

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. bio	re: Christine Cassel (partial) (1 page)	12/07/1999	P6/b(6)
001b. bio	re: Richard Davidson (partial) (1 page)	12/06/1999	P6/b(6)
001c. bio	re: John Rother (partial) (1 page)	12/06/1999	P6/b(6)
002a. fax	Janet Corrigan to Chris Jennings re: SSN (partial) (1 page)	12/06/1999	P6/b(6)
002b. bio	re: Janet Corrigan (partial) (1 page)	n.d.	P6/b(6)
002c. bio	re: William Richardson (partial) (1 page)	n.d.	P6/b(6)

COLLECTION:

Clinton Presidential Records
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FOLDER TITLE:

Errors [Folder 2]

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- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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- 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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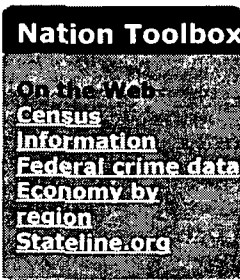
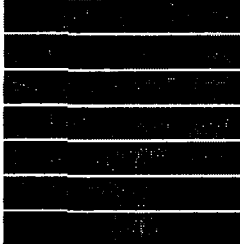
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- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



Medical Errors Blamed for Many Deaths

By Rick Weiss

Washington Post Staff Writer

Tuesday, November 30, 1999; Page A01

As many as 98,000 Americans die unnecessarily every year from medical mistakes made by physicians, pharmacists and other health care professionals, according to an independent report released yesterday that calls for a major overhaul of how the nation addresses medical errors.

More Americans die from medical mistakes than from breast cancer, highway accidents or AIDS, according to the report from the Institute of Medicine, an arm of the National Academy of Sciences. Those deaths, along with serious nonfatal reactions to other medical errors, cost the nation as much as \$29 billion a year, the congressionally chartered research group concluded.

Yet while other areas of the U.S. economy have coordinated safety programs that collect and analyze accident trends, including those that track nuclear reactor accidents, highway crashes and airline disasters, there is no centralized system for keeping tabs on medical errors and using that information to prevent future mistakes.

If such a system were put in place, the report predicts, the number of deaths from medical mistakes could be cut in half within five years.

"These stunningly high rates of medical errors, resulting in deaths, permanent disability and unnecessary suffering, are simply unacceptable in a medical system that promises first to 'do no harm,'" said William C. Richardson, president of the W.K. Kellogg Foundation and chairman of the expert committee that compiled the blunt, 223-page report.

Several medical and public policy organizations have addressed the issue of medical errors since the widely reported death of Boston Globe health columnist Betsy Lehman, who died from a chemotherapy overdose in 1995. But experts said the prestige of the National Academy of Sciences, and in particular its specific proposal to create a federal office to oversee medical accident trends and devise strategies for prevention, could spur real change.

"There's not a controversy here," said David Eddy, a senior adviser to the Pasadena-based health maintenance organization Kaiser Permanente Southern California and an expert in evidence-based medicine. "It's an ideal opportunity to increase quality and decrease costs."

Medical errors can range from a simple miscommunication about a drug's name during a telephone call between a doctor and a nurse to the

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drug's name during a telephone call between a doctor and a nurse to the erroneous programming of a complex medical device at the end of a busy hospital night shift. They include wrong diagnoses from mislabeled blood tubes, mistaken treatments because of poorly labeled drugs, improper dosing because of faulty calculations and a simple lack of communication as a patient gets passed from one provider to the next.

To address the wide range of problems, the report calls for mandatory federal reporting requirements for serious medical accidents. And it calls upon Congress to create and fund a national patient safety center within the Department of Health and Human Services, which would be charged with developing better systems for tracking and preventing patient injuries.

The report also suggests that minor medical errors that have not resulted in serious injuries or death be collected in a confidential database, not available for public review. The hope is that by reducing health care providers' legal exposure and the risk of lawsuits, doctors, hospitals and others may be more open about their errors, and thus give the nation a chance to learn from their mistakes.

"Safety is a cultural matter, and unless you create a cultural environment in which it becomes safe to talk about errors and near misses, you can't get to work on the root causes of error," said Donald M. Berwick, a Harvard professor of health care policy and president of the Institute for Healthcare Improvement, a not-for-profit educational and research organization, who was one of 19 experts who worked on the report.

"You can't use fear or blaming of individuals as a foundation for safety improvement," Berwick said. "We want to set up an environment where more errors will be revealed."

The report concludes that most errors are not the result of flagrant recklessness but occur because of the cumulative opportunities for human error that arise in today's complex medical system. Most are medication errors, Berwick said. "People get the wrong drug or the wrong dose or they get it at the wrong time or it's given to the wrong patient."

Part of the problem is that many new drugs have similar names, which are easily confused when orders are given by voice or are handwritten.

"Physician handwriting has traditionally not been something that has been looked upon highly by calligraphers," said Peter Honig, deputy director of the Food and Drug Administration's office of postmarketing drug risk assessment, the federal unit responsible for tracking medication errors.

Within the past year, Honig said, the FDA has created a "medical errors group" with the explicit job of preventing medication errors. The team reviews new package designs and proposed names for new drugs to make sure they are not too similar to existing ones. In some cases, companies are also addressing the problem, Honig said. Recent ads in medical journals from the makers of the arthritis drug Celebrex, for example, warn doctors not to confuse their product with the anti-seizure drug Cerebyx or the antidepressant Celexa.

Most serious mistakes occur in busy settings such as emergency rooms and intensive care units, according to the report. In some cases they occur because medicines are kept in stock at concentrations known to be toxic, when they probably should be stored in the diluted forms in which they are intended to be given.

Deadly Results

Medical errors may be the fifth-leading cause of death.

- 1.Heart disease 727,000
- 2.Cancer 540,000
- 3.Stroke 160,000
- 4.Obstructive lung disease 109,000
- 5.Medical errors 98,000
- 6.Accidents/adverse effects 96,000
- 7.Pneumonia and influenza 86,000
- 8.Diabetes 63,000
- 9.Suicide 31,000
10. Kidney disease 25,000

SOURCES: Institute of Medicine, Centers for Disease Control and Prevention.

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From The Washington Post

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

OCT 28 1999

MEMORANDUM FOR THE PRESIDENT

On behalf of Secretary Alexis Herman, my co-chair of the Quality Interagency Coordination Task Force (QuIC) and myself, I would like to update you on the progress of the QuIC. You directed us to convene the QuIC to further the recommendations of your Advisory Commission on Consumer Protection and Quality in the Health Care Industry. We are very pleased and proud to report that the QuIC – in existence only a little longer than a year – already has proven to be a valuable and successful means of coordinating Federal efforts to improve the quality of health care services provided in this Nation. We are very confident that the work of the QuIC and its extraordinary collaboration will serve as a model for the private sector.

As you noted in March 1998, Federal agencies with health care responsibilities exert significant power in the health care industry, and working together they could improve the quality of health care for all Americans. Since they first met in May 1998, the Cabinet Departments and Agencies participating in the QuIC --- Departments of Defense, Veterans Affairs, Labor, Commerce, and Health and Human Services, and the Office of Personnel Management, the Office of Management and Budget, the Coast Guard, the Bureau of Prisons, the Federal Trade Commission and the National Highway Traffic Safety Administration -- have proven to be deeply committed to ensuring that we provide or purchase high quality health care services. Dr. John Eisenberg, Administrator of the Agency for Health Care Policy and Research, serves as Operating Chair of the QuIC.

The QuIC has identified five areas that are common to the mission of each agency and that are of profound significance to improved health care quality: 1) providing patients and consumers with information to assist in their choices; 2) pursuing key opportunities for clinical quality improvement; 3) enhancing quality measurement; 4) developing the workforce; and 5) improving information systems. A multi-agency work group has been assigned to each of these areas to develop innovative projects that will achieve its goals. Health care leaders in each agency – and the QuIC as a full body – meet periodically to steer the actions of the work groups and ensure that participating agencies are aware of and contribute to the projects.

The QuIC can already boast a number of significant achievements. We would like to highlight a few:

- Diabetes Care: The QuIC has greatly enhanced Federal collaboration on the Diabetes Quality Improvement Project (DQIP). This is particularly evident in three areas:

- Under the auspices of the QuIC, a number of Federal agencies are collaborating on the creation of a common clinical practice guideline to improve diabetes care. These agencies will use the guideline to improve the performance of providers.
- A conference was held in August to share specific successful strategies for improving diabetes care. The attendees were organizations seeking to improve their current practices. The QuIC agencies brought their success stories and strategies to this conference.
- The QuIC is seeking a broad agreement among Federal agencies to collect and report the performance of providers using diabetes measures developed by DQIP to judge the quality of clinical care.
- Reducing Medical Errors: The QuIC is working with the Institute for Healthcare Improvement (IHI) to create an initiative that will test several strategies for rapidly reducing the number of medical errors committed in “high-hazard” health care settings, including emergency rooms, intensive care units, and on-site rescue operations, around the country. Based on the results of previous IHI initiatives, we hope that some sites will be able to achieve reductions of 25% to 30% in the number of errors within 12 to 15 months.
- Making Information Available to Consumers: The QuIC has aided the Federal Trade Commission in augmenting its Consumer.gov web site to include information on health care quality. Through this gateway, the QuIC now links to all of the Federal sites that provide information to assist people in making choices about their health care plans and providers, including information on the quality of health plans for Medicare beneficiaries, Federal employees, and participants in DoD’s Tricare plans. There are also links to the Department of Labor’s health benefits education campaign to help people understand what they are getting and what their rights are.
- A Glossary of Commonly Used Terms. The QuIC agencies realized that there could be great benefit to the American people if we could agree to reduce the chance of confusion by using the same terms to mean the same things in our public communications. A set of terms has been developed and is being circulated to the Federal agencies to solicit their agreement to use the terms. We expect to have that agreement in October.

The enclosed report includes more detail on these and other accomplishments of the QuIC. We would be pleased to brief you on the work of QuIC to date and its plans for the future.

A handwritten signature in black ink, consisting of a large, stylized 'D' followed by a horizontal line.

Donna E. Shalala

Enclosure:

Progress of the Quality Interagency Task Force as of September 21, 1999

Progress of the Quality Interagency Coordination Task Force As of September 21, 1999

In March 1998, your Advisory Commission on Consumer Protection and Quality in the Health Care Industry reported that one of the critical steps in advancing the quality of health care in this country was to unify providers, purchasers, quality oversight and improvement organizations, and the American people in their aims to improve health care quality. The President noted that the Federal agencies with health care responsibilities exert significant power in the health care industry, and could improve the quality of health care for Americans if they had common aims and better coordination. He asked Secretary Donna Shalala to bring these Agencies together in the Quality Interagency Coordination (QuIC) Task Force to work to improve health care quality. The QuIC has provided a significant opportunity for the Agencies to discuss issues of mutual concern. It has made substantial progress on specific projects to improve health care since it first met in May 1998.

Briefly, the Agencies that have been working together in the QuIC are the Departments of Defense, Veterans Affairs, Labor, Commerce, and Health and Human Services, and the Office of Personnel Management, the Office of Management and Budget, the Coast Guard, the Bureau of Prisons, the Federal Trade Commission and the National Highway Transportation and Safety Administration. Dr. John Eisenberg, Administrator of the Agency for Health Care Policy and Research, serves as Operating Chair of the QuIC.

In its initial meetings, the QuIC identified five areas of shared interest: 1) providing patients and consumers with information to assist in their choices; 2) pursuing key opportunities for clinical quality improvement, 3) enhancing quality measurement; 4) developing the workforce to provide higher quality care, and 5) improving information systems.

The QuIC appointed multi-agency work groups in each of these areas and asked them to develop specific projects that would move toward these goals. Key staff were appointed from each of the participating agencies and are working hard to bring these projects to fruition. The health care leaders in each agency meet periodically to steer the actions of the work groups and to ensure appropriate support is available. Its projects include:

QuIC Efforts to Improve Current Patient Care Practices

The Work Groups identified several key opportunities to improve the care that is delivered. Some are areas in which there is scientific evidence demonstrating what should be done to diagnose and treat patients, but where common practice does not conform to those scientifically proven methods. Others are areas where research is needed to inform the choices that health care providers and managers make when determining what to do. The QuIC has undertaken efforts in these four specific areas:

- **Diabetes Care.** In 1997, you launched the Diabetes Quality Improvement Project (DQIP) which brought together the Health Care Financing Administration, The Department of Veterans Affairs (DVA), and private sector partners to identify ways in which diabetes care could be improved. Working from research sponsored by the Agency for Health Care Policy and Research that identified what is most important and effective in treating patients with diabetes, DQIP created a small set of measures to use in judging clinical performance and determining where improvement was needed. The DQIP efforts led to three specific actions under the QuIC.
 - First, before the QuIC was created, the DVA and the Department of Defense (DoD) had created a common guideline for care of diabetes and had planned to use the DQIP measures to assess performance. Under the auspices of the QuIC, other Federal Agencies were invited to participate in the creation of the guideline and to use the guideline to improve the performance of their providers.
 - Second, the DQIP group held a conference aimed at helping providers and community organization to identify successful strategies to improve the quality of diabetes care. The QuIC was able to enrich this conference by bringing to it the Federal Agencies and care teams with successful strategies to share and by bringing together teams who were seeking new ideas that could be tried in their own communities. The conference was highly successful, and its success will be extended through efforts to compile and disseminate the "best practices" that were described at the conference to other providers and community representatives who were unable to attend.
 - Third, the QuIC is seeking a broad agreement among Federal agencies to collect and report the performance of providers on the DQIP measures. The QuIC discussed the importance of Federal Agencies agreeing to use this common set of measures for patients with diabetes, and concluded that it would significantly help to improve patient care. The QuIC has endorsed the idea of asking the Federal Agencies to agree to use the DQIP measures. We are in the process of making that request of all of the participating Federal Agencies and expect to know by mid-October how they have responded and what it will mean to use the DQIP measures in their programs.
- **Depression Diagnosis and Care.** As with diabetes, there is substantial research showing that the diagnosis and treatment of people with mild to moderate depression could be greatly improved. The DVA and DoD identified this as an area in which they wished to create a guideline to improve the care of their populations. Through the QuIC, their efforts were expanded in two significant ways. First, other Federal agencies were invited to participate in developing and using the guideline. Second, the research agencies, such as the National Institutes of Health, the Agency for Health Care Policy and Research, and the Substance Abuse and Mental Health Administration, were involved and able to bring the latest and most compelling evidence from their research to the effort. A guideline that will enhance the care of depressed individuals will be completed by the end of October and disseminated to

Federal providers and made available to the public. One of the final steps needed is to marry performance measures to the guideline to ensure that the care for people with depression is getting better. Unfortunately, there is no clearly generally accepted superior set of depression care measures like the DQIP measures were for diabetes. Therefore, the QuIC organized a conference of experts in depression and measurement at the end of September and will produce not only the best measures available currently for monitoring performance, but also a research agenda for creating a more enduring set of critical measures.

- **Reducing Errors.** As indicated in the Advisory Commission's report to you, there is currently an unacceptable level of errors in health care. The QuIC is working with the Institute for Healthcare Improvement (IHI) to create an initiative that will test several strategies for rapidly reducing the number of errors committed. Our effort will be targeted specifically at health care delivery settings where patients are in need of urgent assistance and decisions have to be made rapidly, which we are calling "high hazard environments." These would include emergency rooms, operating rooms, intensive care units, and on-site rescue operations. This is the first such initiative targeted at error reduction in these high hazard environments. Based on the results of previous IHI initiatives, we hope that some sites will be able to achieve reductions of 25% to 30% in the number of errors within 12 to 15 months. The QuIC endorsed this effort at its meeting on September 21, and we are in the process of asking the agencies to decide if they wish to participate and how many teams they would like to have participate in the effort. Whatever is learned through this Federal effort will be shared broadly to help others reduce errors in their own health care delivery settings.
- **Effect of Working Conditions on Quality of Care.** From studies in other industries, we know that the conditions under which people work can dramatically affect their productivity and the quality of work that they do, but little research has been done on this issue in health care. Recent changes occurring nationwide in the levels of staffing in hospitals and nursing homes, as well as questions about how the organizational structure and physical environment affect the quality of care delivered, have made this an important topic in health care quality. These questions prompted the QuIC to look for research that could inform provider organizations about working conditions within their control that could influence the quality of care they deliver, but little research was available. Therefore, the QuIC elected to organize an expert meeting that will identify what is known about how working conditions affect the quality of care in health care and, more importantly, to identify the critical questions to be explored about the effect of working conditions on quality of care. We are collaborating in this effort with health care provider organizations, unions and other representatives of health care workers, and experts in facility design, art, organizational design, and quality improvement. This conference will provide a framework for Federal and private research efforts.

Future efforts to improve patient care will be developed based on the priorities of the Agencies involved and are likely to continue to expand on efforts to improve mental

health care and move into cardiac disease, cancer, and other major diseases. For example, the QuIC can take advantage of the National Cancer Institute's Quality of Cancer Care Initiative to affect the quality of cancer care delivered in ways that the NCI can not do solely through research efforts.

QuIC Efforts to Create Quality Improvement Tools

One of the major benefits of the collaboration occurring under the QuIC is the ability to develop and share tools that enable the Federal agencies and others to improve the quality of care. The QuIC Work Groups identified several tools that were needed. By ensuring collective use of these tools, the QuIC will help to minimize the confusion that health care providers encounter in dealing with the various Federal agencies and improve the efficiency of the agencies' work. These include:

- **A Common Credentialing Effort.** Currently, each Federal agency separately credentials the health care professionals who work for them. When professionals seek joint appointments from more than one agency, move from one agency to the other, or are called upon in times of national need, such as the Gulf War, to fill in for their colleagues who are serving abroad, the credentialing effort must begin again at the new agency. To prevent such duplication of effort and to improve the rigor of the initial credentialing process, the Federal agencies are working on a joint credentialing program that would allow electronic sharing of information across the agencies. This process began with an effort between the DVA and the Health Resources and Services Administration to test the feasibility of creating such a credentialing process for physicians and dentists. It has been judged successful, and the QuIC is working to expand both the number of Federal agencies that will use the process and the types of professionals who can be credentialed through the program. We expect this effort will take many more months of effort, but it is progressing.
- **Information on Measures.** A goal of the QuIC is to ensure that the Federal agencies are using common measures and risk adjustment methods when possible. These steps will help to reduce reporting burden for health care providers and increase our ability to compare performance across providers. Initial steps have been taken to enable us to move toward this goal.

The QuIC has created a compendium of all of the measures currently in use by Federal agencies. It is available to all who are seeking information on the measures currently available for use in assessing quality. The information also will be available through a National Measures Clearinghouse web site that is under development by the Agency for Health Care Policy and Research. The QuIC members are sharing and testing the most advanced risk adjustment methods available. Comparisons will be made on the results, the relative costs of each method, and their effectiveness. A workshop is planned to discuss which measures and risk adjustment methods work best for particular purposes, and to agree on which are best.

- **Formulary Guidance.** Several Federal organizations maintain formularies for their beneficiaries. Others, such as the Health Care Financing Administration, must oversee organizations that provide care to their beneficiaries and need a method by which they can ensure that the formularies of provider organizations are adequate to meet the expected needs of the populations they serve. A team of individuals is working to determine how to provide guidance based on scientific evidence that will help provider organizations determine what a formulary must contain to be adequate to meeting these expected needs.

- **A Taxonomy of Quality Improvement Methods.** A tool that is essential if the nation is to learn which quality improvement strategies work best in various situations is a common method and language for identifying and describing quality improvement interventions. The QuIC Agencies conducted an expert meeting and are in the process of finalizing a taxonomy that will allow us to describe and compare the quality improvement strategies used in Federally sponsored research, and in projects of the DVA, DoD and HCFA's peer review organizations. This taxonomy will be published in a professional journal for broad use, and will be put to work immediately upon completion by the Federal agencies in their solicitations for research proposals, descriptions of on-going projects, and instructions to their provider organizations.

- **Improved Information Exchange across Agencies.** Common information is used by the Federal agencies, but much of it is not exchanged electronically in a format that can be used by all agencies. The information systems experts have been studying methods to improve the efficiency and completeness of the data that are used in many agencies. They have started with the "exclusions list," which is the list of individuals and organizations to which the Federal agencies can not make health care payments. Individuals and organizations appear on this list after they have committed fraud or other similar actions in the delivery of health care goods and services. Agencies have noted that they are not sure they have accurate and up to date information on this list, or that they are missing information, such as the individual's or organization's unique identifier code, and must make inquiries to verify identities before paying for services. Work is underway to determine if a single, searchable list that has the complete information needed by the agencies can be maintained and shared electronically. Further projects to explore the impact that information systems improvement can have on quality are being discussed.

- **Strategies for Ensuring Patients' Rights.** In November 1997, the President directed the Federal agencies to bring their programs into compliance with the Patients' Bill of Rights that was developed by the Advisory Commission. As part of the efforts to bring our programs into compliance, key agency staff have been discussing their approaches and the challenges. They have been able to share ideas and strategies for bringing about compliance with the Bill of Rights to the extent that current legislation permits. These discussions have proven useful for all of the agencies.

QuIC Efforts to Help Inform Americans About Health Care

The QuIC agencies share responsibility for communicating with the American people about their health care choices and are developing three products that will greatly enhance our ability to do so. These are:

- **A Gateway to Consumer Information Available from Federal Agencies.** The QuIC has aided the Federal Trade Commission in augmenting its Consumer.gov web site to include information on health care quality. Through this gateway, the QuIC now links to all of the Federal sites that provide information to assist people in making choices about their health care plans and providers, including information on the quality of health plans for Medicare beneficiaries, Federal employees, and participants in the DoD Tricare plans. There are also links to the Department of Labor's health benefits education campaign to help people understand what they are getting and what their rights are.
- **A Glossary of Commonly Used Terms.** The QuIC agencies realized that there could be great benefit to the American people if we could agree to reduce the chance of confusion by using the same terms to mean the same things in our public communications. A set of terms has been developed and is being circulated to the Federal Agencies to solicit their agreement to use the terms. We expect to have that agreement in October.
- **Guidance for Producing Report Cards.** Many organizations, including several Federal agencies, large purchasers, and employers, are attempting to help patients make better choices about their health care by providing "report cards" on provider and plan performance to the American people. There are scientific studies that show what is effective in providing these report cards to various types of people, and there are many organizations with experiences that can help others who are attempting to provide high quality report cards. To inform report card producers, the QuIC agencies have brought together researchers and report card producers to develop guidance based on the science and reported experiences. This information will be made available through a web site that is currently under development. It is expected to be available this spring.

Issues for the SWIFT Team from CCC

1. Scanning

- a. Scanning correspondence takes longer than what was projected and/or anticipated. Will CCC receive another scanner?
- b. Scanned items do not appear in assigned queues in an acceptable amount of time, i.e., scanned items routinely take hours to appear in assigned queues. What solution do you have to allow CCC staff to input priority, rush items for immediate assignment? What are your plans for optimizing the time for scanned assignments?

2. Incomplete Modules

- a. Reassignments have been given a patchwork solution until the entire system is up. The CCC staff has found this patch to be time-consuming and inadequate. Do you have any other solutions to making reassignments in SWIFT?
- b. Close outs cannot be completed until the full system is running. The solution given to CCC is time consuming, given that the work will have to be done again when the system is running. Do you have any other suggestions on this matter?

3. Mishaps Within Working Module

- a. Frequently, CCC Analysts have called the Prescience team about items that were keyed into SWIFT and then reappeared in the assignment queue. What are your proposed solutions for correcting this occurrence?
- b. Reports have not been addressed in an adequate manner, appropriate to the operation of SWIFT. What are your proposals to address the need for producing reports from SWIFT?
- c. We are still experiencing shut downs because the server has to be rebooted. What are your proposals to solve the need for frequent rebooting of the SWIFT server?

eFax Cover Sheet

 Sent Via
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To : FERN
Company : THE WHITE HOUSE/CHIEF OF STAFF
Fax # : 1-202-456-1121
From : BOTP Main Fax
Date : 12/09/99
Re : THE PRESS RELEASE AS PROMISED

cc: Chris
Jennings

Number of pages (Including cover sheet): 3

DEAR FERN,

IF THE PRESIDENT, MR. PODESTA AND/OR MR. JENNINGS WOULD LIKE A COPY OF =
THE BOOK, PLEASE CONTACT ME AND I WILL HAVE IT SENT OUT. AS I SAID, MY =
OFFICE BECAME VERY BUSY YESTERDAY AND I WAS UNABLE TO GET IT OUT TO YOU. =
IN RETROSPECT, PERHAPS THAT WAS BEST. IF THERE IS INTEREST, I'M HAPPY =
TO GET IT OUT. IF NOT, WE UNDERSTAND AND WISH THE PRESIDENT THE VERY =
BEST OF LUCK IN RESOLVING THIS GRAVE PROBLEM OF MEDICAL ERRORS IN =
AMERICA.

ALL MY BEST,
NEAL SUTZ
EDITOR-IN-CHIEF
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FOR IMMEDIATE RELEASE...

Contact Neal D. Sutz at (602) 403-9508

December 9, 1999, SCOTTSDALE, ARIZONA

PRESIDENT CLINTON OFFERED IMMEDIATE, REALISTIC AND NEEDED RECOMMENDATIONS BY CYNTHIA A. FOSTER, M.D., AUTHOR OF STOP THE MEDICINE!, FOR REDUCING MEDICAL ERRORS, FOLLOWING THE PRESIDENT'S ROSE GARDEN SPEECH TUESDAY IN WHICH HE CALLED FOR SUCH CHANGES TO PROTECT THE AMERICAN PEOPLE.

PRESIDENT CLINTON OFFERED IMMEDIATE RECOMMENDATIONS FROM FEMALE M.D.

In response to President Clinton's Rose Garden speech Tuesday, December 7th, 1999, Dr. Cynthia A. Foster, M.D., author of STOP the MEDICINE! A Medical Doctor's Miraculous Recovery with Natural Healing, stepped up to the plate within 24 hours. In her personal memo to the President, (please see www.StopTheMedicine.com for the full memo) Dr. Foster detailed a vast array of methods, products and philosophies which she states can be easily implemented into the American hospital system as a means to solving the problems of which the Institute of Medicine reported and the President spoke.

Understanding that many American industries are supported entirely upon their contracts and business with hospitals, Dr. Foster has offered an approach that not only offers realistic, immediate and truly life-saving resources for all American hospital patients, but also does not disturb the financial well-being of the aforementioned companies.

On the top of Dr. Foster's list of recommendations, she names sleep deprivation on the behalf of hospital staff as a major cause of the rampant medical errors nationwide. She then details the need for greater resident supervision, mandatory drug testing and pre-operative alcohol screenings. Dr. Foster states the pressing need for greater infection control, including a massive need for awareness of tasks as simple as hand washing. She also brings to the President's attention the need for exercise classes, as well as humor and positive thinking movies, books and other periodical resources to be made available to all hospital patients. Dr. Foster further recommends the removal of highly toxic cleaning substances from hospital buildings.

Dr. Foster stresses the need for dramatic nutritional improvements and availability of organic, unprocessed and easy-to-digest foods such as real fruits, vegetables and natural grains. She reminds President Clinton in her memo the human body can be made healthy and kept that way through the use of such simple food products. She also states one fact that all Americans and doctors worldwide are aware of - the continual ingestion of many of the current food products in hospitals can often be more harmful than good for the well-being of the patients, especially those patients suffering from certain ailments such as severe high-cholesterol and blood sugar disorders.

M.D.-GONE-NATURAL IN AGREEMENT WITH PRESIDENT CLINTON ON NEED FOR CHANGES

In her memo, Dr. Foster cites numerous statistics that clearly indicate that what the Institute of Medicine's report stated has actual grounds and need for dramatic and immediate reaction. "I am proud to have President Clinton as my country's leader, as few leaders anywhere would have the compassion and the courage to stand up for their people's most important asset - their health," Dr. Foster stated. "I would love to see traditional Western Medicine and the many branches of natural medicine brought together. I know we would be able to work well together and create a country where our President would never again have to give a special task force two months to begin to solve this tragic problem gone awry."

PRESS RELEASE**STOP the MEDICINE!****PAGE 2****M.D. INSISTS THE NEED TO BRING TOGETHER TRADITIONAL AND ALTERNATIVE MEDICINES**

In her memo, Dr. Foster closes by recommending what she feels to be a great need to allow medical doctors and alternative healers to consult with one another to determine the best for the patient. She stresses that each patient is a different human being and that more personal attention must be given to the patient.

Dr. Foster stated, "The average time of a traditional doctor visit is approximately 6 minutes. This is surely not enough time to determine the full range of the cause of a patient's problem, nor is it enough time to determine the best road to their health. We need to spend more time, give more direct care and allow our patients to be aware of all of their choices of treatment before deciding what is best for them. Whether it's 44,000 or 88,000 or 500,000 patients dying annually as a result of medical errors, it's many, many lives too many. One person dying from a medical error is one too many as far as I'm concerned. When I became a doctor, I took an oath. Now, in the face of our President's call to attention, both I and all other American healthcare professionals must come together and make patient safety and long-term health and well-being our number one priority. If President Clinton would like me to be a member of any committee that is working to solve this grave problem, I am willing and able to serve my country and my fellow Americans on that call."

STOP the MEDICINE! A Medical Doctor's Miraculous Recovery with Natural Healing, by Cynthia A. Foster, M.D., is going into it's third month of international distribution. The book, published by Scottsdale, Arizona-based Break On Through Press, LLC, details the frequent horrors of American hospitals, massive overmedication and misdiagnoses, as well as a broad array of serious medical errors resulting in hundreds of thousands of deaths annually. Her book also details the shocking irony of her own healing, through purely natural means, from what was known as a fatal disease, while she was attending a traditional, Western medical school.

Neal Sutz, Break On Through Press, LLC's Editor-In-Chief said, "This is NOT a book written by an angry zealot. It's a brilliant and touching autobiography, as well as an accurate portrayal of the often questionable practices of the modern medical world. We are well into our second printing of 10,000 books and expect to sell over 50,000 by the end of the year. Everyone that has read this book has come back with rave reviews and commentaries. In a bold and dramatic way, **STOP the MEDICINE!** is changing the way America views medicine and healing. This book will hit the best seller list!"

TEMPE, ARIZONA TO BE THE KICK-OFF CITY FOR INTERNATIONAL TOUR

Dr. Foster will be kicking off her international year 2000 signing and speaking tour in Tempe, Arizona. First appearing on December 15th at the new location of Changing Hands Bookstore at 7pm, Dr. Foster will be continuing on to Gentle-Strength CO-OP in Tempe on December 16th at 7pm, and The Well-Being, in Moon Valley, Arizona on December 17th at from 4:30-7:30pm. Changing Hands has two locations in Tempe and is the largest independent bookstore in Arizona. Gentle-Strength CO-OP is the oldest and most well respected cooperative CO-OP in Arizona. The Well-Being is the newest and most innovative mind-body-spirit healing store in the Southwest.

FIRST TIME AUTHOR RECEIVES RAVE ENDORSEMENTS FROM BEST-SELLING AUTHORS

These endorsements include Louise L. Hay, John Robbins, and Howard F. Lyman, controversial author of Mad Cowboy, as well as Oprah Winfrey co-defendant in the multi-million dollar lawsuit filed by American cattle ranchers.

MINDSPRING SUPERBLY HOSTS WEB SITE OF SOON-TO-BE BESTSELLER

On the WWW, readers are encouraged to purchase the book by going to www.StopTheMedicine.com, a web site superbly hosted by MindSpring(NASDAQ:MSPG), soon to be America's second largest Internet Service Provider. At the web site, readers may also learn more about Dr. Foster and stay abreast of her tour dates and latest events. Further, the publisher is making MindSpring Internet access CD's available at all of Dr. Foster's book signing and public appearances.

10-11 DEC 09 1999 10:11 NACDS #2 TEL NO: 703-536-4869 #71090 PAGE: 1/2

NACDS

NEWS RELEASE

National Association of Chain Drug Stores

For Immediate Release
December 8, 1999

For further information contact:
Phil Schneider
(703) 549-3001
pschneider@nacds.org

Chain Pharmacies Issue Statement Commenting on President Clinton's Proposals for Reducing Medical Errors

The following statement is being issued by the National Association of Chain Drug Stores in response to President Clinton's announcement today of proposed measures to reduce medical errors. The statement is attributable to Craig L. Fuller, NACDS President and Chief Executive Officer.

"As front-line healthcare providers, the nation's chain pharmacies and their pharmacists are committed to the safe dispensing of prescription medications.

Pharmacists provide a major safety net in the medication dispensing process, and efforts to standardize procedures can further reduce the potential for prescribing or dispensing errors.

Standardizing administrative procedures and enabling greater use of technology will improve efficiency and quality in the dispensing process. Encouraging electronic transmission of prescriptions will further reduce errors and improve patient safety. We encourage all state boards of pharmacy to move aggressively to eliminate restrictive barriers that prevent advances in innovation and technology in the dispensing process.

While the Institute of Medicine study focused on hospital medical errors, the nation's chain pharmacy industry welcomes the opportunity to work with the Administration and others in identifying ways to minimize the potential for medication errors in any pharmacy setting."

Founded in 1933 and based in Alexandria, Virginia, the National Association of Chain Drug Stores (NACDS) membership consists of 136 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. The chain community pharmacy industry is comprised of more than 19,000 traditional chain drug stores, 7,000 supermarket pharmacies and 5,000 mass merchant pharmacies. The NACDS membership base operates

P.O. Box 1417-D49, Alexandria, Virginia 22313-1480 (703)549-3001 Web: www.nacds.org

more than 31,000 retail community pharmacies with annual sales totaling over \$158 billion including prescription drugs, over-the-counter (OTC) medications and health and beauty aids (HBA). Chain operated community retail pharmacies fill over 60% of the 3 billion prescriptions dispensed annually in the United States. Additionally, NACDS membership includes nearly 1,400 suppliers of goods and services to chain community pharmacies. NACDS international membership has grown to include 105 members from 26 foreign countries.

Newsday

235 Pinelawn Rd., Melville, NY 11747-4250

Dec. 9, 1999

Christopher Jennings
Deputy Asst. to the President
216 Old Executive Office Bldg.
Washington, DC 20502.

Dear Mr. Jennings,

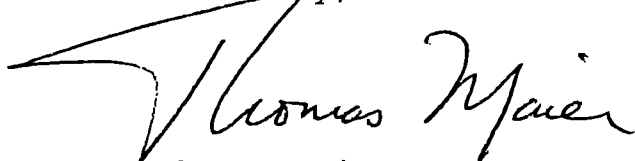
Thanks again for taking time to talk about the HMO industry and the issue of troubled doctors who wind up enrolled in managed care.

Here's a copy of the main story from a six-day series that Newsday devoted to this pressing health problem. When you get the chance, can you let me know if:

1. the President's initiative to improve health care and reduce medical errors will make any efforts to preclude doctors disciplined for serious medical wrongdoing from taking part in the Medicare and Medicaid programs?
2. will the President call on the insurance industry to disclose more information about the doctors in their networks?
3. does the President have any plan to make information from the National Practitioner Data Bank available to the public?

Please give me a call at Newsday 516-843-3408 as soon as possible to discuss these concerns. Once again thanks for your help.

Sincerely,



Thomas Maier

newsday.com

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MORE COVERAGE:
Disciplined Doctors Graphic
 (Requires Adobe Acrobat Reader)

Slap On the Wrist
Left to Die
How to Check Your Dr.
Doctors Respond
About the Series

Day 2: Most Vulnerable
Day 3: Board Certification
Day 4: Office Surgery
Day 5: Weak Penalties
Day 6: National Standards



Newsday Photos/Dick Yarwood
 Gia Hall, above, says she was badly injured during a 1994 gall bladder operation performed by Susan Calabro, below, a doctor who had been disciplined by state medical officials for previous botched surgery. Hall's insurance provider never told her about the state censure and reprimand.



MANAGED CARE & DOCTORS: **the broken promise**

HMOs and the Critical Lists

Managed care promises only the best, but dozens of their doctors have troubled pasts

First in a series
 By Thomas Maier
 Staff Writer

DESPITE PROMISES of high quality and rigorous screening, New York's biggest managed health care networks offered their customers this year dozens of doctors disciplined for serious -- even fatal -- wrongdoing, a Newsday investigation reveals.

Even though the health insurers are fully aware that the state punished these doctors for such offenses as botched surgery, sexual misconduct, drug abuse or cheating government insurance plans, they never tell their millions of customers.

Buried within thick provider directories were 132 doctors punished by state medical authorities since 1990. Newsday found two-thirds of these doctors were disciplined for mistreating patients, including 13 doctors in cases in which a patient died.

And though insurers say they routinely update their directories with careful background checks, Newsday found a Roslyn doctor who sexually abused a patient in his office; a Southampton physician who operated on the wrong knee; and a Manhattan surgeon who abandoned a badly bleeding Westbury woman on his table after cutting an artery and fleeing the room.

Newsday even found doctors barred from practicing -- state officials having permanently revoked their medical licenses -- improperly listed as approved managed care doctors, even though they weren't practicing medicine and couldn't possibly see patients legally. Some were incorrectly listed as available doctors years after their state sanction.

Yet, none of the insurers made any mention of these state disciplinary actions against their network doctors in information routinely given to customers. In fact, the presence of numerous troubled doctors among New York's top managed care plans contradicts their most basic promise to consumers.

"You can feel confident choosing a doctor for you and your family from

our extensive network of physicians," says Aetna U.S. Healthcare, of its 13,000 doctors. In a similar way, Oxford Health Plans, the state's largest managed care plan, pledges a "stringent credentialing process" with its 30,000 state doctors. "We understand your concerns when it comes to selecting a physician," Oxford says, "so our high standards ensure you're getting a top-notch doctor."

Aetna included 58 state-disciplined doctors in its network this year while Oxford offered 57. Other insurers had similar numbers of disciplined doctors, although the two smallest networks had only a handful each.

Gia Hall believes she would have been spared years of suffering if she had known more about her doctor.

Hall's insurance provider, Empire Blue Cross and Blue Shield, never told her that Susan Calabro had been involved in botched surgery and had been disciplined by state medical officials before going to her for a gall bladder operation. She was referred to Calabro by her primary care physician, also in the insurer's network.

Hall says she was badly injured during the 1994 procedure -- more than two years after the state censured and reprimanded Calabro. "I would have gone to another doctor had I known," says Hall, a 30-year-old Queens bank manager who has filed a malpractice lawsuit against Calabro. "I wouldn't have felt comfortable with her operating on me."

Health experts say that having a substantial number of state-disciplined doctors in New York's top managed care plans raises broad questions about the system's methods of oversight and how confident the public can feel about any doctor offered by these plans.

"To the extent that a managed care company contracts with physicians with a serious history of wrongdoing, they are not fulfilling their promise to ensure that enrollees get a high quality of care," says Geraldine Dallek, director of the Georgetown University Institute for Health Care Research and Policy. "I, as a consumer, would be very wary."

Most of these doctors are still licensed to practice medicine, but experts contend that companies owe their customers disclosure of physicians' past wrongdoing and, in severe cases,



Newsday Photo/Dick Yarwood
Gustavo Melamedoff was suspended for three years in January, 1996, based on charges that he sexually abused a patient and improperly gave drugs to another. Yet state officials agreed to put him on probation for the three years. At least four managed care firms offered Melamedoff to customers this year.

removal from the managed care network.

But these insurers defended their quality-control methods and pointed out that state-disciplined doctors account for only a small fraction of their networks, which can include tens of thousands of doctors. They emphasized they depend on independent credentialing panels to do their own review of the incidents that led to state discipline and to make judgments about whether a doctor poses a risk to patients.

Empire's medical director, Dr. William Osheroff, says it's not the insurer's job to let customers know about enrolled doctors who have been state disciplined. "It's inappropriate," he says. "Our job is to work with our doctors to provide better care. It's not to say here are docs that patients should really be wary of going to because these guys have a black mark on their records. It's just not the kind of relationship that we want to establish with our membership or our doctors."

A 10-month Newsday investigation shows that managed care insurers have created a private credentialing system that often fails to meet its own avowed quality standards. The investigation found:

Patients are kept in the dark about the histories of troubled managed care doctors, even though the insurers themselves collect such background information. Furthermore, New York State health authorities notify insurers of their disciplinary actions against doctors, but no law requires that the information be shared with their customers.

All of the 40 doctors officially "suspended" by the state for causing injury or other harm to patients had their punishments immediately frozen or reduced substantially at the time of discipline. This loophole in the regulatory system -- in which doctors are disciplined but rarely feel any impact from those sanctions -- keeps troubled practitioners eligible to be enrolled with these insurers.

Government health programs for the poor and elderly -- increasingly run by managed care insurers in recent years -- have helped keep disciplined doctors in business. Newsday's analysis found \$110 million in tax dollars paid for hospital care overseen by physicians after they were disciplined.

Some traditional safeguards against bad medicine have been swept aside in managed care's push to do more procedures in less expensive settings outside hospitals. Increasingly, surgery is being done in largely unregulated doctor's offices or in private surgery centers, with managed care's encouragement.

Companies often point to certification by the leading medical specialty boards as an indicator of quality, but more than 70 percent of disciplined doctors carried this credential. Contrary to their promotion campaigns, even top industry executives acknowledge board

certification can mean very little in judging a doctor's quality.

Among the 132 disciplined doctors were 86 who were punished on charges of actual patient mistreatment. This includes 40 doctors who had their licenses suspended by state authorities and another 10 whose licenses were revoked. Another 13 doctors were disciplined for sexual misconduct.

A survey of top insurers in five states found a similar pattern of disciplined doctors within managed care. A federal archive of physician background information -- created with taxpayer dollars -- could provide consumers with information about disciplinary actions, malpractice cases and lost hospital privileges, but is kept secret from the public by law.

When managed care swept through New York's health system a decade ago, insurers promised to screen carefully for the finest doctors. These cost-conscious plans replaced traditional indemnity insurance, in which insurers played a relatively passive role and patients were essentially on their own in choosing a doctor.

But under the new managed care approach, companies such as Oxford and others became medicine's new gatekeepers -- vowing to lower health care costs while raising quality.

"Our research showed us that New Yorkers wanted assurance that their doctors adhered to the highest standards of medical practice," declared Oxford's then-president Stephen Wiggins, shortly after Oxford was licensed in New York in 1986. "So we set very strict standards for the doctors who would be permitted to participate in our plans."

Buoyed by employer moves to get rising health costs under control, managed care enrollment more than doubled in a few short years, jumping from 3 million customers statewide in 1990 to 6.7 million by 1997. Double-digit jumps in annual medical costs began to slow. And customers got used to choosing their primary care doctors or a specialist from an insurer's list of participating doctors.

Today, the estimated \$250-billion-a-year managed care business -- one of the world's largest industries -- provides medical coverage to nearly 60 percent of the U.S. population, including 85 percent of whom have employer-based health insurance. Some 950,000 Long Islanders and 2.1 million New York City residents are covered by managed care -- far more than any other form of health insurance. And in their promotions and television ads, New

York's top managed care providers underline their emphasis on quality care.

Empire Blue Cross and Blue Shield promises "the most highly

credentialed and qualified physicians" in its network of 22,000 doctors. HIP Health Plans, New York City's largest managed care firm, assures its customers that: "You want to know you've selected an organization with the experience to make the right decisions about providers."

Top managed care insurers told Newsday their screening methods take an independent look at any disciplinary actions, malpractice charges and lost hospital privileges before enrolling a doctor. A few say they've terminated a handful of these doctors from their plans.

Insurers also say that it's up to their nearly 3 million customers in Long Island and New York City to check out a doctor's history and that they have no plans to disclose a physician's past disciplinary problems in any information given to customers.

"If people are concerned with a physician, they should have the responsibility to check out the physician," says Osheroff of Empire, which offered 28 state-disciplined doctors on its rolls this year.

Patients can check on disciplined doctors by calling the New York State Health Department's toll-free number 1-800-663-6114, or the department's Internet site, www.health.state.ny.us.

In some cases, the problem of disciplined doctors being promoted to the public is as simple as poor record-keeping.

Aetna U.S. Healthcare in New York, for example, offered six doctors with revoked licenses to its customers, even on the company's Web site, which it says is updated three times a week. Senior medical director Jerry Frank couldn't explain the oversight. "I can't say our Web site can be 100 percent," Frank said. "I don't know what happened there."

CIGNA HealthCare, which offered 46 state-disciplined doctors this year, acknowledged several doctors who were terminated from their plans shouldn't have been on its list. "You brought that to our attention and we appreciate you doing that," said Reardon, of CIGNA. "There are some physicians that appeared on the Web site that were terminated from our system. And we've made an adjustment."

In all, Newsday found 10 doctors listed this year whose medical licenses were revoked and involved in some of the most serious kinds of wrongdoing. They include a West Islip dermatologist who lost his license in 1997 for sexually abusing patients and brandishing a gun; a Bronx radiologist whose license was revoked in 1997 after filing more than \$1 million worth of phony Medicaid claims; and a Bellmore pediatrician, found guilty in January of negligence in the deaths of two children, whose name still appeared on a roster of approved doctors in August.

Unless a physician fights license revocation in court, those actions are

permanent and he or she cannot legally practice medicine. Under New York law, anyone caught practicing medicine without a valid license can face felony charges, says Kris Smith, a state Health Department spokeswoman who expressed surprise at how many state-revoked doctors were still listed by managed care plans this year. Smith noted that insurers are required to keep updated records, but said state regulations are so "amorphous" that they don't directly address this problem.

But even the state's former health commissioner says there's little excuse.

"No one with a revoked license should be on any managed care list -- that's clearly a very serious blunder," says Dr. Mark Chassin, New York State's former health commissioner.

Some insurers blame state laws for making it difficult to get rid of a disciplined doctor without a lengthy appeals process.

"New York makes it very onerous to terminate a doctor," says Eleanor Sorrentino, vice president for health services for Vytra, which listed five disciplined doctors. She and other insurers say the slow appeals process can allow troubled doctors to stay in their plans for months, sometimes more than a year. State officials disagree, saying dangerous doctors can be immediately terminated by insurers.

These insurers certainly know about a doctor's past.

Aetna quizzes doctors extensively about their past records and requires them to notify Aetna within 10 business days of any litigation, investigation or other actions brought against the doctor while affiliated with the insurer. Aetna says it can immediately terminate or suspend its involvement with a doctor who has received "a final disciplinary action by a state licensing board," or if continuation with the doctor "could result in imminent harm to patient care."

Insurers contend their initial screening process often weeds out physicians with problems. Though most companies said they don't have statistics on their screening procedures, Vytra estimates as many as 20 percent of doctors applying for enrollment are rejected because of quality concerns. Doctors can be rejected for a variety of reasons, which vary on a case-by-case basis, the insurers added. Most others estimated rejection rates that were much lower.

Ask them to explain how obviously troubled doctors elude the screening process and they can't: "I'm not sure we have a threshold," said Dr. Alan Muney, Oxford's chief medical officer.

As a result, the most crucial decision on enrolling managed care physicians lies with the companies' credentialing committees, which

range from three to as many as 20 members, and are made up almost exclusively of physicians. The screening process, which takes place every two years, includes the status of a doctor's medical license, hospital privileges, malpractice history and other quality concerns. Each year, these panels also refuse enrollment to a number of current and new doctors based on quality concerns, insurers say.

"We want to understand the full picture of what happened and ultimately balance the safety and quality concerns of our members with the issue of fairness and opportunity for our physicians," explains Michael Cropp, executive vice president and chief medical officer for Buffalo-based Independent Health Association, a statewide insurer with more than 6,000 doctors in the New York metropolitan area.

Like other medical directors, Cropp says his company's own panels examine the circumstances surrounding a doctor's disciplinary case and will occasionally come up with different conclusions than New York State Health Department examiners. This year, Independent Health listed 47 state-disciplined doctors on its published directory, including, for example, Gustavo Melamedoff, a specialist in internal medicine from Roslyn.

In January, 1996, Melamedoff was suspended for three years based on charges that he sexually abused a female patient in his office and improperly gave psychotropic drugs to another. In the first case, records show, Melamedoff didn't contest the charge he "inserted his penis, finger, and/or other object into the patient's vagina for no legitimate medical purpose."

Yet, state officials agreed that Melamedoff could be put on a form of probation allowing him to immediately continue practicing medicine as long as he had a chaperone in the presence of female patients. Melamedoff declined to discuss his case, except to say his three-year probation ended on Jan. 15.

After their credentialing committees reviewed his case, Oxford, Aetna U.S. Healthcare, and two other top managed care firms, CIGNA and Independent Health, continued to offer Melamedoff to customers in their directories this year. None of the insurers told customers that Melamedoff had been on state probation, nor that he must have a chaperone when seeing female patients.

"Our process is that we'll look at it independently, evaluate what happened to the extent we can," says Oxford's Muney, of the Melamedoff case. "In terms of sexual misconduct, our general tendency is that they should be out of our network. In this particular instance, having a chaperone for all female patients may be perfectly appropriate and we'd go along with the state monitoring and follow-up of this."

But critics say managed care insurers bend over backward to keep even

disciplined doctors with an active medical license in their network, and that their private screening procedures are far less stringent than investigations conducted by state medical boards.

"Physicians traditionally have always protected their own," says Pat Schoeni, spokeswoman for the National Coalition on Health Care, a Washington-based health study alliance that includes business, labor and consumer groups among its members. "I don't think managed care companies go through the heavy-duty, in-depth checking that the state medical boards do. I think they say, 'This guy has a disciplinary problem, is now clean and we'll put him on our list.'"

Newsday's review suggests that disciplined doctors who remain in managed care networks can still maintain thriving practices.

After being punished by state authorities, New York managed care doctors disciplined since 1990 still oversaw a total of more than 30,000 patient visits in local hospitals, according to state records. Because of changes in recordkeeping over the years, the exact number of patient visits covered by managed care could not be determined. But disciplined doctors did oversee 17,000 patient visits paid for with tax dollars.

Patients rarely find out beforehand about any discipline problems involving their managed care doctors, though a Hofstra University poll commissioned by Newsday suggests they would want to know. More than 80 percent of respondents said it would be "very important" for them to know if their doctor had been disciplined.

Gia Hall, for instance, wishes Empire Blue Cross and Blue Shield had told her that Susan Calabro, a Manhasset surgeon, had been disciplined by state medical officials before going to her for gall bladder surgery.

In court papers, Hall says her intestines and common bile duct were permanently damaged during the June, 1994, gall bladder procedure, forcing her to have further corrective surgery. And for nearly a year, she wore a colostomy bag, a device attached to her side to collect bodily wastes.

Hall's operation took place more than two years after Calabro's 1992 censure and reprimand for actions in an earlier case in which the patient eventually died. "Physically, I was in pain and my life wasn't the same afterward," recalls Hall. "I couldn't lift up my daughter who was a toddler at the time."

In an interview, Calabro defended her medical treatment of Hall and other patients. "I feel I'm a great doctor ... I wish it was on public record all the patients that I've helped and all the patients who love me," said Calabro, who maintains she'd tell patients of her disciplinary action if they inquired. "If they asked me, I'd definitely tell them."

But managed care insurers do know of her previous state disciplinary sanction, Calabro said, and decided to keep her in their programs as an approved surgeon based on the overall quality of her work. "If you look at the applications, they all have that question, and I've notified each one of them."

This year, Calabro was offered as a managed care doctor by Oxford, Vytra, CIGNA and Empire.

Osheroff rejects criticism that insurers favor their enrolled doctors over the interest of their patients. "Our foremost priority is to protect our members from harm," says Osheroff. "If we thought that notifying members that a doc had their license suspended 10 years ago would somehow protect the member, we'd probably do that. But I'm not convinced that plays out."

Both Oxford and Vytra officials said Calabro had met the standards of their credentialing panels. Vytra's Sorrentino added that state-disciplined doctors are "monitored even more closely" than other physicians in their plan.

A potential patient would never be aware of that scrutiny.

Oxford, for example, lets patients know Calabro is board certified, listing her academic credentials. Vytra even lets potential patients know that Calabro speaks the second languages of Spanish and Hebrew.

But neither tells customers about Calabro's discipline by the state's Board for Professional Medical Conduct, which reviews allegations of wrongdoing against physicians.

In January, 1992, state investigators charged that Calabro performed surgery with "gross negligence" on a patient in November, 1987, at the Queens Hospital Center in Jamaica. Calabro was a young surgeon at the time.

The patient (whose identity was not mentioned in state records) had three surgical scars on his abdomen but Calabro didn't find out how they got there before the surgery, documents show. Along with another young surgeon, Calabro misread a chest X-ray and failed to perform an adequate physical exam of the patient prior to surgery, records say, and failed to properly evaluate the patient's tuberculosis at that time.

In addition, Calabro countermanded the treatment plan of a chest surgeon who had been called in during surgery to help because of problems Calabro faced and may have caused during surgery, documents show. After extensive work, the chest surgeon decided a segment of the patient's colon "was still viable." The chest surgeon left the operating room, on the understanding that Calabro would "close the

abdomen after draining the chest" and finish up the operation, records say.

Instead, Calabro and the other young doctor decided that same portion of the patient's colon "was not viable" -- a decision state examiners called "without justification," documents show. Calabro then performed more surgery on the colon, which state investigators also said was not appropriate. Calabro didn't tell the chest surgeon of her changes or keep a medical record that "accurately reflects" what happened to the patient, whose body weight plummeted after the surgery, state investigators said.

In February, 1988, three months after his operation, the patient died at Queens Hospital Center of pneumonia in both lungs and of sepsis, a serious blood infection, state records show.

For reasons not made clear in available documents, investigators took more than four years to file disciplinary action against Calabro and two other doctors involved in the case.

Calabro was charged with "gross negligence" as well as "failure to maintain accurate records." A month later, with the state's consent, Calabro agreed not to contest the second allegation of poor record-keeping "in full satisfaction of all charges" against her. Under the terms of the state's censure and reprimand, Calabro immediately continued practicing medicine.

Calabro says it is unfair to blame her for the death of that patient, and that the incident occurred more than a decade ago when she was a young doctor. "I was a chief resident in a city hospital where there are a lot of difficulties involved, OK?" she says. "I didn't kill anybody. My license was never taken away."

Calabro was a managed care doctor when another serious allegation of medical wrongdoing against her was played out in a Queens courthouse in 1997. A jury found Calabro had committed malpractice during gall bladder surgery a few years earlier on Ann Marie Muir, who received a monetary award for her pain and injuries.

In an interview, Muir says she didn't know of the 1992 state disciplinary finding against Calabro until told by Newsday. (It never came up during the 1997 malpractice trial.) She also expressed surprise that Calabro is an approved doctor with four managed care plans today.

"I can't believe the managed care companies allow her to keep seeing patients," says Muir, a 49-year-old White stone bookkeeper. "I guess it takes a lot for these doctors to be kicked off these lists and they have to do a lot of wrong."

Muir was referred to Calabro as her surgeon in 1990 through

Community Health Program of Queens and Nassau Inc., a now-defunct medical group that employed Calabro at the time. Gia Hall later used the same medical group under her Empire insurance for her surgery. "I just hoped she was a good doctor," recalls Muir. Suffering from stomach pains, Muir visited Calabro in her office, then in New Hyde Park, and was told she needed surgery to remove her gall bladder. Calabro seemed nice and explained that she could do laparoscopic surgery with new miniaturized devices, expected to lessen Muir's pain and time in the hospital, Muir says.

Shortly before Muir's surgery, Calabro attended a two-day symposium in New Jersey on this new form of laser surgery. But Muir would be Calabro's first patient using this new technique -- a fact that Muir says she didn't learn until she was about to be wheeled into the operating room on Dec. 27, 1990.

"I was lying on the gurney, waiting to go into the operating room, and she told me it was her first operation," recalls Muir. "I thought she had done it on humans in the training course, but I was later told she only operated on pigs."

After the surgery, Muir felt nauseous with terrible cramps in her abdomen. "I was supposed to go home right away with this operation, but I kept getting sicker and sicker," she recalls. Muir soon returned to the hospital for a corrective operation on Jan. 2, 1991, and she and her family insisted that Calabro work with another surgeon more experienced with laparoscopic surgery.

"We said we want an expert and she said, 'I AM the expert,'" Muir says Calabro told her family, an account later repeated during her malpractice trial. After several trips to other doctors and further surgery in the mid-1990s, Muir began to overcome pain from her earlier operation with Calabro. In 1997, a Queens jury heard testimony from Calabro and other evidence and rendered a malpractice verdict against Calabro and two other physicians

involved in the first surgery. Calabro declined to discuss the Muir case in any detail. But Muir's lawyer, Bruce Clark, says Calabro's current status as an approved managed care doctor -- despite her history -- illustrates how the 1974 federal Employee Retirement Income Security Act (ERISA) has generally prevented managed care insurers from being sued in malpractice claims that usually include individual doctors and hospitals. "Things like this would change if the HMO was sued along with the doctors they were referring their patients to," says Clark.

Gia Hall says more consumer information and state oversight is needed so patients like her don't discover their doctor's troubled past only after medical treatment.

"I think there should be a means of communication so that I don't have

to go to a courthouse to find out about a doctor," says Hall. "If someone is going to have surgery, it should be your right to that information so you can judge before you have surgery, especially if you're paying your insurance premiums."

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GM Tackles Patient Safety Issue

Last week the Institute of Medicine, an arm of the National Academy of Sciences, issued a very important report on the problem of medical errors, indicating as many as 98,000 Americans die unnecessarily every year from medical mistakes made in the health care system.

As all General Motors employees know, quality and safety are high priority issues for GM. Over the past year, GM has become aware of statistics similar to those reported by the Institute of Medicine and therefore, is currently implementing health care standards to improve patient care and safety.

Strengthening this effort is a priority for our GM Health Care Initiatives team. In July, Chairman Jack Smith called on the Business Roundtable, an organization whose membership includes CEO's from the nation's largest companies, to work with other Fortune 50 companies to also make health care a priority. Smith urged the organization to "drive fundamental improvement in the value, quality and safety of the nation's health care system by applying strict purchasing requirements that reward health plans for patient safety."

"To GM, "quality" means that you have access to the right care and service, at the right time, at the right place," said Jim Cubbin, executive director GM Health Care Initiatives. "Reducing medical error is an integral part of improving quality."

With that in mind, GM has joined with fellow automakers, unions, and other major employers to address key patient safety issues. GM will work with our health plans and hospitals to assure that they implement certain procedures that can prevent serious errors. These procedures include the installation of special computer systems that have been shown to help prevent many serious drug mistakes, referrals to superior hospitals for certain procedures in order to

improve health care quality and save lives, and meeting specialized staffing standards for hospital intensive care units.

Using a computerized physician order entry system in hospitals to prevent prescription medication prescribing errors has been demonstrated to reduce death and serious injury by well over 55 percent.

The importance of referring patients to hospitals that meet specific criteria for certain medical procedures is a key ingredient to combating medical errors. For example, hospitals that treat the greatest number of heart patients demonstrate significantly better outcomes (reduced death and disability) than those that treat fewer patients. In addition, the same trend is true for more than 19 other conditions and treatments.

The Intensive Care Unit standards that are being proposed can have equally dramatic results. ICUs staffed with full-time, board-certified intensive care specialists and which meet other staffing requirements have been shown to reduce mortality by up to 30 percent.

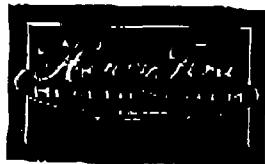
Specifically, General Motors:

- is building safety performance expectations into our HMO purchasing standards,
- is active with other major employers and community organizations in local communities and will require hospitals, health plans and physicians to implement safety related measures,
- expects its health care plans, such as Blue Cross Blue Shield and United Health Care, to hold participating hospitals and physicians accountable for implementing patient safety standards,

- currently has in place a voluntary program called Centers of Excellence through the salaried, Traditional health care programs, that will provide GM employees advice on hospitals which specialize in certain procedures;
- has made huge strides to improve health and safety in GM plants and expects no less from our national health care system.

GM has a very strong quality-based HMO purchasing strategy requiring health plans to meet rigorous standards. The health plans should: provide high quality, appropriate, coordinated care; achieve high member satisfaction; deliver excellent care and disease management; and follow best medical practices. Especially important is a focus on the health plans holding their participating hospitals and providers accountable for patient safety. All of this can be accomplished at a competitive cost for the care and services they deliver.

"We know that these best practices can save lives and help improve care," said Cubbin. "We are working diligently with other major employers and community organizations to make sure that more hospitals and health plans implement them."



Gail L. Warden

Gail L. Warden is president and chief executive officer of Henry Ford Health System in Detroit, one of the nation's leading vertically integrated health care systems.

Warden is an elected member of the Institute of Medicine of the National Academy of Sciences, as well as a member of the Institute's Governing Council, its Board on Health Care Services and its Coordinating Committee on Health Care Quality. He is a member of the Board of Trustees of The Robert Wood Johnson Foundation and director emeritus and past chairman of the Board of the National Committee on Quality Assurance. He is chairman of The Healthcare Research and Educational Trust and serves on the board of the National Resource Center on Chronic Care Integration. He recently was named chairman of the National Forum on Health Care Quality Measurement and Reporting.

Warden is a director of the Detroit Economic Growth Corporation, a member of the Wayne County Airport Commission and a trustee and director of the Citizens Research Council of Michigan. In addition, he is a member of the boards of Detroit Zoological Society and Comerica Bank.

In 1997, President Clinton appointed him to the Federal Advisory Commission on Consumer Protection and Quality in the Health Care Industry. In 1995, Warden was chairman of the American Hospital Association Board of Trustees. He also is a former member of the Pew Health Professions Commission.

Throughout his career, Warden has received several significant awards. In March 1999, he received the American College of Health Care Executives 1999 Gold Medal Award, the highest honor bestowed by the organization. Early in his career, the same organization selected him Young Health Care Executive of the Year. In 1997, Warden received the Columbia University School of Nursing Second Century Award for Excellence in Health Care. In 1993, he received the CEO Award from the American Hospital Association's Society for Healthcare Planning and Marketing. In 1992, he received B'nai B'rith International's National Health Care Award.

Before joining Henry Ford Health System in April 1988, Warden was president and chief executive officer of Group Health Cooperative of Puget Sound in Seattle (1981-88). Previously, he was executive vice president of the American Hospital Association (1976-81) and executive vice president and chief operations officer of Rush-Presbyterian-St. Luke's Medical Center (1965-76).

He is a graduate of Dartmouth College with a master's degree in health care management from the University of Michigan. He holds an honorary doctorate in public administration from Central Michigan University. Warden and his wife, Lois, reside in Grosse Pointe, Michigan.

Henry Ford Health System provides a comprehensive array of health care services for 800,000 Southeast Michigan residents. It provides insurance to more than 550,000 people through its Health Alliance Plan and Alliance Health and Life Insurance units. The Henry Ford Health Sciences Center integrates teaching, research and advanced patient care to make the System a premier academic medical center. Health care services include: a tertiary care hospital, three owned community hospitals, joint ventures or affiliations with eight community hospitals, more than 30 ambulatory care centers, a medical group of 1,000 physicians and scientists, a full-service psychiatric facility, a chemical dependency center, home health care services and two nursing homes.

Post-it: Fax Note	7871	Date	12-6-99	# of pages	1
To	ALEXA MITCHELL	From	Sanjay White		
Co. Dept.		On	HFHS		
Phone #		My (313)	874-4040		
Fax #	(202) 226-2255				

Bruce E. Bradley

Bruce E. Bradley has been Director of Managed Care Plans for General Motors Health Care Initiatives since June 1, 1996.

Bradley joined GM after five years as Corporate Manager of Managed Care for GTE Corporation. In addition to his health care management experience at GTE, he spent nearly 20 years in health plan and health maintenance organizations (HMOs) management. From 1972 to 1980, he was Executive Director of the Matthew Thornton Health Plan, Nashua, N.H. From 1980 to 1990, he was President and Chief Executive Officer for the Rhode Island Group Health Association, Providence, a staff model HMO.

Bradley was a co-founder of the HMO Group, a national corporation of 15 non-profit, independent group practice HMOs, and the HMO Group Insurance Co., Ltd.

He has gained recognition for his work in achieving health plan quality improvement and for his efforts in developing the Health Employer Data and Information Set (HEDIS) measurements and processes. He is a member of the Planning Committee of the National Forum on Health Care Quality Measurement and Reporting, NCQA Committee on Performance Measurement, a member of the board of FACCT and President of the Managed Health Care Association.

A native of Pelham, N.Y., Bradley holds a bachelor's degree in psychology from Yale University and a master's degree in business and health care administration from the Wharton School at the University of Pennsylvania.

More than a third of the 1.5 million enrollees covered by GM health plans are members of managed care options. GM contracts with 125 health maintenance organizations and 20 Preferred Provider Organizations in the United States.

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. bio	re: Christine Cassel (partial) (1 page)	12/07/1999	P6/b(6)

COLLECTION:

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- P1 National Security Classified Information [(a)(1) of the PRA]
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- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[001a]

Biography

Christine K. Cassel, MD, MACP

Dr. Cassel is Chairman of the Department of Geriatrics and Adult Development of Mount Sinai Medical Center and Professor of Geriatrics and Medicine. She joined Mount Sinai in 1995 after ten years as Chief of General Internal Medicine at the University of Chicago, where she was Professor of Medicine and Public Policy Studies, Chief of the Section of General Internal Medicine, Director of the Center on Aging, Health and Society, Director of the Center for Health Policy Research, and Director of the Robert Wood Johnson Clinical Scholars Program at the University of Chicago, and George M. Eisenberg Professor in Geriatrics. Her work has brought together the biomedical, ethical and policy issues in general internal medicine and geriatrics.

Dr. Cassel received an undergraduate degree in humanities at the University of Chicago and completed her MD at the University of Massachusetts in 1976. Dr. Cassel took her training in Internal Medicine at Children's Hospital of San Francisco and at the University of California, San Francisco and did a Fellowship in bioethics at the University of California in 1979 and a Fellowship in Geriatrics at the University of Oregon and the Portland Oregon Veterans Administration Medical Center in 1981.

Among Dr. Cassel's numerous publications are several books, including Geriatric Medicine (first published by Springer-Verlag Publishers in 1984, now in its third edition), Ethical Dimensions in the Health Professions, (now in its third edition), Approaching Death: Improving Care at the End of Life, and A Practical Guide to Aging. Her more than 200 articles are found in many medical, policy and scientific journals.

Dr. Cassel has assumed numerous national leadership roles. She is past president of the American College of Physicians, Physicians for Social Responsibility, the Society for Health and Human Values. She was the first woman to Chair the American Board of Internal Medicine. She has been elected to membership in the Institute of Medicine of the National Academy of Sciences, and the Association of American Physicians. In 1997 she was appointed to the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, and in 1999 to the Advisory Committee to the Director of NIH. She is currently Chair of the of the Board of the Greenwall Foundation and a Trustee of the Russell Sage Foundation. She has served as a consultant to the Veterans Administration, the Health Care Financing Administration, the National Institute on Aging, the Agency for Health Care Policy and Research, and the United States Congress.

Place of Birth: Minneapolis, MN

DOB:

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Rev. 12/7/99

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001b. bio	re: Richard Davidson (partial) (1 page)	12/06/1999	P6/b(6)

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Office of the President

RICHARD J. DAVIDSON

Dick Davidson has been president of the American Hospital Association since July, 1991. He came to the AHA after 22 years as president of the Maryland Hospital Association.

Born in [REDACTED] P6/(b)(6) he earned his bachelor's and master's degrees in education from West Chester State College and Temple University, respectively, both in Pennsylvania, and a doctorate in education from Washington, D.C.'s George Washington University.

He began his health care career as a patient. [REDACTED] P6/(b)(6)

[REDACTED] P6/(b)(6)

[0016]

Davidson became the Maryland Hospital Association's first president in 1969. During his years there, he was involved in many local, state and national health policy groups and initiatives. Under his leadership, the organization was recognized nationally for its work on trustee involvement in state association affairs, payment reform, the development of clinical quality indicators, and medical and corporate values and ethics in the hospital setting. He consulted for national foundations, served on editorial boards and earned a wide reputation as a writer and speaker on contemporary health issues, as well as the future of health care financing and delivery in America. He was also a volunteer leader and officer with a Maryland organization devoted to the health care needs of an unpopular segment of the population: the homeless. He has been active with the AHA for 25 years, volunteering his time for task forces and advisory bodies on issues as diverse as nursing and prospective payment.

He resides in the nation's capital with his wife Janet. They are the parents of three sons and have five grandchildren.

The American Hospital Association, with offices in Washington, D.C. and Chicago, is the nonprofit organization that serves as the national advocate for hospitals and the patients and communities they serve. It provides education and information for its members and informs the public about hospitals and health care issues.

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

One North Franklin
Chicago, Illinois 60606-3421
(312) 422-3000

Mary Foley, MSN, RN
ANA First Vice President

An expert in hospital based nursing practice, health and safety issues, needle, and nursing shortage issues, Mary Foley, MSN, RN is currently the Director of Nursing/Chief Nurse Executive at St. Francis Memorial Hospital in San Francisco, California. In addition, she is a part-time clinical faculty member at the San Francisco State University School of Nursing.

Foley has been elected to a number of ANA offices at the state and national level including chair of ANA's Constituent Assembly and president of the California Nurses Association. She has served as first vice-president of the American Nurses Association Board of Directors for one term (1996-1998), and was reelected for a second term (1998-2000). She presently sits on the board of the ANA Political Action Committee, and the American Nurses Credentialing Center.

She earned her diploma from New England Deaconess Hospital School of Nursing, her baccalaureate degree from Boston University and her masters from the University of California, San Francisco, CA.

For more information contact: ANA Communications Dept., 202/651-7018

8/5/98
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001c. bio	re: John Rother (partial) (1 page)	12/06/1999	P6/b(6)

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[001 C]

D.O.B -

SS# -

P6/(b)(6)

BIOGRAPHICAL SKETCH

JOHN C. ROTHER

John C. Rother is the Director of Legislation and Public Policy for the AARP. He is responsible for the federal and state legislative advocacy activities of the Association, based on in-depth policy research and public information programs. He is an authority on Medicare, managed care, long-term care, Social Security, pensions and the boomer generation's retirement situation.

Prior to coming to AARP, Mr. Rother served eight years in the U.S. Senate as Special Counsel for Labor and Health to former Senator Jacob Javits (R-NY), and as Staff Director and Chief Counsel for the Special Committee on Aging under its Chairman, Senator John Heinz (R-PA).

He serves on several Boards and Commissions, including Generations United, the Health Care Quality Forum, the National Committee for Quality Assurance, the Foundation for Accountability in Health Care, the National Academy on Aging, and Citizens for Long Term Care.

He has served as a member of the Board of the Corporation for National Service, the Institute of Medicine, the ERISA Advisory Council for the Secretary of Labor; as a member of the Secretary's Blue-Ribbon Advisory Commission on the FDA (Edwards Commission); and as a member of the Commonwealth Fund's Commission on Elderly People Living Alone. In 1996, Mr. Rother was on special sabbatical assignment to study the consumer implications of the managed care revolution and the economic challenges facing the boomer generation.

John C. Rother is an honors graduate of Oberlin College and the University of Pennsylvania Law School.

10/99



American Association of
HEALTH PLANS

Karen Ignagni
President and Chief Executive Officer

KAREN IGNAGNI

President and Chief Executive Officer
American Association of Health Plans

As President and Chief Executive Officer of the American Association of Health Plans, Karen Ignagni is the nation's leading authority on the public policy, legislative, and public affairs issues challenging the managed care industry today. Under her leadership, the managed care industry has been transformed into an internationally-recognized model of health care covering nearly 175 million Americans.

Her accolades are numerous: in September 1999, *Washingtonian* magazine named her one of the Top Three "Top Guns" of *all* industry trade association heads, noting that Ms. Ignagni is "widely considered one of the best and most influential in town." In July 1999, *The New York Times* profiled Ms. Ignagni, writing, "In a city teeming with health care lobbyists, Ms. Ignagni is widely considered one of the most effective. She blends a detailed knowledge of health policy with an intuitive feel for politics." In addition, *National Journal* has called the 1,000 member trade association "a force to be reckoned with" on Capitol Hill and *Fortune* magazine has noted that she presided over AAHP's political program in 1998 -- a program it deemed "worthy of a presidential election bid."

Ms. Ignagni has a long and distinguished involvement in health care issues. Prior to coming to AAHP (formerly Group Health Association of America) in 1993, Ms. Ignagni directed the AFL-CIO Department of Employee Benefits. For four years, she was a Professional Staff Member of the US Senate Labor and Human Resources Committee. In the late 1970s, she was assistant executive director for the Committee for National Health Insurance and, prior to that, a research analyst for the US Department of Health and Human Services.

Ms. Ignagni is regularly featured on national television and radio programs and in the print news representing the managed care industry on a wide range of issues.

Ms. Ignagni holds an M.B.A. from Loyola University and an undergraduate degree from Providence College.

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002a. fax	Janet Corrigan to Chris Jennings re: SSN (partial) (1 page)	12/06/1999	P6/b(6)

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THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

National Academy of Sciences
National Academy of Engineering
Institute of Medicine
National Research Council

FAX TRANSMITTAL SHEET

Date: 12/06/99

of pages including cover sheet: 3

TO: Chris Jennings

Fax #: 202-456-5557

FROM: Janet Corrigan, Director

Division of Health Care Services

Telephone: 202-334-2165

Facsimile: 202-334-3862

COMMENTS: URGENT

To follow please find my biosketch as well as Dr. William Richardson's.

SSN:

Richardson:

P6/(b)(6)

[002a]

Corrigan:

P6/(b)(6)

If there is a problem with this fax, please call 202-334-2184

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002b. bio	re: Janet Corrigan (partial) (1 page)	n.d.	P6/b(6)

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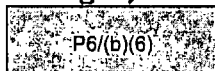
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Biographical Sketch:**Janet M. Corrigan, Ph.D.****SSN:**

C002b7

Dr. Corrigan is director of the Division of Health Services at the Institute of Medicine of the National Academy of Sciences. She is also project director for the IOM Quality of Health Care in America Project. Prior to joining the Institute of Medicine, she was the executive director of the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, a one-year commission responsible for producing the Consumer Bill of Rights and Responsibilities and a comprehensive report on the quality of health care. She also served as principal researcher for the Center for Studying Health System Change established by The Robert Wood Johnson Foundation in 1995 to assess the impact of health system change at the community-level. From 1991 to 1995, she was vice president for planning and development with the National Committee for Quality Assurance. She received her doctorate in health services organization and policy and a master's degree in industrial engineering from the University of Michigan. She also has master's degrees in business administration and in community health from the University of Rochester.

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002c. bio	re: William Richardson (partial) (1 page)	n.d.	P6/b(6)

COLLECTION:

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FOLDER TITLE:

Errors [Folder 2]

2012-0463-S

rc745

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]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Biographical Sketch:

William C. Richardson, Ph.D.,
Chair, Institute of Medicine Committee on the Quality of Health Care in America
President & CEO, W.K. Kellogg Foundation

SSN:

P6(b)(6)

[002c]

Dr. Richardson is chairman of the Institute of Medicine's Committee on the Quality of Health Care in America. He is President and Chief Executive Officer of the W.K. Kellogg Foundation of Battle Creek, Michigan. Before joining the foundation in August 1995, Dr. Richardson was president of The Johns Hopkins University, a position he had held since 1990. In addition, Dr. Richardson was Professor of Health Policy and Management at the university. He has been appointed Professor and President Emeritus. Dr. Richardson is a member of the Institute of Medicine of the National Academy of Sciences and is a fellow of the American Public Health Association. He serves on the boards of the Council of Michigan Foundations and the Council on Foundations. He also serves on the boards of the Kellogg Company, CSX Corporation, the Mercantile Bankshares Corporation, and Mercantile-Safe Deposit and Trust Company. He serves on the external advisory committee of the Fred Hutchinson Cancer Research Center.

THE WHITE HOUSE
WASHINGTON

December 6, 1999

MEETING AND STATEMENT ON MEDICAL ERRORS

DATE:	December 7, 1999
LOCATION:	Cabinet Room (Meeting) Rose Garden (Statement)
BRIEFING TIME:	10:20am – 10:45am
MEETING TIME:	10:45am – 11:15am
STATEMENT TIME:	11:20am – 11:45am
FROM:	Bruce Reed, Mary Beth Cahill, Chris Jennings

I. PURPOSE

You are unveiling a new initiative to improve health care quality, improve patient safety, and prevent medical errors.

II. BACKGROUND

Today, you will:

- **Issue an Executive Memorandum directing the Quality Interagency Coordination Task Force (QuIC) to develop new strategies to improve health care quality and protect patient safety.** Today, you will sign an executive memorandum directing the QuIC to report back recommendations to you, through the Vice President, within 60 days that: identify prevalent threats to patient safety and reduce medical errors that can be prevented through the use of decision support systems, such as automated patient monitoring and reminder systems; evaluate the feasibility and advisability of the recommendations of the Institute of Medicine on patient safety; develop additional strategies, including the use of information technology, to reduce medical errors and ensure patient safety in Federal health care programs; evaluate the extent to which medical errors are caused by misuse of medications and medical devices and consider steps to further strengthen FDA's response to this challenge; and identify opportunities for the Federal government to take specific action to improve patient safety and improve health care quality through collaboration with the private sector, including the newly constituted National Forum for Health Care Quality Measurement and Reporting.

- **Announce that each of the more than 300 private health plans participating in the Federal Employee Health Benefits Program will be required to institute quality improvement and patient safety initiatives.** Today, you will announce that the Office of Personnel Management, which oversees plans serving 9 million Americans, will include in its annual call letter to be issued next spring a requirement that FEHBP plans use error reduction and other patient safety techniques in order to improve the quality of care in the program. In addition, OPM will supplement this initiative using workplace campaigns to improve mammography and medical screening rates among Federal employees, retirees, and their families. Finally, OPM will initiate new ways to measure and report on the quality of care that plans deliver to enrollees.
- **Instruct Federal agencies administering health plans to evaluate and, where feasible, implement the latest error reduction techniques.** You will request that the Departments of Health and Human Services, Veterans Affairs, and Defense, and the Office of Personnel Management evaluate and, where feasible, implement the latest error reduction techniques in a manner consistent with the Administration's recently released draft regulations on patient privacy. These agencies administer Medicare, Medicaid, CHIP, the Federal Employees Health Benefits Program, the nationwide network of veterans hospitals and outpatient clinics, and the military health care system, serving over 85 million Americans.
- **Announce the reauthorization of the Agency for Healthcare Research and Quality, ensuring a multi-million dollar investment in research programs to improve health care quality.** You will announce that you signed legislation yesterday reauthorizing the Agency for Healthcare Research and Quality (AHRQ). To achieve the goals of this legislation, which is the result of the bipartisan efforts of Senators Frist and Kennedy and Congressmen Bliley and Brown, the FY 2000 budget increases the agency's resources by 16 percent over FY 1999 funding levels, for a multi-million dollar investment in health care quality. These new funds will be used for important quality improvement research, including the over-and-under utilization of services, variation in the delivery of services, and efforts to prevent medical errors. In recognition of the critical role that states do and will play in assuring and improving health care quality, AHRQ will hold a nationwide conference this March with senior state health officials to promote best medical practices, to prevent medical errors and improve patient safety, and to better develop a working relationship between the Federal and state governments in this area.
- **Direct the Office of Management and Budget, the Domestic Policy Council, and other agencies to develop additional health care quality and patient safety initiatives for the FY 2001 budget.** You will direct the Office of Management and Budget, the Domestic Policy Council, and the Office of the Vice President to work with the Department of Health and Human Services and other agencies to develop additional initiatives within the context of the FY 2001 budget that build on our current error prevention, quality improvement, and patient safety initiatives.

- **Praise the American Hospital Association for launching a new medication safety campaign.** You will praise the American Hospital Association for launching a new partnership with the Institute for Safe Medication Practices to prevent patient medication errors. Today, the AHA will send a list of "best practices" on prevention medication errors to all 5,000 of their member hospitals. In the coming months, they will also begin to: develop a medication safety awareness test that surveys hospitals' medication error prevention systems; track implementation by the hospital and health system field of the practices for reducing and preventing errors; and working with national experts to develop a model medication error reporting process. By taking these actions today, the AHA joins numerous other health care organizations making an important commitment to this area, including the American Medical Association's initiative to establish the National Patient Safety Foundation.

HIGHLIGHT THE CLINTON-GORE ADMINISTRATION'S LONGSTANDING COMMITMENT TO IMPROVING HEALTH CARE QUALITY. Over the past two years you and Vice President Gore have provided critical consumer protections to the 85 million Americans enrolled in Federal health plans and set the stage for the Congress to pass a strong, enforceable, Patients' Bill of Rights. In March of 1998, you established the Quality Interagency Coordination Task Force, which has been instrumental in promoting advances in health care quality nationwide. You also asked the Vice President to help launch the National Forum for Health Care Quality Measurement and Reporting, a broad-based, widely representative private advisory body that develops standard quality measurement tools to help all purchasers, providers, and consumers of health care better evaluate and ensure the delivery of quality services. In addition to the work and significant potential of the QuIC and Quality Forum, the Departments of Veterans Affairs and Defense have been leaders in patient safety and quality improvement programs. The Department of Veterans Affairs also spearheaded the development of the National Patient Safety Partnership to address issues related to adverse medical events. Finally, the Health Care Financing Administration has implemented new quality improvement initiatives through its peer review organization efforts, and the Food and Drug Administration is working to implement new reporting systems that allow for a rapid response to medical errors causing patient injury.

III. PARTICIPANTS

Briefing Participants:

Bruce Reed
Mary Beth Cahill
Loretta Ucelli
Joe Lockhart
Chris Jennings
Sam Afridi

Meeting Participants:

YOU

Federal participants:

Secretary Alexis Herman

Director Janice LaChance

FDA Administrator Jane Henney

HCFA Administrator Nancy Ann Min DeParle

John Eisenberg, Director of the Agency for Healthcare Research and Quality

Paul London, Department of Commerce

Tom Garthwaite, Acting Undersecretary for Health at the Department of Veterans Affairs

Private sector participants:

Bruce E. Bradley, Director of Managed Care Plans for General Motors

Dr. Christine Cassel, Chairman of the Department of Geriatrics and Adult Development
at Mt. Sinai School of Medicine

Richard J. Davidson, President of the American Hospital Association

Mary Foley, MSN and RN, First Vice President of the American Nurses Association

Karen Ignani, President and CEO of the American Association of Health Plans

Dr. William Richardson, Chair of the IOM Committee on Quality of Health Care in
America and President and CEO of the W. K. Kellogg Foundation

John C. Rother, Director for Legislation and Public Policy of the American Association
of Retired Persons

Gerald M. Shea, Assistant to the President for Government Affairs of the AFL-CIO

Dr. Kenneth W. Kizer, President and CEO of the National Forum for Health Care Quality
Measurement and Reporting

IV. PRESS PLAN

Meeting – Closed Press

Statement – Open Press

V. SEQUENCE OF EVENTS

- **YOU** will meet with representatives of the health care academic and advocate, consumer, provider, and business communities.
- **YOU** will proceed to the Rose Garden to make a statement.
- **YOU** will make opening remarks and introduce Richard Davidson, President, American Hospital Association.
- Richard Davidson will make brief remarks.
- **YOU** will make remarks and depart.

VI. REMARKS

To be provided by speechwriting.

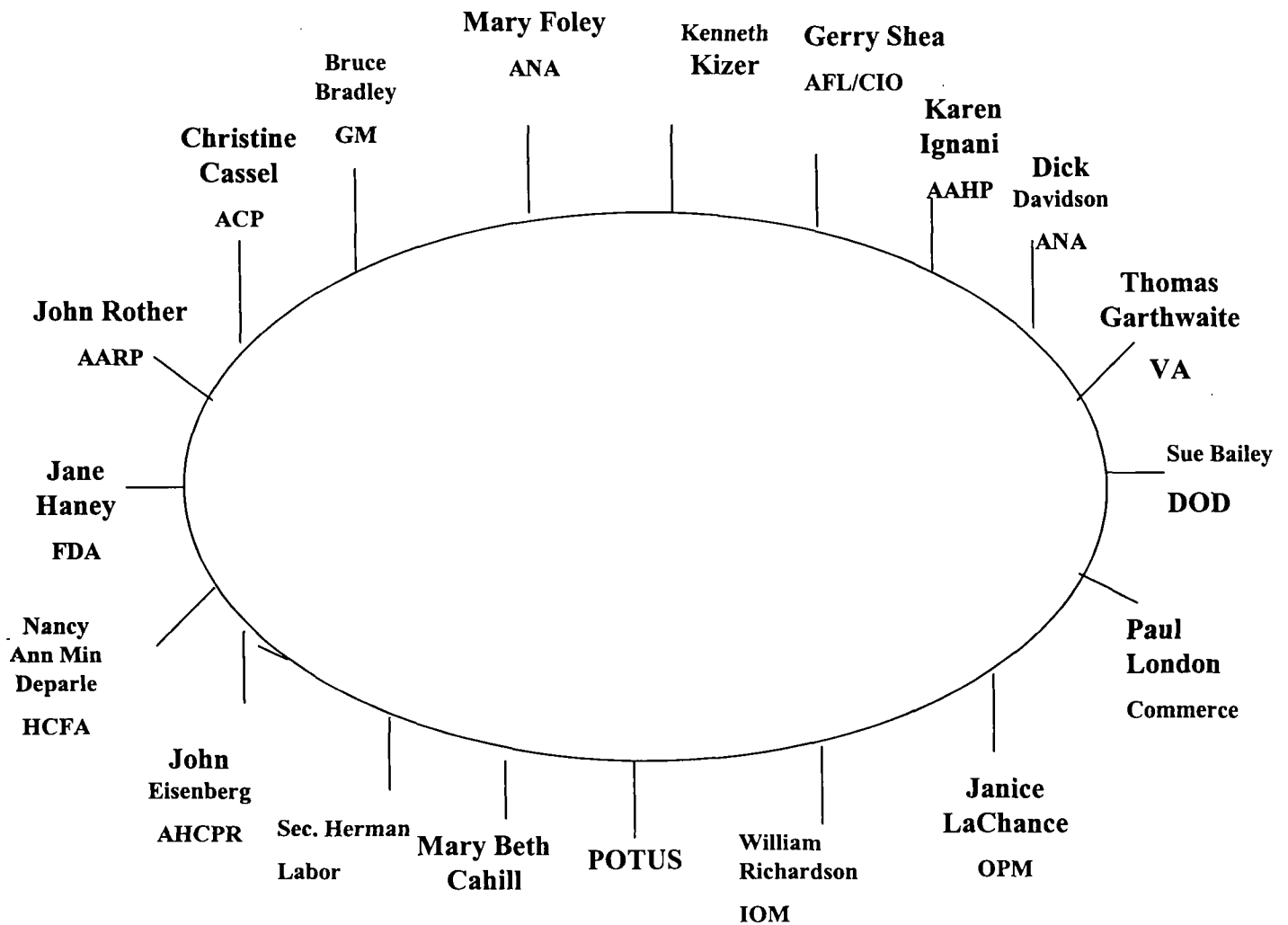
VI. ATTACHMENTS

Seating Chart

Talking Points

Participant Biographies and Statement Summaries

**Medical Errors Event
December 7, 1999
Cabinet Room
10:45-11:15 AM**



SUGGESTED TALKING POINTS ON ENSURING PATIENT SAFETY

BEFORE THE DISCUSSION:

- Thank you for coming today to discuss how we can reduce medical errors, enhance patient safety, and improve overall quality in the health care delivery system. You all come from different backgrounds, but you share a strong and unified commitment to this issue, and I appreciate your presence today.
- Just last week, as we all know, the Institute of Medicine, under the leadership of Ken Shine, , William Richardson, and Janet Corrigan, released their report on medical error prevention entitled "To Err Is Human: Building a Safer Health Care System". I want to commend the IOM and their staff for their fine work, and in a moment I'll want to ask Dr. William Richardson to briefly summarize its findings.
- But first, I want to ask Secretary Herman to make a few opening remarks. As you know, under her and Secretary Shalala's extraordinary leadership, the Quality Commission produced an extremely impressive report on these issues, and the Quality Interagency Coordination Task Force (QuIC), which I established last year, has begun to help coordinate Administration efforts in this area. Almost every one of the member agencies on the QuIC are represented today, and I am pleased that John Eisenberg, who coordinates its work, is here as well.
- The Vice President has also exhibited a great deal of leadership in this area. He helped launch the Quality Forum, a private entity that is developing measurement tools to help evaluate and ensure the delivery of quality health care services. And I am pleased that Ken Kizer, the new President and CEO of the National Quality Forum, is here with us today.
- All of us in this room have been working on this issue for years. Your collective work has been impressive, and I think that you have come a long way in helping the nation address these important issues. I want to thank each and every one of you for your dedication. Now I'd like to turn it over to Secretary Herman.

AFTER THE DISCUSSION:

- I think that the announcement that AHA is making today represents great progress, and I want to commend Dick Davidson and the AHA for it. In addition to highlighting the AHA's initiative, as many of you know, I will be highlighting a number of announcements I'll be making today in order to continue to focus much needed attention on this issue and move forward to apply some of the best practices for avoiding errors and improving patient safety.
- The announcements I'll be making today include:

Issuing an Executive Memorandum directing the Quality Interagency Coordination Task Force (QuIC) to develop new strategies to improve health care quality and protect patient safety.

Announcing that each of the more than 300 private health plans serving more than 9 million Americans participating in the Federal Employee Health Benefits Program will be required to institute quality improvement and patient safety initiatives.

Instructing Federal agencies administering health plans, including Departments of Health and Human Services, Veterans Affairs, and Defense, and others participating within the Quality Interagency Task Force to evaluate and, where feasible, implement the latest error reduction techniques.

Announcing the reauthorization of the Agency for Healthcare Research and Quality, ensuring a multi-million investment in research programs to improve health care quality.

Direct the Office of Management and Budget, the Domestic Policy Council, and other agencies to develop additional health care quality and patient safety initiatives for the FY 2001 budget.

- I believe that these initiatives will further build on the contributions you have already made. I know that I speak for the whole Administration when I say that I look forward to working with each and every one of you. Now, I'd like to invite you to join me in the Rose Garden for these announcements.

PARTICIPANT BIOGRAPHIES AND STATEMENT SUMMARIES

Secretary Herman, the co-chair of the Quality Commission and the QuIC, together with Secretary Shalala, will acknowledge your role as well as the role of everyone in the room for their commitment to improving quality health care. She will speak immediately after your opening remarks and will introduce Dr. William Richardson, the Chairman of the Institute of Medicine's Committee on the Quality of Health Care in America.

Dr. William Richardson is the Chairman of the Institute of Medicine's Committee on the Quality of Health Care in America and the Chief Executive Officer of the W.K. Kellogg Foundation of Battle Creek, Michigan. He will acknowledge the role of Quality Commission in successfully highlighting these issues, present some of the key findings from the report the Institute of Medicine released last week on medical errors, and provide a summary of its key recommendations.

John Rother, Director for Legislation and Public Policy of the AARP, will represent the consumer's perspective and underscore the importance of a proactive effort to eliminate medical errors to patients. He is likely to use the analogy of the safety initiatives at the Federal Aviation Agency as an analogy for what should be done in the health care system. He will also briefly reference the importance of balancing the need for improvements in this area with the importance of protecting the privacy of medical records, although he wants to make sure that we do not overreact to the concerns of privacy advocates and lose out on the opportunity to improve quality.

Chris Cassell, former President of the American College of Physicians and Professor and Chairman, Department of Geriatrics and Adult Development at the Mount Sinai School of Medicine, will present the physician's perspective on quality assurance and the importance of creating approaches to medical error reductions that are designed to improve quality rather than threaten providers. She will acknowledge, however, that numerous errors do take place that are preventable, and that research similar to that put forth by the Institute of Medicine and the Quality Commission are essential to enhancing quality and constraining cost.

Bruce Bradley, the Director of Managed Care Plans for General Motors, will represent General Motors and the entire Business Round Table (BRT). Mr. Bradley has been instrumental in engaging the business community's interest in this issue and has been essential in getting the BRT to support quality improvement tools such as the Health Employer Information Data and Information Set. The business community is extremely interested in being associated with this issue, not only because of its potential to constrain costs and improve quality, but because it allows them to be associated with a pro-patient initiative at a time when they are primarily associated with their opposition to the Patients Bill of Rights.

Mary Foley, a First Vice President of the ANA, will focus on the unique role that nurses play as a front line deliverer and enforcer of quality health care. She will thank you and the Administration for the consistent recognition of their role in the health care delivery system and our consistent records of ensuring that they are at the table for discussions on these and other important health policies.

Kenneth Kizer is the President and CEO of the National Quality Forum and the former Undersecretary for Health at the Department of Veterans Affairs. Ken left the Administration under less than ideal circumstances, as he and OMB frequently tangled over his unwillingness to follow protocol on decisions related to Veterans Affairs health programs. As a consequence, he was not reappointed to his position. Having said this, he is a great innovator on health systems issues and an visionary on the use of information technology to improve the health care delivery system. We are expecting him to praise the Quality Commission's work and the launch of the Quality Forum by the Vice President. He will also emphasize the need for uniform quality standards to evaluate health care delivery, and may compare the use of such standards with the desirability of utilizing similar standards to improve education in the schools.

Gerry Shea, the Assistant to the President for Government Affairs for the AFL-CIO, will represent Labor's commitment in this area. The AFL-CIO has been extremely active in the quality debate, at least partly because they believe it to be useful camouflage for their interest in assuring adequate staffing in health care settings rather than insisting upon specific patient to health care personnel ratios. They believe tough quality standards will serve to achieve that outcome without an explicit personnel to patient ratio mandate. Having said this, they, like the business industry, are always looking for ways to constrain costs so that dollars spent on health benefits for the workforce are not wasted.

Karen Ignagni is President and Chief Executive Officer of the American Association of Health Plans. Although AAHP has been a strong defender of the managed care industry and a steadfast critic of the Administration on the Patients Bill of Rights, she will no doubt highlight the constructive role that managed care plans can play in implementing error reduction programs and improving the quality of care. She has agreed not to raise our differences on the Patients Bill Of Rights publicly at this meeting, but will indicate her commitment to work with the Administration on at least this element of the health care quality agenda.

Dick Davidson, the President of the American Hospital Association, is likely to thank you for your assistance in passing the Balanced Budget Refinement Act, which returned over \$16 billion to Medicare providers over the next five years. He will highlight the commitment that the AHA has in reducing medical errors and summarize the initiative he and the Institute for Safe Medication Practices are unveiling with you, including: sending a list of "best practices" on prevention medication errors to all 5,000 of their member hospitals; developing a medication safety awareness test that surveys hospitals' medication error prevention systems; tracking implementation by the hospital and health system field of the practices for reducing and preventing errors; and working with national experts to develop a model medication error reporting process.

John Eisenberg is the head of the Agency for Research and Healthcare Quality, which you reauthorized yesterday when you signed the Healthcare Research and Quality Act of 1999, and also serves as the lead quality coordinator for the QulC. John's role will be to wrap up the discussion and underscore the importance of all the interests in and outside of this meeting working together for the common purpose of patient safety enhancement, error reduction, and quality improvement. He will focus on the role of Federal agencies in serving as model programs in these areas and might cite a few examples. He will then turn the meeting over to you to make a few final comments about your announcements for today and your appreciation for work of the parties in the meeting on this issue.

8⁰⁰

CNN

785
1466

(29+)
171 →
205

34 million



Executive Office of the President of the United States
Office of Management and Budget

Office of Information and Regulatory Affairs
Human Resources and Housing Branch
New Executive Office Building
Room 10235
Washington, DC 20503

FAX TRANSMITTAL

FAX: 202-395-6974

DATE: 1/21/2000

TO: Deborah Adler

FROM: Allison Eyd

Total number of pages (Including Transmittal Sheet): 15 pgs

Recipient's Fax Number: 6-5557

Recipient's Telephone Number: _____

Comments:

Also,
As we discussed. . . Can we include

Bob Donnelly or someone else

from the RMO side on the call?

I don't want them to feel left out. .

Proposed Rule Text

outpatient care are coordinated to ensure continuity of care for patients who move between levels of care.

→ Sec. 482.25 Condition of participation: Quality assessment and performance improvement.

The hospital must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program. The program must reflect the complexity of the hospital's organization and services (including those services provided under contract or arrangement). The hospital must implement actions that result in improvements across the full range of the hospital's services to patients.

(a) Standard: Program scope.

(1) The hospital's quality assessment and performance improvement program must include, but not be limited to, the use of objective measures to evaluate--

- (i) Access to care;
- (ii) Patient satisfaction;
- (iii) Staff, administrative and practitioner performance;

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- (iv) Complaints and grievances;
- (v) Diagnostic and therapeutic services;
- (vi) Medication error incidents, achievement of drug therapy goals and incidents of adverse drug effects;
- (vii) Nutritional services, including patient's responses to therapeutic diets and parenteral nutrition, if used;
- (viii) Surgery and anesthesia services;
- (ix) Emergency services, if provided;
- (x) Discharge planning activities;
- (xi) Safety issues, including infection control and physical environment; and
- (xii) Results of autopsies.

(2) In each of the areas listed in paragraph (a)(1) of this section, and any others the hospital includes, the hospital must measure, analyze, and track quality indicators or other aspects of performance that the hospital adopts or develops that reflect processes of care and hospital operations. These performance measures must be shown to be predictive of desired outcomes or be the outcomes themselves.

(3) The hospital must use hospital-specific data, as well as PRO data and any other available relevant data, as an integral part of its quality assessment and performance improvement strategy.

(4) Although a hospital is not required to participate in a PRO cooperative project, the hospital must be able to demonstrate a level of achievement through its own quality assessment and performance improvement strategy comparable to or better than that to be expected from such participation.

(5) The hospital must set priorities for performance improvement, considering prevalence and severity of identified problems, and giving priority to improvement activities that affect clinical outcomes.

(6) The hospital must take actions that result in performance improvements and must track performance to assure that improvements are sustained.

(b) Standard: Program responsibilities.

(1) The hospital governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff and administration officials are responsible for ensuring that the hospital-wide quality assessment and performance improvement efforts address identified priorities in the hospital and are responsible for the development, implementation, maintenance and evaluation of improvement actions.

(2) All hospital programs, departments and functions, including contracted services and services provided under arrangement, must be involved in developing, implementing, maintaining, and evaluating the hospital's program of quality assessment and performance improvement.

(c) Standard: Autopsies. The hospital must attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

Sec. 482.30 Condition of participation: Diagnostic and therapeutic services or rehabilitative services.

(a) The hospital is primarily engaged in providing, by or under the supervision of one of the practitioners described in Sec. 410.20(b) of this chapter, either diagnostic and therapeutic services to inpatients, or rehabilitative services to inpatients.

(b) The hospital must provide diagnostic radiology services, including 24-hour emergency diagnostic radiology services, if the hospital provides full-time emergency services (see Sec. 482.50(a)).

(c) The hospital must provide laboratory services, including 24-hour emergency laboratory services, to meet the needs of patients. The laboratory services must be furnished in accordance with part 493 of this chapter.

(d) If the hospital elects to offer other services in addition to the required services, they must be delivered in accordance with the requirements of this part.

→ Sec. 482.35 Condition of participation: Pharmaceutical services.

The hospital provides medication therapy, as needed, through a safe, accurate, effective system that minimizes adverse drug events and evaluates the patient's response to the medication therapy.

(a) Standard: Adverse drug event monitoring.

(1) The hospital develops and operates a system (manual or electronic) to search active clinical records for events that are likely to be associated with adverse drug events and refers these events to the hospital's quality assessment and performance program for action.

(2) The hospital must ensure that its overall medication error rate is no higher than 2.0 percent.

(3) The hospital must ensure that its patients experience no significant medication errors. For purposes of this section, medication errors are considered "significant" if they actually jeopardize or cause serious potential for jeopardizing the health and safety of the patient.

(b) Standard: Drug management procedures.

(1) All drugs and biologicals are stored in secure areas. In addition, all drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within secure storage areas. Only authorized personnel may have access to keys.

(2) The hospital keeps current and accurate records of receipt and disposition of all controlled drugs.

(3) Discrepancies in controlled drugs are reported to the individual responsible for pharmaceutical services and to the administrator of the hospital.

(4) A comprehensive drug information resource (computerized or hard copy) is available to professional staff for ordering, dispensing, and administering of medications. This information resource is readily available at common points of drug ordering, dispensing and administration in the facility, and is merged with, or located in close

proximity to, individual patient information at those common points.

(5) Before medications are administered, a licensed nurse (that is, a registered nurse, licensed practical nurse, or licensed vocational nurse) or a doctor of medicine or osteopathy must review the individual patient's information, and the orders of the practitioner who prescribed the medication.

(6) Medications brought into the hospital by the patient are administered only after positive identification of the medications, and only on the order of the practitioner responsible for the care of the patient under Sec. 482.15(a)(1), in accordance with hospital policy.

(7) The hospital has policies for discontinuing medications that are not specifically limited as to time and/or number of doses to be administered.

(c) Standard: Discharge orders for psychopharmacological drugs. Orders for psychopharmacological drugs are discontinued upon discharge of the patient, unless the patient has a psychiatric diagnosis listed in the Third or Fourth Edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM-III or DSM-IV), or in Chapter Five (Mental Disorders) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) which is available through the Government Printing Office, Washington, DC, stock number 017-022-01392-4 (1977).

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Sec. 482.40 Condition of participation: Nutritional services.

The hospital must provide each patient with adequate nutrition, including therapeutic diets or parenteral nutrition if needed.

(a) Standard: Sanitary conditions. The hospital must provide food to the patient that is obtained, stored, prepared, distributed and served under sanitary conditions.

(b) Standard: Menus. The hospital must prepare menus prepared in advance and meet the nutritional needs of the patients in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.

Sec. 482.45 Condition of participation: Surgical and anesthesia services.

If the hospital provides surgical or anesthesia services, they are provided through the use of qualified staff. The patient receives appropriate pre- and post-procedure evaluations, and all care is accurately documented.

(a) Standard: Staffing.

(1) Surgical procedures are performed only by practitioners with appropriate clinical privileges.

(2) Anesthesia is administered only by a licensed practitioner permitted by the State to administer anesthetics.

(b) Standard: Evaluations.

(1) A comprehensive assessment of the patient's condition is performed before surgery, except in emergency cases where a modified assessment is acceptable.

(2) A preanesthesia evaluation by an individual qualified to administer anesthesia is performed prior to the administration of anesthesia.

(3) A postanesthesia evaluation for proper anesthesia recovery is performed by an individual qualified to administer anesthesia.

(c) Standard: Documentation of care.

(1) The comprehensive or modified presurgical assessment described in paragraph (b)(1) of this section is entered in the patient record before surgery, except in emergency cases, where the assessment may be entered following surgery.

(2) A properly executed informed consent form for the operation is

Preamble Text

so that there is a uniform level of care throughout the hospital. For example, infection control procedures and practices should be followed uniformly throughout the hospital, not merely in inpatient areas, and we would expect a hospital to investigate adverse outcomes among outpatients as thoroughly as those among inpatients. Thus, as noted below, we would expect a hospital's quality assessment and performance improvement program to encompass outpatient services, if the hospital provides those services.

5. Quality Assessment and Performance Improvement (Sec. 482.25)

The current quality assurance condition of participation
(Sec. 482.21)

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relies on a problem-focused approach to identify and correct problems in patient care delivery. During the last decade, the health care industry has moved beyond the problem-focused approach of quality assurance in favor of focusing on systemic quality improvements, as evidenced by the JCAHO's overhaul of its accreditation standards over the last few years. We propose to follow suit by requiring a Medicare-participating hospital to participate in a continuous effort to improve its performance, incorporating to the greatest extent possible an approach that focuses on the hospital's performance in improving patient outcomes and satisfaction. Specifically, we are proposing a new COP that would require that each hospital develop, implement, maintain, and evaluate an effective data-driven quality assessment and performance improvement program.

We do not propose to prescribe specific methodologies to achieve this objective, with the exception of retaining the current rule on autopsies (see below). Instead, we would specify that a hospital's quality assessment and performance improvement program should reflect the complexity of the hospital's organization and services. Thus, each hospital would be free to pursue quality improvement in a manner best suited to its individual characteristics and resources. However, every hospital would be responsible for implementing actions that result in performance improvements across the full range of the hospital's services to patients. Also, we would require that a hospital's quality assessment and performance improvement program must use objective measures that make it possible to track performance to ensure that improvements are sustained over time.

The proposed quality assessment and performance improvement condition (Sec. 482.25) contains three standards, the first addressing the scope and direction of the performance improvement program, the second on responsibility for the program, and the third on autopsies. The first proposed standard would require that a hospital's quality assessment and performance improvement program include the use of objective measures to evaluate performance changes and would delineate the minimum items that must be included in the hospital's program. Specifically, we would require that a hospital objectively evaluate the following areas that we believe are critical to hospital performance: Access to care; patient satisfaction; staff, administrative, and practitioner performance; complaints and grievances; diagnostic and therapeutic services provided; medication error incidents, achievement of drug therapy goals, and incidents of adverse drug effects; nutritional services, including, if applicable, patient's responses to therapeutic diets and parenteral nutrition; surgery and anesthesia services; safety issues, including infection control and physical environment; emergency services (if provided); discharge planning activities; and the results of autopsies. We included the first 11 items as the minimum elements of the performance improvement program because we believe they comprise the fundamental building blocks of a well-managed hospital, whose primary business is achieving desired outcomes for patients and ensuring their satisfaction. We are proposing the twelfth item, "results of autopsies," because we believe that autopsies can be an important source of information to both individual

practitioners and hospitals that can point to opportunities for improvement in both practitioner and hospital performance. We are asking for comments on the minimum content of the Quality Assessment and Improvement Program as well as the twelve elements that are part of the Whole Quality Assessment standard.

The next standard (proposed Sec. 482.25(a)(2)) would then state that for each of the areas listed above, and any others the hospital includes, the hospital must measure, analyze, and track quality indicators or other aspects of performance that the hospital adopts or develops that reflect processes of care and hospital operations. These measures must be shown to be predictive of desired outcomes or be the outcomes themselves. As explained below, we also would require a hospital to use hospital-specific data, as well as Peer Review Organization (PRO) and other relevant data, in its quality assessment and performance improvement strategy.

Again, when we use the word "measure," we mean that the hospital must use objective means of tracking performance that enable a hospital (and a surveyor) to identify the differences in performance between two points in time. For example, we would not consider a hospital's subjective statement that it is "doing better" in a given performance area as a result of an improvement process to be an acceptable measure. There must be identifiable units of measure that any reasonably knowledgeable person would be able to distinguish as evidence of change. Not all objective measures must have been shown to be valid and reliable (that is, subjected to scientific development) to be useable in improvement projects, but they must at least identify a start point and end point stated in objective terms, most often, numbers, that actually relate directly to the objectives and expected/desired outcomes of the improvement project.

We do not believe it is feasible at this time to propose that a specific set of quality indicators or objective performance measures be used. However, systematic collection and analysis of quality indicators or performance measures that each hospital identifies should foster the eventual development of a data-driven system of hospital indicators. Many hospitals are already very active in this area. We recognize that collection and analysis of clinical outcome data may represent an increased burden on some hospitals, particularly on the subset of hospitals that are routinely subject to HCFA's survey process. These non-accredited hospitals typically are smaller than JCAHO-accredited hospitals, are located in more sparsely populated areas, and may not have the resources for extensive data gathering and reporting. However, rather than mandating specific performance measures, we would allow each hospital the flexibility to identify its own measures of performance for the activities it identifies as priorities in its quality assessment and performance improvement strategy. With this in mind, we believe the proposed quality assessment and performance improvement condition would lay the foundation for specific hospital quality indicators that might be developed by consensus in the future.

We anticipate that hospitals, both large and small, rural and urban, will or already use a variety of performance measures to inform their internal quality assessment and performance improvement programs. Some of these measures may be designed by the hospital itself, while others will be developed through research or by consensus groups or other sources outside the hospital. Regardless, HCFA intends, through its survey process, to assess the hospital's success in using performance measures principally in terms of whether the hospital can demonstrate with objective data that sustained improvements have taken place in: (1) Actual care outcomes, patient satisfaction levels, or other performance data, and/or (2) processes of care and hospital operations that are predictive of improved outcomes of care and satisfaction for patients. HCFA does not intend and would not be in a position to judge the measures themselves; instead, we would assess

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their utility for the hospital in its own efforts to improve its performance.

While we recognize that there is no single system available for the measurement of a hospital performance, we are also aware of efforts in the hospital industry to find ways to increase the use of intra- and inter-hospital performance measurement systems. For example, under programs called ORYX and ORYX PLUS JCAHO plans to require hospitals to use a defined number of performance measures that evaluate care to a percentage of patients in an initiative to integrate performance measures with the accreditation process. Initially, we understand these programs set forth an initial framework for evaluating a wide range of performance measurement systems. The specific attributes of the measurement systems that will be evaluated include: the performance measures and data elements (how they focus on processes and/or outcomes related to patient care and organizational performance); the construction of the database; the quality of the database; the extent of risk adjustment/stratification for patient factors; performance-related feedback; and the relevance of the performance measurement system for accreditation.

Under this proposed rule, we would require a hospital to engage in a quality assessment and performance improvement program that uses objective measures, but we are not proposing that a hospital be required to participate in a system of performance measurement with other hospitals. However, we intend to develop such a requirement for inclusion in our final rule, and welcome public comments addressing the appropriateness of such a requirement or how it could best be structured. For example, one possibility is that the final rule would set forth the requirement as suggested above, and would include the evaluation criteria for the system or systems the hospitals might use. We do not envision that we would require the use of a specific system. Again, we are not proposing any specific provisions at this time, but we invite comment on whether HCFA should require non-accredited hospitals to participate in one or more performance measurement systems as part of their overall quality assessment and performance improvement program (both internally and externally).

Example of a quality improvement project. HCFA wants to assure hospitals, particularly smaller, more rural hospitals, that our expectations for the use of performance measures are commensurate with the size and resources available to the hospital. Powerful improvement programs can be and are often premised on simple, straightforward designs, using measures that are direct and uncomplicated. For example, a hospital might collect information on a routine, sampled basis about the rate of utilization of psychoactive medications that are initiated during a hospital stay, when none were used by the patient prior to hospitalization. This data collection could be a part of the hospital's quality assessment and performance improvement program associated with the proposed drug management requirements (proposed Sec. 482.35(b)). The data could be collected manually or electronically and could be analyzed by case mix, age, physician specific prescribing patterns, the shift most likely to request medication orders, etc. This data would fulfill our requirement that it be an "objective measure" because the unit of measure in this example is the number of patients for whom psychoactive medications are prescribed after admission. If this data is taken for 1 month as a start period, and taken again 6 months later as an end period, the differences in the number of patients for whom psychoactive medications were prescribed after admission (both increase and decrease) would inform the hospital staff responsible for this project how well (or poorly) their intervention plan worked.

The hospital's quality assessment and performance improvement team could then use that data to design a specific improvement project, implement it, and continue to collect data to demonstrate, in a nonstatistical way change over time (for example, a steady reduction in orders for psychoactive medications during a hospital stay). The performance measures for a project like this are immediate and simple to collect, and well within the reach of any hospital. Hospitals that

have more resources could be expected to produce more sophisticated measures that involve more complicated issues, but the key expectation of these requirements is that the hospital make an aggressive and continuous effort to improve its performance across the board. HCFA is more interested in the outcomes of such an effort than in the specific processes the hospital uses to achieve the performance improvements. We recognize that: (1) There is not yet a wide menu of available performance measures that have been shown to be reliable and valid that could be offered to a hospital to use to meet these requirements; (2) a hospital cannot control many related nonpatient care outcomes (such as substance abuse practices of the patient, or lack of adequate support systems to ensure lasting positive outcomes from the hospital stay, etc.); and (3) many hospitals will need more experience with data collection methods and in the design implementation and monitoring of improvement projects. However, experience in many hospitals, other health care providers, and business and industry in general has shown convincingly that creating an expectation for continuous improvement is a far more powerful performance incentive than maintaining a set of process and structural requirements.

Therefore, we want to stress that our emphasis at this time is on the improvement of processes. The process of improvement entails: (1) Identification of an organization's critical patient care and services components; (2) application of performance measures that are predictive of quality outcomes that would result from delivery of the patient care and services; and (3) continuous use of a method of data collection and evaluation that identifies or triggers further opportunities for improvement. We do not intend for hospitals to collect data from performance measures for the sake of meeting a regulatory requirement. The hospital must have the flexibility to identify the processes targeted for improvement based on the unique needs and priorities of the facility and its patients. Moreover, we would expect the processes targeted for improvement to change over time as the hospital makes the necessary improvement efforts.

As stated by W. Edwards Deming, the late quality management expert, " * * * quality comes from * * * improvement of process(es) " and the degree to which improvement occurs is measured through analysis of collected data. (Katz, Jacqueline, Managing Quality, St. Louis: Mosby Year Book, 1992, p. 122). Likewise, the intent of this requirement is that each hospital will engage in improvement activities, based on its own analysis of data, that improve care outcomes and patient satisfaction and lead to greater efficiency and economy of operation.

How to Measure Hospital Quality Improvement Efforts--Options for Establishing a Required Minimum Level of Improvement Projects Per Year. As the preceding discussion illustrates, even small, rural hospitals and those without sophisticated "research" capabilities can develop and manage effective quality assessment and

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improvement programs that demonstrate sustained improvement over time. However, we are concerned that some hospitals may make token efforts to meet this requirement, efforts that are aimed primarily at avoiding adverse enforcement action resulting from a survey, rather than at improving processes and outcomes of care and satisfaction for patients. Thus, depending on the comments we receive, we intend to develop for the final regulation a requirement that a hospital engage in a minimum number of improvement projects that are based upon the hospital's own quality assessments of its performance and that show measured, sustained results that actually benefit patients.

We are not proposing specific language in the regulation text at this time because we recognize there are many ways in which a minimum level of effort can be set.

We are inviting comment not only on the advisability and necessity of such a requirement, but also on the best approaches to achieve this minimum level of effort. At a minimum, we would require under the

quality assessment and performance improvement condition of participation that the number of distinct successful improvement activities to be conducted annually must be proportional to the scope and complexity of the hospital's program. The success of the activity would be measured in terms of demonstrated sustained improvement over time. We intend to then supplement this underlying requirement with a more precise explanation of what would be expected of each hospital. Among the possible alternatives that we are considering are the following:

(1) Require the hospital to engage in a specific number of improvement projects equal to not less than 1 project per 1,000 patient discharges.

(2) Require a minimum set number of projects (e.g., five) that are hospital-wide and most broadly affect patient outcomes and satisfaction.

(3) Require a minimum set number of projects (e.g., five) that are not hospital-wide, but that are developed and implemented in various areas of the hospital's range of care and services (e.g., one project might reduce waiting time in the emergency room, another might focus on improving the accuracy of medication administration, etc.).

(4) Require a minimum number of projects based on bed-size, rather than discharges (e.g., 8 projects in a 600-bed hospital, 2 in a 50-bed hospital).

(5) Rather than requiring a minimum number of projects, require the hospital to demonstrate (e.g., to the PRO and/or survey agency) what projects they are doing and what progress is being achieved.

(6) Again, rather than specifying minimum number of projects, establish a minimum set of types of projects that must be done (e.g., hospital operational processes that are predictive of positive outcomes, such as infection control measures, or condition-specific projects that improve certain clinical outcomes, such as emergency room responses to heart attack patients).

We are certain there are many other ways to approach the "minimum effort" discussion. The examples noted above illustrate some of the possible approaches to ensuring that hospitals invest substantial efforts in quality assessment and improvement. The purpose of these examples is to elicit comment and suggestions in this regard, and we welcome alternative approaches. We note that although our intention is to specify in the final rule a minimum level of effort, it is also possible that after reviewing all the comments we may conclude that it is neither feasible nor desirable to do so.

Other Elements of the Proposed Quality Assessment and Performance Improvement Condition. We propose a new requirement at Sec. 482.25(a)(3) that a hospital must use hospital-specific as well as PRO data and any other available relevant data, as an integral part of its quality assessment and performance improvement strategy, to develop its improvement plans and projects. However, if a hospital elects not to participate in an improvement project with its PRO, we propose at Sec. 482.25(a)(4) that it must be able to demonstrate a level of achievement through its own quality assessment and performance improvement strategy comparable to or better than that to be expected from such participation. Thus, we intend that each hospital have the responsibility to engage in improvement projects that are vigorous and needed to improve performance across the range of hospital activities that affect patient outcomes. For example, if a PRO proposes a cooperative project to improve the outcomes for Medicare patients with pneumonia, and the hospital chooses not to participate, HCFA surveyors would expect to find that projects that the hospital designed and implemented on its own (e.g., an improvement project to reduce the use of psychoactive medications and physical restraints as patient management tools) achieved improvements that were demonstrably as important as the expected outcomes that would have been expected from the pneumonia study had the hospital chosen to participate in that cooperative study. (In assessing the comparability of a hospital project with a PRO project, we would consider the number of patients

affected, the projected magnitude of the benefit to individual patients, and the actual changes achieved by the project to the changes achieved by participants in the PRO project.)

We also would require that a hospital set priorities for performance improvement, based on the prevalence and severity of identified problems. Of course, we expect that a hospital will immediately correct problems that are identified through its quality assessment and performance improvement program that actually or potentially affect the health and safety of patients. For example, if a hospital's quality assessment and performance improvement process identifies problems with accuracy of medication administration, it is not enough for the hospital to consider this area a candidate for an improvement program that may or may not be chosen from a priority list of potential projects. Rather, since accuracy of medication administration is critical to the health and safety of patients, the hospital must intervene with a correction and improvement program immediately. Overall, a hospital would be expected to give priority to improvement activities that most affect clinical outcomes.

As noted above, perhaps the most fundamental change proposed in the new quality assessment and performance COP in comparison to the present condition on quality assurance is the focus on taking action to correct problems identified through the hospital's quality assessment and performance improvement program. This change is reemphasized in the proposed requirement at Sec. 482.25(a)(6) that a hospital must take actions based on measurement and tracking that result in demonstrable, sustained improvements. We envision a hospital meeting this requirement by conducting a systems/process analysis when adverse outcomes are identified and then taking action to afford long-term correction and improvement of the identified problems, as illustrated in the above example concerning medication administration.

The second proposed standard under this COP, proposed Sec. 482.25(b), basically builds on the current requirement under Sec. 482.21 that the hospital's governing body ensures that there is an effective, hospital-wide quality assessment and performance improvement program, as well as on the current requirements concerning

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medical staff responsibilities under Sec. 482.22(b) and (c). Under the new proposed standard, we would state that the hospital governing body, medical staff, and administration officials are responsible for ensuring that the hospital-wide quality assessment and performance improvement efforts address identified priorities in the hospital and for implementing and evaluating improvement actions. We would, however, eliminate several procedural requirements under the current medical staffing provisions, such as those concerning the organization of the medical staff.

Finally, in keeping with the cross-cutting, hospital-wide approach to quality improvement that we believe represents current best practices, the standard includes a requirement that all programs, departments, and functions be involved in the hospital's quality assessment and performance improvement program. This would include services that are carried out under contract or by arrangement.

Under the third standard in this COP, we would retain the current requirement on autopsies (existing Sec. 482.22(d)). Under this requirement a hospital's medical staff must attempt to secure autopsies in cases of unusual deaths or of medical, legal, or educational interest. Although this requirement is somewhat prescriptive, we believe it is necessary because autopsies are a valuable educational tool that contribute to the quality of care in a hospital and, as we stated above, can be used by the hospital to improve its performance.

6. Diagnostic and Therapeutic Services or Rehabilitative Services (Sec. 482.30)

We are proposing to restate and consolidate current standards from several COPs that relate to required and optional diagnostic and

→ 7. Pharmaceutical Services (Sec. 482.35)

Overview. Under the proposed condition on pharmaceutical services, which would replace current Sec. 482.25, we would require the hospital to provide needed medication therapy through a safe, accurate, and effective system that minimizes adverse drug events and evaluates the patient's response to the therapy.

In general, we propose to adopt requirements that integrate drug therapy services and support a coordination of services by the various disciplines that provide them (medicine, nursing, and pharmacy). This integration of services is intended to protect patients by establishing a four-layer "safety net" to prevent adverse drug events (including medication errors). It is intended also to detect system errors that result from the multiple nodes in the drug distribution process: Ordering, transcription, dispensing, and administration.

The first layer of this safety net is a peer review activity for the identification of events that are predictive of adverse drug events (see Sec. 482.35(a)(1)). The second layer is the detection of medication errors (see Sec. 482.35(a)(2) and (3)). This layer focuses on the more objective errors of transcription, dispensing, and administration, and leaves the more subjective drug error issues to peer review and nurse review mechanisms. The third layer of the net is the comprehensive drug information resource, which endeavors to provide vital drug and patient information at key points in the drug distribution process (see Sec. 482.35(b)(4)). The fourth layer of the net relies on nursing personnel to review drug orders for

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accuracy of the entire system before drugs are administered (see Sec. 482.35(b)(5)).

As a consequence, we are proposing to delete a number of narrowly focused, structure and process-oriented requirements, as follows:

In existing Sec. 482.25(a)--

- (1) Requiring a full-time, part-time or consultant pharmacist.
- (2) Requiring the pharmaceutical service to have adequate

personnel.

In existing Sec. 482.25(b)--

- (1) All compounding, packaging, and supervision of drugs must be under the supervision of a pharmacist.
- (2) All drugs must be kept in a locked storage area. (Note: Locked storage of only controlled drugs is proposed at Sec. 482.35(b)(1).)
- (3) Outdated, mislabeled or otherwise unusable drugs are not available for patient use.
- (4) When the pharmacist is not available, drugs and biologicals may only be removed from the pharmacy or drug storage area by a designated person.

(6) Drug administration errors, adverse drug reactions and incompatibilities are immediately reported to the attending physician and the quality assurance program.

(9) A drug formulary system must be established by the medical staff to assure quality pharmaceuticals at a reasonable cost.

A drug formulary is a system for determining the best quality and least expensive drugs, listing them in a formulary, and restricting the medical staff to the drugs listed in the formulary. This is a vastly different document than the "comprehensive drug information resource" referred to under Sec. 482.25(b)(4) of this proposed rule. A drug formulary is a cost control and quality mechanism. We do not think it would be a wise investment of survey agency time to pursue this cost control mechanism through enforcement of the COPs, since current efforts at cost controls and an emphasis on managed care will probably be far more effective at constraining drug costs in hospitals.

Finally, we plan to eliminate the explicit, process-oriented requirements for administration of drugs, and acceptance of telephone and other oral orders for drugs, that are now set forth in our nursing services requirements at Sec. 482.23(c)(2).

Description of Standards. The first proposed standard has to do with monitoring of adverse drug events (ADEs) and with eliminating or minimizing medication errors. We believe a separate standard covering ADE monitoring is needed because of its importance to patient care quality and patient health and safety. This standard is based on Journal of the American Medical Association (JAMA) papers on adverse drug events (see Bates, D. W., et al., "Incidence of Adverse Drug Events and Potential Adverse Drug Events," JAMA, 274 (1995): 29-34, and Leape, L. L., et al., "Systems Analysis of Adverse Drug Events," JAMA, 274 (1995): 35-43).

These papers make the following salient points:

- <bullet> Forty-two percent of serious and life-threatening ADEs were preventable (Bates, page 33).

- <bullet> Adverse drug events have multiple etiologies, but the lack of readily accessible and current drug information along with patient care information is a significant part of the problem with adverse drug events (Leape, page 40).

- <bullet> Computerized detection programs that search for events likely to be associated with an ADE (e.g., naloxone, an opiate antagonist), supplemented by spontaneous reporting using the computerized information system and a dedicated person or group with responsibility for evaluating these events have been found to represent an effective, relatively inexpensive method for identifying ADEs and will probably be the strategy of the future (Bates, page 33).

- <bullet> The most common defects were in systems to disseminate knowledge about drugs and to make drug and patient information readily accessible at the time it is needed. System changes to improve dissemination and display of drugs and patient data should make errors in the use of drugs less likely (Leape, page 35).

We have endeavored to implement the principles established in these papers in the first standard, "Adverse Drug Monitoring." First we propose that the facility must establish a system of evaluation of ADEs by searching current clinical records for events that are predictive of an ADE and reporting them to the quality assessment and performance program for action. We have not proposed to require that a computerized system be used by all hospitals since these regulations primarily will affect small, rural, nonaccredited hospitals who may not have the resources to develop such a computer system.

The second and third parts of the ADE standard deal with medication errors. A longstanding body of research exists concerning medication errors in hospitals. In a paper by Allan and Barker (Allan, Elizabeth L. and Barker, Kenneth N., "Fundamentals of Medication Error Research," American Journal of Hospital Pharmacy, 47 (1990): 555-71), the authors documented medication error studies in approximately 40 hospitals and nursing homes in the United States and Canada. These studies covered a period of time from 1962 to 1987. The hospitals' medication error rates ranged from a high of 20.6 percent to a low of 1.6 percent when wrong timing errors were excluded. When wrong timing errors were included, the range was 42.9 percent to 4.4 percent.

This proposal would permit an overall medication error rate in a hospital of no greater than 2 percent and require zero tolerance for significant medication errors. Significant medication errors are defined as errors that jeopardize or cause serious potential for jeopardizing the health and safety of the patient. HCFA has used this concept for many years in long-term care facilities, and has considerable experience at defining what would constitute a significant medication error. The overall error rate would include significant as well as nonsignificant (e.g., wrong timing) errors and would result in a deficiency citation. Setting an overall limit on medication errors, including significant errors, does not mean significant errors are tolerated if they remain below 2 percent. Rather, even though the regulation provides zero tolerance for significant errors, if significant errors do occur, and they are added to the nonsignificant errors, a deficiency occurs where the result is greater than 2 percent. This deficiency is in addition to the separate deficiency for the

significant errors. We are proposing the 2-percent standard because research and expert opinion has determined that this is a reasonable medication error rate to achieve, given modern drug packaging and drug information systems. (See Barker, Kenneth N., et al., "Consultant Evaluation of a Hospital Medication System: Analysis of the Existing System," American Journal of Hospital Pharmacy, 41 (1984): 2013).

In the Bates, et al, paper, adverse drug events are categorized as follows: Ordering, Transcription, Dispensing and Administration. It is important to point out that the medication error regulation proposal would examine all these categories except ADEs occurring from physician ordering questions. For this issue we would rely on the licensed nurse (that is, a registered nurse (RN), licensed practical nurse (LPN), or licensed vocational nurse (LVN)) review, as proposed under Sec. 482.35(b)(5). This is necessary because physician ordering questions dealing with the drug, the dose, the route of

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administration, etc., frequently require consultation before a positive determination about the occurrence of an ADE.

The second standard, "Drug Management Procedures," has seven parts. The first one requires that drugs and biologicals be kept in secure areas; however, those drugs that are "controlled" must be stored in locked areas as required by the Comprehensive Drug Abuse Prevention and Control Act. (We are not requiring that biologicals be stored in locked areas because this Act does not include "biologicals" in its provisions.) We are not requiring that the areas where the controlled drugs are stored be double locked, since what is usually found in most facilities is an individual with a ring of keys containing both keys to the double locked compartment. In this case "double locked" is hardly an added security feature. The key to the locked compartment should be restricted strictly to individuals who have an identified need to access these drugs.

The requirement for the facility to maintain a record of receipt and disposition of controlled drugs may be met in ways other than the use of proof of use sheets for each controlled drug. For example, the facility may use existing patient records such as the medication administration record as a record of disposition of controlled drugs. If the facility wishes to maintain records of receipt and disposition of controlled drugs by using existing patient care records, it will reduce its paperwork burden considerably.

Proposed Sec. 482.35(b)(3) requires that discrepancies in the record of controlled drugs be reported to the individual responsible for pharmaceutical services and to the hospital administrator. Discrepancies in these records indicate that controlled drugs are being used for unauthorized purposes. Proposed Sec. 482.35(b)(3) would require that these discrepancies be reported to responsible individuals in the hospital, who will then decide whether the local police or the Drug Enforcement Agency should be involved.

The fourth part of the Drug Management Procedures standard would require the hospital to establish a computerized or hard copy ability to merge patient information with current comprehensive drug information at the points of drug ordering, dispensing, and administration. This system would promote the development of information systems that bring patient information and drug information together at critical junctures in the drug ordering and distribution process. Comprehensive drug information resources would include the United States Pharmacopoeia-Drug Information, American Medical Association Drug Evaluations, and the American Hospital Formulary Service--Drug Information. (These drug information resources are those used to establish Medicaid drug use review under the provisions of section 1927(g)(1)(B) of the Social Security Act. Drug information resources would not include the Physician Desk Reference since this reference is not considered comprehensive and was not listed in the statute.)

The fifth part of this standard would require that before medications are administered, a licensed nurse, or a physician if he or she is personally administering the drug, review the patient's information and the drug order. (The comprehensive drug information would also be available for review if there was a need for this information.) The purpose of this proposal is to support the established practice of nursing personnel questioning the drug order from the standpoint of the correctness of the order itself in relation to specific patient and drug information that must be readily available before or at the point of drug administration. In reviewing this information to prevent drug errors, a nurse would be acting only within the scope of her or his State licensure. The expectation is that the nurse would report any potential errors in drug prescribing to the physician, so the physician could determine whether the order needed to be changed. This proposed requirement is consistent with current research. Leape identified a total of 334 adverse drug events that were identified by review of all admissions in 11 medical and surgical units in 2 tertiary hospitals for a period of 6 months. Of the 334 adverse drug events, 91 or 27 percent were intercepted (prevented). Of these 91 prevented adverse drug events, 86 percent were prevented by nurses and 12 percent by pharmacists. This proposed regulation is intended to strengthen the potential for nurses and pharmacists to intercept adverse drug events of all kinds by providing them with readily available information necessary to prevent these events.

The sixth part of the Drug Management Procedures standard deals with positive identification of medication. The current regulations do not contain a requirement for positively identifying drugs brought to the facility by the patient and then obtaining physician orders before they can be administered. We are proposing such a requirement here because when an individual is hospitalized it indicates a considerable change in their status. "Positively identified" in the context of this proposed rule means that a pharmacist or someone with similar drug identification skills must make sure that the drugs brought to the facility are in fact the same drugs that the label represents. This is necessary because patients often mix drugs within one container, or they separate drugs from their proper labeling. The drugs that the individual was taking prior to this hospitalization should be reviewed by competent medical personnel to determine if these drugs are still necessary, or if they may interfere with other therapies that are underway in the hospital.

Unlike current regulations, this proposed rule would make it clear that self-administration of drugs is permitted, but only under orders and hospital policy. This proposed rule is important for patients being prepared for discharge. These patients should become familiar with self-administration of drugs (especially eye drops, inhalers, intramuscular injections), so they become well-practiced with this task while still under competent supervision.

Regarding our seventh proposal, existing Sec. 482.25(b)(5) requires that orders for drugs and biologicals be automatically stopped after a reasonable period of time as predetermined by the medical staff. This proposed rule endeavors to achieve the same objective as the current rule, that is, the cessation of drug therapy when it is no longer necessary. However, our proposal would not limit the hospital to the option of automatic stop orders, which discontinue drug therapy (especially on holidays and weekends) by administrative fiat without any medical assessment as to whether the drug therapy has achieved its therapeutic objectives. The proposed rule allows the hospital to develop its own approaches for achieving this objective.

The last standard of the Pharmaceutical Services COP (proposed Sec. 482.35(c)) deals with discharge orders for psychopharmacological drugs. Under this standard, we would require that orders for psychopharmacological drugs be discontinued upon the patient's discharge unless the patient has been diagnosed (using standard criteria for such diagnoses) with a mental illness. This will prevent the use of these drugs (which may be temporarily necessary during a

hospitalization) from becoming routine after discharge unless a valid reason for their use is established. This is particularly necessary in patients

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transferred to long-term care facilities, who can suffer considerable adverse effects from long-term use of antipsychotic and antianxiety drugs that may have been started in the hospital for very valid reasons but that may no longer be valid after discharge. A study by Garrard (Garrard, Judith, et al., "Evaluation of neuroleptic drug use by nursing home elderly under proposed Medicare and Medicaid regulations," JAMA, 265 (1991): 463-467) showed that the rate of use of neuroleptic (antipsychotic) drugs among nursing home admissions was: 16 percent when admitted from hospitals, 18 percent from the community, and 21 percent from other nursing homes. Regulation of the use of these drugs (in the absence of proper differential diagnoses) in nursing homes have been in effect since 1990 (see 42 CFR 483.25), and we have been criticized because similar rules were not imposed on hospital and community practice (Thurston, Ronald G., Letters, JAMA, 265 (1991): 2962). We believe this proposed requirement represents a fair way to address this issue, but invite public comment on alternatives for achieving the same objective.

8. Nutritional Services (Sec. 482.40)

Currently, the food and dietetic services requirements that a hospital must meet are found at Sec. 482.28. These requirements emphasize the organizational aspects of a hospital's food and dietetic services program, including provisions that specify allowable contractual arrangements, employee qualifications, and other process-oriented details.

We are proposing extensive revisions to these provisions under a new nutritional services condition of participation. In keeping with the principles discussed above, the new condition of participation would promote a patient-centered approach to nutrition. Thus, the introductory language for these proposed requirements states explicitly that each patient must receive adequate nutrition, including therapeutic diets or parenteral nutrition if needed.

The proposed condition includes only two standards. The first standard, "Sanitary conditions," requires that food provided to patients be obtained, stored, prepared, distributed and served under sanitary conditions. (Note that the term "food" is intended to include all forms of nutrition, liquid or solid, provided to patients.) Although this requirement is not contained in the current hospital conditions of participation, we believe that it clearly is an underlying necessity for any acceptable nutritional services program. Thus, we are proposing to include it explicitly under the nutritional services condition. The only other standard would require that menus be prepared in advance and meet the nutritional needs of patients based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. We believe the Board's guidelines can appropriately be used here because they represent accepted best practices and are already in widespread use among hospitals.

In developing the proposed requirements, we have attempted to incorporate straightforward statements of a hospital's responsibilities, while eliminating procedural requirements and avoiding unnecessary details of how the hospital should carry out its nutritional services function. We believe that the requirements largely incorporate current best practices in hospital nutrition services, while eliminating several burdensome process requirements that are not central to meeting the patient's dietary needs (such as the requirement under current Sec. 482.28(b)(3) that a current therapeutic diet manual approved by the dietitian and medical staff be readily available to all medical, nursing, and food service personnel.) We considered supplementing the requirements with additional provisions concerning

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TO:

Chris Jennings

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Age Group	Percentage of Respondents
18-29	95%
30-49	90%
50-69	85%
70+	80%

Telephone Number

Fax Number

FROM:

Ed Flynn

DATE:

Telephone Number

Fax Number

COMMENTS:

Based on your conversation with
Janice Lachance

REDUCING MEDICAL ERRORS

OPM'S CENTER FOR BENEFITS DESIGN AND DELIVERY

The President asked the Office of Personnel Management to play a key role in reducing medical errors and improving patient safety through public private partnerships. He expects OPM will demonstrate the same type of leadership that we displayed in implementing the Patients' Bill of Rights, and advancing long-term care and mental health parity. OPM has established solid relationships with over 300 commercial health insurance carriers, and virtually all of the influential entities in the healthcare arena - the National Quality Forum, AAHP, FACCT, NCQA, JCAHO, QuIC, and others. From an employer and purchaser standpoint, OPM is uniquely positioned to make a significant contribution in response to the President's call.

However, our ability to respond to the President in any meaningful way is severely hampered so long as OPM's Center for Benefits Design and Delivery remains underfunded. Without a minimum of \$1.5 million in additional funding, we will not conduct the research, outreach, and oversight activities necessary to move the FEHB Program toward the objectives outlined in the Institute of Medicine's (IOM) Report - "To Err Is Human - Building a Safer Health System."

With supplemental funding of \$1.5 million, which would include funding for 10 additional FTE in FY 2000, we will initiate a program to reduce medical errors that will encompass:

Collecting and analyzing HEDIS measures that bear upon medical error rates as a basis for requesting and monitoring carrier initiatives to reduce medical errors and improve the quality of care.

Monitoring pharmacy benefit managers that serve the FEHB program to assure effective drug interaction programs are in place, and electronic prescription systems are developed and expanded.

Collaborating with credentialing and accreditation bodies and others to develop, put in place, and oversee performance and quality standards for participation in the FEHB Program.

The forthcoming report from the Quality Interagency Coordination (QuIC) Task Force to the President will be asking member agencies to take immediate actions to reduce medical errors and improve the quality of care. OPM is a key QuIC member and must be funded to respond to its, and the President's, call. The statistics contained in the IOM report indicate that 1,800 lives are lost each year within the Federal Employees Health Benefits Program due to avoidable medical errors. Not funding this initiative, or delaying funding, may needlessly put lives of FEHB participants in certain peril.

Patient Safety Initiatives

Dollars in Millions

	1999	2000	2001	3-yr Total
Formal Patient Safety Program <i>National Center for Patient Safety, Patient Registry/Reporting System, Handbook, Oversight Committee, Improvement Awards, Centers of Inquiry, Expert Panel on Systems Design, Quality Scholars Program, Analysis of Injuries and Near Misses, and Patient Safety Field Staff.</i>	120	156	177	453
Bar Code Technology <i>Bar coding of medications and blood products. Includes costs of systems, hardware, training, and implementation..</i>	96	54	12	162
Computerized Patient Record System <i>Physician order entry and pharmacy package.</i>	1	21	8	30
Suicide Prevention <i>Includes prevention and management of suicidal behavior initiatives (Satellite Conference production, travel, etc.)</i>	1	1	1	2
Total	219	232	197	648

specific initiatives to fix

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FDA Initiatives to Improve Patient Safety in the FY 2001 Budget

page 1

Medical errors occur because of failures within the complex systems of modern health care. Doctors, nurses and other health professionals represent the human component of the system. The rest of the system is largely comprised of a vast array of drugs, medical devices, blood and other biological products that are regulated by FDA. While the causes of medical error cover a broad spectrum, from errors attributable to only human mistakes, to errors that are almost entirely attributable to a medical product, most medical errors involve health professionals and the use of medical products. FDA is the federal agency that monitors and regulates the safety and effectiveness of the medical products used to treat patients. Whenever medical errors involve a medical product, FDA has the responsibility to address the safety problem.

The design features of medical products can play a decisive role in minimizing-- or contributing to--human error in their use. Features that contribute to errors in actual product use are not always identifiable before FDA approval. Once products are widely used in today's complex and fast-paced healthcare delivery system, these "human factors" can emerge as safety risks. The agency has surveillance systems to **find harm** resulting from use of FDA-regulated products, including reports from hospitals and other facilities and spontaneous reporting from health care professionals. When alerted to problems with a product, the agency acts to **understand harm** with a thorough safety analysis by medical and scientific experts. The analysis identifies critical factors causing the problem, and may identify product features and safety procedures that should be changed. FDA has the legal authority to take action to then **prevent harm** to other patients, including communicating to doctors and other health professionals, as well as patients, and if necessary, requiring changes to the medical product. The "lessons learned" about safe product features are also incorporated into the agency's review of future products.

Recent and dramatic increases in the numbers of newly-approved drugs and other products, increases in patient use of medical products, and continuing time and cost pressures on health care providers, have raised the level of risk for human error in the use of medical products. FDA needs to increase its capabilities to protect patient safety in each of its 3 core safety activities. The cost of activities currently budgeted for FY 2001 total \$13.5 million. Additional funding would enable FDA to speed these initiatives to further reduce medical errors over the next few years.

- To better **find harm**, FDA needs more capacity for active surveillance of problems with medical products, including links to hospital-based systems, to better support hospital staff working on the "front lines" of patient safety. In FY 2001 this includes improving the reporting systems for blood errors and accidents, continued implementation of the Medical Device Surveillance Network (MeDSuN) to address under-reporting and incomplete reporting of medical device problems, and to extend its capacity to include drug reports, as well as increased use of other electronic systems to monitor problems with use of drug products.
- To better **understand harm** associated with products, especially ones that may be used in combination with several other medical products, FDA needs increased capacity to do the multi-factor analysis to correctly identify the sources of the safety problems and their solutions. In FY 2001 this includes establishing links to safety

FDA Initiatives to Improve Patient Safety in the FY 2001 Budget

page 2

databases maintained within community-level healthcare delivery systems and regional-level safety surveillance systems, and adding to agency expertise in medical epidemiology and statistical analysis.

- To further **prevent harm**, FDA needs a better capacity to act on safety findings, including better risk communication to providers and patients who use medical products, regulatory steps to correct product design and manufacturing problems, and partnerships with other health agencies and health care organizations, to ensure patient safety. Investments in FY 2001 include expanding FDA partnerships and collaboration with medical and patient safety organizations, state and local health agencies, and industry organizations, with the common goal of ensuring product quality and patient safety.

Facsimile

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Also, as John mentioned on the phone,

HCFR's Center for Beneficiary Studies wants
\$1.5 million in FY2001 to ~~be used~~ use in communicating
better with consumers about medical errors.
We have told them to write something that
OMB can review.

Foster, Nancy

From: Gerberding, Julie M.D. [jyg2@cdc.gov]
Sent: Thursday, January 13, 2000 12:56 PM
To: Foster, Nancy (AHRQ)
Subject: CDC Budget FY01

Here is the concept for CDC's 01 budget; I could not send it yesterday because of network problems in DC.

I admire your ability to manage this elephant! Thanks for keeping us in the loop.

Best, jlg

CDC FY 01 Budget Proposal: Preventing Medical Errors and Adverse Healthcare Events

1. Proposal to develop a sentinel voluntary reporting and prevention network to promote patient safety
(CDC lead with FDA, HCFA, AHRQ collaborating partners)

Goal: develop a sentinel network of representative healthcare facilities to report errors and related data and create valid risk-adjusted benchmark error rates that can be used by all comparable healthcare facilities to identify report error rates, detect systematic problems, and monitor the success of prevention interventions

FY2001: In collaboration with FDA and other federal partners, CDC will initiate demonstration programs in 5-8 sites to expand current monitoring capacities (infections, antimicrobial use, invasive medical device use) in healthcare facilities to address new priority medical errors (as defined by AHRQ and others) and develop an epidemiologically sound basis for developing risk-adjusted benchmarks and other data needed to ensure a credible error monitoring system useful to all comparable healthcare facilities

Funding Request: \$8 million

- " \$2.5 for technical development
- " \$5.5 for extramural support of healthcare organizations reporting sources to ensure development of local infrastructure models for error detection, data reporting, information system networking, and prevention interventions

Personnel Request: 10 FTEs

- " 2 FTEs for information systems development
- " 2 FTEs for epidemiologic evaluation and monitoring
- " 2 FTEs for system administration and management
- " 2 FTE for on-site investigations and interventions
- " 1 FTE for interagency liaison and coordination
- " 1 FTE for liaison and training for reporting sites

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February 23, 2000

Experts Cast Doubt on Medical Reporting Plan

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By **ROBERT PEAR**

WASHINGTON, Feb. 22 -- The official leading federal efforts to reduce medical errors told Congress today that he had no firm evidence that mandatory reporting of such errors, as proposed by President Clinton, increased the safety of patients or reduced the number of mistakes in states where it had been tried.

The official, Dr. John M. Eisenberg, director of the Agency for Health Care Research and Quality, said that some of the criticism of the president's proposals was "on target."

"Do we know if these programs work?" Dr. Eisenberg said at a Senate hearing. "No, we don't. We don't know how well they work, and when they work best."

Dr. Eisenberg was responding to comments made on Monday by Dr. Nancy W. Dickey, former president of the American Medical Association, who said, "A number of states have mandatory reporting, and there's no evidence that they have greater safety or fewer errors."

Eighteen states, including New York, New Jersey and Connecticut, require hospitals to report certain kinds of mistakes and "adverse events." President Clinton wants all states to require such reports.

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Dr. Eisenberg said there had been "very little analysis" of states' experience with mandatory reporting. He said that one bit of evidence, from New York State, suggested that such reports could improve the quality of care.

Hospitals in New York have been required to report medical mistakes and other unexpected occurrences to the state Health Department since 1985. Under a separate program, the agency collects information on every patient undergoing heart bypass surgery in New York, regardless of whether there was an error. The state publishes death rates for all hospitals that perform the procedure.

The death rate for bypass surgery has dropped by more than 30 percent since New York first published such data, in 1989. The figures are adjusted to take account of each patient's medical history and other "risk factors."

Dr. Eisenberg said the federal government would develop a research agenda to identify the best methods of mandatory reporting. As a condition of getting Medicare money, he said, hospitals will have to comply with reporting requirements in their states. In addition, Medicare officials will choose up to 100 hospitals to test the value of mandatory reporting.

Dr. Dickey said: "The president has the cart before the horse. He'd put in place mandatory reporting, then study it and do something different if it doesn't improve patient safety."

Dr. J. Richard Gaintner, chief executive of Shands Health Care, which operates seven hospitals in and around Gainesville, Fla., said he feared that the reporting of medical errors would feed the appetite of lawyers eager to sue hospitals for malpractice.

"We take medical errors very seriously," Dr. Gaintner said in an interview. "But the incredible litigiousness in the health care field is a great concern to us. I have been in this business for 30 years and have sat on the boards of several insurance companies. I've seen too many examples of information that gets out and is used in ways that are not good for patients or patient care."

Under the president's proposal, the names of hospitals reporting serious errors would be "made public without identifying patients or individual health care professionals."

The president said that the results of a hospital's internal investigation and analysis of its errors should not be available to patients, their lawyers or the courts.

But Dr. Eisenberg said the president had not recommended any specific penalties for the improper disclosure of such information.

Dr. Spencer Foreman, president of Montefiore Medical Center in the Bronx, said: "These requirements compel hospitals to look at errors and examine them, to find out what caused them and to take reasonable steps to correct them."

Even states with a long history of incident reporting, like New York, don't have a model program to ensure that problems, once identified, are corrected."

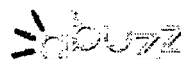
Senators of both parties said President Clinton was apparently trying to impose a new mandate on the states without offering them any money to carry out the task of tabulating and analyzing thousands of error reports from hospitals.

Senator Arlen Specter, the Pennsylvania Republican who heads the Appropriations subcommittee for health care, said he supported mandatory reporting.

Without a federal law, Mr. Specter said, hospitals will not acknowledge their errors, and he cited his state's experience to prove his point. Under state law, he said, hospitals are supposed to report medical errors, but 35 Philadelphia hospitals reported only one medical mistake in the year that ended in June 1999.

David L. Bernd, chief executive of Sentara Health Care, a large nonprofit health care system in Virginia, said: "We support efforts to deal with medical errors. They can be tragic. But if the information is used to browbeat providers who report errors, they won't report. The problem will get worse."

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Date: 1-13-00 # of Pages to Follow: 3
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Dollars in Millions

\$ 4.7 \$ 6.3

For example, they develop and implement the information systems, and the training and mentoring of field patient safety staff.

12.6 11.5

VA has led the way in the development and implementation of an innovative, comprehensive medical error reporting and analysis system (referred to as root cause analysis or RCA). This activity is an overarching process for data collection and analysis and provides the high quality information that enables patient safety improvement to take place. This effort involves in-depth training and simulation, a new computer assisted tool, and a robust process. For example, 850 individuals will get formal 3-day training by NCPS and those trained will train 21,250 RCA team members per year. It allows staff, on the front lines to identify, analyze, and prevent unfortunate occurrences from happening. The promise of these approaches is such that VA's colleagues in the private sector, such as Joint Commission on Accreditation of Healthcare Organizations and American Hospital Association, are currently assessing how these techniques can be employed in all hospitals.

5.0 6.2

Realizing this is a pioneering effort where there are many unknowns, VA created four Patient Safety Centers of Inquiry that serve as living laboratories to further its understanding of how to prevent errors in medicine. For example, the Center in Palo Alto, which is affiliated with Stanford, is recognized as a leader in the area of medical simulation for operating room and anesthesia activities -- you may have seen them on national TV newsmagazines or read about this effort in the newspaper. Based on their activities to date, VA expects to create additional simulation facilities that will be used to train its physicians and other health care professionals. One simulator with appropriate staff can train

around 600 anesthesiologists and residents-in-training per year. This means that virtually all VA anesthesiologists/anesthetists can be trained in a year. Checklist cards for anesthesia have been found to improve performance and will be placed on all anesthesia machines across VA.

Another example is the learning collaboratives that VA has begun in cooperation with the Institute for Healthcare Improvement, another recognized leader in this field. Their focus now is reducing medication errors, a major issue identified by the Institute of Medicine report in late 1999. IHI collaboratives will affect 1000 VHA personnel in FY 2000 and 2000 more in FY 2001 - all across VHA will participate in medical error reduction. IHI collaboratives resulting in a measurable but as yet undetermined reduction in errors.

Field Patient Related Safety Staff

25.9

37.1

The level of staff identified by the medical centers and VISNs associated with patient safety. The dollar estimate was developed from a survey and national roll-up of cost of staff time devoted to patient safety at individual facilities, which currently totals 294 FTE (note that more staff would have direct or indirect involvement than FTE). We estimate that facility patient safety staff will be enhanced through the redirection of buyout staff, estimated to add 190 FTE by FY 2001.

Comprehensive Adverse Event and Close Call Analysis Program

22.0

22.9

VA realized that in order to achieve a significant advance in the area of patient safety they would have to look outside of medicine for solutions as well as develop completely new approaches for solving these problems. They have looked to and industrial community for best practices that can be adapted to Health care's needs. In doing so they have created and implemented an innovative, computer aided, comprehensive reporting, analysis, and improvement system for use in their entire organization. These developments have shown such promise that they are now being assessed for use by other organizations such as the Joint Commission on Accreditation of Healthcare Organizations and the American Hospital Association. A survey and roll-up of current staff time devoted to this effort in VA facilities totals 237 FTE.

VA Quality Scholars Program

To perpetuate and make patient safety a living part of VA professional life, VA created a fellowship in quality and safety that is currently made available for ten physicians per year in five VHA facilities with academic affiliates around the country. This is the first and only program of its type in the United States and the world. This is an investment for the future, since the intent is for these physicians to spread the word throughout the VA and the greater healthcare field.

4.1

9.1

Mandatory Training

Understanding that actions speak louder than words, VA has embraced the goal that half of all full-time staff will receive 20 hours in FY 00, and forward, of patient safety training. This equates to a commitment of over \$39 million in FY 00 and over 1.6 million manhours of training. (ASIDE: these numbers only represent FTE to attend, not travel, materials, tuition, etc.).

38.8

39.4

All Other

All other program costs associated with patient registry and reporting, an employee awards program, education, learning centers, etc. are included here.

4.7

4.8

Total Patient Safety Program 1/

\$ 117.6	\$ 137.3
-----------------	-----------------

1/ This does not reflect the substantial investment made in computerized patient record system and Barcode technology that is continuing forward.

Agency for Healthcare Research and Quality



Immediate Office of the Director

DATE:

11/11/00

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Devorah

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COMMENTS:

• Bonnie

9/6/01

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CJ DRAFT - MEDICAL ERRORS

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Priority #1: Enhancing Patient Safety**Pipeline Summary (THIS TABLE IS NOT UPDATED GIVEN THE NEW BUDGET DETAIL)**

Theme #1 Enhancing Patient Safety (\$20.0 M)			
	New Knowledge on Priority Health Issues	New Tools and Talent for a New Century	Translating Research into Practice
Outreach to Users of Research and Other Stakeholders	.250 M		2.75 M
Fundamental and Applied Research and Demonstrations on Errors and Reporting	8.25 M	.250 M	5 M
Tools and Training for the public and private sector to support efforts to enhance patient safety		3.25 M	.250 M

Background

The recent Institute of Medicine (IOM) report, *To Err is Human*, builds upon the work of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, providing compelling evidence of the need to establish a national focus to create leadership, tools, protocols, and new knowledge to enhance patient safety.

While evidence of the problem has existed for some time, the IOM report succeeded in capturing the public's attention by revealing the magnitude of this medical epidemic and presenting it in a compelling fashion. Box with facts from IOM report Medical errors are estimated to cause between 44,000 and 98,000 deaths annually in the United

States. Using the more conservative figure, medical errors rank as the eighth leading cause of death, killing more Americans than motor vehicular accidents, breast cancer, or AIDS. ~~Box with ranking of causes of death showing where medical errors are in~~

~~relation to other causes.~~ In addition to this extraordinary human toll, medical errors result in annual costs of \$17 – \$29 billion in the United States (Institute of Medicine, 1999).

A requirement for an effective response to patient safety is a thorough understanding of the dimensions of medical errors and what works in preventing them and mitigating their impact. Although there is much to learn from efforts in other industries such as aviation, manufacturing, and banking, it is clear that a substantial body of research will be required to facilitate errors prevention in healthcare. The IOM noted that

Creating an information infrastructure and building a better evidence base for patient safety are critical to taking a more strategic approach to reducing errors and improving patient safety (Institute of Medicine, 1999).

We have only a cursory knowledge of the causes of medical areas and the areas where there is extant knowledge of what works to reduce them (such as in anesthesia), are far outnumbered by those where there is little or no information to guide an evidence based approach to errors reduction. For example, little is known about the ideal characteristics of reporting systems, what can be learned from such systems, and whether they are effective in reducing errors. There are also major gaps in our patient safety knowledge defining the types of medical errors, the factors associated with their occurrence, and their prevalence in settings other than acute care hospitals. It is likely

that patient safety problems in nursing homes, ambulatory care facilities, and patients' homes are common, preventable, and fundamentally different from those in the hospital setting.

The Agency for Healthcare Research and Quality (AHRQ) is a natural focal point for a national effort to enhance patient safety. AHRQ (then the AHCPR) funded the landmark research by Professors Lucian Leape and David Bates that first brought national attention to the issue of medical errors. Subsequent studies sponsored by the Agency have focused on the detection of medication errors, investigation of diagnostic inaccuracies, the relationship between nurse staffing and adverse events, computerized adverse drug event monitoring, and computer-assisted decision-making tools to mitigate errors and improve safety. ~~Box with facts from Leape, Intermountain, and~~

~~other errors studies~~ The Agency is also well positioned to coordinate a comprehensive and sustained effort on reducing medical errors among federal departments and agencies through the Quality Interagency Coordination Task Force, as well as integrating public sector efforts with those of the private sector through collaborative work with the National Quality Forum, National Patient Safety Foundation, and other entities working on this agenda. Under its newly signed reauthorization, which transformed the AHCPR into AHRQ, the Agency has the authority to conduct and support research on reducing medical errors and improving patient safety.

New initiatives to reduce errors in health care and enhance patient safety will build upon recent Agency commitments to research in this area. Last year, AHRQ awarded four

extramural grants to establish Centers for Education and Research on Therapeutics (CERTs). These free-standing centers will conduct research and educate medical practitioners and other decisionmakers concerning the benefits, risks and effectiveness of new uses, existing uses or combined uses of therapeutics—drugs, biologics and medical devices. ~~box with facts from CERTS studies~~ This year the Agency is supporting a research grant examining medical errors in nursing homes and AHRQ recently released an RFA calling for extramural research focused on testing the effectiveness of the transfer and application of “best practices” to improve patient safety by reducing preventable medical errors that are frequent and cause serious harm. AHRQ is also providing ongoing support for a project being carried out by the private sector National Patient Safety Foundation that identifies and aggregates information on funding agencies and organizations and topics of research on medical errors and patient safety in both the public and private sectors. Following up on that activity, the Agency will be supporting a National Summit on Research on Medical Errors in the coming months. This research agenda setting conference will bring researchers, data collection entities, and users of the research (including and in cooperation with private sector organizations such as medical specialty societies, the JCAHO, and the National Quality Forum) to review the current state of the patient safety research field and set priorities in research. In March 2000 the Agency will be sponsoring a workshop for senior state health officials entitled “What States Can Do To Improve Patient Safety and Reduce Medical Errors” as part of AHRQ’s User Liaison Program (ULP). The ULP translates, synthesizes, and disseminates health services research findings, in easily understandable and usable formats, to State, local, and Federal policymakers through interactive workshops and

technical assistance and provides an important vehicle through which the evolving research on patient safety can be translated into action.

These existing research initiatives, however, do not meet the ambitious research agenda described in the IOM report, which suggested a substantial investment in patient safety research. [Box with recommendations from IOM report including \$35

million in research funding for AHRQ, ramping up to \$100 million] It is striking to note

that, given the magnitude of the patient safety problem documented in the IOM report, it is likely that hundreds of millions of dollars in research funding would be applied to the problem if it were an easily defined disease entity.

Development of a Substantial Research Initiative on Patient Safety at AHRQ

The AHRQ proposes a broad research initiative aimed at developing evidence based approaches to the improvement of patient safety. The research and training efforts proposed will ensure that research and improvement efforts for enhancing patient safety will move beyond just describing and defining the problem to providing the knowledge and tools required that will be required to address the patient safety challenge. This initiative will include agenda setting, research support (extramural and intramural), program evaluation, demonstration support, tool development, training initiatives, and dissemination activities. Where possible, these activities will be pursued in partnership with other federal and private sector entities. Specific activities will be designed to meet the priorities articulated in the National Summit on Research on Medical Errors and other stakeholder meetings with public and private sector entities

interested in patient safety to ensure that the research agenda is user-driven. The research proposed will have the potential to make a difference in medical errors and have a measurable impact on patient safety.

Specific Activities to be Pursued in FY 2001

1. Outreach to Users of Research and Other Stakeholders:

- **2ND National Summit on Research on Medical Errors:** This research agenda setting conference (or conferences) will build upon the first conference bringing researchers, data collection entities, and users of the research (including and in cooperation with private sector organizations such as medical specialty societies, the JCAHO, and the Quality Forum) to review the current state of the patient safety research field, to learn from its lessons about programs and policies to translate the research into practice and policy, and to set new priorities for research.
- **Outreach to Stakeholders:** Develop programs to foster research dissemination to users of the research findings including providers and policy makers through AHRQ's ULP; providing support to the National Quality Forum to increase the national discussion on errors and their prevention; fund collaborative agreements with health care professional organizations that foster education; track patient safety initiatives; provide input to research centers; translate, disseminate, and promote adoption of research findings; and provide important dissemination linkages for implementation of new practices and policies.
- **Patient Safety Clearinghouse:** Developing a clearinghouse to be an objective

source of the latest information on patient safety for the nation mechanism in partnership with private sector organizations and initiating a "National Morbidity & Mortality Conference" of de-identified selected cases in a public forum via internet technology to promote quality improvement.

2. Fundamental and Applied Research and Demonstrations on Errors and Reporting:

- Fundamental Research on Errors: Exploring the role of human factors, root cause analyses, informatics, and legal and judicial issues bringing together experts in these fields with health services researchers. This research will provide a strong foundation for efforts to prevent errors following the strategy applied in other industries such as manufacturing, aviation, and banking which began their error reduction programs with a look at the factors underlying efforts and the steps needed to address them.
- Research on Reporting Systems: Identifying critical components for reporting systems, the data needs and structure for reporting, demonstrations programs for reporting, evaluating existing state mandatory reporting system, and the development of techniques for the analysis and dissemination of patient safety data and the impact of reporting. We will also support an evaluation of reporting systems to explore the merits, risks, and costs of reporting options including voluntary systems, de-identified mandatory reporting, and public reporting of information on medical errors.
- Applied Research on Patient Safety: Evaluations of traditional efforts (e.g. incident reports) versus newer approaches (root cause analysis and systems approaches);

using our established Evidence-based Practice Centers (EPCs) to report on the state of the art in errors evaluation using lessons from industry and healthcare; expanding our CERTs program to support research on medication errors; identification and evaluation of best practices in error reduction; and examining how information systems and information technology can be used to identify and, where possible, prevent medical errors and threats to patient safety. Following on the success of the EPC and CERT model, we will be funding patient safety "Centers of Excellence" to provide a focus to some these research and demonstration efforts. To ensure that these centers will address the range of patient safety issues they will be organized on either the site of care (nursing homes, ambulatory care, etc.) or cross-cutting research (e.g. diagnostic accuracy, informatics applications, human factors analysis, etc.).

3. Tools and Training for the public and private sector to support efforts to enhance patient safety:
 - Laboratory Development: To foster the testing and application of tools and approaches from other industries to reduce errors in the health care sector we will create the equivalent of "community based laboratories" through medical specialty societies, primary care networks, and integrated service delivery networks. These laboratories will bring together the best of research on improving patient safety, real world practice, and patient populations to rapidly develop models for wider dissemination.

- Measures: Development and evaluation of measures for reporting on patient safety and working with the National Quality Forum and other private sector efforts on core measures for patient safety.
- Data Synthesis for Research and Policy: Developing a database of de-identified information using AHRQ's Healthcare Cost and Utilization Program as a model which will facilitate comparing oneself to peer organizations and states. The database will not set standards or collect new information but instead provide a vehicle to pull together existing data from the states and private sector. In addition the Agency would provide Technical Assistance to state and private sector entities collecting, analyzing, and disseminating patient safety data.
- Curricula, Tools, and Talent Development: Evaluating programs introducing health professionals to errors analysis and the realities of practicing in a technically challenging environment, evaluating the use of simulators and automation in education to prevent errors, and supporting training in errors research and evaluation which would then provide linkages with states

Patient Safety Initiatives in the Department of Defense for FY 2001

Many current and proposed programs in the Military Health Systems affect patient safety. The initiatives highlighted here have the potential for significant improvements in patient safety.

Program	FY01 Budget	Increase in FY01 Budget Needed to Initiate or Accelerate Program	Discussion
Deployment of the Military Computer-based Patient Record (CPR)	78.1M	+70M	CPR will provide the ambulatory clinical information needed for a computer-based patient record. Most adverse medical incidents result from errors of omission or commission. These errors can be significantly reduced only through widespread use of tools that ensure availability, completeness, and accuracy of patient records. This is the single most important objective of the military computerized patient record. It assures availability, completeness, and accuracy of medical information about each patient, provides relevant scientific medical knowledge to the clinician, includes alerts and reminders and supports clinical practice guidelines. Key to reduction of pharmaceutical errors, a large portion of medical errors, alerts and reminders will be available during patient care encounters. The CPR will provide the ability to assess clinical outcomes information and enable providers to take appropriate remedial action. Significant reduction in medical errors cannot be achieved consistently and globally without broad-based investment in the CPR. Acceleration of CPR deployment will bring the

Pharmacy Data Transaction Service (PDTS)	3.5M	0
Integrated Pharmacy System (IPS)	0	+10M
Full Pharmacy Barcoding Capability	0	+2M
Commercial Standardized Medication Error Tracking System	0	+2M
Establish a Patient Safety Center at the Armed Forces Institute of Pathology	0	+2M
Enhance Patient Safety	0	+30M

advantages of a computer-based patient record to the MHS worldwide by end FY 01 instead of end FY 02 as currently planned.

PDTS provides a single medication profile that enables clinical screening for drug interactions among dispensing systems, i.e.: retail pharmacy, National Mail Order Pharmacy, and Military Treatment Facilities, thus reducing the risk of medication errors.

The IPS will enhance functionality of PDTS and the current Composite Health Care System (CHCS) Pharmacy module, including drug-diagnosis interaction and inpatient drug screening. The IPS is a necessary component for prospective drug utilization review, and provides complete medication information to providers through the CPR therefor reducing possible death from medication errors. IPS will enable interfaces to other proven Pharmacy technology, such as robotics, to eliminate drug dispensing errors across the MHS. IPS will further reduce medication errors by standardizing drug nomenclature across the MHS.

Removes the risk of providing a patient with a prescription intended for someone else by scanning a patient's military ID card and the medication bar code at the time of delivery, thus enabling timely recording and tracking of pharmaceuticals dispensed. Fully funds all hardware needed to complete worldwide deployment of this Pharmacy functionality

Will anonymously record and standardize pharmaceutical error reporting and facilitate provider education and process changes to decrease patient risk. Will significantly enhance medication error reporting.

The Patient Safety Center will support the DoD Medical Error Reporting System and related quality improvement programs with data management and analysis, technical assistance, and dissemination of information.

MTFs will enhance their patient safety programs through participation

Programs in the Military
Treatment Facilities
Defense Blood Standard
System (DBSS)

0.9M +5.8M

in the DoD Medical Error Reporting System and quality improvement interventions to solve the problems identified using that data.

DBSS will ensure that the DoD Blood system is in compliance with Food and Drug Administration regulations, assuring minimum risk of blood transfusion reactions and administration of contaminated blood. DBSS is the key system for every DoD blood bank to manage its blood supply; tracking blood products from acquisition through transfusion; recording transfusion incidents in the CPR; evaluating usage of individual blood units and blood supplies as a whole. New functionality will link regional DBSS databases to track infectious blood products and identify ineligible blood donors. It will also create interfaces to instruments which will eliminate transcription errors. Both enhancements reduce patient risk.

Deployment of the MHS
Population Health
Operational Tracking and
Oversight (PHOTO)
Capacity

0.6M +2M

This system provides operational, workload, clinical and customer satisfaction performance outcomes in support of the MHS. Many of the performance outcomes in PHOTO are available at the provider of care level. These provider-specific metrics will assist the MHS in the identification of those providers in need of focused education, training, and counseling, with respect to application of most recent, validated scientific knowledge to their patients' problems. This will assure that providers apply the latest medical knowledge consistently to all patients treated in MHS medical treatment facilities. PHOTO will help the MHS reduce medical errors and health risks due to inappropriate variation in provider treatment patterns that can lead to excessive rates of such care as C-sections, angiography, cardiac surgery, back surgery, etc...

Defense Occupational
Health Readiness System
(DOHRS)

9M 0

DOHRS will provide the basis for exposure based medical surveillance for the Theater Medical Information Program and fixed facilities throughout the DoD. It is designed to support the prevention of work related illness and injury to military members and civilian personnel from exposure to noise, chemical, biological and physical hazards and when there is a potential for exposure. DOHRS will capture the

MHS Data Repository (MDR)	6.1M	+6M
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exposure data in a repository available to medical providers at the point of care. This includes pre-assignment and post assignment medical surveillance and monitoring of environmental exposure vital to health care of the individual and protecting active duty forces in the future from such exposures. DOHRS provides MTF Commanders, Industrial Site Commanders, Field Commanders, and Installation Agencies timely and efficient access to exposure data. It also provides necessary information for deployment planning, population studies, ad hoc reporting, workplace environmental monitoring, personnel protective equipment usage and education.

This project is necessary to measure the incidence of inappropriate treatment, to allow MHS leaders to focus corrective actions most efficiently. This effort will provide the analytic capability to identify and assess the appropriateness of variations in practice patterns across DoD. Initially the repository will be most robust in the ambulatory setting with the patient health care delivery data collected through the *military computer-based patient record*. Extension to hospitalized patients will occur with the expansion of the CPR to this area. This data repository will allow leadership to answer population health, medical surveillance, and disease outcomes questions related to approximately 8 million MHS beneficiaries. Without this system DoD will continue to lack the population information necessary to apply resources to best avoid diagnostic and therapeutic errors.

Theater Medical Information Program	14.2M	0
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Due to the unique mission of the MHS, theater medical requirements are critical issues that impact patient care. TMIP provides for tracking of critical medical information on deployed personnel before, during, and after deployment on military operations. This includes detailed information about exposures such as anthrax and other immunizations, environmental exposures, accidental and intentional, vital to health safety of the warfighter. TMIP provides field commanders with all necessary medical components of readiness information on their

Patient Movement – (US Transportation Command (TRANSCOM) Regulating and Command and Control Evacuation System (TRAC ² ES))	16M	+7.3M
--	-----	-------

fighting forces. TMIP also provides information necessary for medical planning of military operations, both for individual member health protection and casualty handling and transport.

TRAC²ES assures support for patient care in-transit and rapid arrival at the facility best equipped to handle the patient needs as those needs change, to minimize the possibility of death and complications en route. TRAC²ES provides decision support for patient in-transit care, movement and visibility, and scheduling lift-bed capability to assure patient safety, preventing the loss of patients “in the system”.

U.S. Department of Labor Fiscal Year 2001 Budget Request for the Health Benefits Education Campaign: Total Request - \$500,000.00

Last month, the President signed an Executive Order directing the Departments of Labor & HHS to develop a plan of action to help prevent adverse medical events before they occur. As part of this new plan of action to improve health care quality, the President has asked OMB, the Domestic Policy Council and federal agencies to develop health care quality initiatives for the FY 2001 budget.

Assuring quality health care to America's workers and their families has been a longstanding commitment by the Clinton Administration and by the Department of Labor. It is generally accepted that the quality of health care is an important measure of patient safety. In fact, the Health Plan Employer Data and Information Set (HEDIS) performance measures are based on this premise. Private-sector employer and union sponsored group health plans governed by the Employee Retirement Income Security Act (ERISA) provide health coverage for 127 million workers, retirees and their family members. It is critical, therefore, that employers who sponsor group health plans and, in most instances, select health care providers for their employees, understand the significance of incorporating and evaluating quality factors into their selection process.

The U.S. Department of Labor's (DoL) Pension and Welfare Benefit Administration (PWBA) issued guidance in February 1998 making it clear that it is a fiduciary responsibility under ERISA to take into account the quality of health care services in the process of selecting a plan's health care provider. DoL's PWBA is leading the Health Benefits Education Campaign, a coalition with public and private sector partners, with the aim of educating and informing consumers about their rights and responsibilities under current law. Through the Campaign, the Department will assist employers in carrying out their legal responsibilities and employees participating in employer-provided health plans and empower them when making decisions with respect to their health plan, including the consideration of the quality of the health care services provided under the plan. We have momentum with 70 partners in the Campaign and the President's directive. Now is the time to invest sufficient resources in this effort to educate workers and their families about their health benefits so that quality choices can be made.

FY 2001, the third operating year of the Campaign, is expected to be busy, especially with significant activities devoted to addressing the issue of quality. Campaign activities will include the development and distribution nationwide of several publications including materials tailored to particular populations such as women, the blind (Braille), Asian and Pacific Islander Americans, Hispanic Americans and African Americans; the creation and dissemination of educational and promotional videos in conjunction with these written materials to reach populations that cannot read or have difficulty learning visually; continued expansion and updating of the Department's interactive Web site; integration of PWBA's regional offices including addressing the needs of each region; and marketing and promotion including radio and television public service announcements and news columns.

Foster, Nancy

From: Smith, Kermit C. [KSmith@HQE.IHS.GOV]
Sent: Thursday, December 30, 1999 12:08 PM
To: Foster, Nancy
Subject: Budget info on Error Reduction and Patient Safety



Error recuction, Patient

safet... Hi Nancy, Happy New Year! I am attaching and including the document in this e-mail. Hope you had a great holiday.

INDIAN HEATLH SERVICE Budget Information on Error Reduction and Patient Safety

The Indian Health Services' FY2001 budget does not include a specific budget category that is related to error reduction or improvement of patient safety, however systems are in place throughout the Indian Health Service to address error reduction and to monitor and improve patient safety. An estimate of the amount spent on these activities is:

For All IHS:

Payment to JCAHO for Surveys	\$2.4 Million
Facility Maintenance and Improvement Costs	\$3 Million
QI and Risk Management Costs	\$8 Million
Safety Officers at each site	\$2.5

Million

Headquarters QA/QI

\$350,000

We will also attempt to identify funds in the FY2001 budget for technology to automate manual tasks related to prescription writing and dispensing. This technology exists as provider point-of-care medication management and distribution. There are also robotic prescription dispensing systems. Both of these automate manual tasks while reducing costs and dispensing errors. We plan to test this technology at several sites in Montana and New Mexico in FY2000. Pending results at these test locations, the Agency may spend an additional to \$9.45 Million in FY2000 to implement this technology.

<<Error recuction, Patient safety.doc>>

Kermit C. Smith, D.O., M.P.H.
Chief Medical Officer
Indian Health Service
(301) 443-1083
FAX: (301) 443-4794

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

January 3, 2000

TO: Operating Chair, QuIC Steering Council

FROM: Administrator

SUBJECT: Budget Information on Error Reduction and Patient Safety

In response to your request of December 27, 1999, HRSA has reviewed its Fiscal Year 2001 Budget submission and related materials for potential policy initiatives which might address the President's directive. In addition we have asked our major programs to report any "meaningful health care quality and patient initiatives" which might be forwarded to address medical error reduction and improve patient safety through FY 01 budget proposals.

Attached are the brief descriptions of these initiatives which you requested. We will provide more specific narratives to supplement these brief responses as soon as you or the staff of the White House Domestic Policy Council request them.

Please contact me as soon as you determine what additional information you might need. In addition, my other point of contact is:

William A. Robinson, M.D., M.P.H.
Director, Center for Quality
Telephone: 301-443-0458, - 0459
Fax: 301-443-9795
e-mail: brobinson@hrsa.gov

Finally, this information will also be available through the HRSA Budget Office (Division of Financial Management), through Kirk Donovan or Bob Heil at Telephone Number 301-443-6826.

A handwritten signature in cursive script, likely of Claude Earl Fox, is written in black ink.

Claude Earl Fox, M.D., M.P.H.

Attachment

cc: Dr. Robinson
HRSA Executive Council
Mr. Donovan/Mr. Heil

Health Resources and Services Administration

Proposed Activities to Promote Medical Error Reduction and Improve Patient Safety - FY 2001

HIV/AIDS

In current budget proposal for FY 2001:

Collaboration with Institute for Healthcare Improvement (IHI) for Ryan White CARE Act funded clinical sites and clinical leaders in HIV/AIDS treatment, to identify and address improvement of systematic functions and delivery of services to improve the quality of medical care at clinic sites.

Est. Cost \$450,000

New proposed initiative:

Establish new medical error reduction program to be conducted through the network of AIDS Education and Training Centers (AETC) programs. The AETC's play a critical role in the continuing education of medical providers (physicians, nurses, pharmacists, et al) in HIV care. Since HIV treatment is especially prone to medical errors because of increasing complexity of therapy, multiple drug interactions, and the numerous drugs necessary to treat the disease, this computer-oriented program should significantly promote error reduction.

Est. Cost \$10 M

Health Resources and Services Administration

Proposed Activities to Promote Medical Error Reduction and Improve Patient Safety - FY 2001

PRIMARY CARE

In current budget proposal for FY 2001

Continue collaboration with Institute for Healthcare Improvement (IHI), Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), et al. to build in safe designs and promote effective team functioning, while enhancing the quality of health care in community and migrant health centers and other clinical sites.

Est. Cost \$2.8 M

New proposed initiative:

To establish a patient safety task force within the Bureau of Primary Health Care that addresses the President's Initiative in the context of the Institute of Medicine (IOM) Domains of Quality. Efforts will focus on primary care centers by providing leadership in monitoring patient safety; re-designing systems (e.g. medication management) to improve safety; enhancing team functioning; establishing new treatment standards; and creating a learning environment for providers which encourages sentinel event reporting, risk management, medication safety, and patient involvement.

Est. Cost \$5.2 M

Health Resources and Services Administration

Proposed Activities to Promote Medical Error Reduction And Improve Patient Safety – FY 2001

Health Professions

New Initiatives

Health Professions Education and Training – Health professions schools have an obligation to train future health care practitioners to limit the number of medical errors from occurring. Current health professions training curricula do not foster a “team” (interdisciplinary) approach. The Federal Government must play a key role in the protection of the public by providing incentives, via demonstration grants, to augment interdisciplinary curricula and provide for faculty development at Schools of Medicine, Dentistry, Nursing, Public Health, Allied Health and Pharmacy. **\$5M**

Research, Surveillance and Education – The Division of Quality Assurance’s National Practitioner Data Bank and Healthcare Integrity and Protection Data Bank are poised to research the percentage of malpractice suits which are related to medical errors. From the information gathered, DQA can promote enhanced quality assurance programs to assist the current health workforce in its continuing medical education activities related to medical error reduction and protection of the public. **\$1.5M**

The Division of Vaccine Injury Compensation – An expanded role for this Division that oversees compensation of injuries related to immunizations is to monitor those errors attributable to vaccines and immunizations. **\$250,000**

The Division of Public Health and Allied Health – Grant programs in public health and particularly in preventive medicine identify and analyze health related problems in communities, including health care delivery systems. Demonstration grants to Preventive Medicine Residency Programs, Schools of Public Health, Schools of Medicine, Schools of Pharmacy and Schools of Allied Health to survey why medical errors occur and determine steps to prevent such problems from occurring. Such programs are directly linked to interdisciplinary training. **\$2.5M**

Division of Interdisciplinary and Community-Based Programs – Demonstration dollars will expand the education and training capacity of Area Health Education Centers (AHECs), Health Education Training Centers (HETCs), Geriatric Education Centers (GECs), and Rural Interdisciplinary Training Centers (RITCs). Interdisciplinary education and training programs will be developed to enhance the competency and skills in minimizing medical errors in the existing health care workforce. **\$10M**

Estimated Cost: \$19.250M

Health Resources and Services Administration

Proposed Activities to Promote Medical Error Reduction and Improve Patient Safety - FY 2001

Maternal and Child Health

New proposed initiative for 2001:

Issues of patient safety and avoidance of medical errors are key to the health of children as well as adults. The Emergency Medical Services Program of HRSA's Maternal and Child Health Bureau is proposing to undertake an initiative to demonstrate the effectiveness of a color-coded system, the Broselow-Luten RainbowCare System (BLRS) as a reference tool in pediatric resuscitation events. All drugs and equipment needed in an emergency are based on patient weight, which is often unobtainable in an emergency situation. This color-coded system allows access to accurate precalculated medication doses and equipment sizes and other emergency size-related treatments such as resuscitation fluids for shock. To date, no program has examined the effectiveness of the color-coded system in the clinical setting for which it was created, pediatric acute/emergent care. The quality enhancement objectives of this initiative are in accordance with the IOM recommendations and the presidential mandate.

Est. Cost \$1.0 M

New Proposed initiative for 2001:

Failure to differentiate between the needs of adult and pediatric emergency patients has been documented to be linked to poorer medical outcomes for pediatric patients. This is because the needs of children in emergency situations differ from those of adults and require special attention. The Emergency Medical Services for Children program will develop a set of clinical practice guidelines applicable to all medical personnel with independent responsibility for treating children's emergency conditions (e.g., pediatricians, family practitioners, nurse practitioners, physicians working in the emergency department, physician associates). The guidelines will be oriented to the needs of the practitioner who necessarily doesn't have easy access to pediatric emergency specialty services, but who is nevertheless likely to encounter a child with a serious emergency health condition. (The purpose of the guidelines will be to improve care for common problems that present in emergency departments and doctors' offices) The guidelines will be based upon a rigorous assessment of published research, combining data where appropriate to permit the accumulation of valid summary statistics.

Est. Cost \$1.0 M

Health Resources and Services Administration

Proposed Activities to Promote Medical Error Reduction and Improve Patient Safety - FY 2001

RURAL HEALTH

In current budget proposal for FY 2001

Under the Rural Hospital Flex Grant Program, the HRSA Office of Rural Health Policy is planning to develop program requirements to have state grantees promote error reduction and patient safety in their designation process for critical access hospitals.

Est. Cost \$1.0 M

Under the Rural Network Development Grants Program, some grantees are expected to address error reduction and patient safety issues through the development of quality performance standards. Results and products of these efforts will then be shared among all grantees.

Est. Cost \$1.0 M

New proposed initiative:

Establish new Rural Clinicians' Care Councils as an incremental expansion to the Office of Rural Health Policy's Outreach and Network Development Program. The proposed program would provide grants to develop and evaluate the effectiveness of ten local organizations of rural clinicians, rural hospitals and health care agencies called "Rural Clinicians' Care Councils", (RCCCs). These Councils will coordinate the care of patients with complex medical problems, expedite referrals of these patients among the multiple agencies involved in their care; and detect, avert, analyze and prevent recurrence of prescribing errors and other patient management errors. As the Councils develop, their clinician membership and patient enrollment will expand to include other health providers and patients of their local communities. Their first priority will be to manage the care of local patients to raise quality and prevent iatrogenic injury and death. As they become secure in their ability to manage care to increase quality, the Councils will be able to contract with Managed Care Organizations (MCOs) to manage the local care of their subscribers.

Est. Cost \$5.0 M

Health Resources and Services Administration

Proposed Activities to Promote Medical Error Reduction and Improve Patient Safety - FY 2001

Center for Quality/Office of the Administrator

New proposed initiative for FY 2001:

Using Program Management resources, the HRSA Center for Quality would conduct an expanded error reduction and patient safety program, including coordination of such activities across all Bureaus and Offices. Activities would include carrying out studies of patient safety; expanded support staff to provide an infrastructure for quality research (in collaboration with the Agency for Health care Research and Quality, et al); supporting intramural and extramural technical assistance in health services error reduction and patient safety for HRSA programs and their clients. The program would fund a campaign to promote patient safety throughout the health professions community, building on the related efforts of HRSA's Bureaus/Offices, AHRQ, and other members of the Quality Interagency Coordination (QuIC) Task Force.

Est. Cost \$3 M



UNITED STATES
OFFICE OF PERSONNEL MANAGEMENT
WASHINGTON, DC 20415-0001

OFFICE OF THE DIRECTOR

JAN 3 2000

Honorable Jacob J. Lew
Director
Office of Management and Budget
Washington, DC 20503

Dear Mr. Lew *Jack*

On December 7, 1999, the President directed the Office of Management and Budget, the Domestic Policy Council, and other agencies "to develop additional health care quality and patient safety initiatives for the 2001 budget." His directive was spurred by a report of the Institute of Medicine that underscored the frequency of preventable medical errors. The statistics contained in that report indicate that more than 1,800 lives are lost each year in the Federal Employees Health Benefits (FEHB) Program alone due to avoidable medical errors.

The President and the Quality Interagency Coordination (QuIC) Task Force are looking to Office of Personnel Management (OPM), among others, for leadership in forging effective public/private sector strategies to reduce medical errors. I believe this expectation flows from our success in working collaboratively with over 300 commercial health benefits carriers to implement the Patients' Bill of Rights at virtually no cost. As you know, our purchasing power in the healthcare marketplace gives us a unique advantage to serve as a model, with a multiplier effect unlike any other employer-sponsored health insurance program.

Rather than wait until 2001, the potential that we have to make a significant contribution to the President's call this year leads me to request supplemental spending authority from the Federal Employees Health Benefits Trust Fund for 2000, and a similar increment for 2001. The \$1.5 million in additional authority I request would begin to make our Center for Benefits Design and Delivery a strong force for undertaking the initiatives that will be addressed in the QuIC's forthcoming report to the President. I have enclosed a short paper that describes some of the activities that we contemplate. Not funding this initiative, or delaying funding, may needlessly put the lives of 1800 FEHB participants in certain peril. I look forward to your support and to the day when no lives are lost due to avoidable medical errors.

Sincerely,

Janice R. Lachance
Director

Enclosure

FORM CQM/AHCPR

NO. 9502 P. 3 12/003

REDUCING MEDICAL ERRORS

OPM'S CENTER FOR BENEFITS DESIGN AND DELIVERY

The President asked the Office of Personnel Management to play a key role in reducing medical errors and improving patient safety through public private partnerships. He expects OPM will demonstrate the same type of leadership that we displayed in implementing the Patients' Bill of Rights, and advancing long-term care and mental health parity. OPM has established solid relationships with over 300 commercial health insurance carriers, and virtually all of the influential entities in the healthcare arena - the National Quality Forum, AAHP, FACCT, NCQA, JCAHO, QuIC, and others. From an employer and purchaser standpoint, OPM is uniquely positioned to make a significant contribution in response to the President's call.

However, our ability to respond to the President in any meaningful way is severely hampered so long as OPM's Center for Benefits Design and Delivery remains underfunded. Without a minimum of \$1.5 million in additional funding, we will not conduct the research, outreach, and oversight activities necessary to move the FEHB Program toward the objectives outlined in the Institute of Medicine's (IOM) Report - "To Err Is Human - Building a Safer Health System."

With supplemental funding of \$1.5 million, which would include funding for 10 additional FTE in FY 2000, we will initiate a program to reduce medical errors that will encompass:

- Collecting and analyzing HEDIS measures that bear upon medical error rates as a basis for requesting and monitoring carrier initiatives to reduce medical errors and improve the quality of care.

- Monitoring pharmacy benefit managers that serve the FEHB program to assure effective drug interaction programs are in place, and electronic prescription systems are developed and expanded.

- Collaborating with credentialing and accreditation bodies and others to develop, put in place, and oversee performance and quality standards for participation in the FEHB Program.

The forthcoming report from the Quality Interagency Coordination (QuIC) Task Force to the President will be asking member agencies to take immediate actions to reduce medical errors and improve the quality of care. OPM is a key QuIC member and must be funded to respond to its, and the President's, call. The statistics contained in the IOM report indicate that 1,800 lives are lost each year within the Federal Employees Health Benefits Program due to avoidable medical errors. Not funding this initiative, or delaying funding, may needlessly put lives of FEHB participants in certain peril.

Office of Personnel Management Initiatives to Reduce Medical Errors And Improve Patient Safety

The Office of Personnel Management will use its existing purchasing authority in 2001 and beyond to initiate actions to reduce medical errors and improve patient safety as outlined in the Institute of Medicine's Report. By doing so, we perform a leadership role in this vital area and serve as a model for other healthcare purchasers. In communicating its expectations to health plans for 2001, the Office of Personnel Management will:

Advance the Use of Automated Drug Order Entry Systems by adopting and advocating standards and positions taken by National Committee for Quality Assurance, the Business Roundtable Leapfrog Group, the National Quality Forum, the Quality Interagency Coordination Task Force, and others. There is broad consensus that these systems can make significant reductions in errors in a short time.

Embrace Specific Patient Safety Standards by first supporting the efforts of accreditation bodies to adopt such standards, and then requiring all participating health plans to seek accreditation in 2001 for the 2002 contract year.

Improve Major Medical Outcomes by strengthening incentives for patients to receive complex treatments in centers of excellence with proven track records.

Heighten Consumer Awareness and Action by featuring the role that consumers can play in reducing medical errors and improving patient safety as part of the open enrollment publicity and publications that will be deployed in the fall. We will collaborate with the Quality Interagency Coordination Task Force and other public and private employers to assure that messages about the consumer's role are consistent and cohesive.

The Federal Employees Health Benefits Program covers 9 million participants and encompasses almost 300 health plans. These same plans provide health benefits to almost one-half of all Americans. Because of that, these patient safety initiatives to improve plan and provider practices within the Program will benefit the nation at large.

FAX TRANSMITTAL SHEET

U. S. OFFICE OF PERSONNEL MANAGEMENT
RETIREMENT AND INSURANCE SERVICE
1900 E STREET, N.W., ROOM 4A10
WASHINGTON, D.C. 20415

Telephone (202) 606-0600

Number of Pages 3
(Including Cover Sheet)

TO: Devorah Adler

DATE: _____

Telephone Number _____

Fax Number _____

FROM: Ed Flynn

DATE: _____

Telephone Number _____

Fax Number _____

COMMENTS: _____

Note for Devorah Adler:

Devorah, here is a brief description of the Patient Safety/Medical Error initiatives for the FEHB, as we discussed at our meeting earlier today.

As I indicated to Chris, there are no administrative dollars associated with these initiatives in the FY 2001 Budget.

Give me a call if you have any questions or want to talk.

Thanks.



Ed Flynn
January 21, 2000

Attachment

Office of Personnel Management Initiatives to Reduce Medical Errors And Improve Patient Safety

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