Testimony of
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Minnesota Department of Health
Before the United States Senate
Permanent Subcommittee on Investigations
Hearing on
Patient Safety: Instilling Hospital with a Culture of Continuous Improvement

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Thank you for providing me the opportunity to participate in this very important hearing. I am Dianne Mandernach, the Commissioner of the Minnesota Department of Health.

Today I am pleased to share with you some very exciting steps that the State of Minnesota has recently taken to establish a process for the mandatory reporting of serious adverse events, commonly referred to as "medical errors." These efforts go beyond the mere reporting of the events to include the review of information on the underlying cause of the events, the review of corrective actions taken by the reporting hospital, dissemination of information regarding these events and public reporting by type and location of the event. This law integrates many of the recommendations of the Institute of Medicine (IOM) but more importantly, the law provides for accountability within hospitals and to the public. Before discussing the specifics of our legislation, however, I would like to make a few general comments on the issue of patient safety.

Since the 1999 release of the Institute of Medicine's landmark report on patient safety; To Err is Human, we have been flooded with information on this issue from a variety of sources – the media, professional associations, government agencies, and academia. However, the issue of patient safety has been one of my core values for many years.

As the former CEO of a hospital in northern Minnesota, I was very aware of the need for assuring that systems were in place to promptly and accurately identify both errors and potential errors, often referred to as the "near misses." It was my responsibility to assure that steps were taken to quickly, fairly and objectively review any incident and then to make sure that corrective actions were implemented to minimize the occurrence of similar events. The need for ongoing, continuous quality improvement within every institution is a theme that we have repeatedly heard today. I strongly support the initiatives that are being taken by the Joint Commission regarding the reporting of sentinel events as well as the efforts of the Agency for Healthcare Research and Quality (AHRQ), the Leapfrog Group, the National Patient Safety Foundation and the National Quality Forum (NQF). However as the topic of the hearing suggests – instilling hospitals with a culture of continuous improvement, - we must understand that the efforts taken within the hospital will always be the most important, the most direct and the most timely to truly minimize and prevent the occurrence of medical errors.

As Commissioner of Health, I am ultimately responsible for assuring that the care and services provided in state licensed facilities protect the health and safety of patients. Every media story reporting on the serious consequences of medical errors reinforces this need to assure that there is public accountability and follow-up on these serious events.

The formation of the Minnesota Alliance for Patient Safety (MAPS) was one of Minnesota's key responses to the IOM report. MAPS was jointly established by the Minnesota Department of Health, the Minnesota Hospital Association and the Minnesota Medical Association with the mission to "promote optimum patient safety through collaborative and supportive efforts among all participants of the health care system in Minnesota." MAPS now consists of over 50 health care related organizations. MAPS has become a collaborative forum to discuss the implications of medical errors in the health care system; to provide educational and training programs, and to disseminate the successful efforts undertaken by hospitals to reduce errors. The public/private make-up of MAPS has provided opportunities for frank but open discussion on many of the sensitive issues surrounding this topic – access to information, confidentiality, public reporting, legal liability, and others. Without this collaborative process, passage of our mandatory reporting law would have been much more difficult if not impossible. As chair of the Minnesota Hospital Association, David Page played a pivotal role in convincing other hospitals to actively participate in MAPS and the importance to support the efforts to improve patient safety.

The need for and the development of a mandatory reporting system was one of the more controversial discussion topics undertaken by MAPS. Concerns were raised about the benefits of a mandatory versus voluntary reporting system, the types of events to be reported, the ability to analyze the information to identify trends, the ability to provide appropriate follow-up and recommendations for change and the role of government in this process. A subgroup of MAPS was established to review the provisions of the Minnesota's current reporting law, to discuss elements that would be included in any effective medical error reporting system and to prepare recommendations for changes for the 2003 legislative session. I am very pleased that these efforts lead to the bipartisan sponsorship and passage of our Senate File 1019, the Minnesota Adverse Health Care Events Reporting Act of 2003.

One of the key attributes of this law is the inclusion of the reportable events recommended by the National Quality Forum. This list of 27 "never events" i.e., events that should never occur in a hospital such as wrong site surgery, represented a consensus of many interested parties as to what should be included in any mandatory reporting system. This list provided an effective starting point for a medical error reporting system. It is our understanding that Minnesota's law is the first ever in the nation to specifically incorporate the NQF recommendations. The NQF list was consistent with the criteria established by the IOM that a mandatory reporting system focus on serious adverse events and that the events to be reported be defined as clearly as possible.

However, in order to take steps to provide patient protection, any reporting law must go beyond the mere collection of statistics. Our reporting law mandates that information be reported as to the cause of the error as well as the corrective actions taken by the facility. These crucial elements address our concerns as to internal and external accountability and assure that appropriate actions are taken in the facility to protect patient health and safety. In addition, the law directs the Commissioner to review the information to determine whether trends or system problems are being identified and to also furnish information to all providers to assist in the improvement of their patient safety systems.

While Senate File 1019 made significant changes to the reporting laws in the state, the legislation was discussed, debated and enacted in an environment of consensus. As with every piece of legislation, the fine points of the law were often debated; but there was no serious opposition to the need for the law or its value to the enhancement of patient safety. The collaborative process of

MAPS, and the public/private nature of that organization was an asset during the legislative deliberations on the bill.

The major stumbling block to passage was the fiscal impact of the bill in a legislative session focused on dealing with major budget deficits. A "transition plan" was proposed that would allow for a phased implementation of the law. A key provision was the agreement that the Department would not be required to implement the law until sufficient non-state funds were obtained. Bill proponents, and especially the Minnesota Hospital Association believed that the initial start-up funds of approximately $125, 000 could be obtained from either private sources or through grants. The willingness of the hospitals to secure the necessary funds to implement the transition phase of the bill was strong recognition of the commitment to this process.

The transition phase requires that hospitals report the 27 events to the incident reporting system currently maintained by the Hospital Association and requires that the Department be provided summary data on the numbers and types of reported events. This information will for the first time provide a clear picture of the magnitude of the occurrence of medical errors in the state.

We are aware that many states have established systems for the reporting of medical errors. However, we are proud that our law is based on the 27 "never events" recommended by the NQF. The inclusion of these events, which were based on a consensus process among many stakeholders, will hopefully minimize underreporting or non-reporting of the events. This specific listing will allow for easier trend analysis within the state. The use of this listing greatly contributed to gaining consensus on the mandatory reporting law.

There are some recommendations and suggestions that I would like you to consider in the future.

We would encourage a national system that would focus on the mandatory reporting of these specific events. I realize that this will generate some problems for states with existing reporting systems; however, this is the only way that we can get a national perspective on the true extent of this problem. The collection of clearly identified events across state lines will also assist in the identification of trends, the identification of system problems and will encourage more collaborative responses to improving patient safety.

A part of this recommendation is a request for obtaining funds to support these efforts. We realize that funding is always a concern but if steps can be taken to minimize the extent of medical errors, the price paid for these systems will be money well spent. Funding could be directed at the development of demonstration projects or pilot programs to allow for an analysis of the effectiveness of various state systems. However, we are well past the time for continued discussion and debate and systems need to be put in place as quickly as possible.

We hope that the efforts of AHRQ and other organizations continue to address these concerns and to provide information on both public policy and clinical issues. While mandatory reporting is very important, there needs to be continuing efforts to assure that hospitals and other health care facilities have the resources and tools to continue their efforts in developing effective internal quality improvement systems. The federal government should continue to support research in patient safety.

Finally, we encourage that steps be taken through the Medicare and Medicaid survey and certification programs to address both the internal and external reporting of medical errors. Regulations and regulatory agencies should balance the need for public accountability and safety

with the need for internal quality improvement efforts. Consistent expectations for the reporting and monitoring of these events and funding for these activities is a critical component to provide accountability to the public that we represent.

I would be happy to respond to your questions.