Withdrawal/Redaction Sheet
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: SSN and DOB (partial) (4 pages)	n.d.	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20472

FOLDER TITLE:
Health Care Quality Event

2012-0463-S
rc694

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
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C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
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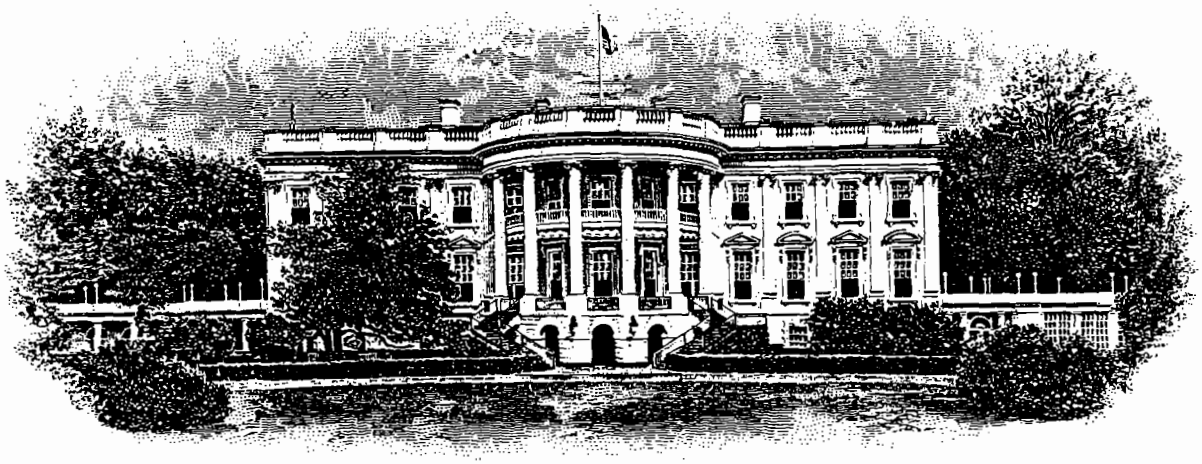
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Q: Looks like Admin w/ insurance?

Health care quality event

The White House



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.

FEDERAL RESPONSE TO THE INSTITUTE OF MEDICINE'S RECOMMENDATIONS	
IOM Recommendation	**Federal Action**
4.1 Creation of a Center for Patient Safety at AHRQ	The President's budget creates the Center for Quality Improvement and Patient Safety in FY 2001 and invest $20 million in research.
5.1 Establishment of a nationwide mandatory reporting system that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm.	The QuIC supports the development of a 50 state system to collect standardized information on adverse events. If the majority of states have not implemented mandatory reporting systems within three years, the QuIC will develop recommendations to assure that all health care institutions are reporting serious preventable adverse events. DOD will implement a mandatory reporting system in its over 500 hospitals and clinics serving 8 million patients. FDA will expand its mandatory reporting system for medical errors related to blood products to include all blood banks and establishments nationwide.
5.2 Encourage the development of voluntary reporting efforts	The VA is implementing a voluntary reporting system for both adverse events and "close calls" nationwide. HHS will evaluate the effectiveness of existing voluntary reporting systems and develop recommendations for improvement.
6.1 Congress should pass legislation to extend peer review protections to data collected to improve patient safety and quality	The QuIC is supportive of this legislation and believes it should apply to both mandatory and voluntary reporting systems. However, it must include provisions to ensure that new protections do not undermine current mechanisms to address criminal activity or negligence.
7.1 Performance standards and expectations for health care organizations should focus greater attention on patient safety	HCFA will require hospitals in the Medicare program to have error reduction programs. OPM will require FEHBP plans to use error reduction techniques.
7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety	The QuIC endorses this recommendation and will provide technical assistance to state or professional agencies seeking to undertake these activities.
7.3 FDA should increase attention to the safe use of drugs in both pre and post marketing processes	FDA will invest $13 million to develop: new standards to help prevent medical errors caused by proprietary drug names that sound similar or packaging that looks similar; new label standards that highlight common drug interactions and dose errors.
8.1 Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility	DOD will launch a patient safety program that includes a new computerized medical record and pilot a safety program to improve care in "high hazard areas". VA will increase patient safety training for staff to 20 hours a year, implement a safety awards program, and place "patient safety checklists" in ORs.
8.2 Health care organizations should implement proven medication safety practices	VA will fully implement its computerized order entry system. DOD will improve drug interaction screening. In order to comply with the new proposed requirement that hospitals in Medicare must have error reduction programs, hospitals are likely to implement automated pharmacy order entry systems.

STATE ADVERSE REPORTING SYSTEMS (found in 23 states)				
STATE	**INFORMATION REPORTED**	**INSTITUTIONS PARTICIPATING**	**MANDATORY OR VOLUNTARY**	**PUBLIC ACCESS**
AL	Unexpected patient deaths; suicide; restraint deaths; serious injuries; burns	Nursing homes	Mandatory	Reports are aggregated by nursing home and made public
CA	Epidemic outbreaks; poisonings; catastrophic and criminal activity or unusual occurrences that threaten the welfare, safety, and health of patients, health care professionals, or visitors	Hospitals, nursing homes, and other health care providers	Mandatory	Reports that do not contain confidential information are accessible to the public
CO	Deaths arising from unexplained causes; brain and spinal cord injuries; life threatening complications of anesthesia or transfusions; burns, missing patients, malfunction or misuse of equipment	All state licensed health care facilities	Mandatory	Patients and personnel information is kept confidential; the name of the facility is disclosed. Reports are posted on the internet when complete.
CT	All accidents that result in serious injury, death, or disruption of facility services	Nursing homes and hospitals	Mandatory for nursing homes; voluntary for hospitals	Reports disclose the name of the facility but no information on patients or personnel; they are available to the public
DC	Unexpected patient deaths; suicide; restraint deaths; infant abduction or wrong infant discharge; transfusion reaction; major loss of function due to surgery or treatment	Hospitals, nursing homes, home health agencies, intermediate care facilities	Mandatory	Reports are accessible to the public.

STATE	INFORMATION REPORTED	INSTITUTIONS PARTICIPATING	MANDATORY OR VOLUNTARY	PUBLIC ACCESS
FL	All serious adverse events, including wrongful death, brain injury, incorrect surgery, wrong limb removal	Hospitals and ambulatory surgical centers	Mandatory	Aggregate data is released annually
IA	Unexpected patient deaths; suicides; restraint deaths; patient elopement	Nursing homes	Mandatory	Confidential
ID	Unexpected patient deaths; suicides; restraint deaths	Hospitals, nursing homes, home health agencies, intermediate care facilities	Mandatory	Individual reports are not released; the results of state survey site visits are
KS	Acts by health care providers that are below the applicable standard of care	All licensed medical care facilities	Mandatory	Confidential.
LA	Unexpected patient deaths; suicides; restraint deaths; injuries of unknown origin	Hospitals, nursing homes, home health agencies	Mandatory	Information (without patient identifiers) is released upon request
MA	Adverse events, wrongful deaths; medication errors; errors requiring patients to undergo additional treatment measures; surgical errors; transfusion errors; maternal deaths within 90 days of delivery	All licensed health care facilities	Mandatory	De-identified reports are made available to the public
MN	Unexpected patient deaths; suicides; restraint deaths	Hospitals, nursing homes, home health agencies, ambulatory surgical clinics	Mandatory	Substantiated findings are released to the public without patient identifiers
NJ	Any incident that endangers the health and safety of a patient or employee	All state licensed health care facilities	Mandatory	Information disclosed only if the facility is sanctioned by the state; information is posted on the internet

STATE	INFORMATION REPORTED	INSTITUTIONS PARTICIPATING	MANDATORY OR VOLUNTARY	PUBLIC ACCESS
NY	Unintended adverse / undesireable development in an individual patient's condition	Hospitals, ambulatory surgical clinics	Mandatory	Aggregate data by hospital is made public
OH	Death or injury resulting from equipment malfunction or treatment of the wrong ailment	Free standing therapy, imagery, and chemotherapy centers	Mandatory	Aggregate data by type of incident is made public
PA	Deaths due to injuries, medication error, malnutrition, dehydration, or sepsis; transfusion reactions; infant discharge to the wrong family, surgery on the wrong patient or limb	Hospitals, nursing homes, home health agencies, IMF-MR facilities, ambulatory surgical clinics	Mandatory	Confidential
MS	Suicide; attempted suicide; wrongful death; abuse; unexplained injuries	All licensed health care facilities	Mandatory	Actual reports are not accessible to the public; limited information is available in a de-identified fashion
RI	Brain injuries, mental impairment; paralysis or other disability caused by treatment; subjecting patients to any procedure not ordered by the physician	Hospitals	Mandatory	Reports are confidential but subject to subpoena
SD	Unnatural deaths; missing patients or residents; incidents of abuse and neglect	All licensed health care facilities, ambulatory surgical clinics	Mandatory	Reports are confidential; de-identified summaries are subject to subpoena
TN	Unusual occurrences or events (left to organization's discretion)	Hospitals, nursing homes, ambulatory surgical clinics	Mandatory	Confidential

STATE	INFORMATION REPORTED	INSTITUTIONS PARTICIPATING	MANDATORY OR VOLUNTARY	PUBLIC ACCESS
UT	Unexpected patient deaths	Hospitals, nursing homes, ambulatory surgical clinics	Voluntary	Substantiated complaints are released to the public
WA	Unexpected patient deaths; suicides; restraint deaths, wrong site surgery, infant abduction or wrong infant discharge, transfusion reaction, major loss of function due to treatment or surgery	Hospitals	Mandatory	Confidential
WI	Unexpected patient deaths; suicides; restraint deaths; medication deaths	Psychiatric hospitals, nursing homes, and community mental health centers	Mandatory	Information is aggregated by incident and released

SUMMARY

23 states have implemented reporting systems to track preventable medical errors.
21 states have mandatory reporting for nursing homes, hospitals, or other health care providers.
18 states have mandatory reporting for hospitals.
18 states have reporting systems with a public disclosure component.
15 states have mandatory reporting for hospitals with a public disclosure component.

This chart is a compilation of previous surveys done by the Institute of Medicine and the Joint Commission on Accreditation of Healthcare Organizations.

EVENT: HEALTH CARE QUALITY EVENT
DATE: TUESDAY, FEBRUARY 22, 2000
TIME: 12:25 AM-1:05 PM
LOCATION: PRESIDENTIAL HALL, 450 OEOB

MEMBERS OF CONGRESS ATTENDING (3):
Sen. Tom Harkin (D-IA)
Sen. Jim Jeffords (R-VT)
Sen. Arlen Specter (R-PA)

MEMBERS OF CONGRESS PENDING (6):
Sen. Bob Kerrey (D-NE)
Sen. John Rockefeller (D-WV)
Rep. Connie Morrella (R-MD)
Rep. David Obey (D-WI)
Rep. John Porter (R-IL)
Rep. William Thomas (R-CA)

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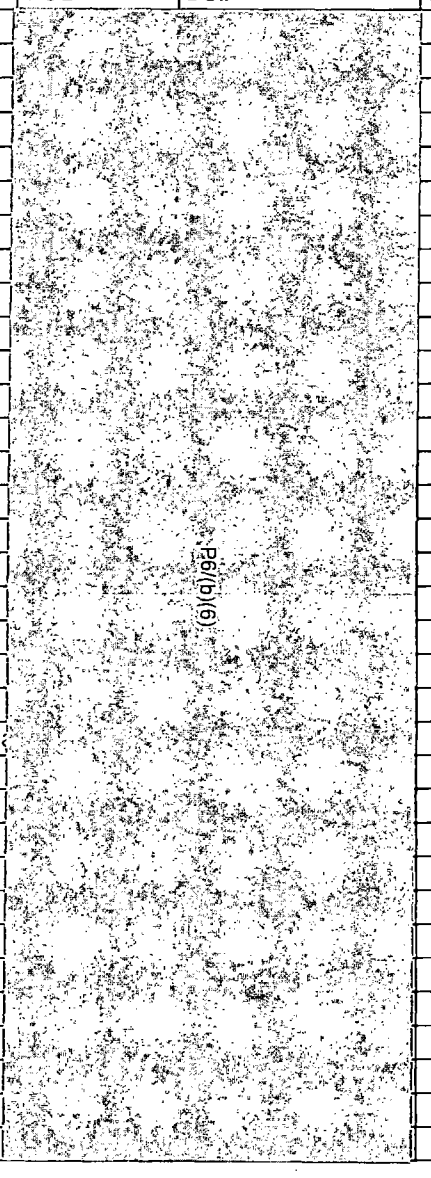
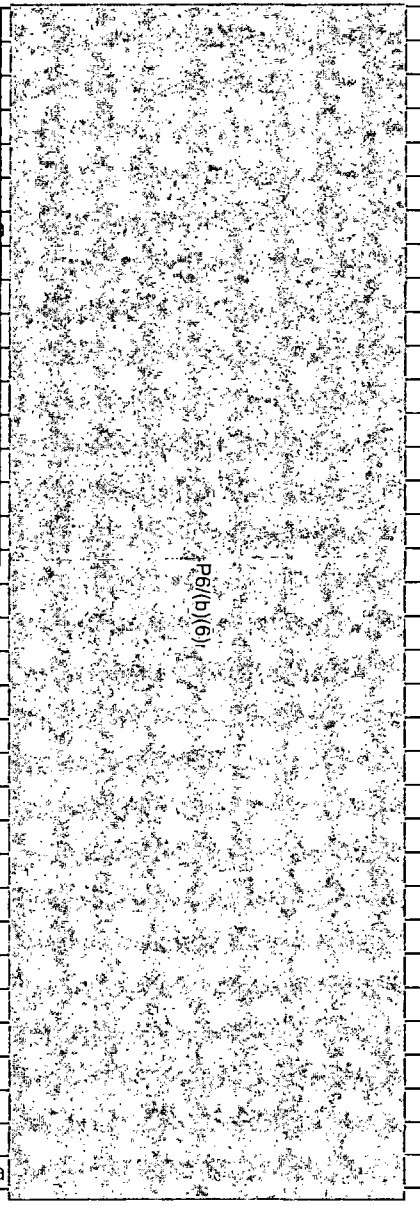
Bill Richardson
NOT Coming
[001]

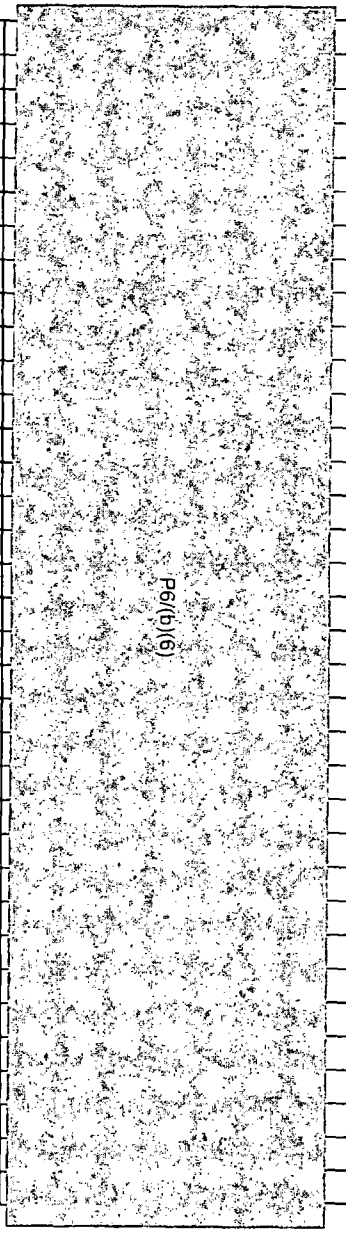
LAST NAME, FIRST NAME	ORGANIZATION	DOB	SS#	CONTACT	PHONE
ALLEN, BARBARA	American College of Physicians				
ARZUAZA, PATRICIA	HHS				
BEHAN, JIM	HHS				
BELTRAN, JANETTE	Nat Latina Health Network				
BERWICK, DONALD	Quality Commission Member Valid				
BOOTH, MAUREEN	IGA				
BUDAHN, PHILIP	VHA				
BUKKAPATNAM, RAGHU	HHS				
CERRIANO, CHERILYN	IGA				
CHATMAN, PRISCILLA	Nat Com to Preserve Social Sec & Medicare				
CHILDRESS, KERRY	VHA				
COHEN, SHARON	HIAA				
CONWAY, JAMES	CEO, Dana Farber Cancer Institute Val				
COUFAL, BARBARA	AFL-CIO				
CRESPO, HILDA	Hispanic Work Group on Healthcare				
CROWLEY, JEFFREY	Nat Assn of People w/ AIDS				
CUTLER, CHARLES	CMO, American Assn of Health Plans				
DAVIS, LYNNE	Assn of American Medical Colleges				
DELIA, GLORIA	HHS				
DEPARLE, NANCY ANN	HHS, HCFA				
DOWLING, MICHAEL	Exec VP, North Shore-Long Island Jewish He				
DREYFUS, ANDREW	Mass. Hospital Association				
EISENBERG, JOHN	HHS, AHCPR				
ENGLAND, MARY JANE	Washington Business Group on Health				
FEIT, CARRIE	LABOR				
FOSTER, NANCY	HHS, AHCPR				
FROH, RICHARD	Kaiser Permanente				
GALBRAITH, SUELLEN	American Network of Community				
GANSER, CONNIE	Mass. Hospital Assn.				
GARTHWAITE, TOM	VA				
GILGOFF, KAREN	AFSCME Retirees				
GIRARD, YVETTE					
GOLDING, DEBRA	HHS				



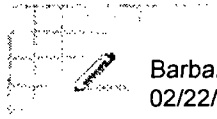
GRAUSE, BEATRICE	Mass. Hospital Assn.			
GRISS, ROBERT	Center on Disability and Health			
HANSON, JOHN	VHA			
HENNEY, JANE	HHS, FDA			
HOLLAND, HOWARD	HHS			
HOUSTAD, JOANNE	Nat Partnership for Women & Families			
IGNAGNI, KAREN	President & CEO, American Ass of Health Plan			
IMPARATO, ANDREW	American Assn of People w/ Disabilities			
JENKINS, JENNIFER	American College of Physicians			
JUDGE, VALENTINA	AFL-CIO			
KETTER, JONI	AFL-CIO			
KIRLE, LESLIE	Mass. Hospital Assn.			
KIZER, KENNETH	President, Quality Forum			
KOFMAN, MILA	HHS			
KRAMERICH, LESLIE	HHS			
KUNKLE, CATHERINE	Nat Business Coalition on Health			
LAWING, JACKIE	HHS			
LEAPE, LUCIAN	Harvard School of Public Health			
LEHMAN, GREG	Nat Business Coaltion			
LEVIN, ARTHUR	Center for Medical Consumers			
LEWIN, DAVID	HHS			
LORRAINE, CATHERINE	HHS			
LOVE, DENISE	Nat Assn of Health Data Organ.			
MAGUIRE, DANIEL	HHS			
MCALISPER, LYNN	EDS			
MCLANE, SHELLEY	Nat Assn of Protection & Advocacy Syst			
MEYER, GREG	HHS			
MIGDAIL, KAREN	HHS			
MILNE, DEBORAH	HHS			
NICOLL, ANNE	California Hospital Assn.			
NIELSEN, MARCIA	AFL-CIO			
NOVOTNY, LOUISE	AFL-CIO			
NOYES, ELIZABETH	American Academy of Pediatrics			
OKANE, MARGARET	President, Nat Committee for Quality Assuranc			
OLEARY, DENNIS	President, Joint Comm Acc of Health Care Qua			



OTTEN, JEFF	President, Brigham Young Women Hosp				
PEARSON, CYNTHIA	National Women's Health Network				
PESTAINA, KAYE	HHS				
PIACENTINI, JOSEPH	HHS				
POLLACK, RONALD	Quality Commission Member				
QUERAM, CHRIS	Quality Commission Member				
RABBU, RONALD	HHS				
RASKE, KENNETH	President, Greater New York Hosp Assn				
RECTOR, JOHN	National Community Pharmacists Assn.				
REED, STEPHANIE	American Nurses Association				
RICH, DAVID	Greater New York Hospital Assn				
RILEY, TRISH	Nat Acad of State Health Policy				
RODGERS, MICHAEL	Nat Assn for Homes for the Aging				
ROSERO, LUIS	HHS				
SAWE, ARTHUR					
SAWE, CAROLINE					
SCHERR, LAWRENCE	Senior VP, North Shore Univ. Hospital				
SCHNEIDER, PHILLIP	National Ass of Chain Drug Stores				
SCHULDER, DAN	National Council of Senior Citizens				
SHARFSTEIN, STEVEN	Quality Commission Member				
SHEARER, GALE	Consumers Union				
SHULKE, DAVID	Exec VP, American Health Quality Assn				
SIMMONS, HENRY	National Coalition on Health Care				
SISTO, DANIEL	President, Healthcare Assn of New York State				
SMITH,PATRICK	AARP				
STEWART, THOMAS					
SUH, DONG					
TAPLIN, CAROLINE	HHS				
THOMAS,PETER	Quality Commission Member				
UGORETZ, MARK	President & CEO, ERIC				
VANAMERONGEN, DEREK	American Assn of Health Plans				
WAKEFIELD, MARY	Quality Commission Member				
WALTMAN, SUSAN	Greater New York Hospital Assn				



WEIL, ALAN	Quality Commission Member				
WEISS, ALICE	HHS				
WEISS, MARINA	March of Dimes				
WOODCOCK, JANET	HHS				
WYATT, LANCE	White House Fellow				
ZURAWSKI, PAUL	Business Roundtable Group				



Barbara D. Woolley
02/22/2000 10:22:18 AM

Record Type: Record

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

Final 2/22/00 9:30 am
Sam Afridi

PRESIDENT WILLIAM J. CLINTON

REMARKS ON PREVENTING MEDICAL ERRORS

THE WHITE HOUSE

February 22, 2000

Acknowledge: Barbara Blakeney for your words and your work on the front-lines; Secretary Shalala; Secretary Herman; Janice LaChance; John Eisenberg; Tom Garthwaite; Sue Bailey and other officials from throughout the federal government; Senator Specter; Ken Kizer; leaders representing consumers, health care plans and providers, business, labor and quality experts; and, of course, the National Academy of Sciences' Institute of Medicine for its landmark report.

As Secretary Shalala said, the IOM study focused new light on what has been one of this Administration's highest priorities: ensuring that all Americans receive the highest quality health care in the world.

We've heard the numbers, but we know this is about more than statistics, it's about saving lives. And the dollar costs of these errors don't begin to measure the toll that's taken on families and the trust that's drained from the health care system when the wrong drug is dispensed, when a blood transfusion is mismatched, when a surgery goes awry.

We're not here to point fingers and find fault—we're here to join hands and find answers. No American should have to fear that their health care could jeopardize their health.

Let me be clear. We are blessed with the finest health care system and the finest health care professionals in the world. Thanks to new drugs, new procedures, and new technologies, we are living longer, better, healthier lives. And we're on the cusp of far greater advances. Later this year, researchers expect to finish the mapping of the human genome which will lead to a revolution in our ability to detect, treat and prevent many diseases.

But as health care gets more advanced, the system gets more complex. We need to take a step back and ask ourselves some critical questions: How can we better design the system to better the care for patients?

Have our professional caregivers been adequately trained to keep pace with the rapid changes in heath care? Are they communicating and coordinating with each other? Are the right kinds of teams and systems in place in every setting that work for safety?

We have asked these kinds of questions and invested in the right kind of research when it comes to aviation safety and workplace safety—and it's worked. In the 1980's, our manufacturing sector undertook a disciplined review of every process in every complex operation to reduce errors. Now we must do the same in the health care system.

Last December, I directed our own Health Care Quality Task Force to analyze the IOM study—and report back with ways we can implement their recommendations, protect patients and promote medical safety. This morning, I received the Task Force report and I am proud to accept all of its recommendations.

Our goal is clear: to reduce preventable medical errors by fifty percent within five years. Today, I want to announce our national action plan to help make that a reality.

First, we agree with the need to establish a focal point within the federal government to target this challenge.

So today, I am proposing the creation of a new Center for Quality Improvement and Patient Safety. My budget includes $20 million to support this center which will invest in research, develop national goals, issue an annual report on the state of patient safety, and translate findings into better practices and policies.

Second, we will ensure that each and every one of the 6,000 hospitals participating in Medicare has patient safety programs in place to prevent medical errors—including medication mistakes. These new systems save lives—and, over time, save money.

I want to commend hospitals for the steps they have already taken—and we will work with them and other health care experts to develop this regulation in the coming months.

Third, as we seek to make sure that the right systems are in place, we also need to make sure they are working. Today, I am unveiling our plan for a nationwide state-based system of reporting medical errors to be phased in over time. This will include mandatory reporting of preventable medical errors that cause death or serious injury, and voluntary reporting of other medical mistakes and so-called "near misses" or "close calls".

Reporting is vital to holding health systems accountable for delivering quality care—and educating the public about the safety of their health system. It is critical to uncovering weaknesses, targeting widespread problems, analyzing what works and what doesn't and sharing it with others.

Twenty-one states already have mandatory error reporting systems. We want to make sure they have the tools to do it right—and that every other state will follow. That's why we will be working with the National Quality Forum—a public-private group of health care experts--to develop a set of patient safety measurements that would lay the foundation for a uniform system of reporting errors.

We also want to replace what some call a culture of silence with a culture of safety—an environment that encourages others to talk about errors, what caused them, and how to stop them in the first place. So we will support legislation that protects provider and patient confidentiality but that does not undermine individual's rights to remedies when they've been harmed. People should have access to information about a preventable medical error that causes serious injury or death of a family member--and providers should have protections to encourage reporting and prevent mistakes from happening again.

And when it comes to reporting, we want the federal government to continue to lead by example. The Department of Veterans Affairs already has a mandatory reporting system for death and serious injuries. Beginning this spring, all 500 Department of Defense hospitals and clinics will do the same—and the VA will add a voluntary reporting system in its hospitals nationwide.

Finally, I am announcing a number of new steps we will take that specifically target medication errors. Each year, medication mix-ups claim thousands of lives. Sometimes mistakes occur because many different drugs sound or look the same--sometimes, because people are taking multiple medications and going to multiple doctors.

I am calling on the Food and Drug Administration to develop new standards to help prevent medical errors caused by drugs that sound similar or packaging that looks similar. In addition, we will develop new label standards that highlight common drug interactions and dosage errors. The VA also will put in place computerized systems to prevent medication mistakes. No more hand-written prescriptions that no one can read. Hospitals that have already taken these steps have eliminated two out of three medication errors.

Taken together, the actions I announce today represent the most significant effort our nation has ever taken to reduce medical errors.

It is a balanced, common sense approach. It is based on prevention not punishment—problem-solving, not blame-placing.

We know there's more to do. But by working together, we will keep making progress. We will cut preventable medical errors in half within five years. We will reduce concerns about lawsuits as we reduce medical mistakes. We will avoid needless injuries. We will save lives. And we will make the best health care system in the world even better for all Americans.

# # #

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.

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 <u>preventable</u> 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.

GREATER NEW YORK HOSPITAL ASSOCIATION
GNYHA

555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350
Kenneth E. Raske, President

FACSIMILE TRANSMISSION

Date: Feb. 22, 2000

Time:

TO: Chris Jennings
FAX # 202-456-5557

FROM: **Kenneth E. Raske**
President

Phone: 212-246-7100
e-Mail: raske@gnyha.org

We are transmitting 2 pages including this cover sheet. If you have not received all of the pages PLEASE CALL OUR OFFICE AS SOON AS POSSIBLE.

MESSAGE:

Chris - we would like to issue the attached statement at 11:00 a.m.
Is it OK? See you at 12:30.

Main Number (212) 246-7100
Fax Number (212) 262-6350

Hard Copy [ ] will [x] will not be sent by mail.

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.

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

FAX

Division of Media and Information
1101 Vermont Avenue,
Washington, DC 20005

Date FEBRUARY 21, 2000

Number of pages including cover sheet 2

To: Chris Jennings
White House

From: BRENDA L. CRAINE
AMA MEDIA DIVISION

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REMARKS:

☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please comment

Rich Deem asked me to forward to you....

Brenda

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
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Date:

To: Chris Jennings
456-5557

From: Alicia Mitchell
Director, Media Relations
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Subject:

Attached is our statement.

Washington, DC Center for Public Affairs
Chicago, Illinois Center for Health Care Leadership

Liberty Place, Suite 700
325 Seventh Street, N.W.
Washington, DC 20004-2802
(202) 638-1100

Contact: Carol Schadelbauer, (202) 626-2342
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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.

Liberty Place, Suite 700
325 Seventh Street, N.W.
Washington, DC 20004-2802
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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.

February 22, 2000

Report on Medical Mistakes Sought

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

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

hearings.

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 to Propose State-Based System To Protect Patients

By SHAILAGH MURRAY
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — President Clinton today 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 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 today 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 yesterday he was "optimistic Congress will act quickly to solve this glaring problem."

CLINTON TO ORDER STEPS TO REDUCE MEDICAL MISTAKES

A MANDATE FOR HOSPITALS

States, in Turn, Will Be Asked to Add Systems to Require the Reporting of Errors

A1 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 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 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."

An effort to lessen (and disclose) errors in health care.

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.

The New York Times

TUESDAY, FEBRUARY 22, 2000

between the two Democrats was their first opportunity for the spotlight since the New Hampshire primary, which Gore won, because all the political activity since then has been focused on the Republican race. For Bradley, it was a much- needed chance to regain some attention and attempt to throw the vice president off-stride.

Held in the historic heartbeat of the city's black community, the two Democratic contenders sought support both among black and Hispanic voters, who embody a pivotal voting block in the March 7 New York primary, but also among the wider, national television audience.

They debated health care, assistance to AIDS patients and bringing education and redevelopment to urban areas.

But down in the polls and needing the political equivalent of a medical crash cart to rescue his insurgent candidacy, Bradley was hoping to revive his campaign largely by becoming the aggressor and questioning Gore's fitness as the party's best standard-bearer in the fall election.

He said that Gore, for all his support of affirmative action, backed a White House effort that considered abolishing the program, based on an account in a memoir by former Clinton aide George Stephanopolous.

Gore, in a less-than-subtle dig at his recent drop in the polls in key states like New York, said at one point, "I think it's pretty clear what's going on. You're sounding a little desperate because your are trying to build yourself up. It's very clear. Very clear."

But Bradley, with 16 states holding primaries and caucuses two weeks from Tuesday apparently plans to continue to press his criticism.

In what his campaign has billed as a major speech, Bradley is expected to further hammer Gore today by turning around the vice president's earlier criticism of him for leaving the Senate in 1996 when the Republicans took control. Gore had accused Bradley of not being a loyal Democrat because he didn't stay and fight.

A Bradley aide said the former New Jersey senator will ask in his speech today," who is the real Democrat," then detail his differences with Gore by the degree to which each has embraced core Democratic issues, such as abortion, gun control, universal health care and opposing the tobacco lobby.

The battle for support among black voters, one of the party's most reliable constituencies and a key element to victory in New York, has been fast and furious. In New York City, they can account for upwards of 30 percent or more of the primary turnout.

With that in mind, Gore and Bradley had been in and out of the Empire State with increasing frequency as the March 7 primary approaches. Gore has the distinct advantage, basking in the aura of the consistently strong support for President Clinton that black voters have show for more than seven years, even at the height of the impeachment scandal.

Gore has lined up most, if not all, of the black political establishment, from preachers to public officials, including prominent black Democrats in New York such as Rep. Charles B. Rangel of Harlem and state Comptroller H. Carl McCall. Bradley, meanwhile, hopes that an endorsement and ad on his behalf from former basketball great Michael Jordan trumps the crowd of vice presidential backers.

Both men have courted the Rev. Al Sharpton, a controversial political leader in the city's black community. Bradley has openly appeared with him, while Gore's campaign initially tried to keep their contacts secret, even denying at first that negotiations were even in the works.

Sharpton said before the debate that he would announce his endorsement after hearing the debate.

Clinton to call for drastic decrease in medical errors
By Andrea Gerlin
Knight Ridder Newspapers

PHILADELPHIA President Clinton Tuesday is expected to call for a 50 percent reduction over the next five years in the number of preventable medical errors that kill or injure patients each year.

In a report prepared at the President's request, a White House task force has recommended a sweeping array of initiatives to reach that goal, a senior administration official said Monday. The official, who spoke on the condition of anonymity, said the President fully supports the initiatives.

Among the measures that Clinton is expected to endorse is creating a nationwide, mandatory system for reporting errors that cause deaths or serious injuries, and a voluntary system for reporting other errors and "near misses." At present, 23 states including Pennsylvania and New Jersey have reporting systems, but not all are mandatory.

"We think that within three years all 50 states should have their programs up and running," the official said.

A November report issued by a panel of the Institute of Medicine at the National Academy of Sciences estimated that medical errors kill as many as 98,000 people in the U.S. each year, higher than the death toll from AIDS, auto accidents or breast cancer. Based on that estimate, medical errors are among the nation's eight leading causes of death and cost as much as $29 billion a year.

The Institute of Medicine report recommended that Congress create mandatory and voluntary reporting systems. It also recommended the establishment of a national patient safety center.

"The (IOM) recommendations have been strongly endorsed" by the White House, the administration official said. "They actually go beyond them in a number of areas."

Tuesday, the President is also expected to emphasize that his proposed budget for the coming year will include $20 million to establish the Center for Quality Improvement and Patient Safety within the existing Agency for Healthcare Research and Quality.

Clinton has also set aside $33 million in additional funding for the Food and Drug Administration's medical error and adverse drug event reporting systems. The FDA currently reviews prescription drugs for approval before they can be sold. It will look more closely at similarly packaged drugs, names that cause confusion, interactions and dosage errors.

The Health Care Financing Administration will develop regulations that require more than 6,000 hospitals that participate in Medicare to implement error reduction programs. Most U.S. hospitals would be affected.

The President is expected to say that information from mandatory reporting systems should be made publicly available with names of hospitals and numbers of errors, but not names of individuals. Providing that information would keep the public informed about the safety of health systems, according to the White House report.

Mandatory error reporting and public disclosure of the information are likely to be unpopular with healthcare provider groups. The American Medical Association and the American Hospital Association have previously expressed opposition to government reporting requirements, and have favored voluntary systems. They say mandatory reporting is punitive, and could expose their members to lawsuits and drive the problem further underground.

The administration official acknowledged but downplayed anticipated opposition from the trade groups and said the White House would seek their cooperation.

"I think there are those who will be opposed," the official said. "Do I think they will embrace every issue? No. Do I think they will oppose us on every issue? No. We will be working with them."

Clinton's reporting requirements will be phased in over three years, which administration officials believe will allow healthcare providers adequate time to prepare. The government's funding to the various agencies also includes money for new research to determine which error reduction methods work best.

The White House supports legislation protecting internal "peer review" information gathered at confidential hospital meetings for the purpose of analyzing errors in order to prevent their recurrence. Too great a restriction on that information, however, could provoke resistance from lawyers who represent malpractice victims.

The administration official said, "We do not in any way undermine individuals' right to seek redress."

Existing mandatory reporting systems have proven problematic, as hospitals and health systems frequently do not comply with state requirements. The Inquirer which published a four-part series in September showing the extent of the nation's medical error problem reported last month that 35 hospitals in

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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.

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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.

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- *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.

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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.