

Barbara D. Woolley
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To: Mark A. Kitchens/WHO/EOP@EOP, Stephanie A. Cutter/WHO/EOP@EOP
cc: Devorah R. Adler/OPD/EOP@EOP, Karin Kullman/OPD/EOP@EOP
Subject: Press Stake Out List - Medical Errors Event

Barbara Blakeney
1st Vice President, American Nurses Association
Waltham, MA

Donald Berwick, MD
President and CEO, Institute for Healthcare Improvement
Boston, MA

Lucian Leape, MD
Adjunct Professor of Health Policy
Department of Health Policy Management, Harvard School of Public Health
Boston, MA

Gail Warden
President and CEO, Henry Ford Health System
Detroit, MI

Mary Wakefield, RN
Director, Center for Health Policy and Ethics
Fairfax, VA

Janet Corrigan
Director, Quality of Care Initiative
Washington, DC

Brian Lindburgh
Consumer Coalition for Quality Healthcare
Washington, DC

Arthur Levin, MPH
Director, Center for Medical Consumers
New York, NY

Ken Kizer, MD
President and CEO, National Quality Forum
New York, NY

Chris Queram
National Business Coalition on Health
Madison, WI

WASHINGTON

Clinton proposes ways to stop medical errors

President Clinton announces today a series of steps designed to improve patient safety, including creation of a nationwide system to closely monitor and reduce the number of serious medical mistakes that kill tens of thousands of Americans each year.

Senior White House officials said the proposals are aimed at reducing medical errors by 50% within five years. The reporting system, which would be state-

based, would require the reporting of preventable medical errors that led to death or serious injury. Twenty-three states now require that serious medical mistakes be reported to state health authorities.

Also, regulations will be issued requiring the 6,000 hospitals that participate in Medicare to have error-reduction programs. The Defense Department, which operates 500 hospitals and clinics that serve 8 million patients, will also be required to report mistakes and have such programs.

A presidential task force submitted the recommendations after a National Academy of Sciences report that estimated 44,000 to 98,000 Americans a year die because of medical errors.

The report said those mistakes range from doctors misinterpreting symptoms to illegible prescriptions causing the wrong drugs to be given.

— Laurence McQuillan

American Medical Association

Physicians dedicated to the health of America



FOR IMMEDIATE RELEASE

February 22, 2000

AMA SUPPORTS PATIENT SAFETY GOALS; CAUTIONS AGAINST "CULTURE OF BLAME"

Statement attributable to:

Nancy W. Dickey, MD
AMA Immediate-Past President

"The AMA supports President Clinton's goal of reducing health system errors and improving patient safety, and we agree with many of his proposals. However, we are concerned that the proposal for mandatory reporting will not improve patient safety and may, in fact, have the perverse result of driving errors underground. Effective aviation safety programs have taught us that a culture of safety is created by avoiding a culture of blame. The same principle holds true for the health system.

"The AMA and the medical specialty societies have been pioneers in the effort to reduce health system errors. Based on our work, we agree with many of the President's proposals for steps the private sector and government can take to improve patient safety. We support the President's call for increased funds to research errors and disseminate the findings to improve health care. We also concur with the proposal to modify pharmaceutical packaging and marketing practices to reduce medication errors. Prompt action is needed on many consensus areas for improving patient safety.

"However, the AMA is opposed to the expansion of mandatory reporting of medical errors. There is no evidence to show that mandatory reporting improves patient safety. Before we expand data collection activities we need to analyze existing state systems to determine the most effective use of finite resources.

"The AMA appreciates President Clinton's statement of support for protecting the confidentiality of peer review activities. But we are concerned that the protections do not go far enough to promote the type of information sharing that would help create a culture of safety where all members of the health system can learn from and prevent errors."

#

For more information, please call:

Brenda L. Craine
AMA Media - Washington
202/789-7447



Contact: Carol Schadelbauer, (202) 626-2342
Alicia Mitchell, (202) 626-2339
Dionne Dougall, (202) 626-2284

Statement on the Federal Quality Interagency Coordination Task Force Report

Dick Davidson
President
February 22, 2000

Providing the best care possible to our patients is the mission of every one of the nation's hospitals. Our dedicated caregivers strive to give the best care 24 hours a day, 7 days a week. And we continually try to improve.

That's why hospitals have systems in place to reduce the potential for error, including strong quality policies and procedures and intensive staff training. They have quality teams of caregivers who examine unexpected deaths, treatment errors and accidents to identify and correct the cause swiftly. And hospitals have safety departments to develop and oversee policies to prevent these incidents.

Just a few weeks ago, I stood in the Rose Garden with the President committing the nation's hospitals to a focused effort to prevent and reduce medication errors. Since then, we've shared "best practices" on error prevention with each and every hospital and they're taking the steps needed to make real change within their institutions. We're committed to providing the tools and resources necessary to help them in this effort.

We're pleased that the Administration shares our goal of improving safety. Congressional proposals and today's plan from the Administration demonstrate a commitment to improving patient care. The Administration's plan is an important part of the debate. While we have only seen a draft outline of the plan, it has some good ideas, raises many unanswered questions and requires additional work to become a prescription for patient safety.

To have an effective reporting system that actually reduces errors, we need strong protections so doctors and nurses will come forward without fear of retribution. The heart of the issue is finding ways to improve our systems—the checks and balances designed to help prevent future errors. Without these protections, we could drive error reporting underground and miss important opportunities to protect patients.

One of our key questions is does the Administration's plan include adequate protections that create an environment that spurs discussion and learning. We will work with the Administration, Congress and all caregivers to answer this and other important questions.

**Statement of Greater New York Hospital Association (GNYHA)
on President Clinton's Initiative to Reduce Medical Errors**

Greater New York Hospital Association (GNYHA) is totally committed to the reduction of medical errors and, with its members, is exploring all avenues to make sure the patients of New York receive the best and safest medical care possible.

In New York, we have a sophisticated, mandatory reporting system in place that has public accountability and disclosure at many points. Under the New York Patient Occurrence Reporting and Tracking System (NYPORTS), hospitals must report all serious adverse events to the New York State Department of Health (DOH). Hospitals are also required to submit a full analysis of the event within 45 days. While the content of each report is not publicly disclosable, the aggregate number of reports by each provider as well as the categories of the reports are disclosable. In addition, the DOH has the option to follow up and investigate any adverse event that was reported. Any deficiency that is identified by the DOH is publicly disclosable.

The initiative that is being announced today by President Clinton demonstrates a commitment to reducing medical errors and improving patient safety. Its broad principles should be embraced by all hospitals. GNYHA looks forward to working with the Administration and Congress on this important initiative.

Greater New York Hospital Association represents 175 not-for-profit hospitals and long term care facilities, both public and voluntary, in the New York metropolitan area.

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February 22, 2000

Clinton to Propose a System to Reduce Medical Mistakes

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By ROBERT PEAR

WASHINGTON, Feb. 21 -- President Clinton will order all hospitals in the United States to take steps to reduce medical errors that kill tens of thousands of people each year, and he will urge states to require the reporting of such errors, administration officials said today.

At the White House on Tuesday, Mr. Clinton plans to call for a nationwide system of reporting medical errors, somewhat like the system used by airlines to report aviation safety hazards, the officials said. Rather than trying to impose a federal requirement now, he is pressuring the states to adopt reporting requirements within three years.

The American Medical Association and the American Hospital Association have vehemently opposed mandatory reporting of errors, saying it could expose doctors and hospitals to more lawsuits. If doctors and hospital employees fear being sued, they said, they will be reluctant to discuss the lessons that could be learned from their mistakes. Even Mr. Clinton's own advisers had suggested that the administration move cautiously.

But aides said Mr. Clinton would endorse virtually all the recommendations made three months ago by the National Academy of Sciences in a report on medical errors.

Specifically, they said, Mr. Clinton will endorse the academy's goal of reducing medical mistakes by 50 percent over five years. He will also ask Congress for \$20 million to create a Center for Quality Improvement and Patient Safety, as part of the federal Agency for Health Care Research and Quality, in the Department of Health and Human Services.

While some of the president's recommendations require

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Congressional approval, he already has ample authority under existing laws to require other steps.

For example, officials said, the federal government is developing a regulation to require more than 6,000 hospitals that participate in Medicare to have programs to reduce medical errors, including mistakes in the dispensing of drugs. Under the regulation, to be published this year, many hospitals would establish automated systems for ordering prescription drugs, to avoid the mistakes caused by a doctor's bad handwriting or by confusion over telephone orders.

Hospitals must meet federal standards as a condition of getting Medicare money, which accounts for about 40 percent of hospital revenue, on the average. Using this lever, the federal government sets detailed standards covering every aspect of hospital activity, from sanitation to fire safety to infection control.

President Clinton's proposals, or something similar, seem likely to become reality for four reasons. The issue has great appeal to consumers, and this is an election year. The government already has the power to do much of what Mr. Clinton wants. Congress is eager to take action. And lawmakers have a convenient vehicle, the patients' bill of rights, now pending before a conference committee of House and Senate negotiators.

White House documents say the Food and Drug Administration will develop new standards to prevent errors caused by drug names that sound alike and packages that look alike. In addition, new labeling standards will require drug makers to highlight dangerous drug interactions and common dosage errors.

The F.D.A. is also developing a system to allow doctors, nurses and pharmacists to report medication errors online.

All 500 military hospitals and clinics and more than 3,000 blood banks will have to report serious errors under the president's plan.

But the most controversial element of the president's plan is his support for mandatory reporting to the states of all medical errors that cause serious injury or death.

Hospitals reporting errors would be publicly identified. The names of doctors, nurses and patients would be kept confidential. But doctors and hospitals said that such details could often be inferred and that even the public reports could be used to strengthen the hand of plaintiffs' lawyers in malpractice lawsuits.

In addition, the president, like the National Academy of Sciences, will call for voluntary reporting of less serious errors, including close calls, administration officials said.

Medical mistakes include the use of the wrong drugs, errors in blood transfusions, surgery on the wrong body part or the wrong patient and improper insertion of catheters or feeding tubes.

The White House struggled to find the right balance between

mandatory and voluntary reporting, between secrecy and disclosure. In interviews last month, federal health officials said they were unwilling to embrace the academy's call for a new federal law requiring hospitals to report all mistakes that cause serious injury or death. Despite such reservations, Mr. Clinton decided to support mandatory reporting.

White House documents show that Mr. Clinton will announce three basic conclusions on Tuesday:

- Patients should have access to information about "preventable medical errors" that cause serious injuries. If a person dies because of such a mistake, the patient's relatives should be able to get information about the error.
- Congress should pass legislation to prevent patients and their lawyers from gaining access to a hospital's analysis and investigation of the causes of medical errors.
- Patients should not lose any of the rights they now have to sue doctors and hospitals for malpractice or negligence.

Chris Jennings, the health policy coordinator at the White House, said: "These actions will significantly reduce the likelihood of lawsuits and concerns about liability. We will avoid errors and problems that might be subject to litigation."

The president's initiative leaves some important questions unanswered: What is the definition of a serious medical error? What is the federal role in the proposed new reporting system? Will states get additional money to catalog and analyze reports of errors?

Dr. Nancy W. Dickey, former president of the American Medical Association, said: "We are opposed to mandatory reporting. It may well drive underground the very information you need to improve safety. A number of states have mandatory reporting, and there's no evidence that they have greater safety or fewer errors."

Richard J. Davidson, president of the American Hospital Association, said his group had been invited to the White House event but would not attend.

"We thought we had an agreement to work with the White House in a public-private partnership, but there has been little or no consultation," Mr. Davidson said. "That's a serious disappointment. The idea that a mandatory reporting system is going to change behavior is naïve at best. You need to focus on making a cultural change in hospitals, to promote open discussion of errors, and that's not possible if some plaintiff's attorney is climbing on your back."

The White House said that 18 states, including New York, New Jersey and Connecticut, already required hospitals to report certain kinds of mistakes and "adverse events." But in many states, the number of reports is relatively small, because doctors and hospitals fear the data will be used in lawsuits.

President Clinton's goal is to ensure that "all 50 states have

mandatory reporting systems" within three years, the White House said. If that does not happen, federal officials will offer further recommendations on what should be done to achieve the goal. And if research shows that mandatory reporting does not enhance patient safety, the White House said, federal officials will reconsider their recommendations.

The report from the National Academy of Sciences last November touched off a flurry of activity on Capitol Hill. Members of Congress from both parties -- led by Senators Arlen Specter, Republican of Pennsylvania, and Joseph I. Lieberman of Connecticut and Edward M. Kennedy of Massachusetts, both Democrats -- have held a half-dozen hearings and drafted several bills to reduce medical errors. Lawmakers say that passage of legislation this year appears likely.

In its report, the academy's Institute of Medicine said that medical errors caused 44,000 to 98,000 deaths a year -- more than the number resulting from auto accidents, breast cancer or AIDS, and far more than the numbers killed or injured in plane crashes each year.

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February 22, 2000

Clinton to Call on All States to Adopt Systems for Reporting Medical Errors

By SHAILAGH MURRAY

Staff Reporter of THE WALL STREET JOURNAL

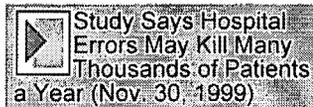
WASHINGTON -- President Clinton on Tuesday will outline a series of steps to help reduce **medical errors**, including proposing a phased-in, state-based system that would require the reporting of all medical mistakes that cause death or serious injury.

Twenty-three states have reporting systems that track **medical errors**, and Mr. Clinton is calling on the rest to pass legislation requiring such reporting within three years. If they don't, further federal action may be necessary, administration officials said.

President Clinton, by choosing the state-based route, has decided against seeking federal legislation for mandatory reporting of errors -- a controversial idea, especially among doctors. Some in Congress, however, may want to move forward with legislation requiring that mistakes be reported.

Mr. Clinton's actions are a response to a report issued in November by the Institute of Medicine saying that 44,000 to 98,000 Americans die annually as a result of medical mistakes. The institute, part of the National Academy of Sciences, a body that advises the government on scientific matters, found that most **medical errors** can be avoided and proposed a national campaign to reduce preventable errors by half within five years.

The most hotly debated issue has concerned the process for reporting



Mr. Clinton's actions are a response to a report issued in November by the Institute of Medicine saying that 44,000 to 98,000 Americans die annually as a result of

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errors. Doctors, in particular, are worried that mandatory reporting of errors could be used against them in court. To reduce the liability risk, Mr. Clinton supports prohibiting the use of such error data as "discoverable information" in any litigation, similar to the approach taken in aviation to promote air safety without penalizing pilots. He also would encourage voluntary reporting of other errors and "close calls." Information to be made public would be grouped by institution, without identifying patients or clinicians.

Mr. Clinton's proposal attempts both to inform the public about local hospitals and other medical facilities and to improve the flow of information within the medical community, so it can learn from mistakes. The question is whether doctors and other health-care professionals will feel threatened by the additional disclosure requirements, which the American Medical Association has warned could dissuade physicians from admitting mistakes. Carmela Coyle, senior vice president of the American Hospital Association, called the provision "too murky."

In other areas, Mr. Clinton would create a Center for Quality Improvement and Patient Safety, which would fund research and education efforts and help to smooth state standards to make data collection uniform. The agency would help establish best practices and uniform procedures.

The Food and Drug Administration would toughen regulations on naming and labeling standards for drugs. One common mistake, according to the report, is for health-care professionals to confuse medications, because of their similar names or packaging.

Hearings on **medical errors** will continue Tuesday in the Senate. Lawmakers are hopeful they can produce a bill this year. Sen. Edward Kennedy (D., Mass.), one of the leaders of the patient-protection drive, called Mr. Clinton's proposal "effective" and said Monday that he was "optimistic Congress will act quickly to solve this glaring problem."

Write to Shailagh Murray at shailagh.murray@wsj.com

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Clinton Seeks Medical Error Reports

Proposal to Reduce Mistakes Includes Mandatory Disclosure, Lawsuit Shield

By Marc Kaufman

Washington Post Staff Writer

Tuesday, February 22, 2000; Page A02

President Clinton will propose today that all medical errors in hospitals that result in death or serious injury be publicly reported as part of a mandatory national error prevention system, White House sources said yesterday.

The recommendation, which is controversial among health care providers, is contained in a wide-ranging administration initiative to reduce the estimated 44,000 to 98,000 hospital deaths caused each year by medical mistakes.

The plan also calls for creation of a new federal office to research and promote "patient safety," for new standards to reduce medical errors caused by similar-sounding prescription drug names, and for legislation that would allow hospitals and doctors to investigate their errors without fearing that the information would later be used in malpractice suits against them.

"The president believes we should set up a multifaceted system to eliminate preventable medical errors--that it's really overdue," said an administration official involved with the plan. While acknowledging some opposition to mandatory reporting was likely, he said the White House was confident the proposals would be popular among consumers, many health providers and businesses that pay for health care.

The proposals, which will be announced today at the White House, are in response to a critical report from the Institute of Medicine (IOM) that outlined the magnitude of the medical errors problem.

The congressionally chartered research group, which is part of the National Academy of Sciences, concluded in November that preventable mistakes kill more Americans yearly than do breast cancer, highway accidents or AIDS. Many of the group's recommendations, including the creation of a national error reporting system, are embraced in the president's initiative.

Medical and hospital officials agree that mistakes are a significant and sometimes deadly problem. But they do not all agree that a mandatory reporting system--even with safeguards to keep the information from malpractice lawyers--is necessary or even useful.

"Our fear is the mandatory reporting would actually drive information

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about errors underground," said Nancy Dickey, past president of the American Medical Association. "If appropriate and tough protections are not in place, then providers will be very concerned--and rightly concerned--that after reports are turned in, the next person they'll hear from is a plaintiff's attorney."

Carmela Coyle, senior vice president of the American Hospital Association, said that her organization was also concerned about the legal implications of any mandatory reporting.

"Nobody is seeking to lessen the current liability we have when medical errors occur," she said. "Our big fear is that we'll be creating a new system into which information will be reported, and some in the legal community will use it for fishing expeditions."

Under Clinton's plan, specific information about preventable and serious medical errors would be available, as it is now, to patients and their families for malpractice purposes. In a significant change, however, hospitals would be obliged to investigate the "root causes" of those errors. That information, with the names of patients and health care professionals removed, would be compiled and made available to the public.

To protect hospitals and health systems, the administration will propose legislation to place the results of those "root causes" investigations beyond the reach of lawyers in malpractice suits. Officials said yesterday that the protection should be enacted before or just as the reporting system is implemented.

While the plan calls for new federal regulations requiring hospitals to increase their efforts to reduce medical mistakes, states would implement the error reporting systems over the next three years. Administration officials say that 18 states already have some form of error reporting systems.

But according to Janet Corrigan, director of the IOM's health care quality initiative, those state programs tend to be underfunded and inconsistent in what they report. She said the IOM recommended mandatory reporting and increased funding for error reduction programs because "health care providers clearly need to analyze their errors better so they can make sure they don't happen again."

"We believed strongly that information from the mandatory system about specific facilities should be made available to the public," she said. "We don't believe specific information about individuals should be public, but the community has a right to know generally about errors occurring in its hospitals and facilities."

Karen Ignagni, president of the American Association of Health Plans, said her organization saw Clinton's initiative as "a serious proposal to begin discussion." Bills on medical errors have already been introduced in the Senate and House, and the Senate Appropriations and Health, Education, Labor and Pensions committees will hold a joint hearing today on the subject.

To support the error-reduction effort, Clinton will announce today a \$20 million increase in funding for the Agency for Healthcare

Research and Quality. The money, which represents a 500 percent increase in agency funding, will be used to create a new IOM-recommended center to fund research on patient safety and to develop national goals on error reduction.

The White House official said that while Vice President Gore is not scheduled to be present today when the plan is announced, he has been actively involved in the health quality program for several years. The National Quality Forum, a public-private foundation established by Gore, will develop the national standards for error reporting, the official added.

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February 22, 2000

Report on Medical Mistakes Sought

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Filed at 2:15 a.m. EST

By The Associated Press

WASHINGTON (AP) -- President Clinton wants hospitals to tell patients and the government how often they kill or seriously injure those in their care.

Hospitals nationwide would have to disclose serious and deadly mistakes if Congress adopts a White House plan developed in response to a report last year that estimated medical mix-ups kill as many as 98,000 Americans each year.

Clinton also planned today to order several new requirements that do not need congressional approval, including an immediate mandatory reporting requirement for the 500 Defense Department-administered hospitals that serve an estimated 8 million people. And the Health Care Financing Administration will require error reduction plans this year in all 6,000 hospitals that participate in Medicare.

The Food and Drug Administration has a year to develop new standards to help prevent medical mistakes caused by sound-alike drug names or look-alike products. The agency will also come up with new standards for labels that highlight common problems such as errors in dosage size.

The White House wants all hospitals to report errors within three years, but cannot force compliance without legislation from Congress.

There already are plans in Congress to respond to the Institute of Medicine report on medical mistakes that could short-circuit the White House plan by requiring faster or more comprehensive reporting.

Sen. Edward Kennedy, D-Mass., predicted a bipartisan medical error bill will pass this year, and two Senate committees are holding

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The White House sees its plan as a compromise between patient advocates who want full disclosure of medical mistakes and representatives of doctors and hospitals who fear more disclosure means more lawsuits.

The White House wants a mandatory national reporting system, administered by the states, that would collect information about preventable deaths and major injuries by hospital and type of problem. Names of individual doctors or other health care workers would not be public.

Hospitals would not have to report less serious mistakes or close calls, although the White House hopes they would do so voluntarily, a senior White House official said Monday.

"The whole idea here is to not blame people," said the White House official, who spoke on condition of anonymity. "Obviously, we have a problem in medical errors, and we have to acknowledge it. Acknowledging it is the first step, but we can't make it punitive."

The president's proposed budget for next year includes \$33 million to improve the reporting system for medical mistakes at the FDA.

Clinton's proposed budget also includes \$20 million for new research on reducing medical errors and to create a new patient safety clearinghouse. The new study center would fund research on patient safety nationwide and promote ways to apply the findings.

Dr. Sidney Wolfe, head of the Washington-based Public Citizen's Health Research Group, said the White House approach does not go far enough. Hospitals can still mask the true level of mistakes by failing to perform enough autopsies, and patients deserve a full accounting, Wolfe said.

"To be silent on this major source of finding out the nature of mistakes both in diagnoses and treatment is just irresponsibility," Wolfe said.

On the other end of the argument is Dr. Nancy Dickey, immediate past president of the American Medical Association. She said there is no evidence that hospitals are safer in states with reporting systems in place.

"We are opposed to mandatory reporting," Dickey said.

Eighteen states already have some kind of mandatory reporting system.

In November, the Institute of Medicine, a private organization chartered by Congress to advise the government on scientific matters, estimated that medical mistakes kill between 44,000 and 98,000 Americans each year. The institute said it found flaws in the way hospitals, clinics and pharmacies operate.

The mistakes ranged from botched surgeries to misunderstandings

over dosages and effects of prescription drugs.

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**CLINTON-GORE ADMINISTRATION ANNOUNCES NEW ACTIONS TO IMPROVE
PATIENT SAFETY AND ASSURE HEALTH CARE QUALITY**

Goal to Reduce Preventable Medical Errors By 50 Percent Within Five Years

February 22, 2000

President Clinton today will receive a new report on medical errors from the Administration's Quality Interagency Coordination Task Force (QuIC) and unveil a series of landmark initiatives to boost patient safety. These initiatives will help create an environment and a system in which providers, consumers, and private and public purchasers work to achieve the goal set by the Institute of Medicine (IOM) to cut preventable medical errors by 50 percent over five years.

Developed in response to the President's call for action in December, the QuIC response endorses virtually every IOM recommendation proposed and includes actions that go beyond it. Consistent with the QuIC recommendations, the President will call for: a new Center for Patient Safety; the development of a regulation requiring each of the over 6,000 hospitals participating in Medicare to have in place error reduction programs; new actions to improve the safety of medications, blood products, and medical devices; a mandatory reporting system in the 500 military hospitals and clinics serving over 8 million patients; and a nationwide state-based system of mandatory and voluntary error reporting, to be phased in over time. The President will also commend the Vice President for his leadership on this issue, thank members of Congress in both parties for their work, and praise the efforts of consumers, doctors, hospitals, nurses, health plans and businesses to improve patient safety.

PREVENTABLE MEDICAL ERRORS: A NATIONAL CHALLENGE. Although the U.S. offers some of the best health care in the world, the number of medical errors is still too high.

- **Medical errors are common and costly.** The IOM estimates that over half of adverse medical events are due to preventable medical errors, causing 98,000 deaths a year and costing as much as \$29 billion annually. One study of over 30,000 patients indicated that nearly 60 percent of patients suffering adverse events in a hospital stay were subjected to a preventable medical error.
- **Medication errors account for a significant portion of preventable adverse events.** The IOM estimates the number of lives lost to preventable medication errors account for at least 7,000 deaths annually in hospitals. These errors increase hospital costs by an estimated \$2 billion, and nursing homes costs by over \$3 billion. When other preventable mistakes with drugs are included, the death toll rises to tens of thousands yearly. A study of hospitals in New York indicated that drug complications represent 19 percent of all adverse events, and that 45 percent of these events were caused by medical errors. In this study, 30 percent of individuals with drug-related injuries died.

PRESIDENT UNVEILS NEW COMPREHENSIVE PLAN TO IMPROVE PATIENT SAFETY. Today, the President will announce the following new actions to assure patient safety:

A new Center for Quality Improvement and Patient Safety. Today, the President will announce that his FY 2001 budget includes \$20 million, a 500 percent increase over last year's funding level, to conduct research on medical errors reduction and create a new, IOM-recommended Center for Quality Improvement and Patient Safety. The Center will: fund research on patient safety; develop national goals for patient safety; issue an annual report on the state of patient safety; promote the translation of research findings into improved practices and policies; and educate the public.

The development of a regulation assuring that all hospitals participating in Medicare implement patient safety programs. This year, the Health Care Financing Administration will publish regulations requiring the over 6,000 hospitals participating in Medicare to have in place error reduction programs that include new systems to decrease medication errors. This action mirrors contractual requirements planned by the Federal Employees Health Benefits Plans and by many private sector purchasers. It also complements the voluntary efforts recently announced by the American Hospital Association.

The development of new standards to ensure that pharmaceuticals are packaged and marketed in a manner that promotes patient safety. Within one year, the Food and Drug Administration will develop new standards to help prevent medical errors caused by proprietary drug names and packaging that are easily confused with other those of other drugs. The agency will also develop new label standards that highlight common drug-drug interaction problems and other dosage errors related to medications. It will also implement a system that makes it possible to report serious adverse drug events on-line. The President is committing \$33 million in the FY 2001 budget, a 65 percent increase over last year's funding level, for medical error and adverse event reporting systems at FDA.

Modernized patient safety systems at the Department of Veterans Affairs and the Department of Defense to improve medication safety. The VA and DOD have been and continue to be leaders in the use of automated and other systems to reduce medical errors. The President will announce:

- *Full implementation of VA patient safety programs.* This year, VA will complete implementation of an automated order entry system in all its health care facilities, along with a barcoding system for medication administration. These systems match patients with the medication they are supposed to receive. A 1999 pilot test indicates that they can reduce medication errors by up to 70 percent. In addition, the VA will increase patient safety training for staff from 15 to 20 hours a year and place "patient safety checklists" in operating rooms at every VA hospital.
- *Launch of new DOD patient safety programs.* The DOD will launch an integrated pharmacy system for their over 8 million beneficiaries by the end of 2000. This new system will allow DOD physicians to accurately track prescriptions as they are filled in both public and private pharmacies worldwide. This fall, DOD will begin implementing a new computerized medical record that makes all relevant clinical information on a patient available when and where it is needed. It will be phased to all 500 DOD hospitals and clinics over three years.

Comprehensive plans for a nationwide system of error reporting. Currently, 23 states (18 of which require hospital reporting) have reporting systems to track preventable medical errors and to help providers take corrective actions. Today the President will announce support for a nationwide system of error reporting – one that will be state-based and phased in over time.

When fully implemented, this system will require mandatory reporting of preventable medical errors that cause serious injury or death, and will encourage voluntary reporting of other medical errors and "close calls." Information will be aggregated and made public (without identifying patients or individual health care professionals) to educate the public about the safety of their health systems. Both mandatory and voluntary reporting will enable providers to target widespread problems and develop the best preventive interventions. The Administration will take several actions to promote the importance of developing and using medical error reporting systems, including:

- *Launching new research to help implement mandatory reporting systems.* The QuIC will ask the National Quality Forum to develop a set of patient safety measurements that can lay the foundation for a uniform system of medical errors data collection. HCFA will launch a pilot project in up to 100 hospitals to help them implement confidential mandatory reporting systems. HCFA will also work with hospitals in states that currently have mandatory reporting systems to identify and address issues associated with presenting medical errors data to the public.
- *Supporting expansion of "peer review protections" to encourage development of post-error review processes.* Individuals or family members should have access to information about a preventable medical error causing serious injury or death. But analyses to determine the shortcomings of the hospital's delivery system (root-cause analysis) and subsequent action to prevent such errors in the future should not be "discoverable information" used in litigation. That is why the Administration will support legislation that protects provider and patient confidentiality in order to encourage post-error review – without undermining individual rights to redress for malpractice. Such legislation should be enacted in conjunction with, or prior to implementation of, nationwide mandatory and voluntary reporting systems.
- *Implementing a required reporting system at the Department of Defense.* Beginning this spring, DOD will implement a new mandatory reporting system in its 500 hospitals and clinics, which serve approximately 8 million patients.
- *Expanding mandatory reporting requirements for all blood banks.* By the end of the year, FDA will release regulations requiring the over 3,000 blood banks and establishments dealing with blood products to report serious errors affecting patient safety.
- *Implementing a voluntary reporting system nationwide for veterans' hospitals.* VA currently operates a mandatory reporting system. By the end of the year, VA will also implement a voluntary nationwide reporting system for adverse events and "close calls." Information will be collected by an independent entity and disseminated to all VA health care networks. Implementing this system is likely to lead to a richer database of information, as incidents are reported on a de-identified basis, and will allow researchers to compare the effectiveness of identified systems to de-identified ones.
- *Encouraging the development of voluntary systems and learning from existing systems.* The Center for Quality Improvement and Patient Safety, with its Task Force partners, will evaluate current voluntary reporting systems at the federal and state levels and develop recommendations to improve them. This study will demonstrate which entity or entities would be best to collect, analyze, and disseminate information on frequently occurring errors and the best interventions to prevent them.

If all states have not implemented mandatory reporting systems within three years, the QuIC will deliver recommendations to the President that assure all health care institutions are reporting serious preventable adverse events. If research conducted by the Agency for Healthcare Research and Quality and other agencies indicates that the implementation of these systems does not enhance (or even detracts from) patient safety, the QuIC will modify its recommendations accordingly.

COMMENDS CONGRESS AND THE PRIVATE SECTOR FOR WORKING TO PROMOTE PATIENT SAFETY. Today, President Clinton noted the strong bipartisan interest in improving patient safety and that committees in the House and Senate held hearings to explore possible avenues to address this issue. The President noted that the Senate Appropriations and Health, Education, Labor, and Pensions (HELP) Committee will hold a joint hearing today, and have separately held several previously. He thanked the members of these Committees and other leaders in the Congress on this issue, including Senators Kennedy, Jeffords, Spector, Harkin, Dodd, Frist, Lieberman, Kerrey, Grassley, and several members of the House in both parties for their work. He also recognized and commended the ongoing work of the American Hospital Association, the American Medical Association, the American Nurses Association, and the Business Roundtable's "Leapfrog Group".

BUILDS ON THE CLINTON-GORE ADMINISTRATION'S LONGSTANDING COMMITMENT TO IMPROVING PATIENT SAFETY. In early 1997, the President established the Advisory Commission on Consumer Protection and Quality in the Health Care Industry (Quality Commission) and appointed Health and Human Services Secretary Shalala and Labor Secretary Herman as co-chairs. The Quality Commission released two seminal reports on patient protections and quality improvement. Subsequent to the Commission's second report on patient safety and quality improvement, and consistent with its recommendations, the President established the Quality Interagency Coordination Task Force (QuIC), an umbrella organization also co-chaired by Secretary Shalala and Secretary Herman, to coordinate Administration efforts to improve quality. Also consistent with the Quality Commission's recommendations, Vice President Gore launched the National Forum for Health Care Quality Measurement and Reporting. The "Quality Forum" is a broad-based, widely-representative private advisory body that develops standard quality measurement tools to help purchasers, providers, and consumers better evaluate and ensure the delivery of health care services. In addition to the work and significant potential of the QuIC and Quality Forum, other Federal agencies have made significant efforts to reduce medical errors and increase attention on patient safety. Last December, at the President's direction, the Office of Personnel Management announced it will require all plans participating in the federal health program to implement error reduction and patient safety techniques.

Thank you Secretary Herman. President Clinton, Mr. Otten and distinguished guests.

Between Valentine's Day – which was just a week ago – and people getting married sight-unseen on television, . . .

. . . I can't resist the temptation to tell a quick story about Secretary Herman.

As you probably know, Secretary Herman is a newlywed.

She was married two weekends ago at the National Cathedral.

But you probably don't know that Secretary Herman was dating her husband-to-be while she and I were co-chairing the President's Advisory Commission on Consumer Protection and Quality.

Now you're probably thinking that heartfelt talks about such romantic subjects as: ...

...New statistical models for measuring errors at publicly supported hospitals was *not* what brought these two wonderful people together.

But you would be wrong.

Secretary Herman claims that talking about patient care, the Commission's work, and most important – the need to reduce medical errors – actually enhanced her relationship.

*** * ***

Of course, Secretary Herman and I both know that reducing medical errors has to be more than a private conversation.

This problem calls for an ongoing public dialogue.

Let me briefly describe what we're up against.

As the Institute of Medicine pointed out: At least 44,000 deaths occur every because of preventable medical errors.

That number could be as high as 98,000.

This makes medical errors the eighth leading cause of death in the United States.

One percent of the medical interventions in intensive care units turn out to be wrong. And 20 percent of that one percent cause death or serious bodily harm.

That may not sound like much. But when you add up the numbers, you end up with thousands of deaths every year.

Not to mention pain, suffering and disabling injuries.

There are also financial costs, . . .

. . . 29 billion dollars in lost income, disability and health care costs every year.

*** * ***

This is why we needed a public dialogue about medical errors.

Ours began three years ago when the President's Advisory Commission issued a landmark report that included the first Patient's Bill of Rights.

Since we just celebrated President's Day, let me be clear: Thanks to President Madison we have a Bill of Rights. And thanks to President Clinton we *will* have a Patient's Bill of Rights.

The Patients Bill of Rights was not the Advisory Commission's last word on quality.

We issued a second report about health care quality and the need to identify and reduce medical errors.

We also called for the establishment of a federal Quality Interagency Coordination Taskforce. Now known as the QuIC.

At the President's request, Vice President Gore launched the Quality Forum – a group of mostly private sector advisors – to come up with uniform quality standards.

Our Agency for Health Care Research and Quality is the lead agency in improving quality health care, . . .

. . . and under the leadership of Dr. John Eisenberg has funded critical research into the frequency and causes of medical errors.

In fact, this research was used by the Institute of Medicine in its own report.

*** * ***

The President likes to say: Our goal is not to fix blame, but to fix the problem.

That's why in addition to bringing together the best minds from both inside and outside government, we're devoting more money and attention to the problem of medical errors than ever before.

The CDC collects data on adverse events, including hospital-acquired infections.

HCFA demands high standards for hospitals that participate in Medicare.

FDA compiles data on errors related to drugs and medical devices.

*** * ***

Other federal agencies including the Department of Defense and the VA – as well as states and the private sector – are working hard on this problem too.

Still, much of the battle to reduce medical errors is being fought right on the front lines.

In hospitals. In doctors offices. In community clinics.

And by dedicated health care professionals like Jeffery Otten.

STATEMENT BY BARBARA BLAKENEY

Thank you, Secretary Shalala. Good morning, President Clinton, Secretary Herman, and other distinguished guests.

We are here today to discuss a problem that I know makes many in the health care community uncomfortable -- the problem of preventable medical mistakes.

The American Nurses Association represents 2.6 million nurses nationwide. I believe that my colleagues in the field are truly modern heroes. We work tirelessly every day to protect the best interests of our patients. But as health care gets more sophisticated, it gets more complex. The practice of medicine is a noble endeavor, but it is also a human one, and humans -- including health care professionals -- are fallible.

It's important to realize that the medical errors we've been hearing so much about since the release of the IOM report -- like patients who die because of a fatal drug interaction -- are not big mistakes made by one individual. They're usually the result of a systems failure that produces a long chain of small errors by a number of individuals or technologies involved in the patient's care.

Because of this, blaming individual caregivers usually serves no purpose, and rarely helps us improve patient care. In order to protect our patients, we need to design safer systems that reduce the possibility that individual caregivers will be placed in situations that make errors likely.

There's a wide range of issues, ranging from basic shortcomings in quality assurance systems to inadequate staffing and provider communication, that make health care settings more susceptible to medical errors than need be. Mr. President, I am proud to say that the nurses I represent are ready to work with our colleagues to meet this challenge and change the system to ensure that our patients receive the high quality care they expect and deserve.

Nurses know patient safety programs make a difference. Physician order entry systems improve medication safety by ensuring that prescriptions are automatically checked against patient records for potential drug allergies or interactions. Ensuring that IV solutions are mixed at the pharmacy rather than on patient floors and prepackaging medications in the exact doses necessary for patient use prevents patients receiving the wrong dose accidentally. Implementing computer systems that automatically alert doctors when patients have abnormal lab results. But we know too, that implementing the programs that we can readily identify will not be enough. We must remedy the root causes of systemic processes and behaviors that lead to repeated errors and injury to our patients.

Mr. President, on behalf of the ANA, I strongly support the steps you are taking today. It takes a comprehensive and measured approach in assuring consumers, public and private purchasers, and providers work together to eliminate all preventable errors and improve patient safety. It appropriately rejects an emphasis on blame and punishment and works to create a health care delivery system that places patient safety first and foremost.

We must acknowledge that mistakes occur, and we owe it to our patients to learn from our errors. I am honored to stand with you today as you begin an long overdue national dialogue on a subject that is critically important to improving the quality of health care that all Americans receive.

And now, it is my pleasure and privilege to introduce the man who has set a new standard for leadership in improving health care delivery systems and the quality of medical care in this country than anyone else – the President of the United States, William Jefferson Clinton.

THE WHITE HOUSE

WASHINGTON

February 21, 2000

MEDICAL ERRORS EVENT

DATE: February 22, 2000
LOCATION: Presidential Hall – OEOB 450
BRIEFING TIME: 12:00pm – 12:15pm
EVENT TIME: 12:25pm – 1:05pm
FROM: Bruce Reed, Chris Jennings, Mary Beth Cahill

I. PURPOSE

To accept a report from the Quality Interagency Coordination Task Force (QuIC) which evaluates and endorses the recommendations of the Institute of Medicine's study of medical errors; and to unveil a series of initiatives to significantly enhance patient safety.

II. BACKGROUND

Last December, you hosted a meeting at the White House to commend the Institute of Medicine for its report on medical errors. At that event, you directed the OPM to ensure that all future contracts with health plans would emphasize a commitment to the establishment of medical error reduction systems. You also directed Federal agencies to work collaboratively to review the IOM report and provide you with recommendations.

Today, you will receive that report and endorse its recommendations, including its goal of reducing preventable medical errors by 50 percent over the next five years. As is outlined below, you will embrace the IOM recommendations but actually go further, particularly with respect to the operations of Federal health systems.

We had scheduled a hospital administrator from Boston to outline the latest error techniques utilized in hospitals, as well as to be supportive of your patient safety recommendations. However, at the last moment this afternoon, he cancelled, citing his discomfort and that of the Massachusetts Hospital Association (MHA) in taking a position that was too far ahead of the American Hospital Association (AHA). The AHA strongly suggested that MHA not participate, for fear that their presence would be perceived as an implicit endorsement of the announcement you are unveiling. They had major concerns that it would reflect (accurately) that several hospital associations, such as those from New York, California, and Massachusetts would not impose – and in fact, live under – mandatory reporting systems.

Rather than seek a major public confrontation with the AHA on this issue, we chose to get a representative from the American Nurses Association. The nurse, Barbara Blakely, will relay the ANA's unconditional endorsement for your proposal and describe its importance to improving patient safety in the health care delivery system.

Today, you will unveil a comprehensive plan to improve patient safety, and announce the following new actions:

A new Center for Quality Improvement and Patient Safety. Today, you will announce that your FY 2001 budget includes \$20 million, a 500 percent increase over last year's funding level, to conduct research on medical errors reduction and create a new, IOM-recommended Center for Quality Improvement and Patient Safety. The Center will: fund research on patient safety; develop national goals for patient safety; issue an annual report on the state of patient safety; promote the translation of research findings into improved practices and policies; and educate the public.

The development of a regulation assuring that all hospitals participating in Medicare implement patient safety programs. This year, the Health Care Financing Administration intends to publish regulations requiring the over 6,000 hospitals participating in Medicare to have in place error reduction programs that include new systems to decrease medication errors. This action mirrors contractual requirements planned by the Federal Employees Health Benefits Plans and by many private sector purchasers. It also complements the voluntary efforts recently announced by the American Hospital Association.

The development of new standards to ensure that pharmaceuticals are packaged and marketed in a manner that promotes patient safety. Within one year, the Food and Drug Administration will develop new standards to help prevent medical errors caused by proprietary drug names and packaging that are easily confused with other those of other drugs. The agency will also develop new label standards that highlight common drug-drug interaction problems and other dosage errors related to medications. It will also implement a system that makes it possible to report serious adverse drug events on-line. You are committing \$33 million in the FY 2001 budget, a 65 percent increase over last year's funding level, for medical error and adverse event reporting systems at FDA.

Modernized patient safety systems at the Department of Veterans Affairs and the Department of Defense to improve medication safety. The VA and DOD have been and continue to be leaders in the use of automated and other systems to reduce medical errors. You will announce:

- *Full implementation of VA patient safety programs.*
- *Launch of new DOD patient safety programs.*

Comprehensive plans for a nationwide system of error reporting. Currently, 23 states (18 of which require hospital reporting) have reporting systems to track preventable medical errors and to help providers take corrective actions. Today you will announce support for a nationwide system of error reporting – one that will be state-based and phased in over time.

When fully implemented, this system will require mandatory reporting of preventable medical errors that cause serious injury or death, and will encourage voluntary reporting of other medical errors and “close calls.” Information will be aggregated and made public (without identifying patients or individual health care professionals) to educate the public about the safety of their health systems. Both mandatory and voluntary reporting will enable providers to target widespread problems and develop the best preventive interventions. The Administration will take several actions to promote the importance of developing and using medical error reporting systems, including:

- *Launching new research to help implement mandatory reporting systems.*
- *Supporting expansion of “peer review protections” to encourage development of post-error review processes.*
- *Implementing a required reporting system at the Department of Defense.*
- *Expanding mandatory reporting requirements for all blood banks.*
- *Implementing a voluntary reporting system nationwide for veterans’ hospitals.*
- *Encouraging the development of voluntary systems and learning from existing systems.*

III. PARTICIPANTS

Briefing Participants:

Secretary Donna Shalala

Secretary Alexis Herman

Bruce Reed

Mary Beth Cahill

Loretta Ucelli

Chris Jennings

Dan Mendelson

Sam Afridi

Event Participants:

YOU

Secretary Donna Shalala

Secretary Alexis Herman

Barbara Blakeney, First Vice President of the American Nurses Association

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- **YOU** will be announced onto the stage, accompanied by Secretary Donna Shalala, Secretary Alexis Herman, and Barbara Blakeney.
- Secretary Alexis Herman will make brief remarks and introduce Secretary Donna Shalala.
- Secretary Donna Shalala will make brief remarks and introduce Barbara Blakeney.
- Barbara Blakeney will make brief remarks and introduce **YOU**.
- **YOU** will make remarks, work a ropeline, and depart.

VI. REMARKS

To be provided by speechwriting.

QUESTIONS AND ANSWERS ON MEDICAL ERRORS

Q: Why do you believe the imposition of mandatory reporting and its accompanying risk of disclosure of confidential information is so critically important to ensuring patient safety and improving quality?

A: We believe that mandatory and voluntary reporting are important elements of a strong patient safety / error reduction system. They are not adequate in and of themselves, but their use helps ensure that we have the most effective mechanism to achieve results. Reporting systems are necessary to evaluate the extent to which there is a problem, whether that problem is being addressed, and whether or not there is a need to alter current approaches to achieve desired safety results.

Q: Do you believe that AHA and AMA's vehement opposition to the approach you are taking dooms the President's initiative to failure?

A: First, we don't believe that the AMA or AHA vehemently opposes the vast majority of the President's initiative. While each organization has raised concerns about the mandatory reporting component of today's announcement, they both have also indicated strong support for virtually every other element of the President's initiative. Their opposition to the reporting requirement is not surprising, but we believe when they fully understand the details and our commitment to working with them to ensure a workable transition to a desired error reduction system, they will be a constructive force. Finally, it is our strong belief that the comprehensive approach taken by the President, including reporting systems, will work towards eliminating the very errors that have increased liability concerns.

Q: How will you define serious adverse events?

A: We will be working with consumers, purchasers, providers, health policy experts, and other interested parties to help refine this definition, which has also been generally recommended by the IOM.

Q: Would you oppose the implementation of your patient safety initiatives without the use of mandatory reporting?

A: We believe that each recommendation is intricately related to the others. With this in mind, we'd be very hesitant to drop our support for moving towards a mandatory system unless it becomes clear that doing so would enhance our commitment to patient safety and error reduction. As was indicated in the report, if we determine that mandatory reporting becomes a detriment to our fundamental goals, we will support altering our current position.

Q: How do you respond to charges leveled by the AMA and others that mandatory reporting will only force this problem underground?

A: Once again, it is important to remember that the President's recommendation does not immediately implement a mandatory reporting system. In fact, it explicitly rejects the IOM recommendations to do so, and instead calls for a phased-in system that would only be acceptable if other systematic changes, including meaningful comparable data evaluation systems and liability protections, are instituted and are successfully creating an environment that encourages reporting.

Q: Are you willing to implement public disclosure of medical errors in Federal health care systems?

A: Absolutely. The QuICs recommendations are intended to be applicable to all hospitals – whether they be public or private institutions. The DOD and VA wish to be held to the same standards as those being applied to the private sector, and as a consequence, are prepared to meet the timetable outlined in the QuIC report.

Q: Is there any evidence that mandatory reporting works?

A: Experts in the field widely concur that the use of mandatory reporting systems can have either detrimental or extremely positive impact on patient safety program. There is broad based agreement, however, that mandatory and voluntary standardized reporting systems combined with appropriate liability protections are an important component of a successful patient safety / error reduction system.

Q: HCFA is proposing to require all hospitals participating in the Medicare program to implement error reduction programs. When and how will your regulation be released?

A: The Medicare COP regulation is intended to be released this year. It will be developed with input from hospitals, consumers, and other interested parties.

Q: What will be included in your regulation and what will be the penalty for non-compliance?

A: We have not made any final determination about what will be included in the final regulation, although we do believe there will be requirements oriented towards eliminating medication errors. We will be working with hospitals, consumers, and other interested parties as we develop this regulation. We believe that hospitals will be able to and will comply with any regulation that is developed, as has been the case with virtually every modification to the Medicare COP since the program has been in operation. Obviously, like any other facility found to be out of compliance with the Medicare COP, such hospitals would be given time to come into compliance. Having said this, should they not do so, the final penalty for non-compliance is the loss of Medicare funding.

Q: Won't this new requirement be very expensive?

A: We don't think so. Not all patient safety programs require large financial investments. Sometimes, error reduction programs can be very simple – as simple as prepackaging medications in the exact doses necessary for patient use. There will be enough flexibility in the final regulation to allow hospitals to design the types of error reduction programs that are best suited to their hospitals' needs.

Q: As the AHA announced in December, over 5,000 hospitals are already implementing patient safety systems that focus on medication errors. Why is additional Federal action necessary when the private sector is acting on its own?

A: The new HCFA requirements will build on the foundation laid by the AHA announcement. The new regulation will apply to over 6,000 hospitals and require the implementation of patient safety programs that are unrelated to the current AHA efforts to prevent medication errors. The reason why we are pursuing this course of action is that, as a large purchaser – like any other purchaser – it is important that we define our quality priorities for the providers participating in the program.

Q: What is the total Federal investment in medical error reduction in FY 2000? In FY 2001?

A: Please defer these questions to Chris Jennings.

Health Care Privacy Event
Tuesday, Feb. 22, 2000
Room 450, OEOB
12:00 Noon

LIST OF PARTICIPANTS

Christine Cassel
Mt. Sinai School of medicine
212-241-4844

Tom Nickels for Dick Davidson
American Hospital Association
626-2314

Marj Vanderbilt for Mary Foley
American Nurses Association
651-7085

Carmella Bocchino for Karen Ignagni
American Association of Health Plans
778-3278

William Richardson,
Chair, IOM Committee on Quality of Health Care in American
President and CEO, W. K. Kellogg Foundation
616-968-1611

Rich Deem for Thomas Readon or nancy dickey
American medical Association
789-7413

Barbara Allen
American Collge of Physicians
686-4341

Robert Graham
American Academy of Family Physicians
232-9033

Charles Kahn,
Health Insurance Assn of America
824-1725

Eileen McGrath

21
20
101

5 Labor
5 AARP
5 Nurses
5 Carmella
ANA
AMA
NIAA
AAHP

Don Lamm
Ken Ignagni

American Medical Women's Assn
730-838-0500

Marsha Simon
ACOG
863-2511

Jackie Noyes or graham newson
American Academy of Physicians
347-8600

Jack Bresch for Rev. Michael Place
Catholic Health Assnociation
296-3993

Chris Burch
National Ass of Public Hospitals
585-0100

Pete Willson
National Ass of Children's Hospitals
703-684-1355

Tom Scully
American Federation of health Systems
624-1500

Dan Sisko or Steve Kroll
New York Hospital Association
639-1502

Ann Nichol
California Hospital Assnociation
488-4494

hold
Bea Grouse
Mass Hospital Assn
261-7340

hold
Josephine Nieves
National Ass of Social Workers
336-8200

1
Gail Scheer
Consumers Union
462-6262

Mary Woolley
Research America
703.739.2577

Jordan Cohen
Association of American Medical Colleges
202-828-0400

Mohammed Atker
American Public health Assn
789-5656

Ron Pollack
Families USA
628-3030

Janet Corrigan
334-1383

hold

Dan Hawkins
National Ass of Community Health Centers
659-8008

Alzheimer's Association
Judy Riggs
393-7737

Deb Briceland Betts
Older Women's League
783-6686

Bob Blancato or Emily
789-0470

hold

Jerry Klempner
408-5300

Joel Marks
American Small Business Alliance
337-0037

Michael Rodgers
American Ass of Homes and Services for the Aging
508-9436

Karen Gilgoff or Steve Regenstreif
AFSCME Retirees
429-1265

Sam Simmons
National Caucus and Center on Black Aged
637-8400

Max Richtman
National Comm to Preserve Social Security and Medicare
216-0420

Victoria Wagman
National Council of the Aging
479-6613

Dan Schulder
National council of Senior Citizens
301-578-8800

Phil Schnieder
National Ass of Chain Drug Stores
703-549-3001

John Rector
National community Pharm Assn.
703-683-8200

Tom Spangler
American Dental Assn.
898-2400

Val Halamandaris
National Ass for Home Care
547-7424

Bruce Yarwood
American Health Care Association
898-2858

Brian Lindberg
789-3606

Asian Americans

Dong Suh

Asian & Pacific Islander American Health Forum (APIAHF)
(202)624-0007 - voice
(202)624-9488 - fax

Mary Chung or Afton Hirohama
National Asian Women's Health Organization
202-331-4790 - voice
202-331-4791 - fax

hold
Shamina Singh
White House Initiative on Asian Americans and Pacific Islanders
301-443-2492 - voice

DISABILITY GROUPS

Kathy McGinley, The Arc, 202-785-3388, [P6/b(6)]

Shelley McLane, National Association of Protection and Advocacy Systems, 202-408-9514, [P6/b(6)]

Jeff Crowley, National Association of People with AIDS, 202-898-0414, [P6/b(6)]
[P6/b(6)]

Peter Thomas, Powers, Pyles, Sutter & Verville, (202) 466-6550, [P6/b(6)]

Andrew Imparato, American Association of People with Disabilities, (202) 457-0046,
[P6/b(6)]

hold
Suellen Galbraith, American Network of Community Options and Resources, (703) 642-6614, [P6/b(6)]

Robert Griss, Center on Disability and Health, (202) 842-4408, [P6/b(6)]

hold
Gerben DeJong, National Rehabilitation Hospital Research Center, (202) 466-1900,
[P6/b(6)]

Thomas Stewart, National Rehabilitation Association, (703) 836-0850, [P6/b(6)]
[P6/b(6)]

Vicki Shepard, EDS, (202) 637-4972

AFRICAN AMERICAN CONSTITUENCY

Angela Vincent, Senior Health Policy Analyst
National Medical Association
202-347- 1895

Millicent Gorham, Executive Director
National Black Nurses Association (NBNA)
301-589-3200

Ruth Perot, Executive Director
Summit Health Institute
301- 567-2410

Hispanic

Dr. Elena Rios
Nat Hispanic Medical Assn
202-265-4297

Jane Delgado
COSSMHO
202-387-5000

hold
Hilda Crespo
Hispanic Working Group on Healthcare
202-835-3600 ext. 114

WOMEN

hold

| | | |
|--|------------------------------------|--|
| Alejandra, Sylvia National Latina Health Network | 301-951-9633 | |
| Pearson, Cynthia National Women's Health Network | 202-347-1140 | Washington DC |
| Lichtman, Judith President National Partnership for Women & Families | W: 202-986-2600 F: 202-986-2539 | 1875 Connecticut Av. NW #710 Washington DC 20009 |
| | | |

| | | |
|---|------------------------------------|--|
| Greenberger, Phyllis Executive Director Society for the Advancement of Women's Health Research | W: 202 233 8224 F: 202 833 3472 | 1828 L St. NW Suite 625 Washington DC 20036 |
| Mager, Mimi Vice President Heidepriem and Mager, Inc. | W: 202 822 8060 | 888 17th St. NW Suite 800 Washington DC 20006 |
| Howes, Joanne Principal Bass & Howes, Inc. | W: 202 530 2900 F: 202 530 2901 | 1818 N St. NW Suite 450 Washington DC 20036 |

OTHERS

Mary Wakefield
George Mason University
703-993-1931

Patrick Smith
Medical Group Management Association
202-293-3450

Lance Wyatt
202-273-8151
White House Fellow

Business Groups

1. Business Roundtable Group (GM) – Paul Zurawski, 872-1260

2. Leap Frog Group (GTE) –
 - Pacific Business Group on health – Pat Powers [ALREADY LISTED]
 - and Arnie Milstein
 - 415-743-8803 phone
 - 415-743-8950 fax

 - Byers Health Care Action Group, Min. St. Paul –
 - Steve Wetzell
 - 612-896-5190 phone
 - 612-896-5184 fax

 - Dell – Kathelyn Angel
 - 512-723-0126
 - 512-728-9455 fax

 - GM – Jim Cubbin
 - 313-665-4576
 - 313-665-4577 fax

 - GM - Bruce Bradley
 - 313-665-4604 phone
 - 313-665-4685 fax

 - GTE – Bruce Taylor
 - 972-507-5403
 - 972-507-5494 fax

 - GE – Bob Galvin
 - 203-373-3435
 - 203-373-3772 fax

 - GE - Chuck Buck
 - 203-373-2436
 - 203-373-3915 fax

 - U.S. West – Paul Johnston
 - 1-888-331-8794 x 2652

 - OPM – Ed Flynn – on cabinet list

Suzanne Banco - Chair
415-281-7344 work

svelbanco@hotmail.com
202-486-3838 cell phone

Other companies w/ interest:

AT& T

United Parcel

Employer, Manged health Care Coalition
– Pam Kayland 202-218-4138

3. National Business Coalition on health – regional, purchasing cooperatives, small and medium businesses.

--Chris Quorum, 608-276-6620

-- Greg Lehman, 1-877-775-6224.

4. ERIC – mark ugoretz, 789-1400

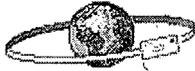
5. APPWP – 289-6700, Kim Klein or paul dennett

Consumer Groups

1. Art Levin, Center for Medical Consumers, 212-674-7105

States – 20 states

Trish Riley, national academy of State Health Policy, 207-874-6524



Don Berwick <DBerwick@IHI.org>

02/20/2000 10:20:31 PM

Record Type: Record

To: Devorah R. Adler/OPD/EOP

cc:

Subject: Errors Statement

Chris.... I have received and read the statement. It is superb. It covers most of the important matters, and deals respectfully with what's controversial. Here are three minor specific reactions for you to think about, or not, as you see fit:

1. Mandatory reporting of "preventable adverse events" would be very hard to make real. The issue is judging preventability. The best way to start is to define a series of sentinel adverse events, which individually may or may not be caused by errors, and then assuring sound investigation of the nexus of causes. If one asks for mandated reports of certain events without prior regard to their relationship to error, it invites less gaming at the front end. What should be mandated is reports of the serious adverse events per se, not of a "preventable" subset of events.
2. In any system of reporting (mandatory or voluntary) the key to learning is the analysis, not the report. The analysis process should be quite expert and based on narrative more than on statistics. It is in the analysis phase (not the collection of reports) that state-based or organizational systems are likely to fall short. Your draft makes it usefully clear that we need to learn about how to analyze reports to draw lessons from them. (The best expert on this point is Dr. Charles Billings at Ohio State University. He is the MD who designed the aviation safety reporting system, and, if you haven't had a chance to speak directly with him, you might find it useful to do so sometime.)
3. The most valuable use of voluntary reports is probably at the organizational level (hospital, health system, HMO), where good detailed analyses can yield lots of lessons. Sometimes in your draft you seem to imply that voluntary reporting systems might be mainly at large aggregate levels -- states, etc. It would be helpful to stress as well that hospitals and health systems that care about safety will establish and nurture excellent, blame-free local systems for reporting and analyzing errors, near misses, hazardous circumstances, etc. As I mentioned on the phone, the first indicator of an effective system of this type is that a hospital's apparent error rate will increase (by 10 to 20 fold) as it becomes aware of latent safety issues that have never surfaced before. That should be rewarded. (A good example is the 20-fold increase in reports at the Luthger-Midelfort Clinic division of Mayo Clinic in Eau Claire, Wisconsin, where committed executive and Board action has led to a 10-fold mincrease in reports of latent errors in just a few months, and a resulting

superb opportunity for them to make dramatic safety gains. CEO there is Dr. William Rupp, and he is truly committed.)

Thanks.

---Don Berwick

