Legislation**
- **Appendix B – Health Care Guidelines Work Group Membership List**
- **Appendix C – Guideline Reference**
- **Appendix D – Descriptions of Evidence-based Health Care Guidelines for Asthma, Diabetes and Hypertension**

Appendix A - Legislation

SESSION LAWS 2004, CHAPTER 288, ARTICLE 7, SECTION 2: HF 2277
Article 7: Health Care Cost Containment
Sec. 2. [62J.43] [BEST PRACTICES AND QUALITY IMPROVEMENT.]

(a) To improve quality and reduce health care costs, state agencies shall encourage the adoption of best practice guidelines and participation in best practices measurement activities by physicians, other health care providers, and health plan companies. The commissioner of health shall facilitate access to best practice guidelines and quality of care measurement information to providers, purchasers, and consumers by:

(1) identifying and promoting local community-based, physician-designed best practices care across the Minnesota health care system;

(2) disseminating information available to the commissioner on adherence to best practices care by physicians and other health care providers in Minnesota;

(3) educating consumers and purchasers on how to effectively use this information in choosing their providers and in making purchasing decisions; and

(4) making best practices and quality care measurement information available to enrollees and program participants through the Department of Health's Web site. The commissioner may convene an advisory committee to ensure that the Web site is designed to provide user friendly and easy accessibility.

(b) The commissioner of health shall collaborate with a nonprofit Minnesota quality improvement organization specializing in best practices and quality of care measurements to provide best practices criteria and assist in the collection of the data.

(c) The initial best practices and quality of care measurement criteria developed shall include asthma, diabetes, and at least two other preventive health measures. Hypertension and coronary artery disease shall be included within one year following availability.

(d) The commissioners of human services and employee relations may use the data to make decisions about contracts they enter into with health plan companies.

(e) This section does not apply if the best practices guidelines authorize or recommend denial of treatment, food, or fluids necessary to sustain life on the basis of the patient's age or expected length of life or the patient's present or predicted disability, degree of medical dependency, or quality of life.

(f) The commissioner of health, human services, and employee relations shall report to the legislature by January 15, 2005, on the status of best practices and quality of care initiatives, and shall present recommendations to the legislature on any statutory changes needed to increase the effectiveness of these initiatives.

(g) This section expires June 30, 2006.

SESSION LAWS 2004, CHAPTER 288, ARTICLE 7, SECTION 2: HF 2277
Article 7: Health Care Cost Containment
Sec. 2. [62J.43] [~~BEST PRACTICES~~ EVIDENCE-BASED HEALTH CARE GUIDELINES AND QUALITY IMPROVEMENT.]

(a) To improve quality and reduce health care costs, state agencies shall encourage the use ~~adoption~~ of ~~best practice~~ evidence-based health care guidelines and participation in ~~best practices~~ evidence-based health care guidelines measurement activities by physicians, other health care providers, and health plan companies. The commissioner of health shall facilitate access to ~~best practice~~ evidence-based health care guidelines and quality of care measurement information to providers, purchasers, and consumers by:

(1) identifying and promoting local community-based, physician-designed ~~best practices~~ evidence-based health care guidelines care across the Minnesota health care system;

(2) disseminating information available to the commissioner on ~~adherence~~ to ~~best practices~~ evidence-based health care guidelines care provided by physicians and other health care providers in Minnesota;

(3) educating consumers and purchasers on how to effectively use this information in choosing their providers and in making purchasing decisions; and

(4) making evidence-based health care guidelines ~~best practices~~ and quality care measurement information available to enrollees and program participants through the Department of Health's Web site. The commissioner may convene an advisory committee to ensure that the Web site is designed to provide user friendly and easy accessibility.

(b) The commissioner of health shall collaborate with a nonprofit Minnesota quality improvement organization specializing in best practices and quality of care measurements to provide ~~best practices~~ evidence-based health care guidelines criteria and assist in the collection of the data.

(c) The initial ~~best practices~~ evidence-based health care guidelines and quality of care measurement criteria ~~developed~~ reviewed shall include asthma, diabetes, and at least two other preventive health measures. Hypertension and coronary artery disease shall be included within one year following availability.

(d) The commissioners of human services and employee relations may use the data to make decisions about contracts they enter into with health plan companies.

(e) This section does not apply if the ~~best practices~~ evidence-based health care guidelines authorize or recommend denial of treatment, food, or fluids necessary to sustain life on the basis of the patient's age or expected length of life or the patient's present or predicted disability, degree of medical dependency, or quality of life.

(f) The commissioner of health, human services, and employee relations shall report to the legislature by January 15, 2005, on the status of ~~best practices~~ evidence-based health care guidelines and quality of care initiatives, and shall present recommendations to the legislature on any statutory changes needed to increase the effectiveness of these initiatives.

(g) This section expires June 30, 2006.

Appendix B - Health Care Guidelines Work Group Membership List

Dr. Macaran Baird, Co-Chair
University of Minnesota

Patsy Riley, Co-Chair
Stratis Health

Dr. Gordon Mosser
Institute for Clinical Systems Improvement

Dr. Patricia Lindholm
MN Medical Association

Dr. Brian Anderson
MN Hospital Association

Dr. John St. Peter
MN Pharmacists Association

Kathi Koehn
MN Nurses Association

Carolyn Jones
Chamber of Commerce

Carolyn Pare
Buyers Health Care Action Group

Dr. Charlie Fazio
MN Council of Health Plans

Appendix C – Guideline References

Asthma Guidelines from Other Organizations and Electronic Sources

1. Acute and chronic asthma. University of Texas Medical Branch Correctional Managed Care 1999 Jan (revised 2002 Apr). http://www.guidelines.gov/summary/summary.aspx?doc_id=3474

2. Allergen immunotherapy: a practice parameter. American Academy of Allergy, Asthma and Immunology - American College of Allergy, Asthma and Immunology - Joint Council of Allergy, Asthma and Immunology, 1996 (revised 2003 Jan). http://www.jcaai.org/Param/ParamDocs/Shots.doc

3. Allergic rhinitis and its impact on asthma. Allergic Rhinitis and its Impact on Asthma Workshop Group - 2001 Nov. http://www.guidelines.gov/summary/summary.aspx?doc_id=3421

4. Asthma. University of Michigan Health System. 1996 Dec (revised 2000 Jan). http://cme.med.umich.edu/pdf/guideline/asthma.pdf

5. British guideline on the management of asthma. British Thoracic Society Scottish. 2003 Jan. http://www.guidelines.gov/summary/summary.aspx?doc_id=3656

6. Evidence based clinical practice guideline for managing an acute exacerbation of asthma. Cincinnati Children's Hospital Medical Center. 1998 Jul 20 (revised 2002 Sep 3) http://www.cincinnatichildrens.org/Services/Departments-Divisions/Health_Policy_Clinical_Effectiveness/clinical-guidelines.htm

7. Global strategy for asthma management and prevention. National Heart, Lung, and Blood Institute (U.S.) - World Health Organization. 1995 Jan (revised 2003). http://www.ginasthma.com/wr.html

8. Key clinical activities for quality asthma care: recommendations of the National Asthma Education and Prevention Program. Centers for Disease Control and Prevention & National Asthma Education and Prevention Program. 2003 Mar http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5206a1.htm

9. Management of asthma. National Medical Research Council (Singapore Ministry of Health) 2002 Jan. http://www.guidelines.gov/summary/summary.aspx?doc_id=3275

10. Pulmonary rehabilitation. American Association for Respiratory Care-Professional Association. 2002. http://www.rcjournal.com/online_resources/cpgs/prcpg.html

11. The diagnosis and treatment of adult asthma. New Zealand Guidelines Group - 2002 Sep. http://www.guidelines.gov/summary/summary.aspx?doc_id=3462

Appendix C – Guideline References *(continued)*

Diabetes Guidelines from Other Organizations and Electronic Sources

1. Aspirin therapy in diabetes. American Diabetes Association - Republished 2003 Jan). http://www.guidelines.gov/summary/summary.aspx?ss=15&doc_id=3575&string=

2. Basic guidelines for diabetes care. California Diabetes Prevention and Control Program - revised 2002 Jan). http://www.guidelines.gov/summary/summary.aspx?ss=15&doc_id=3414&string=

3. Benefits and risks of controlling blood glucose levels in patients with type 2 diabetes mellitus. American Academy of Family Physicians & American Diabetes Association. http://www.guidelines.gov/summary/summary.aspx?ss=15&doc_id=2377&string=

4. Care of children with diabetes in the school and day care setting. American Diabetes Association - 1998 (republished 2003 Jan). http://www.guidelines.gov/summary/summary.aspx?ss=15&doc_id=3586&string=

5. Care of the patient with diabetes mellitus. 3rd edition. American Optometric Association - Association. 1993 (revised 2002 Aug 17). http://www.aoanet.org/eweb/Documents/CPG-3.pdf

6. Diabetes mellitus. Nutrition management for older adults. American Academy of Family Physicians - Medical Specialty Society American Dietetic Association Nutrition Screening Initiative - 2002. http://www.aafp.org/PreBuilt/NSI_DM.pdf

7. Diabetes nutrition recommendations for health care institutions. American Diabetes Association - Professional Association. 1996 Aug, republished 2004. http://care.diabetesjournals.org/cgi/content/full/27/suppl_1/s55

8. Diabetic foot disorders: a clinical practice guideline. American College of Foot and Ankle Orthopedics and Medicine & American College of Foot and Ankle Surgeons. 2000 http://www.acfas.org/diabeticcpg.html

9. Diabetic retinopathy. American Academy of Ophthalmology - 1998 Sep (revised 2003). http://www.aao.org/aao/education/library/ppp/index.cfm

10. Gestational diabetes mellitus. American Diabetes Association 1986 (revised 2000; republished 2004 Jan). http://care.diabetesjournals.org/cgi/content/full/27/suppl_1/s88

11. Gestational diabetes practice guidelines. International Diabetes Center - 2000 (revised 2003). http://www.guidelines.gov/summary/summary.aspx?ss=15&doc_id=4160&string=

12. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. National Academy of Clinical Biochemistry - 2002. http://www.clinchem.org/cgi/content/full/48/3/436

13. Hyperglycemic crises in diabetes. American Diabetes Association (republished 2004 Jan). http://care.diabetesjournals.org/cgi/content/full/27/suppl_1/s94

Appendix D – Descriptions of Evidence-based Health Care Guidelines for Asthma, Diabetes and Hypertension

Asthma

GUIDELINE TITLE: Diagnosis and management of asthma.
AUTHORSHIP: Institute for Clinical Systems Improvement (ICSI). May 2003
MAIN OBJECTIVES OF THE GUIDELINE:

1. To promote the accurate assessment of asthma and its severity by the use of objective measures of lung function.
2. To promote the long term control of persistent asthma by the use of corticosteroid medications.
3. To promote partnership relations between health care professionals and patients/guardians through asthma education and utilization of written action plans.

SCOPE OF THE GUIDELINE:

- Covers both acute and chronic asthma in patients 5 years of age or older with asthma like symptoms and/or previous diagnosis of asthma.
- Includes recommendations for couseling, diagnosis, evaluation, management and treatment of the condition.

MAJOR RECOMMENDATIONS:
ICSI presents its recommendation for diagnosing and managing asthma in the form of an algorithm (see website) with 10 components connected by an integrated pathway. The algorithm is accompanied by detailed explanations and annotations. The main clinical highlights include:

1. Conducting evaluations of asthma at regular intervals including medical history and physical exam, and evaluation of potential asthma triggers, allergens, measurement of breathing function, and consideration of allergic testing.
2. Regular assessment of asthma control.
3. Matching medical intervention with the severity of asthma symptoms and adjusting as future evaluations necessitate.
4. Use of anti-inflammatory drug treatment to achieve the effective control of chronic persistent asthma.
5. Provide asthma education to patients and parents including basic facts, proper inhaler use, written action plans and home peak flow rate monitoring, symptom diary, steps to achieve environmental control, and importance of regular follow-up visits with care provider.

ELECTRONIC SOURCE: http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=162

GUIDELINE TITLE: Guidelines for the Diagnosis and Management of Asthma.
AUTHORSHIP: National Asthma Education and Prevention Program – National Institute of Health (NIH) – 1997 (Revised in Nov 2002).
MAIN OBJECTIVES OF THE GUIDELINE (revised version):

1. To convey the importance of the essential components of the original asthma management document produced by this panel in 1997 (assessment, monitoring, controlling, pharmacotherapy, and education).
2. To identify essential steps on the preventative aspects of asthma care.
3. To provide information to help employer health benefit managers and health care planners make decisions regarding the delivery of quality health care for employees-enrollees with asthma to

reduce patient symptoms, aggravation of symptoms and thereby to reduce the overall nationl burden asthma related illness and death.

SCOPE OF THE GUIDELINE:

- Addresses the condition of asthma without mention of acute/chronic status.
- Targeted patients include infants, children and adults with asthma.

MAJOR RECOMMENDATIONS:

While the NAEPP does not use an algorithm diagram like ICSI to summarize its guideline, it does have a detailed recommended path of action for the diagnosis, management and prevention of asthma symptoms. The main clinical highlights include:

Assessment and monitoring, establishing the asthma diagnosis.

1. Classify the severity of the asthma.
2. Scheduling of routine follow-up care.
3. Assessment for possible referral to specialty care.
4. Recommending measures for the control of asthma triggers.
5. Consider and treat all comorbid conditions.
6. Prescribe medications as indicated by the assessment of severity.
7. Monitor the use of Beta2-Agonist Drugs.
8. Develop a well-written clear asthma management plan document.
9. Provide regular self-management education to patient/parents.

ELECTRONIC SOURCE: http://www.nhlbi.nih.gov/guidelines/asthma/

Diabetes

GUIDELINE TITLE: Management of Diabetes Mellitus Type 2.
AUTHORSHIP: Institute for Clinical Systems Improvement. November 2004
MAIN OBJECTIVES OF THE GUIDELINE:
To provide a comprehensive approach to the management of "prediabetes" (impaired fasting glucose or impaired glucose tolerance) and type 2 diabetes mellitus to include nutrition therapy, physical activity recommendations, pharmacologic therapy, self-management, as well as prevention and diagnosis of diabetes-associated complications and risk factors.
SCOPE OF THE GUIDELINE:

- Type 2 diabetics account for 90% of all diabetics patients in the USA (estimated to be about 7 million people). Applies to adult patients 18 and over with pre or type 2 diabetes.
- Clinical specialities addressed endocrinology, family practice, internal medicine, nutrition, and pharmacology.

MAJOR RECOMMENDATIONS:
ICSI's best practice recommendations for the patients with type 2 diabetes are summarized in four distinct algorithms accompanied by a detailed description. The four algorithms are for 1) Diagnosis and Early Treatment, 2) Glycemic Control, 3) Blood Pressure Control, and 4) Ongoing Diabetes Management. See the ICSI web site for detailed discussion and annotations of the algorithms.
ELECTRONIC SOURCE: http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=182

GUIDELINE TITLE: [Diabetes] Clinical Recommendations for 2004.
AUTHORSHIP: American Diabetes Association, Inc.. January 2004
MAIN OBJECTIVES OF THE GUIDELINE:
To provide clinicians, patients, researchers, health plans, and benefits purchasers with the necessary components for quality diabetic care, desired treatment outcomes, and the tools and methods necessary to evaluate the quality of diabetic care being delivered.
SCOPE OF THE GUIDELINE:

- Type 1 & 2 diabetes, gestational diabetes, and other forms of diabetes attributed to other causes.
- Applicable to all individuals currently with or with known risk factors for developing diabetes as well as all pregnant women.
- Germain to the fields of endocrinology, geriatrics, family practice, internal medicin, pediatrics and OBGYN.

MAJOR RECOMMENDATIONS: The focus of recommendations in this guideline addresses four key areas. These are 1) Screening, 2) Diagnosis, 3) Treatment, 4) Management. While not presented in an ICSI like algorithm, the main components of this guideline are included in the website.
ELECTRONIC SOURCE: http://care.diabetesjournals.org/content/vol27/suppl_1/

Hypertension

GUIDELINE TITLE: Hypertension Diagnosis and Treatment.
AUTHORSHIP: Institute for Clinical Systems Improvement. February 2004
MAIN OBJECTIVES OF THE GUIDELINE:

- Increase the percentage of patients in blood pressure control.
- Improve the assessment of patients with hypertension.
- Increase the percentage of patients not at blood pressure goal who have a change in subsequent therapy.
- Increase the percentage of patients with hypertension who receive patient education, especially in the use of non-pharmacological treatments.

SCOPE OF THE GUIDELINE:
Adults age 18 or older.

- Confirmation of hypertension is based on the initial visit, plus two follow-up visits with at least two blood-pressure measures at each visit.
- Standardized blood pressure measurement techniques should be employed when confirming an initially elevated BP and for all subsequent measures during follow-up and treatment for hypertension.

MAJOR RECOMMENDATIONS:

- A thiazide-type diuretic should be considered as initial therapy in most patients.
- Physician reluctance to intensify treatment is a major obstacle to achieving treatment goals.
- Systolic blood pressure level should be the major factor for the detection, evaluation and treatment of hypertension, especially in adults 60 years and older.

ELECTRONIC SOURCE: http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=173

GUIDELINE TITLE: Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure – JNC7. December 2003
AUTHORSHIP: U.S. Department of Health and Human Services – National Institutes of Health; National Heart, Lung and Blood Institute
MAIN OBJECTIVES OF THE GUIDELINE:

- Provide an update to the 1997 JNC6 guideline through the inclusion of new hypertension observational studies and clinical trial information.
- Simplify the classification of blood pressure for adults ages 18 and older.
- Provide clinicians with a more clear and concise guidelines that may be used to their maximum benefit.
- The classification of blood pressure includes the addition of a prehypertension category and stage 2 and 3 hypertension has been combined.

SCOPE OF THE GUIDELINE:

- Adults ages 18 and older.

MAJOR RECOMMENDATIONS:

- Thiazide-type diuretics should be used in drug treatment for most patients with uncomplicated hypertension.
- Certain high-risk conditions are compelling indications for the initial use of other antihypertensive drug classes.
- Emphasizes the need for increased education of health care professionals and the public to reduce blood pressure levels. The guideline provides hypertension prevention strategies.

ELECTRONIC SOURCE: http://www.nhlbi.nih.gov/guidelines/hypertension/jncintro.htm