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001. draft	re: Outline of the QulC Report to the President on Medical Errors (partial) (1 page)	12/14/199	P6/b(6)
002. article	re: phone numbers (partial) (3 pages)	12/19/1999	P6/b(6)
003. press release	re: phone number (partial) (1 page)	01/20/1995	P6/b(6)

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Errors [Folder 3]

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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]

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- 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]

**Agency for Health Care Policy and Research
Liaison Office for Quality**

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FAX 

Date: Dec. 1, 1999

Number of pages including cover sheet:

To: Deborah Adler

Fax: 202-456-5557

Phone:

From: Nancy Foster

Comments: E-mail is not working. Sorry!
Here is the information on the
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via Fax or someone else's e-mail.
-Nancy

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 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:

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- 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.

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 QulC 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.

QulC Efforts to Help Inform Americans About Health Care

The QulC 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 QulC has aided the Federal Trade Commission in augmenting its Consumer.gov web site to include information on health care quality. Through this gateway, the QulC 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 QulC 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 QulC 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.

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DRAFT: December 7, 1999

MEMORANDUM FOR THE QUALITY INTERAGENCY TASK FORCE

SUBJECT: IMPROVING HEALTH CARE QUALITY AND ENSURING PATIENT SAFETY

Assuring quality through patient protections is a longstanding priority for this Administration. Over the past two years, with the leadership of the Vice President, Secretary Shalala and Secretary Herman, this Administration has 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. Equally as important as assuring high quality health care services, however, is improving the quality of the services.

Inappropriate utilization of services, unnecessary variations in the delivery of health care services, and preventable medical errors are responsible for thousands of deaths, unnecessary illnesses, and instances of prolonged disability annually. Early detection and appropriate treatment for illnesses such as diabetes, breast and cervical cancer, and heart attacks reduce mortality by over 40 percent in some cases. Millions of Americans receive health care services, such as unnecessary prescription of antibiotics or performing of hysterectomies, that are unnecessary, increase costs, and often endanger their health. There is a continuing pattern of wide variation in health care practice, including regional variations and small area variations, clearly indicating that the practice of health care has not caught up with the science of health care, to ensure evidence-based practice in the United States.

Preventable medical errors present an extraordinary example of the importance of efforts to ensure the delivery of high quality health care services. Over half of the adverse medical events occurring each year are due to preventable medical errors, placing tens of thousands of Americans at unnecessary risk. More people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. Recent study by the Institute of Medicine estimates that the cost associated with these unnecessary errors in lost income, disability, and health care costs is as much as \$29 billion annually. The financial impact of these errors is compounded by the cost of patients' loss of trust in the health care system, the physical and psychological discomfort associated with longer hospital stays or permanent disability, reduced school attendance, and lower levels of population health status.

Last year, in order to begin to address these issues, I established the Quality Interagency Coordination Task Force, which is responsible for the dissemination of information on evidence based medical research, and has been instrumental in developing disease management protocols that have been adopted nationwide. In addition, the Vice President launched a public-private body known as the Quality Forum to coordinate our quality improvement efforts with the private sector to provide consumers with a consistent set of standards in order to base their health care choices on quality—not cost. Although they have only been in operation for two years, these entities are well on their way to making contributions to improving the delivery of high quality health care, but it is clear that more must be done.

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Even though computerizing and streamlining health care processes can improve health care quality, eliminate dangerous medical errors, lower costs by improving communications between doctors, eliminating redundant tests and procedures, and building automatic safeguards against harmful drug interactions and other adverse side effects into the treatment process, very few hospitals, health care systems, and employers use these new techniques. ~~It is clear that we must take a comprehensive approach to improve patient safety.~~

Therefore, I hereby direct the Quality Interagency Coordination Task Force, to report to me a set of recommendations on specific actions to improve health care outcomes and prevent medical errors in both the public and private sectors in a manner that does not unnecessarily and ~~not~~ ^{in any way} ~~unlawfully~~ infringe upon patient privacy. This report shall ~~be submitted to me~~ ^{be submitted to me}

- Identify prevalent medical errors that can be prevented through the use of decision support systems, such as patient monitoring and reminder systems;
- ^{Propose steps to eliminate barriers preventing adoption of effective information technology systems in different health care settings in both the public and private sectors;}
- ^{Propose a strategy to reduce medical errors in Federal health care programs that will reduce medical errors nationwide}
- ^{Detail specific actions that the Federal government can take with the private sector to reduce medical errors nationwide, including the}
- ^{Provide a plan for continued, coordinated, collaboration on health care quality issues with the QIIC and the Quality Forum; and}
- Evaluate the feasibility and advisability of the recommendations of the Institute of Medicine's Quality of Health Care in America Committee on patient safety, including the:
 - Creation of a Center for Patient Safety within the Agency for Healthcare Research and Quality;
 - Establishment of a nationwide mandatory reporting system on adverse events that result in death or serious harm to patients;
 - Encouragement of the development of voluntary reporting systems on medical errors;
 - Extension of peer review protections to data related to patient safety;
 - Inclusion of patient safety components in performance standards for health care organizations and health care professionals;
 - Requirement for the Food and Drug Administration to consider patient safety in pre and post-marketing processes for pharmaceuticals; and
 - Encouragement of private health care organizations to establish patient safety programs with defined executive responsibility and to implement proven medication safety practices.

I direct the Department of Health and Human Services to serve as the coordinating agency to assist in the development and integration of recommendations and to report back to me in 60 days. The recommended actions should lay the foundation for a national system that prevents adverse medical events before they occur.

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S. 580, The Healthcare Research and Quality Act of 1999
(Senator Frist's substitute for the original text of S.580)

**SUMMARY OF LEGISLATION TO REAUTHORIZE THE
AGENCY FOR HEALTH CARE POLICY AND RESEARCH**

SECTION-BY-SECTION ANALYSIS

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S. 580 deletes the existing text of Title IX of the Public Health Service Act, which authorized the Agency for Health Care Policy and Research, and provides a complete substitute for that title. This document summarizes the changes that will be made by S. 580 to the current statute if enacted.

PART A - ESTABLISHMENT AND GENERAL DUTIES

Part A of the current statute contains five sections (901-905). This bill retains, with modifications, Sections 901 and 902. Existing Section 903 (Dissemination) moved to Part C and is renumbered Section 924. Existing sections 904 (Technology Assessment) and 905 (Centers for Education and Research on Therapeutics) moved to Part B. Sec. 904 became sec 916, Health Care Practice and Technology Innovation; sec.905 became sec. 912(b)

Sec. 901 Mission and Duties

This section changes the name to the Agency for Healthcare Research and Quality (AHRQ, pronounced "arc") and renames the head of the Agency "director" instead of "administrator." The Mission statement retains much of the current text but adds language regarding the Agency's responsibility to promote health care quality through (1) research, (2) synthesizing and disseminating available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policymakers, and educators; and (3) advancing private and public efforts to improve health care quality. The bill also expands the priority populations listed in the existing statute to include women, children, and people with special health care needs (the term includes disabilities, chronic care, and end-of-life health care) and adds inner-city as another priority. The Director is required to ensure that the priority populations and geographic areas are addressed throughout the Agency's research portfolio and is required to establish an Office of Priority Populations to assist in carrying out this requirement.

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Sec. 902 General Authorities

This section outlines the mechanisms that the Agency can use and provides examples of the types of research authorized under this title. The changes are minimal but the bill adds to the statute such terms as the appropriateness and

value of health care services, quality measurement and improvement, cost-effectiveness, access, database development, technical assistance, and multidisciplinary centers. Other subsections [relationship with Medicare and Medicaid (subsection c), and multidisciplinary centers (subsection d)] are retained with minor editing from current law. Two changes are made in training, subsection (b): (1) to support training, the statute now cross-references the Agency's existing authority to use funds authorized by Sec 487 of, the PHS Act (which provides the Agency with 1% of National Research Service Award, NRSA, funds) as well as appropriated funds; and (2) in allocating training funds, the Director is required to take into consideration shortages in the number of trained researchers whose work addresses the priority populations [listed in Sec. 901(c)] and indications of long-term commitment by applicants to address the health care needs of these populations..

The bill adds a new Disclaimer (e), a Rule of Construction (f), and a required Annual Report (g) to the statute. Subsection (e) prohibits the Agency from mandating "national standards of clinical practice or quality health care standards." Subsection (f) states that nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. These two sections are intended to reinforce the point that the Agency has no regulatory authority; its role is to build the science of quality measurement and improvement. Subsection (f) requires an annual report, beginning in FY 2003, on prevailing disparities in health care, focusing on racial and socioeconomic factors as they relate to the priority populations in sec. 901(c).

PART B – HEALTH CARE IMPROVEMENT RESEARCH

The bill deletes existing Part B (entitled Forum for Quality and Effectiveness in Health Care) and the existing four sections (911-914); these sections had mandated Agency support for the development of clinical practice guidelines, establishment of an Office of the Forum to manage the guideline development process, and specified the duties of the Forum. The bill establishes a new Part B (entitled Health Care Improvement Research) with the seven sections (sections 911-917) outlined below.

Sec. 911 Health Care Outcome Improvement Research

Subsection (a) requires the Agency to identify and disseminate methods or systems for rating the scientific strength of research studies. The Agency is expected to put on its web site the methods and systems for rating evidence that are used by the Agency and its contractors as well as alternative approaches.

Subsection (b) is intended to ensure that promising research findings are translated more rapidly into improvements in daily practice by promoting the

use of health care improvement research centers, multidisciplinary research centers linked with relevant sites of care, provider-based research networks, and similar innovative mechanisms. The language also stresses the need for geographic diversity.

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Sec. 912 Private-Public Partnerships to Improve Organization and Delivery

Subsection (a) outlines six roles for the Agency, including (1) identification and assessment of methods for the evaluation of health of enrollees in health plans, (2) development and testing of quality measures, including measures of health and functional outcomes, (3) compilation and dissemination of measures (a reference to the Agency's existing CONQUEST database), (4) assistance in the development of information systems, (5) development of survey tools (a reference to the Agency's existing CAHPS project), and (6) research on the ways that purchasers and consumers use quality information in making decisions.

Subsection (b), the Centers for Education and Research on Therapeutics (CERTs), is a restatement of existing law with minor modifications. This section was added to the Agency's statute by the FDA Reform Bill. This bill makes 7 changes to the CERTs language: (1) deletes the words "demonstration program"; (2) broadens the type of research that CERTs can undertake by referring only to "state-of-the-art research" (the prior statute had limited research to clinical and laboratory); (3) adds the word "patients" and "pharmacists" in the list of target audiences; (4) adds cost-effectiveness to the list of authorized research; (5) eliminates two paragraphs that were redundant of the Agency's general grant authority; (6) adds the words "biologic products and devices" for consistency in the section prohibiting use of CERTs funds to pay for FDA reviews; and (7) the separate authorization for CERTs is deleted. CERTs will be funded through the Agency's main authorization in sec. 927(b).

Subsection (c) directs the Agency to conduct and support research and build partnerships to support research on reducing errors in medicine.

Sec. 913 Information on Quality and Cost of Care.

This section directs the Agency to support a nationally representative survey (a reference to the Agency's Medical Expenditure Panel Survey, MEPS) and expand its sample size, beginning in FY 2001, so that MEPS can provide information on the quality of patient care and outcomes for frequently occurring conditions beginning in FY 2003. The Agency is required to develop information on children and persons with special health care needs through over-sampling or periodic updates. The section also requires the development of databases and tools to provide information to states (a reference to the existing HCUP state database). Beginning in FY 2003, the Secretary, acting through the Director, is to submit an annual report on national trends in quality, drawing upon the MEPS survey (enhanced in FY 2001) and other

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available data. The Committee expects the Agency to use a variety of measures to develop this annual picture of how quality is faring. The compromise retains a Senate amendment that requires the Agency's MEPS survey and its quality report to reflect "rural residents."

Sec. 914 Information Systems for Health Care Improvement

Subsection (a) directs the Agency to conduct and support research to evaluate and support initiatives to advance: (1) the use of information systems for the study of health care quality; (2) training for researchers and practitioners in the use of information systems; (3) creation of effective linkages between various sources of health care information, including development of information networks; (4) support the development of information networks and real-time decision support systems; (5) in consultation with other Federal entities, the structure; content, definition, and coding of information; (6) evaluation of computer-based records as a personal health record and for monitoring public health and outcomes of care within populations; and (7) the protection of individually identifiable information in health services research and quality improvement. Subsection (b) requires the Agency to support demonstrations on the use of new information tools to improve shared decisionmaking between patients and care-givers.

Sec. 915 Research Supporting Primary Care Delivery and Access in Underserved Areas.

This section reflects current activities of the Agency. It requires the Agency to support the work of the U.S. Preventive Services Task Force (which was transferred to the Agency by the Office of the Secretary several years ago), requires the Agency to maintain a Center for Primary Care Research (which now exists), and outlines several areas of primary care research (which the Agency currently supports).

Sec. 916 Health Care Practice and Technology Innovation

This section is a streamlined version of the existing technology assessment provision in the current statute (sec. 904), and changes the title to Health Care Practice and Technology Innovation. The bill adds a requirement that the Agency work with the NLM and the public and private sector to support an electronic clearinghouse for assessments, deletes the current law requirement that the Director make coverage recommendations to the Secretary (recognizing that HCFA, not AHRQ, makes coverage determinations), requires the Director to publish a description of methods of assessment no later than December 31, 2000, modifies slightly the existing statutory list of considerations when conducting technology assessments, adds the Assistant Secretary of Health and HCFA Administrator to the list of required consultations, and clarifies that Historically Black Colleges and Universities and Hispanic Institutions are eligible for grants. The statute explicitly recognizes the authority of the Director to undertake assessments on a reimbursable basis. New subsection (d) requires the Director to develop a report on evidence-based clinical practices

for the medical examination of sexual assault victims.

Sec. 917 Coordination of Federal Government Quality Improvement Efforts

This section has two major provisions. The first, directs the Secretary, acting through the Director, to coordinate all research, evaluations, and demonstrations related to health services research and quality measurement and improvement supported by the Federal Government. The Director is to develop and manage a process to improve interagency coordination, strengthen the research infrastructure, set specific goals for furthering health services research and quality improvement and strengthen the management of QI programs. The second provision requires the Secretary to contract with the IOM to develop two reports on the organization and coordination of the quality improvement, research, and oversight activities of the Federal Government, with particular attention to DHHS activities under titles XVIII, XIX, and XXI of the Social Security Act, and recommendations on how to improve the efficiency and effectiveness of QI activities.

quality improvement
Institutionalizing the QVIC

PART C – GENERAL PROVISIONS

Part C governs the day-to-day operations of the Agency; most of Part C remains unchanged from prior law. The bill adds one new section to Part C by moving the dissemination section (sec. 903 of Part A in prior law) to Part C, designating it as new section 924.

Sec. 921 Advisory Council on Healthcare Research and Quality

This section (much of which repeats current law) authorizes the Agency's existing national advisory council. The bill modifies the name of the Council to reflect the new name of the Agency, increases the number of members (from 17 to 21), changes the categories from which Council members must be chosen, and restates the Council's mission to reflect the new roles of the Agency outlined in this bill. The old role of the Council included references to providing advice on guidelines, technology assessments, and technical aspects of outcomes research. The new mission directs the Council to more broadly focus on overall priorities for health care research (quality, outcomes, cost, use, and access to care), the field of health services research (especially training and dissemination), and identification of opportunities for public-private sector partnerships, and the appropriate roles the Agency can play in specific areas, taking into account the level of private sector activity. A technical change permits appointment of up to 4 experts who have part-time or full-time clinical appointments at Federal health care facilities and requires that at least one member of the Council reflect rural interests. There were three additions to the statutory list of ex officio: the Assistant Secretary for Health, the Commissioner

of the FDA (who already is represented on the Council, and the Director of OPM.

Sec. 922 Peer Review With Respect to Grants and Contracts.

This section provides the Agency with the authority to establish peer review study sections and establishes guidelines for their operation. The bill restates current law with 3 exceptions. First, it adds a new Qualifications subsection (c)(4), requiring study section members to sign confidentiality and conflict-of-interest statements and requiring their recusal from review if there is even an appearance of conflict. This addition strengthens current practice. Second, the requirements in (d)(1) of existing statute for a dissemination study section were deleted. There is sufficient authority at the beginning of this subsection to establish any necessary study sections. Third, the bill increases the limit on small grants from \$50,000 to \$100,000 to reflect inflation.

Sec. 923 Certain Provisions with Respect to Development, Collection, and Dissemination of Data.

Current law requires the Agency to establish guidelines for methods of developing and collecting data that will assure its utility, accuracy, and sufficiency. When these guidelines have any impact on the Medicare or Medicaid programs, they are to be sent to the Secretary as a recommendation. S.580 clarifies and limits the scope of the Director's authority but these changes actually reflect existing practice. The Director is required to consider other Federal health data collection standards and the differences between types of plans, delivery systems, providers, and provider arrangements in developing standard methods for data being collected by or for the Agency.

In current law, there is also a provision, originally drawn from the NCHS statute, that "upon request of a public or nonprofit private entity, the Administrator may tabulate and analyze statistics..." under arrangements where these entities pay the cost. The bill broadens the existing statute to include requests from private entities as well as public and non-profit entities and substitutes the words "research or analyses" otherwise authorized by this title for "tabulating statistics," recognizing that statistical tabulation is a very small portion of the Agency's work.

Sec. 924 Dissemination of Information

In current law, this is section 903 of the statute and strongly emphasizes the Agency's dissemination role, prohibits the Director from restricting publication of Agency work, mandates the Agency's User Liaison Program for state and local officials, and includes the Agency's confidentiality safeguards. This bill adds a penalty clause for violations of the confidentiality provisions, changes the reference in the confidentiality clause from the Secretary issuing regulations to the Director, and provides the Agency with increased flexibility for meeting the statutory mandate to promptly publish all findings. The bill also deletes two requirements in current law [903(d) and (e)] for interagency

agreements with NLM.

Sec. 925 Additional Provisions with Respect to Grants and Contracts.

This section is a restatement of existing law, which outlines miscellaneous provisions related to grants and contracts.

Sec. 926 Certain Administrative Authorities.

This section is a restatement of current law related to personnel (Deputy, employees, consultants, experts) and facilities. Under current law, the Agency can only award grants to and enter into cooperative agreements with public and non-profit entities and individuals while contracts can be awarded to public and private entities and individuals. The one change in this section authorizes the Agency to enter into cooperative agreements with private entities as well.

Sec. 927 Funding

This section revises the existing authorization of appropriations section to add an "intent" clause expressing the intent of Congress to provide a proportionate increase in health care research as funding for biomedical research increases and establishes a funding level of \$250 million for FY 2000 and "such sums as necessary" for FY 2001-FY 2005, a 6 year reauthorization. The section retains the language in current law for the Agency to draw upon 1% evaluation funds. Three currently unused authorizations are deleted: (1) funding for an information center; (2) funding for technology assessments; and (3) funding for innovative assessments. [A separate authorization for CERTs was also deleted but that deletion was noted in commentary on sec 912(b) above.]

Sec. 928 Definitions

This section defines 3 terms in the bill: Advisory Council, Agency, and Director.

The bill also includes language (that will not appear in Title IX of the Public Health Service Act) stating that existing references in statute to AHCPR will be deemed to be references to the agency's new name, deems existing references to the Administrator to be references to the Director, and provides that the name change will not inadvertently affect existing personnel appointments or existing appointments to the Advisory Council or study sections.

Revised: November 4, 1999.



AHCPR

ERRORS ; near misses / prevention processes

8 months qual / 18 months data

CERTS ; pharmaceutical placements & plugging

904

UTIL

VARIATION

direction OMB BPE
budget race for

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widon B
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Model tried in private sector
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**DRAFT: PRESIDENT CLINTON TAKES STRONG NEW STEPS TO IMPROVE
HEALTH CARE QUALITY AND ENSURE PATIENT SAFETY**

December 7, 1999

Today, President Clinton will sign an executive memorandum directing the Federal Quality Interagency Coordination Task Force report back to him in 60 days with an action plan to improve health care quality and ensure patient safety through the prevention of medical errors. The President also directed the Office of Management and Budget to invest in health care quality and patient safety initiatives when developing the FY 2001 budget; directed the Health Care Financing Administration to integrate patient safety initiatives into the Medicare, Medicaid, and CHIP programs; and announced a new, multi-million dollar investment in research programs to improve health care quality. The new actions being taken by the President today build upon the Clinton-Gore Administration's longstanding commitment to improving health care quality.

INCONSISTENCIES AND AVOIDABLE ERRORS IN MEDICAL PRACTICE COST LIVES AND UNDERMINE HEALTH. Inappropriate utilization of services, unnecessary variations in the delivery of health care services, and preventable medical errors are responsible for thousands of deaths, unnecessary illnesses, and instances of prolonged disability annually.

- **Preventable medical errors.** Over half of the adverse medical events occurring each year are due to preventable medical errors, placing tens of thousands of Americans at unnecessary risk. More people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. A recent study by the Institute of Medicine estimates that the cost associated with these unnecessary errors in lost income, disability, and health care costs is as much as \$29 billion annually. The financial impact of these errors is compounded by the cost of patients' loss of trust in the health care system, the physical and psychological discomfort associated with longer hospital stays or permanent disability, reduced school attendance, and lower levels of population health status.
- **Under-utilization of services.** Early detection and treatment for illnesses prevents unnecessary complications, higher costs, and premature mortality. For instance, despite the fact that early detection of breast cancer can prevent up to 30 percent of breast cancer deaths annually, 30 percent of women aged 52 to 69 do not receive regular mammograms.
- **Overuse of services.** The excessive and unnecessary delivery of health care services can increase costs without improving health and place patients at greater risk for injuries and complications. For example, an analysis of hysterectomies provided by seven managed care plans indicated that 16 percent were unnecessary. In another example, the overuse of antibiotics imposes unnecessary health care costs and contributes to the emergence of antibiotic-resistant pathogens, causing as much as \$7.5 billion in unnecessary costs annually.
- **Variation in services.** There is a continuing pattern of wide variation in health care practice that cannot be accounted for by differences in the health status of patients, available resources, patient preferences, or clinical uncertainty. For example, the percent of C-section births in Washington state hospitals ranged from 0 to 43 percent. In another example, hospital discharge rates and lengths of stay in the Northeast were over 40 percent higher than in Western states. Such variation is a clear indicator that clinical practice does not ensure evidence-based practice in the United States.

NEW ACTION TO IMPROVE HEALTH CARE QUALITY AND ENSURE PATIENT SAFETY. Today, President Clinton:

- Done on Executive Memorandum directly*
- ① • **Directed the Quality Interagency Coordination Task Force to develop an action plan to improve health care quality and prevent medical errors.** Today, President Clinton signed an executive memorandum directing the Quality Interagency Coordination Task Force (QuIC) to report back to him in 60 days with an action plan that: identifies medical errors that can be prevented through the use of decision support systems; includes proposals to eliminate barriers preventing adoption of information technology systems in different health care settings; proposes a strategy for the reduction of medical errors in Federal health care programs; detail specific actions that the Federal government can take with the private sector to reduce medical errors; provides a plan for continued, coordinated, collaboration on health care quality issues with the QuIC and the Quality Forum; and evaluates the feasibility and advisability of the recommendations of the Institute of Medicine on patient safety.
 - ⑤ • **Directed the Office of Management and Budget to invest in health care quality and patient safety initiatives when developing the FY 2001 budget.** Today, the President directed the Office of Management and Budget to work with the Domestic Policy Council and the Department of Health and Human Services to develop initiatives within the context of the FY 2001 budget that build on and enhance the ongoing work of the QuIC and to develop models of applied research that can be implemented in the public and private sectors.
 - ⑨ • **Directed the Health Care Financing Administration to integrate patient safety initiatives into the Medicare, Medicaid, and CHIP programs.** Today, President Clinton directed the Health Care Financing Administration (HCFA) to develop pilot projects that promote patient safety and improve health care quality. These new programs, which will be implemented by the Summer of 2000, will be designed to reduce medical errors, prevent over and under-utilization of services, and assure the use of the most recent treatment protocols in the Medicaid, Medicare, and CHIP programs.
 - ⑩ • **Announced a new, multi-million dollar investment in research programs to improve health care quality.** President Clinton announced with the signature of legislation re-authorizing and providing new authority to the Agency for Healthcare Quality and Research (AHQR) AHQR will invest over \$2 million in FY 2000 in new research, to be completed during the coming year, to prevent medical errors and promote patient safety. The President also announced that AHQR will increase its current investment in research focusing on the over and under utilization of services and geographic variation in the delivery of services by ___ percent over the next year.

THE CLINTON-GORE ADMINISTRATION'S LONGSTANDING COMMITMENT TO IMPROVING HEALTH CARE QUALITY. Assuring quality through providing patient protections is a longstanding priority for the Clinton-Gore Administration. Over the past two years President Clinton 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, the President established the Quality Interagency Coordination Task Force, which has been instrumental in developing disease management protocols that have been adopted nationwide. In addition, the Vice President launched a public-private body known as the Quality Forum to coordinate Federal quality improvement efforts with the private sector to provide consumers with a consistent set of standards in order to base their health care choices on quality – not cost.

Requesting that you look into this

DRAFT: November 30, 1999

Dear Secretaries Shalala and Herman,

An information technology revolution in health care is already in the making. Now, providers in inner city and rural areas can access clinical decision-support systems that provide access to the most current medical knowledge. Providers can use computerized systems to streamline and improve many areas of routine practice, including monitoring vital functions of patients, alerting them to changes in those functions that threaten the patient's health, reminding them that a patient is due for routine procedures such as flu shots or eye exams, and warning them when a patient is at risk for a dangerous drug interaction.

Computerizing and streamlining health care processes can improve health care quality, eliminate dangerous medical errors, and lower costs by improving communications between doctors, eliminating redundant tests and procedures, and building automatic safeguards against harmful drug interactions and other adverse side effects into the treatment process. It also can empower employers and others who purchase health insurance on their behalf to evaluate the quality of care by making it possible to fairly compare hospitals, managed care organizations, and treatment regimens. However, very few hospitals, health care systems, and employers use these new techniques.

This new technology has the potential to change our system from one which pays for treatment into a system which pays for outcomes. It is critical that the Federal government take advantage of the opportunities these new technological developments offer to improve health care quality and lower costs. For that reason, I am directing the Quality Interagency Coordination Task Force to develop a report on the existing barriers to integrating computerized information systems and other decision support systems, such as diagnostic and treatment support systems, patient monitoring and reminder systems, and public information systems, into routine practice conducted in a variety of health care settings.

This report, which should be completed by February of 2000, should include recommendations for the:

- Elimination of barriers preventing adoption of effective information technology systems in different health care settings and design options;
- Reduction of medical errors in health care programs operated by Federal agencies;
- Establishment of a public-private task force to promote safety and prevent injuries in the nation's health care system; and
- Development of research programs to design and evaluate medical error interventions.

specific actions

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how best to continue
to collaborative
set up QVIC
and quality forum

New Page
This report will lay the foundation for a national system that prevents medical errors before they occur. It will build on the research sponsored by the Agency for Health Care Policy and Research (AHCPR) the National Library of Medicine (NLM), and the work of the Quality Forum. It should also review the remarkable advancements within the health care delivery systems of the Department of Defense and the Department of Veterans Affairs. DoD, DVA, and the Commerce Department have been leaders in employing information technology to enhance their ability to provide higher quality of care to patients. These new efforts will be a strong next step as we work to ensure the best for patients in the Nation's ever-changing health care system.

WJC

the most prevalent errors
in the health care
delivery system
most amenable
to interventions

evaluate current interventions
with great potential

what are the barriers
for implementing
these errors

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 13, 1998

March 13, 1998

MEMORANDUM FOR THE SECRETARY OF DEFENSE
THE SECRETARY OF LABOR
THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF VETERANS AFFAIRS
THE DIRECTOR OF THE OFFICE OF PERSONNEL MANAGEMENT

SUBJECT: Establishment of the Quality Interagency
Coordination Task Force

Last November, I endorsed the "Patient Bill of Rights" recommended by the Advisory Commission on Consumer Protection and Quality in the Health Care Industry (the "Quality Commission"). On February 20, 1998, after receiving your encouraging reports from the Vice President about the degree to which your agencies are in compliance with these rights, I directed you to take all administrative actions under your authority to come into compliance.

As a result of my February 20 memorandum and your commitment to implement the Patient Bill of Rights, the Federal Government will be taking the lead in ensuring patient protections. By holding the Federal Government accountable, we are strengthening our call on the Congress to pass patient rights legislation that extends these protections to all Americans.

Yesterday, in their report to me through the Vice President, the Quality Commission took the next logical step. Building on the Patient Bill of Rights, which is explicitly designed to ensure quality, the Commission's final report includes recommendations that I am confident will actually improve quality care. Specifically, the Commission called for the development of national health care quality improvement goals and the use of measurement standards that will empower consumers and businesses to make informed purchasing decisions based on health plans' quality performance records.

The Quality Commission recommends establishing "two complementary entities, one public and one private, to provide ongoing national leadership in health care quality improvement." The Commission recommends the creation of a broadly represented, publicly administered "Advisory Council for Health Care Quality" and a privately administered "Forum for Health Care Quality Measurement and Reporting." The Commission's approach represents a creative balance to achieve constructive involvement from all the parties that have important expertise and experience in this area.

It is my strong belief that we must ensure that all relevant agencies within the Federal Government build on their leadership role in health care quality. As the Quality Commission report makes clear, the lack of coordination and uniform quality standards in both the public and private sectors has created conditions that fall "short of fully meeting users' needs, and often are duplicative and unduly burdensome on health care providers, plans, and others." To that end, the Federal Government must use improved standards and goals to better inform and empower health care consumers and purchasers under Federal

jurisdiction. Moreover, we must do a better job of collaborating within and across the Federal Government to most efficiently and effectively ensure we achieve the national goal of improving quality and health outcomes.

Therefore, I am directing the Secretary of Health and Human Services to immediately establish a "Quality Interagency Coordination" (QuIC) task force to ensure better coordination among the executive agencies with jurisdiction over health programs. I hereby direct you to take the following actions consistent with your authority and the mission of your agency to meet or exceed the recommendations of the Quality Commission.

First, I direct that all participating agencies shall have equal standing on the QuIC task force.

Second, I direct the task force to, wherever feasible, collaborate on goals, models, and timetables that are consistent with the Quality Commission's six "National Aims for Improvement": reducing the underlying causes of illness, injury, and disability; reducing health care errors; ensuring the appropriate use of health care services; expanding research on effectiveness of treatments; addressing oversupply and undersupply of health care resources; and increasing patient participation in their care.

Third, I direct the Secretary of Health and Human Services to serve as the convener of the QuIC task force and to schedule the first task force meeting to order by no later than March 27, 1998.

Fourth, I direct the task force to improve cooperation by the participating agencies on the development and utilization of quality measurement mechanisms for public sector programs; these efforts should be flexible enough to respond to changing needs, technology, and information, while being sufficiently standardized to be comparably measured.

Fifth, I direct the task force to work to increase the development and dissemination of evidence-based health care information to help guide practitioners' actions in ways that will improve quality and potentially constrain costs.

Sixth, I direct the task force to consult with health care workers and their representatives, as well as other affected parties, in developing models for quality improvement.

Seventh, I direct the task force to enhance efforts to develop user-friendly information for both consumer and business purchasers that facilitates meaningful comparisons of quality performances of plans, facilities, and practitioners.

Eighth, I direct all participating agencies, where feasible and appropriate, to seek to avoid inefficient duplication of ongoing quality improvement efforts and resources.

Finally, I direct the task force, to every extent possible, to endeavor to coordinate the Federal programs' quality reporting and compliance requirements to reduce administrative burdens on private entities who administer, oversee, or participate in the Nation's Federal health programs.

WILLIAM J. CLINTON

back down the
paper from 2nd report

DRAFT: December 7, 1999

was the
VP there
that day?
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from
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VP

MEMORANDUM FOR THE SECRETARIES OF HEALTH AND HUMAN SERVICES AND
LABOR

SUBJECT: IMPROVING HEALTH CARE QUALITY AND ENSURING PATIENT
SAFETY

which has _____

My Administration has a longstanding commitment to assuring and improving health care quality nationwide. Over the past two years, I have highlighted this issue through the work on the Advisory Commission on Consumer Protection and Quality in the Health Care Industry. In March of 1998, I established the Quality Interagency Coordination Task Force to design strategies to improve health care quality. I also created a public-private body known as the Quality Forum to coordinate our quality improvement efforts with the private sector.

We know that computerizing and streamlining health care processes can improve health care quality, eliminate dangerous medical errors, and lower costs by improving communications between doctors, eliminating redundant tests and procedures, and building automatic safeguards against harmful drug interactions and other adverse side effects into the treatment process. It also can empower employers and others who purchase health insurance on their behalf to evaluate the quality of care by making it possible to fairly compare hospitals, managed care organizations, and treatment regimens. However, very few hospitals, health care systems, and employers use these new techniques.

As a result, thousands of Americans are placed at unnecessary risk for adverse events due to preventable medical errors. More people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. The cost associated with these unnecessary errors in lost income, disability, and health care costs is estimated to be over \$17 billion annually. The financial impact of these errors is compounded by the cost of patients' loss of trust in the health care system, the physical and psychological discomfort of patients associated with longer hospital stays or permanent disability due to medical errors, reduced school attendance by children, and lower levels of population health status. It is clear that we must take a comprehensive approach to improve patient safety.

Therefore, I hereby direct you, as co-chairs of the Quality Interagency Coordination Task Force, to report to me a set of recommendations on specific actions to improve health care outcomes and prevent medical errors in both the public and private sectors in a manner that does not infringe upon patient privacy. This report shall:

- Identify prevalent medical errors that can be prevented through the use of decision support systems nationwide;

clearly underscored
that this problem needs
even greater attention

fine
work
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the
secretaries
praise

- Propose steps to eliminate barriers preventing adoption of effective information technology systems in different health care settings in both the public and private sectors;
- Propose a strategy for the reduction of medical errors in health care programs operated by Federal agencies;
- Detail specific actions that the Federal government can take with the private sector to reduce medical errors nationwide;
- Provide a plan for continued, coordinated, collaboration on health care quality issues with the QUIC and the Quality Forum; and
- Evaluate the feasibility and advisability of the recommendations of the Institute of Medicine's Quality of Health Care in America Committee on patient safety, including the:
 - Creation of a Center for Patient Safety within the Agency for Healthcare Research and Quality;
 - Establishment of a nationwide mandatory reporting system on adverse events that result in death or serious harm to patients;
 - Encouragement of the development of voluntary reporting systems on medical errors;
 - Extension of peer review protections to data related to patient safety;
 - Inclusion of patient safety components in performance standards for health care organizations and health care professionals;
 - Requirement for the Food and Drug Administration to consider patient safety in pre and post-marketing processes for pharmaceuticals; and
 - Encouragement of private health care organizations to establish patient safety programs with defined executive responsibility and to implement proven medication safety practices.

I direct the Department of Health and Human Services to serve as the coordinating agency to assist in the development and integration of recommendations and to report back to me in 60 days. The recommended actions should lay the foundation for a national system that prevents medical errors before they occur and build the work of the Quality Forum. They should be developed in collaboration with state and local officials as well as representatives of the private sector. The recommended actions should be complementary aggressive, and consistent with the Administration's overall initiative to improve health care quality while protecting the privacy of patients.

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FOR IMMEDIATE RELEASE

Preventing Death and Injury From Medical Errors Requires Dramatic, System-Wide Changes

WASHINGTON - Reducing one of the nation's leading causes of death and injury - medical errors - will require rigorous changes throughout the health care system, including mandatory reporting requirements, says a new report from the Institute of Medicine (IOM) of the National Academies. The report lays out a comprehensive strategy for government, industry, consumers, and health providers to reduce medical errors, and it calls on Congress to create a national patient safety center to develop new tools and systems needed to address persistent problems.

The human cost of medical errors is high. Based on the findings of one major study, medical errors kill some 44,000 people in U.S. hospitals each year. Another study puts the number much higher, at 98,000. Even using the lower estimate, more people die from medical mistakes each year than from highway accidents, breast cancer, or AIDS.

Moreover, while errors may be more easily detected in hospitals, they afflict every health care setting: day-surgery and outpatient clinics, retail pharmacies, nursing homes, as well as home care. Deaths from medication errors that take place both in and out of hospitals - more than 7,000 annually - exceed those from workplace injuries.

"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,'" says William Richardson, chair of the committee that wrote the report and president and chief executive officer of the W.K. Kellogg Foundation, Battle Creek, Mich. "Our recommendations are intended to encourage the health care system to take the actions necessary to improve safety. We must have a health care system that makes it easy to do things right and hard to do them wrong."

The know-how exists to prevent many of these mistakes, and so the committee sets as a minimum goal a 50 percent reduction in errors over the next five years. "We believe that with adequate leadership, attention, and resources, improvements can be made," says Richardson. "As we say in the report, 'It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives, and meet the challenges ahead.'"

The majority of medical errors do not result from individual recklessness, the report says, but from basic flaws in the way the health system is organized. Stocking patient-care units in hospitals, for example, with certain full-strength drugs - even though they are toxic unless diluted - has resulted in deadly mistakes. And illegible writing in medical records has resulted in administration of a drug for which the patient has a known allergy. Medical knowledge and technology grow so rapidly that it is difficult for practitioners to keep up. And

the health care system itself is evolving so quickly that it often lacks coordination. For example, when a patient is treated by several practitioners, they often do not have complete information about the medicines prescribed or the patient's illnesses.

To achieve a better safety record, the committee recommends a four-part plan designed to create both financial and regulatory incentives that will lead to a safer health care system. Taken together, these recommendations and findings represent a systematic way to design safety into the process of care. They should be evaluated after five years to assess progress in making the health system safer.

A National Center for Patient Safety

Health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety. The chance of dying in a domestic airline flight or at the workplace has declined dramatically in recent decades, in part because of the creation of federal agencies that focus on safety. Using that model, Congress should create a center for patient safety within the U.S. Department of Health and Human Services (HHS), the committee said. This center would set national safety goals, track progress in meeting them, and invest in research to learn more about preventing mistakes.

The center also would act as a clearinghouse, an objective source of the latest information on patient safety for the nation. For example, if a health care organization improves safety, its practices should be shared with a broad audience, and the center, working with others, would help provide the needed channel.

Administratively, the home for the center should be in the HHS Agency for Health Care Policy and Research; Congress would need to spend \$30 million to \$35 million to set it up, the committee says. This estimate is based on the kind of work the center would perform and on investments in issues of similar magnitude, as well as safety research by the public and private sectors. Funding would need to grow to at least \$100 million, a little more than 1 percent of the \$8.8 billion spent each year as a result of medical errors that cause serious harm.

Mandatory and Voluntary Reporting Systems

The committee defines "error" as the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim, and notes that not all errors result in harm. To learn about medical treatments that lead to serious injury or death and to prevent future occurrences, the committee recommends establishing a nationwide, mandatory public reporting system. Hospitals first, and eventually other places where patients get care, would be responsible for reporting such events to state governments. Currently, about a third of the states have their own mandatory reporting requirements.

While the committee believes that the public has a right to know about errors resulting in serious harm, it nevertheless recommends federal legislation to protect the confidentiality of certain information. Specifically, data should be protected on medical mistakes that have no serious consequences, where the information is collected and analyzed solely for the purpose of improving safety and quality. This would encourage the growth of voluntary, confidential reporting systems so that practitioners and health care organizations can correct problems before serious harm occurs. Without such legislation, fears that reported information might ultimately be subpoenaed and used in lawsuits could discourage participation by health care organizations and providers.

Role of Consumers, Professionals, and Accreditation Groups

A top-down system won't be enough to bring about the kind of fundamental changes needed to improve patient safety, the report says. Pressure from all directions will be necessary. Public and private purchasers of health care insurance - such as businesses buying coverage for their workers - must make safety a prime concern in their contracting decisions. Doing so will create financial incentives for health care organizations and providers to make needed changes.

One reason consumers do not push harder for patient safety is that they assume accrediting and certifying organizations, as well as local and state regulators, do it for them. But regulators and accreditors should make patient safety a key component of their evaluations, the committee says. For most health care professionals, there is no assessment of clinical performance once they get their licenses to practice, for example. Licensing and certifying bodies should implement periodic re-examinations of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices.

The U.S. Food and Drug Administration, which regulates prescription and over-the-counter drugs and medical devices, should increase its attention to public safety. Efforts should be made to eliminate similar-sounding drug names as well as confusing labels and packaging that foster mistakes. Numerous studies have documented errors in prescribing medications and dispensing by pharmacists and unintentional mistakes on the part of the patient.

Building a Culture of Safety

Health care organizations must create an environment in which safety will become a top priority. This culture of safety means designing systems geared to preventing, detecting, and minimizing hazards and the likelihood of error - not attaching blame to individuals. The report stresses the need for leadership by executives and clinicians, and for accountability for patient safety by boards of trustees. That means creating and adequately funding systems to monitor safety. Well-understood safety principles should be adopted, such as designing jobs and working conditions for safety; standardizing and simplifying equipment, supplies, and processes; and avoiding reliance on memory.

All hospitals and health care organizations should implement proven medication safety practices, the committee says, such as using automated drug-ordering systems. Medication errors occur frequently in hospitals, yet many are not making use of known methods for improving safety. Patients themselves could provide a major safety check in most hospitals, clinics, and practices. They need to know which medications they are taking, the appearance, and the side effects. They also should be responsible for notifying their doctors of medication discrepancies and the occurrence of side effects.

There are no "magic bullets," the report emphasizes; no one part of this plan will be sufficient to bring about the degree of change needed. And responsibility for taking action should not be borne by any single group of providers, but must be addressed by all parts of the health care enterprise.

This report is the first in a series expected to be released through an IOM initiative to develop a strategy for improving the quality of health care in America. The study was funded by the National Research Council and the Commonwealth Fund. The Institute of Medicine is a private, nonprofit institution that provides health policy advice under a congressional charter granted to the National Academy of Sciences.

Copies of **To Err Is Human: Building a Safer Health System** are available from the National Academy Press at the mailing address in the letterhead; tel. (202) 334-3313 or 1-800-624-6242. The cost of the pre-publication report is \$45.00 (prepaid) plus shipping charges of \$4.50 for the first copy and \$.95 for each additional copy. Reporters may obtain a copy from the Office of News and Public Information at the letterhead address (contacts listed above).

INSTITUTE OF MEDICINE
Division of Health Care Services

Committee on Quality of Health Care in America

William C. Richardson, Ph.D.* (chair)
President and Chief Executive Officer
W.K. Kellogg Foundation
Battle Creek, Mich.

Donald M. Berwick, M.D., M.P.P.*



THE WHITE HOUSE
OFFICE OF LEGISLATIVE AFFAIRS

West Wing
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RON KLINK
Congress of the United States
House of Representatives
1st District, Pennsylvania

December 7, 1999

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William Jefferson Clinton
The White House
1600 Pennsylvania Ave.
Washington, DC

Dear Mr. President:

I am writing you today regarding the recently released report of the Institute of Medicine citing that medical error is responsible for the lives of tens of thousands of Americans each year.

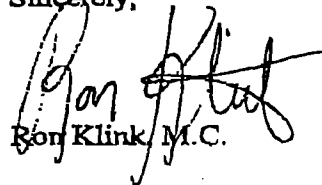
As ranking member of the House Commerce Oversight & Investigations subcommittee I am hopeful that we can take a closer look at this matter in the second session of the 106th Congress. I intend to ask Chairman Upton schedule hearings on this matter as soon as possible.

I was pleased to see your announcement that you were commissioning an interagency task force to review the problem. In my four terms in Congress I have been an advocate for public safety and consumer protection. For this reason, I would like to be included in the interagency task force that you announced earlier today.

I agree with you that we should move quickly to address this problem. Americans are fortunate to have the finest health care delivery system in the world. We must do everything we can to ensure that confidence in hospitals, clinics and pharmacies is not compromised by the release of this report.

I thank you in advance for consideration of my request. I look forward to working with you on this important issue. If you have any questions or need additional information please do not hesitate to contact my office.

Sincerely,


Ron Klink, M.C.

Page 1 of 2

U.S. Department of Commerce
Bureau of Export Administration
Advisory Committees MS: 3876
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Washington, D.C. 20230
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Date: 12-8-99

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Attached is a draft agenda for the December 14th meeting of the President's Export Council Subcommittee on Encryption (PECSENC). If you have not already done so, please let me know whether or not you or a representative will be attending the meeting.

Lee Ann Carpenter
Committee Liaison Officer

**President's Export Council
Subcommittee on Encryption
December 14, 1999
U.S. Department of Commerce
Herbert Hoover Building
Room 4832**

9:30	Opening Comments (OPEN)	William Crowell, PECSENC Chairman
9:35	Public Comments	
9:40	BXA Update	William A. Reinsch Under Secretary for Export Administration
10:30	Briefings	Report on the Wassenaar Arrangement Meetings
11:00		Report on the AES Algorithm Review Process James Foti, Mathematician National Institute of Standards and Technology
11:30		Discussion of PECSENC's Next Steps
12:30		Lunch for Subcommittee members
1:30	Briefing	The Cyberspace Electronic Security Act (CESA) Department of Justice (invited) Peter Swire, Chief Counselor for Privacy Office of Management and Budget (invited)

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12/6/99

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David Nexon

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4

MESSAGE:

FYI

FACT SHEET: THE ERROR REDUCTION AND IMPROVEMENT OF PATIENT SAFETY ACT (ERIPSA)

The Need

The Institute of Medicine's recent report, *To Err is Human: Building a Safer Health Care System* documents the compelling need for national action to reduce errors and improve patient safety:

- Between 44,000 and 98,000 patients die each year as a result of medical errors, making medical errors the eighth leading cause of death.
- Errors in the health care system result in more deaths each year than highway accidents, breast cancer or AIDS. Errors that seriously injure or otherwise harm patients are even more prevalent.
- In 1993, medication errors alone are estimated to have accounted for 7,000 deaths. Two percent of patients admitted to hospitals experience an adverse event caused by medication errors, resulting in \$2 billion in national spending for additional hospital costs related to preventable medication errors for inpatients.
- Total annual national costs (e.g., health care, lost wages/productivity, disability) resulting from medical errors are estimated to be between \$38 and \$50 billion, including \$17-29 billion for preventable events.

An Effective Program to Reduce Medical Errors Can Save Lives and Reduce Health Care Costs

- The report found that most medical errors are the result of flaws in the health care system, rather than carelessness by health professionals. They include, for example, confusing drugs that look or sound alike, or misreading a physician's handwritten prescription. The report notes that these problems that can be minimized through better systems and computerization.
- Over the last two decades, a systematic effort to reduce deaths from errors in administering anesthesia has resulted a decline from two deaths per 10,000 patients in the early eighties to one death per 300,000 patients today.
- One study found that 60 percent of preventable adverse drug events could be avoided by physician computer-entry order systems.
- The experience on other industries has shown the effectiveness of concerted efforts to reduce errors. Since 1976, the death rate from airline accidents has declined 400%. Since the creation of the Occupational Health and Safety Administration in 1970, the workplace death rate has been cut in half.

- The Institute of Medicine report concludes that a reduction in errors of 50% over the next five years is not only achievable but should be a minimum target for national action.

The Error Reduction and Improvement of Patient Safety Act

Consistent with the IOM recommendations, the legislation will include the following:

- Create a National Center for Patient Safety to be housed in the HHS Agency for Health Care Policy and Research. This new center will set national safety goals, track progress in achieving them, serve as a clearinghouse for health organizations seeking to enhance safety, and work with licensing bodies and health organizations to identify and implement ways to increase medical safety.
- Provide grants and contracts for:
 - research on prevention of health system errors;
 - creation and operation of academic centers of excellence providing a multidisciplinary focus on error prevention;
 - state and local consortia of providers, professional societies, and licensing authorities to develop and implement error reduction plans and reporting systems;
 - dissemination of information on error prevention.
- Establish mandatory and voluntary reporting systems.
 - Mandatory reporting: Hospitals and other health organizations would be required to report to state governments (based on national standards) any medical errors that result in serious injury or death. Roughly one-third of the states currently have some requirements in this area.
 - Voluntary reporting: The legislation will encourage health organizations to share experiences and best practices. To enable this exchange, the legislation will deem such communications confidential, as long as they involve only "near misses or lesser injuries" and not cases of serious injury or death.
- Establish minimum error reduction standards for health care institutions as a condition of participation in federal programs. Such standards would include implementation of specific error reduction policies as well as an internal error-reduction system.
- Require the FDA to adopt a program to minimize confusion in prescribing and dispensing drugs arising from drug names or appearance.

- **Require all federal agencies involved in health care to implement an error reduction program for relevant programs under their jurisdiction.**
- **Consistent with the recommendations of the IOM, the budget for the new center and its associated grants and contracts will be \$30 million the first year, rising to \$100 million over five years.**

Quality Interagency Coordination Task Force

Background

The Federal Government plays many important roles that have an impact on the quality of health care Americans receive. In fact, the Federal Government is the largest purchaser and provider of health care services in the United States. Programs like Medicare and Medicaid, the Federal Employee's Health Benefits Plan (FEHBA), as well as the networks of hospitals and facilities providing care to people in the armed forces and veterans, serve millions of Americans. In addition, the Federal Government provides billions of dollars in support of health care research each year, oversees employer-based health care coverage, and ensures fair competition in the health care market.

The goal of the Quality Interagency Coordination Task Force (QuIC), which President Clinton established in response to the final report of the President's Commission on Consumer Protection and Quality in the Health Care Industry, is to ensure that all Federal agencies involved in purchasing, providing, studying, or regulating health care services are working in a coordinated way toward the common goal of improving quality of care. The goals of the QuIC are to provide people with information to assist them in making choices about their care, to improve the care delivered by Federal providers and purchased on behalf of Federal beneficiaries, and to develop the infrastructure needed to improve the health care system. This infrastructure will include knowledgeable and empowered workers, well-designed systems of care, and useful information systems. ■

Composition

Donna Shalala, Secretary of Health and Human Services (HHS) and Alexis Herman, Secretary of Labor (DoL), serve as the co-chairs of the QuIC. John

Eisenberg, Administrator of the Agency for Health Care Policy and Research (AHCPR) serves as chairman for day-to-day operations. In addition to HHS and DoL, the other Federal members of the QuIC are the Departments of Defense, Veterans Affairs, and Commerce; the Office of Personnel Management; the Office of Management and Budget; the U.S. Coast Guard, the Federal Bureau of Prisons; the National Highway Transportation and Safety Administration; and the Federal Trade Commission. ■

Key Activities

Recommendations made by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry form the foundation for the QuIC's work. The QuIC began by reviewing these recommendations and examining ways that the group could further the aims outlined by the Commission. Five themes emerged from the QuIC's initial discussions: improving patient and consumer information on health care quality; identifying key opportunities for improving clinical quality; improving efforts to measure quality of care; developing the health care work force; and improving information systems. Work groups have been established to identify and work on specific projects within each of these topic areas. ■

Work Groups

Each work group is co-chaired by representatives from two different Federal agencies and involves all of the Agencies that wish to participate on the chosen topics.

Patient and Consumer Information. (Health Care Financing Administration [HCFA] and Office of

The Quality Interagency Coordination Task Force (QuIC) is an interagency effort bringing together all Federal agencies with health care responsibility. It is designed to coordinate their activities to improve health care and enhance the effectiveness and efficiency of their efforts. The Agency for Health Care Policy and Research (AHCPR) a component of the U.S. Public Health Service, provides the lead staffing for this effort. AHCPR sponsors and conducts research that provides evidence-based information on health care outcomes; quality; and cost, use, and access.

Personnel Management [OPM], co-leaders). This group is addressing critical barriers to effective communication with patients about quality. It will provide an opportunity for Federal agencies to learn what is most effective in helping people understand quality issues and how their choices influence the quality of the services they receive. It will also develop a common vocabulary, or set of terms, for Federal agencies to use in communicating with patients and consumers about quality.

Improving Quality Measurement. (AHCPR and HCFA, co-leaders). The focus of this group will be on developing the "tool box" of quality measures and risk adjustment methods used by Federal agencies, particularly those that reflect outcomes of care. The work group is developing an inventory of all of the measures and risk adjustment methods being used by Federal agencies, documenting their uses, strengths and weaknesses, and examining how to institute appropriate risk adjustment methods to account for factors outside the control of the delivery system.

Developing the Workforce. (Department of Labor [DoL] and the Health Resources and Services Administration [HRSA], co-leaders). This group is determining how to expand and improve the current methods of ensuring the skills of the health care workforce and equipping health care workers to improve the care they deliver. For example, the work group has chosen to begin by improving the credentialing process for Federal health care providers. This group is also looking at the relationship between the working conditions and health and safety of health care employees and the quality of care delivered. An expert panel is planned for fall 1999 to study the issue and develop an agenda for further research.

Key Opportunities for Improving Clinical Quality. (Departments of Defense [DOD] and Veterans Affairs [VA], co-leaders). This group has selected diabetes and depression as the first two areas for which it will mount an effort to improve clinical quality of care. For diabetes, the work group is focusing its efforts on having all Federal programs agree to use the Diabetes Quality Indicator Project measures of care and then to improve health care provider performance based on these indicators. For depression, the work group is developing an evidence-based guideline to improve the identification and treatment of depressed individuals served by Federal health care programs

Improving Information Systems. (DoD and VA, co-leaders). This work group is exploring how its efforts can augment those of Federal groups that are already working to develop a standardized language that will enable computerized comparisons of quality across Federal agencies. The work group is also examining the potential uses of telemedicine for helping to improve quality of care, and it is in the process of developing a site for the QuIC on the World Wide Web to share information about what the QuIC is doing. ■

For More Information

To obtain more information about the Quality Interagency Coordination Task Force and its activities, contact Nancy Foster, staff liaison for the QuIC, at the Agency for Health Care Policy and Research, 301-594-1609, or by e-mail to nfoster@ahcpr.gov. ■



U.S. Department of Labor

Pension and Welfare Benefits Administration
Washington, D.C. 20210Date: 12/7TO: Deborah Adlen

TELEPHONE: _____ FAX: _____

FROM: Leslie B. Kramerich
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COMMENTS:

Secretary Herman's remarks

Should you experience any difficulties in receiving this transmission, please call
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There are 3 pages including this page.

Talking Points**White House Event on Medical Errors / 12/7/99**

- Thank you, Mr. President, for those kind words. And thank you even more for your effective leadership on improving the quality of American health care and your determination to reduce the medical errors that jeopardize that quality and cause so much needless human suffering.
- I had the honor of co-chairing the President's Advisory Commission on Health Care Quality in 1997. Our Commission felt strongly that improvements were needed to reduce and prevent errors in health care treatment, and to find ways to improve the reporting of medical errors and to address their causes.
- I want to commend all of you here today for your commitment to improving the quality of our health care system. Many of us are partners in the President's Quality Interagency Coordination Task Force or "QuIC" Task Force, which I am proud to co-chair with HHS Secretary Donna Shalala. Through QuIC, several health-related agencies - including Labor, HHS, Veterans' Affairs, Defense, OPM, Commerce and OMB - work together to fulfill the President's directive on quality care. I particularly want to acknowledge the leadership Dr. John Eisenberg, of the newly-renamed Agency for Health Care Research and Quality, has brought to QuIC as its Operating Chair.

- The President's Advisory Commission has made another important contribution to quality health care through the National Forum for Health Care Quality Measurement and Reporting. Through the Quality Forum, efforts throughout the government are part of a coordinated approach to improved quality which we pursue along with representatives of all parts of the health care system, including consumers, employers, health care professionals, labor unions and providers. We're very glad to have the Forum's President and CEO, Dr. Ken Kizer, with us today.
- Just one year ago, in December 1998, the Labor Department, with the Department of Health and Human Services, launched a national health benefits education campaign. This is another way we are getting the word out about reducing medical errors and improving health care quality.
- As you know, last week the Institute of Medicine issued a report that very effectively highlighted the prevalence of medical errors and the harmful impact they are having on our nation's health. I'm pleased to welcome (name to come), the _____ of IOM, to tell us about this report.

###

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concerning wells [(b)(9) of the FOIA]

John Eisenberg at home

Draft Outline of the QuIC Report to the President on Medical Errors

Approximately 40 pages

[601]

- I. Preamble - 2 pages; Lead - AHRQ (Gregg Meyer, gmeyer@ahrq.gov;)
 - A. The issue of errors: definition, component of broader quality agenda
 - B. The Commission
 - C. The IOM Report
 - D. The President's Directive

II. Introduction to the Error Problem - 6 - 7 pages

- A. Growing concern about prevalence of medical errors - ½ page; Lead - AHRQ (Gregg Meyer, gmeyer@ahrq.gov;)
 1. Types of errors
 2. Lessons from other industries
 3. Unique aspects of health care errors
 4. The impact of the organizational/ professional culture
 5. Lessons learned from efforts to reduce health care errors in the US
 6. Lessons from other countries
- B. Framework for thinking about errors - 3 - 3 ½ pages; Lead - AHRQ (Gregg Meyer, gmeyer@ahrq.gov;)
 1. What is known about the prevalence of errors
 2. What is known about the extent to which misuse of medications and devices cause errors?
 3. What programs are currently in place (broadly) to reduce errors?
 4. Why are these protections insufficient?
 5. What are the major barriers to the use of programs currently available?

- C. Evidence of errors - 2 - 3 pages; Lead CDC (Steve Solomon, 404-639-6476, sls1@cdc.gov)
 1. What is known about the prevalence of errors
 2. What is known about the extent to which misuse of medications and devices cause errors?
 3. What programs are currently in place (broadly) to reduce errors?
 4. Why are these protections insufficient?
 5. What are the major barriers to the use of programs currently available?

III. Federal Response to the IOM Report 9 - 12 pages

- A. National focus and leadership 2 ½ - 3 pages; Lead - AHRQ - (Gregg Meyer, gmeyer@ahrq.gov;)
 1. Center for Patient Safety to foster research and learning
 - a. Recommendation
 - b. Response
 2. Identifying research priorities
 - a. Recommendation
 - b. Response --- research agenda setting conference; joint solicitations; evaluation of current efforts
 3. Creating a national summit
 - a. Recommendation
 - b. Response --- discuss education of health professionals, development of a culture of disclosure and learning
 4. Other efforts

touch
base
1st
wk of
Jan

Private
sector
3 State
role

mandatory
reporting
issues

liability
issue

primary

explicit examples
of things that
can happen

B. Learning from errors - 2 ½ - 3 pages; Lead VA – James Bagian; 734-930-5890; James.Bagian@med.va.gov; Also participating will be CDC (for reporting systems)

1. Develop an inventory of current federal programs to detect and prevent errors (1/2 page highlighting an appendix detailing the programs)
2. Reporting systems ---
 - a. IOM recommendation
 - b. Compare mandatory and voluntary advantages and disadvantages; maintaining confidentiality; peer review
3. Standardizing data reporting - with the Quality Forum
 - a. IOM recommendation
 - b. Response --- The importance of standardized language, work of VA/DoD toward this, role of NIST
4. Protections from discovery
 - a. IOM recommendation
 - b. Response
5. Creating information/ knowledge from the data
 - a. IOM recommendation
 - b. Response --- analysis of information intramurally, extramurally
6. Using the information
 - a. IOM recommendation
 - b. Response --- getting the information into the hands of users, developing incentives through purchasing strategies, accreditation and other mechanisms
 - c. Response --- raising expectations of purchasers

C. Raising the standards for health care organizations and professionals - 2 - 4 pages; Lead HCFA (to be announced)

1. Strengthening the FDA's oversight
 - a. IOM recommendation
 - b. Response
2. Raising the standards for accreditation/ regulation --- requirements, incentives
 - a. IOM recommendation
 - b. Response - Regulatory initiatives
3. Raising the expectations of health professionals --- requirements, curriculum, education;
 - a. IOM recommendation
 - b. Response --- health professions education levers include DoD schools, VA role in professional education, BHP's role, Federal credentialing process
4. Incorporating safety into guidelines
 - a. IOM recommendation
 - b. Response

D. Creating safety systems inside health delivery organizations – 2 pages; Lead VA - James Bagian; 734-930-5890; James.Bagian@med.va.gov ;also participating will be DoD

1. Patient safety efforts
 - a. IOM recommendation
 - b. Response --- purchaser incentives, accreditation and participation requirements
2. Reporting systems
 - a. IOM recommendation
 - b. Response --- organizational versus national
3. Safe medication practices
 - a. IOM recommendation
 - b. Response --- NPSP recommendations, decision assistance.
4. System changes
 - a. IOM recommendation
 - b. Response --- NPSP recommendations, decision assistance.

IV. What actions should be taken to identify and implement other strategies that should be used to reduce errors? 10 ½ - 11 ½ pages Lead DoD (Frances Stewart, 703-681-1703 x5214, frances.stewart@ha.osd.mil) Participating VA, FDA

- A. Development of a substantial research program**
 1. What is currently underway in Federal agencies?
 2. What needs to be done next?
- B. Using decision support systems and other information technologies to increase quality and safety 2- 2 ½ pages;**
 1. What is currently underway in Federal agencies?
 - a. Federal Role in standard setting
 2. What should be done next?
- C. Using standardized procedures, checklists, and other devices found effective in human factors research - 2 pages;**
 1. What is currently being done in Federal programs?
 2. What needs to be done next?
- D. Work station re-design for safety - 2 pages**
 1. What is currently being done in Federal programs?
 2. What needs to be done next?
- E. Process re-design to simplify, improve safety - 2 pages**
 1. What is being done?
 2. What needs to be done next?
- F. What other strategies can be employed to reduce errors? 1 ½ - 2 pages**
 1. What is being done?
 2. What needs to be done next?
- G. What other levers do Agencies have to address the issue of errors? 1 page**
 1. What are the levers?
 2. What can be done with them to draw attention to the need for increased safety, learn what is effective in preventing errors, ensure that proven strategies get widely adopted?

- V. Working with the private sector - 5 pages; Lead OPM (Frank Titus, fdtitus@opm.gov, 202-606-0549) Also participating – DoL, DoD**
- A. What actions should be taken to involve and encourage the private sector in our activities to improve safety? - 1 ½ pages**
 - B. In what private sector activities should the Federal agencies become involved or enhance current involvement- 1 ½ pages**
 - C. What new public-private sector initiatives might be considered? - 2 pages**
 - 1. With other health care entities?
 - 2. With other industries concerned with improving safety?
- VI. Conclusions - 1 page; Lead AHRQ – Nancy Foster (nfoster@ahrq.gov)**

Comforting
language

on what we
approve

they are

Advise
us

on
whether

there
is

a
privacy
congrat

Contact: John Kelly, M.D.

215/775-5186

Jill Griffiths

215-775-6890

White House, Congress Focus on

Institute of Medicine Findings

Aetna Urges Healthcare Industry to Work Together to Reduce Deaths Caused by Medical Errors

Blue Bell, PA, December 13, 1999 – “Managed care organizations can play a critical role in reducing medical errors that result in 44,000 to 98,000 avoidable deaths each year through their data analysis and quality improvement capabilities and by working together with hospitals, physicians and government agencies,” said John T. Kelly, M.D., Aetna U.S. Healthcare’s director of physician relations.

“We applaud both the White House and Congress’s attention to this critical public safety and health issue, but think the entire healthcare industry can and must do more,” said Dr. Kelly.

The alarming statistics from a recent Institute of Medicine study are the focus of hearings today on Capitol Hill and a new agency review ordered by the White House. “These statistics have raised concerns among Americans. As good as the U.S. healthcare system is, our focus as an industry must be on continuous improvement,” said Kelly.

Managed care organizations have a vital role in reducing medical errors through their partnerships with physicians and hospitals, information management techniques and support of research, according to Dr. Kelly.

(More)

"The opportunities for managed care organizations to reduce errors in the healthcare system are significant," said Carol Diamond, MD, MPH, president of U.S. Quality Algorithms, the quality measurement affiliate of Aetna U.S. Healthcare. Aetna U.S. Healthcare systems frequently alert pharmacists at the point of purchase that the drugs being dispensed to an Aetna U.S. Healthcare member might have potential drug-to-drug, drug-to-disease or even drug-to-age contraindications.

Dr. Diamond pointed to The Institute of Medicine report to show how managed care can be a part of the solution. The report highlighted examples of patients who are prescribed medications by different physicians. In many cases, no one physician has a complete picture of what medications a patient is taking. Managed care organizations sit in a critical position in the healthcare delivery system and are uniquely positioned to provide information that can make an impact on care that might otherwise be fragmented. "Our information and technology infrastructure allows the company to identify members who have been prescribed six or more different medications, often by different physicians," said Diamond. "This can lead to the medical errors the IOM study identified."

The healthcare industry's ability to improve quality -- whether by reducing error or raising the standard of what constitutes optimal care -- will depend to a large extent on its ability to ensure access to information. Because of the enormity of the task of managing information, collaborative efforts among health plans, medical institutions, healthcare professionals and federal agencies are essential to ensure that information and research are effectively applied to the challenge of improving care.

Aetna U.S. Healthcare is the nation's leading health and related benefits organization, providing a full spectrum of products ranging from health maintenance organizations (HMOs) to indemnity health insurance, group life and disability products, and dental, vision, and pharmacy benefits to approximately 29 million Americans. In addition, Aetna U.S. Healthcare provides quality measurement and improvement programs and data analysis for providers and purchasers of healthcare, and supports medical research through the Academic Medicine and Managed Care Forum.

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Tom garwaite

P6/(b)(6)

(002)

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December 19, 1999

**Report Details Medical Errors in V.A.
Hospitals**live
interviews
WABC →**Forum**

Join a Discussion on Health in the News

of 74
SafetyBy **ROBERT PEAR**

WASHINGTON, Dec. 18 -- Federal investigators have documented almost 3,000 medical mistakes and mishaps in less than two years at veterans hospitals around the country, and more than 700 patients have died in those cases, the Department of Veterans Affairs says in a new report.

The accidents and deaths occurred from June 1997 to December 1998, in the first 19 months of a new policy that requires employees to report medical errors and "adverse events." Since then, the department has been getting such reports at a rate of more than 200 a month.

The problems include medication errors, like prescribing or dispensing the wrong drugs, the failure of medical devices, abuse of patients, errors in blood transfusions, surgery on the wrong body part or the wrong patient, improper insertion of catheters or feeding tubes, and a variety of "therapeutic misadventures" that caused serious injuries or deaths.

The comprehensive self-examination by the Department of Veterans Affairs, believed to be the first of its kind by any health care system in the nation, shows what could be expected if all hospitals had to report their errors, as recommended recently by the National Academy of Sciences. The number of reported errors would be high, but health care executives would get useful information about problems that need to be fixed, officials said.

Starting in June 1997, the Department of Veterans Affairs ordered its hospitals to report their mistakes to the agency's regional offices, which in turn send the information to Washington, where it is logged into an official file known as the patient safety register. Hospitals must try to identify the causes of each incident, to reduce the likelihood of a repetition.

Resp
msKen
Kizer

OMB

James McManus

P6/(b)(6)

The new emphasis on patient safety was prompted by several factors: sporadic complaints of substandard care at veterans hospitals, pressure from Congress and the zeal of a senior official, Dr. Kenneth W. Kizer, who was under secretary of veterans affairs from October 1994 to June of this year.

For decades, the veterans health care system had a reputation as hidebound and bureaucratic. But under Dr. Kizer, it emerged as a national leader in efforts to improve patient safety.

The report's author, Dr. James E. McManus, a surgeon from New York City who is the veterans department's medical inspector, said in an interview that "the adverse events reported by the V.A. were so serious that 24 percent of the patients died. One in four died." The study found 2,927 errors in the first 19 months of mandatory reporting, and 710 deaths.

The number of deaths in 1999 has not been determined. While each hospital analyzes its own cases, the department has not yet analyzed this year's figures for the nation as a whole.

As medical inspector for the Department of Veterans Affairs, Dr. McManus is a sort of watchdog and ombudsman, continually evaluating the quality of care provided to veterans. The department runs the nation's largest health care delivery system, with 172 hospitals, 132 nursing homes and more than 650 outpatient clinics.

Dr. McManus and other health care experts said they believed that the prevalence of errors at veterans hospitals was similar to that at other hospitals. "I don't think it's any different from the private sector," Dr. McManus said.

Dr. Dennis S. O'Leary, president of the Joint Commission on Accreditation of Healthcare Organizations, which inspects 80 percent of hospitals in the United States, said he knew of no other health care system that collected such data.

"The V.A. is doing the right thing," Dr. O'Leary said.

Dr. Donald M. Berwick, a member of the study panel convened by the National Academy of Sciences, said, "The first sign of a serious endeavor to deal with errors is that the number of reported errors should go way, way up."

The joint commission encourages private hospitals to report "unexpected occurrences" involving death or serious injury to patients, but it does not require such reports. Since January 1995, the commission says, 714 such events have been voluntarily reported. The Department of Veterans Affairs has tallied a much larger number of accidents in just 19 months of mandatory reporting.

The Institute of Medicine, an arm of the National Academy of Sciences, said last month that medical errors killed 44,000 to 98,000 people a year in hospitals alone. More people die from medical mistakes each year than from highway accidents, breast cancer or

testing better method
of reporting — focus
on near misses that can lead to harm

separate place that they send
data to be de-identified —
near misses only

VA policy to report back to
patient — rx: errors

AIDS, it said. The institute said Congress should require hospitals to file reports with state governments, disclosing any medical errors that cause death or serious harm.

The population served by veterans hospitals is, on the average, somewhat older than the population served by community hospitals, and men account for a larger share of the patients. Experts who served on the academy's study panel said the reporting requirements of the veterans health care system were an example of what they had in mind for hospitals in general.

The academy said the nation could and should reduce medical mistakes by 50 percent over the next five years. But no one knows how many mistakes are now made, so it will be difficult to measure progress toward that goal. The veterans department study suggests that the numbers may be higher than many people have assumed.

"When you seek out problems and errors, you find them much more frequently," Dr. Kizer said. "But no one really believes that errors happen more frequently at V.A. hospitals. We must uncover and define the full extent of the problem before we see progress."

Of the 2,927 "adverse events" analyzed by the Department of Veterans Affairs, 171 were medication errors, in which patients received the wrong dose of a drug or the wrong medication. Patients died in 22 of these cases.

Dr. McManus, the medical inspector, said he believed such drug errors were "greatly underreported."

The veterans agency defines "adverse events" as untoward incidents, illnesses or injuries caused by treatments or directly associated with care provided by the department.

Hospitals varied greatly in the number of errors they reported. Dr. McManus's report did not analyze the reasons for the wide variation.

Veterans hospitals in the New York City area reported the smallest number of errors (37), even though this is the second largest district of the veterans health care system, after Southern California. The New York City hospitals reported 2.3 "adverse events" for every 10,000 veterans treated, while the veterans medical centers in upstate New York reported 18.9 adverse events for every 10,000 patients.

Health care experts said this disparity suggested that the upstate hospitals were more diligent in reporting errors, not that they were less safe.

In its report, the Department of Veterans Affairs described many kinds of "adverse events."

About 540 patients were injured in falls at veterans hospitals and nursing homes, 250 of them suffered hip fractures and 44 of them died.

In addition, the department said, 277 patients committed suicide at

**PHOTOCOPY
PRESERVATION**

700# not direct correlation
between error & death 277
suicides

all of these are preventable

22 adverse drug events
falls @ nursing home
What can we do in our settings
to help prevent this

actions by OA personnel →
most harmful?

Federal torts system

can go to court & seek damages

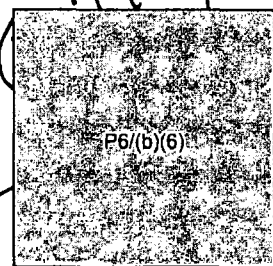
they can get punitive damages?

(report was leaked)

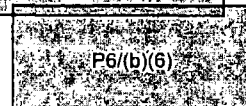
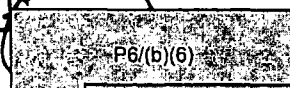
summary of 1st 19 months →
not annual; internal
working document



Jim
Hollen



Jim
Bajian



Melinda

veterans hospitals or soon after being discharged, and 476 patients tried to kill themselves but survived. Doctors said some of the suicides might have been prevented if the patients had received appropriate treatment for depression.

The government lost track of 113 patients, who were listed as missing from veterans hospitals and nursing homes where they were expected to be. Eighty-seven of them were later found, but 20 were not found and the whereabouts of the other 6 were not specified. Reporting of medical accidents is a duty for veterans hospital employees. In theory, they may be disciplined for failing to report such events, but officials prefer to encourage reporting by training employees and assuring them that they will not be punished for acknowledging mistakes.

The Department of Veterans Affairs offers cash awards to employees who make improvements in patient safety, paying a maximum of \$5,000 to an individual and \$25,000 to a hospital, clinic or nursing home.

The department also created a National Center for Patient Safety, headed by Dr. James P. Bagian, a former astronaut. The center analyzes reports of medical mistakes, looking for patterns and trends, and suggests corrective actions.

Lessons learned from the experiences of individual hospitals are disseminated throughout the veterans health care system. For example, Dr. Bagian said, doctors and nurses have concluded that they must pay more attention to suicide attempts, and they are alert to the need to provide mental health care to older patients with terminal illnesses and no close relatives.

The veterans hospitals, unlike some private hospitals, are required to inform patients of any injuries that result from medical errors. The veterans hospitals are also supposed to advise injured patients of their options, including the right to seek disability benefits and, in some cases, the right to sue the government for damages.

Most other studies of medical errors were based on reviews of medical records months or years after patients received care. By contrast, Dr. Kizer said, the study of veterans hospitals was based on information from clinical employees, who were supposed to report "adverse events" within 24 hours after they occurred.

right
to address
Ct or govt

When
is this
feasible
how
does
this
work

What law
makes
this possible

PHOTOCOPY
PRESERVATION

ABC

AP

WPost

P6(b)(6)

P6(b)(6)

ERIC

q&a done?

• Jim Begik

• Meelinda Murphy

• msq -

reporting means
you identify reporting
problems -

any incidence of this
prob is transiting &
we're going to — — — .

banding for pts
track lost pts
key taking off shelves
process of fixing things
we find.

of the X million svcs today

22,000 deaths/year

700 adverse events out of
35,000

Department of Veterans Affairs
Veterans Health Administration
Office of the Under Secretary for Health
810 Vermont Avenue, N.W.
Washington, DC 20420
Fax: 202.273.7090



Date: 12-20-99 # of Pages to Follow: 3
To: Devora (zap) Phone: 202.456.5557 (fax)
From: _____

Comments:

Tort info, *as discussed*
~~for follow~~

Please call 202.273. 5806 if you have any questions.

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If you have received this communication in error, please notify us immediately at the telephone number shown above. Thank you.

January 13, 1998

(2) The Office of Performance and Quality will share alerts and innovative system designs identified in the literature and through ongoing discussions with benchmarking organizations;

(3) The Office of the Medical Inspector will share alerts and innovative system designs identified in its reviews of sentinel events and other significant quality of care variations;

(4) The PSI Oversight Committee will share alerts and innovative system designs identified in its reviews of adverse events.

9. RESEARCH SUPPORT OF PSI

a. While the advantages of some system modifications will be self-evident, rigorous assessment will be needed to determine the effectiveness of others in reducing risk. Rigorously conducted research studies will also be needed, at times, to test hypotheses regarding the etiology of adverse events.

b. Support of both types of research efforts is strongly encouraged. VISNs should consider establishing programs to support local research efforts directed at these goals (see reference f for a description of a research program at several university hospitals designed to assess the effectiveness of innovations to improve the quality of patient care, relatively rapidly and inexpensively).

10. INFORMING PATIENTS ABOUT ADVERSE EVENTS

a. Background Information

(1) VHA is obligated to inform patients and their families about injuries resulting from adverse events and the options available to them. There is also evidence that patients desire acknowledgment of errors from their caregivers and that doing so reduces the likelihood that patients will take legal or administrative action (see reference t).

(2) The two primary options available to injured patients or their survivors are claims for compensation under 38 U.S.C., Chapter 11, Section 1151, and tort claims under the Federal Tort Claims Act, 28 U.S.C., Chapter 171.

(a) Claims under 38 U.S.C. Section 1151 that have been submitted before October 1, 1997, can result in payment of monthly benefits for additional disability or death incurred as the result of VA hospitalization, medical or surgical treatment, or examination, regardless of whether the disability or death was caused by negligence. Claims under section 1151 provide for the payment of a monthly benefit based on the percentage of disability and eligibility for VA medical care, without having to demonstrate negligence. Claims for 1151 benefits are processed by VBA Regional Offices.

(b) Claims under 38 U.S.C. Section 1151 that are submitted on or after October 1, 1997, can result in payment of monthly benefits for additional disability or death incurred as the result of

VA hospital care, medical or surgical treatment or examination, but only if the disability or death was proximately caused by negligence or an unforeseen event. The claims can still result in monthly benefits and eligibility for VA medical care, but benefits will not be available unless negligence or an unforeseen event is established.

(c) Tort claims may result in a settlement or in a judgment if a Federal court determines that negligence by medical practitioners caused injury or death (and jurisdictional requirements are met). The claimant frequently receives money in a lump sum payment, but structured settlements, which can include annuities, medical trusts, future payments, and reversionary interests, are also used where appropriate. Tort claims can result in monetary awards for pain and suffering, which are not necessarily included in veterans benefits. Tort settlements or judgments can also be used to provide for family members in ways that veterans benefits statutes do not allow. However, an attorney is usually retained, and attorney fees capped at 20 (administrative settlements) to 25 (litigation) percent of the damages reduce the award the veteran or survivors receive. Tort claims are processed by the Regional Councils.

(d) Veterans and survivors may pursue both section 1151 and tort claims. However, if both claims are successful, 38 U.S.C. Section 1151 benefits will be withheld until the amount that would have been paid equals the amount of the tort claim settlement or judgment.

b. Communication with Patients Regarding Adverse Events

(1) VISNs will ensure that its facility staff, typically the attending physician or treatment team, promptly inform patients and their families about pertinent clinical facts associated with injuries resulting from adverse events, assuring them that measures have been taken to maintain life and minimize disability and discomfort.

(2) VISNs will ensure that its facility staff provide appropriate and timely communication with patients and their families regarding adverse events that involve potential organizational liability. Potential organizational liability can be assessed based on discussions with practitioners and the Regional Counsel. **NOTE:** Actual liability can be determined only after consideration of a claim under the provisions of the Federal Tort Claims Act, 28 U.S.C. 1346(b), 2671-2680. The patients and their families shall be advised of appropriate remedial options. These options should include locally available interventions (e.g., arranging for second opinions, expediting clinical consultations, inpatient admission) and referral of patients to the 38 U.S.C. Section 1151 claims process and the tort claims process.

(3) One mechanism to facilitate such communication is a standing PSI group, e.g., the Chief of Staff or designee, Regional Counsel, patient representative, and PSI staff, that assesses liability issues and coordinates conferences with patients and families. To provide prompt responses, the group needs to be able to meet on short notice. Another approach is to have PSI staff assume these responsibilities with support and consultation from facility management and Regional Counsel.

(4) A collaborative relationship between Regional Counsel and VA medical center staff is necessary to ensure that appropriate and timely communication with patients occurs. Each VISN

VHA HANDBOOK 1051/1**January 13, 1998**

should ensure that its staff develop an understanding with its Regional Counsel regarding the procedures for obtaining Regional Counsel input prior to discussing an adverse event with a patient.

11. REVIEW OF TORT CLAIMS

- a. Each VISN shall ensure that its staff conduct peer reviews of all new tort claims and share the findings with their Regional Counsel.
- b. Practitioners involved in new tort claims should be identified in these peer reviews and notified as soon as possible.
- c. After a tort claim has been paid, a second peer review will be conducted to determine whether reporting to the National Practitioner Data Bank is required (see reference bb).

12. EDUCATION OF PSI STAFF

VISNs are encouraged to regularly send their facility PSI staff to the educational programs of the National Patient Safety Foundation of the American Medical Association, the American Society for Health Risk Management of the American Hospital Association and similar organizations.

13. REFERENCES

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- b. American Society of Hospital Pharmacists. Top-priority Actions for Preventing Adverse drug events in hospitals: Recommendations of an expert panel. American Journal Health-Systems Pharmacy 747-751, 1996.
- c. Andrews LB, et al. An Alternative Strategy for studying adverse events in medical care. Lancet 349:309-313, 1997
- d. Bates DW, et al. "Potential Identifiability and Preventability of Adverse Events Using Information Systems," Journal of American Medical Informatics Association. 1994;1:404-411.
- e. Berwick DM. "Taking Actions: Leading the Reduction of Error." Keynote Address at Conference on Examining Errors in Health Care. Annenberg Center for Health Sciences, October 14, 1996.
- f. Black ER, et al. "Innovations in Patient Care: Changing Clinical Practice and Improving Quality," Joint Commission Journal of Quality Improvement. 21:376-391, 1995.

some individuals → but eventually
~~but then~~ suit against DVA
w/c in Federal court

cannot sue if a benefit is
denied → administrative
process to go thru.

you can file a claim w/
board of Veterans appeals →

Court of Veterans Appeals
(which is part of the Veterans
Administration) don't know what
level of independence they
have —

Tort claims is outside of
your system

**ALBERT EINSTEIN COLLEGE OF MEDICINE
OF YESHIVA UNIVERSITY**

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FAX

TO: Christopher C. Jennings FAX #: 202-456-5557

NUMBER OF PAGES: (4)
(Including cover page)

COMMENTS: "To Err is Human"

But to expect sleep deprived,
chronically fatigued & inadequately
supervised resident physicians "Not to
Err" is pure palaver!!

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EMAIL: bbell@accorn.yu.edu
FAX 202-456-5557
December 16, 1999

Dear Mr. Jennings:

I thought I might expand a bit on my letter to The President. I do believe that much can be learned from New York State's experience in attempting to reduce error in hospitalized patients by studying both the "405/Bell/Zion regulations" and the New York State adverse events reporting system (PETS). The reports by Mark Green, the Public Advocate of New York City may be particularly informative.

In reading the landmark IOM report "To Err is Human" I was surprised to find no mention of the serious role mentally and physically impaired residents play in the etiology of egregious errors among hospitalized patients, particularly since a number of prominent members of the committee that wrote the report are very aware of this unfortunate situation. I do believe that in order to reduce the kinds of error discussed in the report, such as medication errors, consideration must be given not only to computers, etc. but to the people who write the orders and perform and or participate in the many procedures characteristic of hospital medicine in 1999. In our teaching hospitals the physicians who bear the major responsibility for patient care, particularly for the poor, the uninsured and others without identifiable and committed "private doctors" are resident physicians. In spite of the fact that there is a huge literature documenting the serious adverse effects of sleep deprivation on performance, scheduled sleep deprivation, chronic fatigue and inadequate supervision are features of graduate medical education. Medical educators believe that their trainees are different (physiologically??) from those who work in other high risk industries and therefore the need for reducing error in the practice of medicine by rationalizing the working conditions and the supervision of resident is unnecessary.

As you may know, since 1987 I have attempted to convince the doyens of American medicine (they all know of me and my work) that this view is antediluvian. While a few, notably Lucian Leape and Don Berwick, agree with me the vast majority have refused to take me seriously. They do not like to hear me remind them that it is government (in New York both state and federal) which supports graduate medical education and that unless they address and repair this dangerous situation the government ultimately will. The tradeoff of allowing the care of the poor to be tied to medical

education is immoral when the "care" is given by inadequately supervised, sleep deprived residents. The President's Task Force must address this obvious cause of preventable deaths and serious accidents in hospitalized patients.

I would be pleased to hear from you and help in any way that I can.

Sincerely,

A handwritten signature in black ink that reads "Bertrand M. Bell" followed by a stylized flourish.

Bertrand M. Bell, M.D.
Distinguished University Professor
Professor of Medicine

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Distinguished University Professor
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Professor of Family Medicine

President William Jefferson Clinton
The White House
1600 Pennsylvania Avenue
Washington, DC 20502

COPY

December 13, 1999

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Dear Mr. President:

Your prompt response in acting on the recommendations of the Institute of Medicine report, **"To Err is Human, Building a Safer Health System"** is wonderful. It is well known to our profession that errors are a very serious cause of death and disability in hospitalized patients, particularly errors caused by inadequately supervised, sleep deprived and chronically fatigued resident physicians; yet, little has been done to improve this deplorable situation.

Ten years ago, in an effort to address this serious cause of error and thereby improve the quality of care of hospitalized patients, New York State incorporated the 405 regulations (aka the "Bell Regulations") into the public health law. These statutes mandated that resident physicians must be closely supervised by the attending physician and limitations imposed on their hours. Since 1990 teaching hospitals in New York State have received more than one billion 200,000 million dollars to comply with the law. After a recent survey of the hospitals by the NY State Health Department the health commissioner noted in the "New York Times" that, "Our survey revealed widespread abuse of the resident working hour limits particularly among surgical residents in New York City." It was found that 77% of surgical residents in NY City worked in excess of 95 hours per week. This situation is clearly a significant cause of "adverse events."

The landmark IOM Report did not mention that the system of Graduate Medical Education is a significant cause of egregious error in hospitalized patients. It is my hope that your task force as well as the various agencies which finance or administer health plans remember, as they explore ways to reduce medical errors, to include in their deliberations approaches to reduce the adverse effects that the system of graduate medical education has on hospitalized patients. I would be pleased to discuss with your task force various strategies available for addressing this most serious situations.

Sincerely,
Bertrand M. Bell, MD
Distinguished University Professor

cc: Christopher C. Jennings

up from 20 to 30 hrs
training for
all emp.

~ Preliminary Draft ~
Patient Safety Initiatives - Funding Estimates
(Dollars in Thousands)

100%
computerized
order
entry

	1999	2000	2001
National Center for Patient Safety			
National Center's Budget			
Ann Arbor	\$ 294	\$ 1,858	\$ 2,348
Washington DC		412	548
Patient Registry/Reporting System			
Registry (Phase I)	45	45	-
Reporting System (Phase II)	-	25	TBD
Patient Safety Improvement Handbook, etc.	-	TBD	TBD
Patient Safety Improvement Oversight Comm	-	14	14
Patient Safety Improvement Awards Program	19	39	39

Other Patient Safety Elements:

VHA Expert Advisory Panel on System Design

Costs incurred in FY 1998

Patient Safety Centers of Inquiry

Cincinnati	222	500	500
Palo Alto	276	500	500
Tampa	355	500	500
White River Junction	189	500	500

National Bar Code Medication Administration <i>no maintenance & replacement costs</i>	29,684	6,809	908
National Surgical Quality Improvement Program	57	57	57

* Global Positioning System (Wandering Patients) *on line pilots 2000* TBD TBD

Suicide Summit (Natl. Consensus Conference) TBD TBD

Clinical Guidelines & Reminders (part of CPRS) 225 225 225

Quality & Performance Staff/Development of Initiatives 110 - -
barcoding for blood
VA Research in Patient Safety *Invested \$1.5M from '97-'99 & Increasing*

Field-based activity:

Office of Medical Inspector	TBD	TBD	TBD
Field	TBD	TBD	TBD
Virtual Learning Center <i>internal webpage</i>	TBD	TBD	TBD

Total Resources Specifically Identified

\$ 31,477 \$ 11,484 \$ 6,139

anesthesia simulator →
for training Stanford VA

training
and
research

critical
items
checklist

Draft Outline of the QuIC Report to the President on Medical Errors
Approximately 40 pages

- I. Preamble - 2 pages; Lead – AHRQ (Gregg Meyer, gmeyer@ahrq.gov;)**
 - A. The issue of errors: definition, component of broader quality agenda**
 - B. The Commission**
 - C. The IOM Report**
 - D. The President's Directive**
- II. Introduction to the Error Problem - 6 – 7 pages**
 - A. Growing concern about prevalence of medical errors - ½ page ; Lead – AHRQ (Gregg Meyer, gmeyer@ahrq.gov;)**
 - B. Framework for thinking about errors -3 – 3 ½ pages; Lead – AHRQ (Gregg Meyer, gmeyer@ahrq.gov;)**
 - 1. Types of errors
 - 2. Lessons from other industries
 - 3. Unique aspects of health care errors
 - 4. The impact of the organizational/ professional culture
 - 5. Lessons learned from efforts to reduce health care errors in the US
 - 6. Lessons from other countries
 - C. Evidence of errors - 2 - 3 pages; Lead CDC (Steve Solomon, 404-639-6476, sls1@cdc.gov)**
 - 1. What is known about the prevalence of errors
 - 2. What is known about the extent to which misuse of medications and devices cause errors?
 - 3. What programs are currently in place (broadly) to reduce errors?
 - 4. Why are these protections insufficient?
 - 5. What are the major barriers to the use of programs currently available?
- III. Federal Response to the IOM Report 9 - 12 pages**
 - A. National focus and leadership 2 ½ - 3 pages; Lead – AHRQ – (Gregg Meyer; gmeyer@ahrq.gov;)**
 - 1. Center for Patient Safety to foster research and learning
 - a. Recommendation
 - b. Response
 - 2. Identifying research priorities
 - a. Recommendation
 - b. Response --- research agenda setting conference; joint solicitations; evaluation of current efforts
 - 3. Creating a national summit
 - a. Recommendation
 - b. Response --- discuss education of health professionals, development of a culture of disclosure and learning
 - 4. Other efforts

B. Learning from errors - 2 ½ - 3 pages; Lead VA – James Bagian; 734-930-5890; James.Bagian@med.va.gov; Also participating will be CDC (for reporting systems)

1. Develop an inventory of current federal programs to detect and prevent errors (1/2 page highlighting an appendix detailing the programs)
2. Reporting systems ---
 - a. IOM recommendation
 - b. Compare mandatory and voluntary advantages and disadvantages; maintaining confidentiality; peer review
3. Standardizing data reporting - with the Quality Forum
 - a. IOM recommendation
 - b. Response --- The importance of standardized language, work of VA/DoD toward this, role of NIST
4. Protections from discovery
 - a. IOM recommendation
 - b. Response
5. Creating information/ knowledge from the data
 - a. IOM recommendation
 - b. Response --- analysis of information intramurally, extramurally
6. Using the information
 - a. IOM recommendation
 - b. Response --- getting the information into the hands of users, developing incentives through purchasing strategies, accreditation and other mechanisms
 - c. Response --- raising expectations of purchasers

C. Raising the standards for health care organizations and professionals - 2 - 4 pages; Lead HCFA (to be announced)

1. Strengthening the FDA's oversight
 - a. IOM recommendation
 - b. Response
2. Raising the standards for accreditation/ regulation --- requirements, incentives
 - a. IOM recommendation
 - b. Response - Regulatory initiatives
3. Raising the expectations of health professionals --- requirements, curriculum, education;
 - a. IOM recommendation
 - b. Response --- health professions education levers include DoD schools, VA role in professional education, BHP role, Federal credentialing process
4. Incorporating safety into guidelines
 - a. IOM recommendation
 - b. Response

D. Creating safety systems inside health delivery organizations – 2 pages; Lead VA - James Bagian; 734-930-5890; James.Bagian@med.va.gov ;also participating will be DoD

1. Patient safety efforts
 - a. IOM recommendation
 - b. Response --- purchaser incentives, accreditation and participation requirements
2. Reporting systems
 - a. IOM recommendation
 - b. Response --- organizational versus national
3. Safe medication practices
 - a. IOM recommendation
 - b. Response --- NPSP recommendations, decision assistance.
4. System changes
 - a. IOM recommendation
 - b. Response --- NPSP recommendations, decision assistance.

IV. What actions should be taken to identify and implement other strategies that should be used to reduce errors? 10 ½ - 11 ½ pages Lead DoD (Frances Stewart, 703-681-1703 x5214, frances.stewart@ha.osd.mil) Participating VA, FDA

- A. Development of a substantial research program**
 1. What is currently underway in Federal agencies?
 2. What needs to be done next?
- B. Using decision support systems and other information technologies to increase quality and safety 2- 2 ½ pages;**
 1. What is currently underway in Federal agencies?
 - a. Federal Role in standard setting
 2. What should be done next?
- C. Using standardized procedures, checklists, and other devices found effective in human factors research - 2 pages;**
 1. What is currently being done in Federal programs?
 2. What needs to be done next?
- D. Work station re-design for safety - 2 pages**
 1. What is currently being done in Federal programs?
 2. What needs to be done next?
- E. Process re-design to simplify, improve safety - 2 pages**
 1. What is being done?
 2. What needs to be done next?
- F. What other strategies can be employed to reduce errors? 1 ½ - 2 pages**
 1. What is being done?
 2. What needs to be done next?
- G. What other levers do Agencies have to address the issue of errors? 1 page**
 1. What are the levers?
 2. What can be done with them to draw attention to the need for increased safety, learn what is effective in preventing errors, ensure that proven strategies get widely adopted?

- V. Working with the private sector - 5 pages; Lead OPM (Frank Titus, fdtitus@opm.gov, 202-606-0549) Also participating – DoL, DoD**
- A. What actions should be taken to involve and encourage the private sector in our activities to improve safety? - 1 ½ pages**
 - B. In what private sector activities should the Federal agencies become involved or enhance current involvement- 1 ½ pages**
 - C. What new public-private sector initiatives might be considered? - 2 pages**
 - 1. With other health care entities?
 - 2. With other industries concerned with improving safety?
- VI. Conclusions - 1 page; Lead AHRQ – Nancy Foster (nfoster@ahrq.gov)**

***** FACSIMILE COVER SHEET *****

DEC 16 1999 15:35

Message To:

#94565557

Message From:

LEGISLATIVE STRATEGIE

03

Pages

Follow This Cover Page

1001 Pennsylvania Ave, N.W.
Suite 760 North
Washington, D.C. 20004
202-661-7070 – direct line
202-661-7060 – firm line
202-661-7066 (FAX)
jcoster@legstrat.com

**Legislative Strategies
Group, LLC**

Fax

To: Chris Jennings

From: John M. Coster, Ph.D., R.Ph.

WH/OEOB

Fax: 456-5557

Pages: Multiple

Phone:

Date: 12/16/99

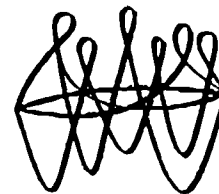
☐ Urgent ☒ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

- Comments: Chris - this is the letter that I referred to in our conversation - can you let me know if you can meet with these guys? Thanks.

The National Patient Safety Foundation at the AMA

515 North State Street
Chicago, Illinois 60610
Telephone 312 464-4848
Fax 312 464-4154
E-mail npsf@ama-assn.org

December 10, 1999



Christopher Jennings
Deputy Assistant to the President for Health Policy Development
The White House
216 Old Executive Office Building
Washington, DC 20502

Dear Mr. Jennings:

We are requesting to meet with you to discuss how the National Patient Safety Foundation (NPSF) can support President Clinton in his patient safety initiatives.

The recent Institute of Medicine (IOM) report "To Err Is Human", highlights the two and a half year agenda of the National Patient Safety Foundation. The IOM report specifically suggests that some of the initiatives should be delegated to the NPSF (page 69). In your role as The White House Deputy Assistant to the President for Health Policy Development, you may be aware that the NPSF is making rapid and substantial progress in advancing patient safety as an accepted area of inquiry and public interest among healthcare stakeholders. Specific accomplishments in advancing patient safety during 1999 include:

- ◆ Convening a group of national authorities concerned with reducing medication errors, following a process to identify problems and potential solutions, and establishing Pharmaceutical Safety as a national priority;
- ◆ Developing an official *Agenda for Research and Developing in Patient Safety* that defines the landscape of patient safety research and identifies the core issues that should be targeted by the broader research community;
- ◆ Continuing the research grants program that so far has awarded eight grants for up to \$100,000, with the clear potential to advance patient safety. Two of these grants honor the memory of James S. Todd, MD;
- ◆ Initiating a *Cataloguing Patient Safety Research* project, with the support of the AHCPR, that will identify the extent of patient safety research and its funding mechanisms in the leading agencies as well as identify the gaps in existing knowledge.
- ◆ Conducting a series of regional meetings around the country in collaboration with state medical societies and other local leaders to build local patient safety communities and initiate local action;

- ◆ Advocating a "new look" at errors in health care that emphasizes a systems-learning approach, as opposed to methods that focus only on blame and punishment for mistakes, to numerous national audiences;
- ◆ Conducting a national policy-focused patient safety workshop in July of 1999 in Washington DC to heighten awareness of the issue and engage key leaders from across the country to take action to improve patient safety;
- ◆ Developing the voice of patient safety through the publication of a quarterly newsletter, *Focus on Patient Safety*, a biweekly *NPSF News Brief* e-mail news update, special publications, and a web site;
- ◆ Developing a clearinghouse of multi-disciplinary literature relevant to patient safety;
- ◆ Initiating "*A Call for Solutions*" - a meeting that is being organized by the NPSF and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) that will focus on patient safety innovations and solutions in 2000.

Indeed, we are well situated to move forward with the recommendations outlined in the IOM report. We want to support the President in his health care safety initiative and would like to work together. I will be calling soon to set up a meeting with you, Henri Manasse, Chair of our NPSF Board, and myself to discuss the next steps of action. Please feel free to contact me if you would like to receive a more detailed information about the NPSF activities and its achievements or have any questions regarding this letter.

Sincerely,



Anne Shea, RN, MBA
Chief Operating Officer and
Acting Executive Director

cc: Henri R. Manasse, Jr. PhD, ScD, RPh
Chairman of the Board



151 Farmington Avenue
Hartford, CT 06156

Richard L. Huber
Chairman, President and CEO
(860) 273-7851
Fax: (860) 273-6872

December 13, 1999

The Honorable William J. Clinton
President of the United States
The White House
Washington, DC 20500

Dear Mr. President:

I was very pleased to read about your recent directive to have every public health program explore ways to reduce, and hopefully eventually eliminate, medical errors that result in approximately 44,000 to 98,000 deaths each year. There are many steps – some simple, some more complex – that can be implemented to reduce this number.

I wanted to express my personal commitment and the commitment of Aetna U.S. Healthcare to this goal. Today's evolving managed care industry has the capability to help improve the quality of health care delivered through the use of effective partnerships with hospitals and physicians and sophisticated information management strategies. We must all work to maximize the use of this information and do nothing to unduly restrict such use.

At Aetna U.S. Healthcare, we have invested more than \$100 million to build state-of-the-art information systems to give physicians and hospitals tools to allow them to practice better medicine.

To this end, I would like to propose the creation of an industry working group, that we would be honored to chair, that could work and consult with the existing federal taskforce under the direction of Secretaries Shalala and Herman. I strongly believe that the private sector, working with the public sector, can help increase the quality and safety of the U.S. health care delivery system.

I hope to discuss with you, Gene Sperling or Chris Jennings how this idea could be implemented.

Sincerely,

A handwritten signature in black ink, appearing to read "Dick". The signature is written in a cursive, flowing style.

Date: 12/3

FAX

▼ Health Division ▲
Office of Management and Budget
Executive Office of the President
Washington, DC 20503

To: DAN

From: MATT

Number of Pages (excluding cover) 2

Subject: ~~EXEC~~ MEMO ON QUIC (Medical Errors)

Comment:

Dan: This fax contains our edits to the memo.
Note - It does not include NSD comments (The memo refers to DoD)
Call w/ any questions. Thanks

Voice Numbers:

Health Division (Front Office)	(202) 395-4922
Health & Human Services Br	(202) 395-4925
Health Programs & Services Br	(202) 395-4926
Health Financing Br	(202) 395-4930

Fax Numbers:

(202) 395-3910
(202) 395-3910
(202) 395-5648
(202) 395-7840

DRAFT: December 7, 1999

EXECUTIVE MEMORANDUM FOR THE QUALITY INTERAGENCY COORDINATION TASK FORCE

and Director Lachance,

SUBJECT: IMPROVING HEALTH CARE QUALITY AND ENSURING PATIENT SAFETY

Assuring quality through patient protections is a longstanding priority for this Administration. Over the past two years, with the invaluable assistance of the Vice President, Secretary Shalala, and Secretary Harman, this Administration has 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. Equally as important as assuring high quality health care services, however, is improving the quality of the services.

and supporting continuous improvements in patient quality.
Inappropriate utilization of services, unnecessary variations in the delivery of health care services, and preventable medical errors are responsible for thousands of deaths, unnecessary illnesses, and instances of prolonged disability annually. *Early detection and appropriate treatment for illnesses such as diabetes, breast and cervical cancer, and heart attacks can reduce mortality by over 40 percent.* Millions of Americans receive health care services, such as unnecessary or inappropriate prescriptions or surgeries that endanger health and increase costs. In addition, there is a continuing pattern of wide variation in health care practice, including regional variations, clearly indicating that the practice of health care has not caught up with the science of health care.

Preventable medical errors present an extraordinary example of the importance of efforts to ensure the safety of patients and the delivery of high quality health care services. A recent study by the Institute of Medicine indicates that over half of the adverse medical events occurring each year are due to preventable medical errors, placing tens of thousands of Americans at unnecessary risk. More people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. *The cost associated with these unnecessary errors in lost income, disability, and health care costs is as much as \$29 billion annually. The financial impact of these errors is compounded by the cost of patients' loss of trust in the health care system, the physical and psychological discomfort associated with longer hospital stays or permanent disability, reduced school attendance, and lower levels of population health status.*

diminished patient satisfaction,
Last year, in order to begin to address these issues, I established the Quality Interagency Coordination Task Force (QUIC), which is responsible for the dissemination of information on evidence based medical research, and has been instrumental in developing disease management protocols that have been adopted nationwide. The Vice President launched a public-private body known as the Quality Forum to coordinate our quality improvement efforts with the private sector to provide consumers with a consistent set of standards in order to base their health care choices on quality outcomes – not just cost. Although they have only been in operation for a short period of time, these entities are well on their way to making contributions to improving the delivery of high quality health care. In addition, the Departments of Defense, Commerce, and Veterans Affairs have been leaders in employing information technology to enhance their ability to provide higher quality of care to patients. However, it is clear that more must be done.

Does not
fit in
here; could
use elsewhere

*strong
and enforceable
patients
rights*

IOM

estimates that

are highly trained and dedicated. The problem is not the people, the problem is the system they work in.

Computerizing and streamlining health care processes can improve health care quality, eliminate dangerous medical errors, lower costs by improving communications between doctors, eliminating redundant tests and procedures, and building automatic safeguards against harmful drug interactions and other adverse side effects into the treatment process. Despite this fact, very few public and private health plans, hospitals, and employers use these new techniques.

Therefore, I hereby direct the Quality Interagency Coordination Task Force, to report to me a set of recommendations on specific actions to improve health care outcomes and prevent medical errors in both the public and private sectors in a manner that does not unnecessarily and inappropriately infringe upon patient privacy in any way. This report shall:

- Identify prevalent medical errors that can be prevented through the use of decision support systems, such as patient monitoring and reminder systems;
- Propose steps to eliminate barriers preventing adoption of effective information technology systems in different health care settings in both the public and private sectors;
- Propose a strategy to reduce medical errors in Federal health care programs that will reduce medical errors and ensure patient safety;
- Detail specific actions that the Federal government can take with the private sector to reduce medical errors and improve patient safety nationwide, including continued collaboration on health care quality issues with the QUIC, the Quality Forum, and the National Center for Vital Statistics; and
- Provide technical support to the Health Care Financing Administration in the development of pilot projects implementing patient safety initiatives in Medicare, Medicaid, and CHIP.
- Evaluate the feasibility and advisability of the recommendations of the Institute of Medicine's Quality of Health Care in America Committee on patient safety, including the:
 - Creation of a Center for Patient Safety in the Agency for Healthcare Research and Quality;
 - Establishment of a nationwide mandatory reporting system on ^{medical errors and} adverse events that result in death or serious harm to patients;
 - Encouragement of the development of voluntary reporting systems on medical errors; ^{and} adverse events
 - Extension of peer review protections to data related to patient safety; ^{less serious}
 - Inclusion of patient safety components in performance standards for health care organizations and health care professionals;
 - Requirement for the Food and Drug Administration to consider patient safety in pre and post-marketing processes for pharmaceuticals; and
 - Encouragement of private health care organizations to establish patient safety programs with defined executive responsibility and to implement proven medication safety practices.

I direct the Department of Health and Human Services to serve as the coordinating agency to assist in the development and integration of recommendations and to report back to me within 60 days. The recommended actions should lay the foundation for a national system that prevents adverse medical events before they occur.

DRAFT: December 7, 1999

EXECUTIVE MEMORANDUM FOR THE QUALITY INTERAGENCY COORDINATION TASK FORCE

SUBJECT: IMPROVING HEALTH CARE QUALITY AND ENSURING PATIENT SAFETY

Assuring quality through patient protections is a longstanding priority for this Administration. Over the past two years, with the invaluable assistance of the Vice President, Secretary Shalala and Secretary Herman, this Administration has 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. Equally as important as assuring high quality health care services, however, is improving the quality of the services.

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~~that we've already done - that we've already started on~~ ^{improving} ~~the~~ ^{health care} ~~quality~~ ^{quality.}

Don't allow in delivery & inpatient systems can help

Delete Computerizing and streamlining health care processes can improve health care quality, eliminate dangerous medical errors, lower costs by improving communications between doctors, eliminating redundant tests and procedures, and building automatic safeguards against harmful drug interactions and other adverse side effects into the treatment process. Despite this fact, very few public and private health plans, hospitals, and employers use these new techniques.

Replicate what's successful

DES thru the

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consistent w/ the Sec's proposed recommendations on med. privacy

- Identify prevalent medical errors that can be prevented through the use of decision support systems, such as patient monitoring and reminder systems;
- Propose steps to eliminate barriers preventing adoption of effective information technology systems in different health care settings in both the public and private sectors;
- Propose a strategy to reduce medical errors in Federal health care programs that will reduce medical errors and ensure patient safety;
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 - Establishment of a nationwide mandatory reporting system on adverse events that result in death or serious harm to patients;
 - Encouragement of the development of voluntary reporting systems on medical errors;
 - Extension of peer review protections to data related to patient safety;
 - Inclusion of patient safety components in performance standards for health care organizations and health care professionals;
 - Requirement for the Food and Drug Administration to consider patient safety in pre and post-marketing processes for pharmaceuticals; and
 - Encouragement of private health care organizations to establish patient safety programs with defined executive responsibility and to implement proven medication safety practices.

delete for now? Usurps DES decision to choose where it goes

huh?

delete

~~I direct the Department of Health and Human Services to serve as the coordinating agency to assist in the development and integration of recommendations and to report back to me within 60 days. The recommended actions should lay the foundation for a national system that prevents adverse medical events before they occur.~~

Direct HCFA to implement successful
strategies & enhance safety.

Janet (301) 317
5952



Melissa Skolfield <mskolfie@os.dhhs.gov>

12/03/99 12:28:54 PM

Please respond to mskolfie@os.dhhs.gov

Record Type: Record

To: Devorah R. Adler/OPD/EOP

cc: Ellen Dahl <edahl@os.dhhs.gov>

Subject: ...no subject...

6 phone calls
Sunday
2 to 3 pm

*
Carmella

Devorah -- here are Richard Sorian's and my suggested edits to the memo, mainly for paragraphs 2-4 (see below). In addition, we think the bulleted action items are in a bad order. We would suggest reordering them so that the third bullet (propose a strategy to reduce errors) is first, the fourth bullet (detail specific actions*) is second, and the sixth bullet (evaluate the feasibility. . .) is third.

Rich and I would both delete the HCFA bullet, since we REALLY don't need additional scrutiny of Medicare (or Medicaid or CHIP) right now.

The most important thing to us, and the Secretary, is to lay down the history of the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, so we look ahead of the curve rather than reactive.

Suggested new first sentences for paragraphs 2-4:

As the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry reported earlier, the United States has some of the finest medical institutions and best trained health care professionals in the world. Yet millions of Americans are harmed - or even killed - each year as a result of inappropriate or erroneous medical treatment. These health care quality problems include the underutilization of needed services, the overutilization of unnecessary services, and medical errors committed in the delivery of care. In addition, there is a continuing pattern of wide variation in health care practice, including regional variations.

As the recent Institute of Medicine study confirms, preventable medical errors present an extraordinary example of the importance of improving the quality of health care in our nation. Preventable errors cause the deaths of as many as 98,000 Americans every year and add as much as \$29 billion to our nation's health care spending. These costs are far outweighed by the impact these errors have on the lives of individuals and families and in the trust of the American people in the quality of the care they receive. We know that more than half of the adverse medical events that occur each

cc: Mr. Reber

year could be avoided if we marshall our resources wisely.

Three years ago, I created the Advisory Commission on Consumer Protection and Quality in the Health Care Industry to bring together the best minds from the fields of medicine, health care delivery, consumer protection, large and small employers, the legal profession, medical ethics, and others to help us identify the challenges ahead in improving the quality of our health care system. The Commission's landmark 1998 report gave us a blueprint for action and the IOM report provides us with an additional impetus for action.

10/1/01 11:27 AM

10/1/01 11:27 AM

10/1/01 11:27 AM

FOTUS remarks

Background on who's there

What they're going

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."

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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THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

Tuesday, November 30,
1999

REMARKS BY THE PRESIDENT
ON PARENTAL LEAVE

The Oval Office

9:20 A.M. EST

THE PRESIDENT: Hello. Thank you. Good morning, ladies and gentlemen. The people here with me at the podium are, obviously, Secretary Herman, but also Katie and Eric Banks and their son, Collin, of Fairfax, Virginia; Jonathan and Teresa Graham and their two children from Baltimore; Darsie Cahall and James Baker and their three children from Takoma Park, Maryland.

I'll say a little more about them in a moment. You can see this is a family event. (Laughter.) We've orchestrated the children.

Before I leave for the World Trade Organization meeting on the West Coast, I want to talk a little about how we're using the strength of our economy to help strengthen working families.

Yesterday I signed a budget that maintains the fiscal responsibility that has given us what will be in February the longest economic expansion in our history, and at the same time lives up to the values of the American people. We have no higher value than family, but too many of our families are having trouble balancing the demands of home and work. Today I'm using my executive order -- authority -- to give these parents new tools to succeed at home and on the job.

The surging technology and soaring prosperity we currently enjoy are the result of a lot of hard work and very long hours by the American people. In fact, today many working parents are forced to make the unacceptable choice between being good workers and good parents. Too often, in our round-the-world, round-the-clock economy, there just don't seem to be enough hours in the day for parents to do what they need to do. That's why we've worked hard to help parents balance work and family.

Last May I asked Secretary Herman to develop new ways to address this problem. Today I'm announcing a proposed Labor Department rule that lets states use their unemployment insurance to offer paid leave to new parents. This initiative is totally voluntary for states. It helps them empower more working parents, like the ones standing with me today. With this act, the United States joins the rest of the world's advanced economies, all of whom already have some form of paid leave for parents.

When little Collin was born, his mother, Katie, was working as a waitress, his dad was working as a head electrical technician for a small company. Unfortunately, he was born ill and had to be intensive care for several weeks. Katie took unpaid leave and eventually quit

her job to be with her son. Collin's dad, Eric, wanted to take leave, but couldn't afford to do so. Once Collin was well enough, Katie looked for and, fortunately, landed another job. But both Katie and her husband would have, and should have, been able to take paid leave to care for their son. That's what this parental leave initiative is all about.

I believe giving states the flexibility to experiment with paid employment leave is one of the best things we can do to strengthen our families and help new mothers and fathers meet their responsibilities both at home and at work.

State flexibility and the voluntary nature of this effort are key to its success. In our strong economy, we hope states will take advantage of this new option, and we believe those that do will balance this new benefit with the imperative of maintaining a fiscally sound unemployment insurance program.

This effort builds on our commitment to give working families more tools to help them adapt to the new economy, from expanding the earned income tax credit to our welfare-to-work efforts, from increasing funding for child care to HOPE scholarships.

In the budget bill I signed yesterday, we fought for and won a doubling of resources for after-school programs to give young people a safe place to study between the end of their school day and the end of their parents' work day.

I'm especially proud that the first bill I signed as President, in 1993, was the Family and Medical Leave law. Since then, millions of Americans -- we believe well over 20 million -- have used it to take up to 12 weeks of unpaid leave to care for a newborn or sick relative without losing their jobs. The importance of this benefit has been confirmed by the testimony of experts and parents at the first ever White House Conference on Early Childhood Development in 1997, and from groups like the Academy of Pediatrics. They all reinforce what we already know from common sense, giving parents and primary care givers time to bond with children leads to healthy development including boosting critical language and literacy skills.

But the current law meets just a fraction of the need. And the number one reason families give for not taking advantage of Family and Medical Leave is that they simply can't afford to take time off without a paycheck. The actions we take today will go a long way toward alleviating that burden if the states take up the challenge. I believe it will strengthen parents' bonds with both their children and their jobs.

As I've said, on the eve of this new century, we ought to set a goal that all parents can take time they need for their families, without losing the income they need to support them. The new state authority will move us in the right direction and gives another tool in our national efforts to both strengthen our families and reward the dignity of work.

Thank you very much.

Q Mr. President, what do you hope to achieve in Seattle at the WTO?

THE PRESIDENT: Well, I hope we'll get a new round launched that will slash tariffs and other trade barriers in agriculture and other areas. I hope that we will agree to keep e-commerce free of unusual burdens, and that we will lead to more transparent and open rules among nations so that they believe the trading system is fair.

I also strongly, strongly believe that we should open the process up to all those people who are now demonstrating on the outside. They ought to be a part of it. And I think we should strengthen the role and the interests of labor and the environment in our trade negotiations.

This is not going to be easy to do, partly because some nations, particularly a lot of

developing nations, see our concern for the environment and labor standards as a way to sort of keep them down. But that is not true. What we want to do is to make sure that when we open the trading system, that ordinary Americans benefit.

In our country, about 30 percent of our growth has come from expanded trade. We have kept inflation down because we've kept our markets open and other people have been able to sell good quality products at lower prices in our markets. So we've had this huge growth with low inflation. I just want to make sure that ordinary people everywhere are benefitted by the trading system, and that the economy is not damaged by trading rules that could put short-term economic considerations over long-term environmental considerations.

So I'm very sympathetic with a lot of the causes being raised by all the people that are there demonstrating. And since this has now become a global society with global communications, as well as a global economy, I think it was unrealistic to assume that for the next 50 years, trade could be like it's been for the last 50 -- primarily the province of business executives and political leaders. I think more people are going to demand to be heard, and I think that's a good thing.

Q Mr. President, yesterday a report documented the problem of medical mistakes, and said that 44,000 Americans at least are killed every year because of these medical mistakes. What's your reaction to that, and is there anything that your administration is planning to do about it?

THE PRESIDENT: Well, you may remember that we had a task force a couple of years ago, headed by Secretary Herman and Secretary Shalala, which issued -- in fact, two reports -- one of them recommended the patients' bill of rights. The other set up a quality commission to deal with problems like this.

If you looked at it, to me, one of the most interesting things was that a lot of these hospitals, which are very over-crowded and have people coming in all the time, and have doctors seeing all kinds of patients in rapid succession, have people lose their lives because of improper prescriptions of medicine, not knowing about a patient's allergy, or not knowing about what other medication they're taking. That's a -- and I think that we have an opportunity here to work with the public-private partnership which the task force set up to use modern technology, information technology, and to also do some basic old-fashioned changes in procedures that will save a lot of these lives.

I'm convinced we can do that. I talked yesterday, on the patients' bill of rights, to one of the leading managed care providers in the country, and suggested that they ought to be helping, too, and they agreed with that. We've all got to get together. No one has an interest in seeing these kinds of mistakes made. And we know that otherwise competent people are making a lot of these mistakes. So we've got to work through how we can use technology and how we can maybe even slow some of the actions to make sure that mistakes like this aren't made.

But I think we need -- this is a very welcome report; we need to study it very carefully. And in order to get something done on it, it's going to take a partnership of everybody involved in health care.

Q Mr. President, there's been yet another case of espionage from Russia. Are you concerned that there's some sort of epidemic of spying going on? And what does this say about U.S.-Russian relations?

THE PRESIDENT: From where, from Russia? Well, I think what we should do is investigate this like we do all others. But I don't think we should stop our efforts to try to drastically cut nuclear weapons, or end corruption in Russia, or do all the other things we're supporting. I think this shows the importance of our work that the Congress ratified to continue to reduce the nuclear weapons in Russia and the nuclear threat associated with the

decommissioning of nuclear weapons.

And I think that what we have to do is continue -- we have to deal with espionage firmly, but we need to try to reduce the consequences of error and mistakes and wrongdoing.

Q What do you hear about Yeltsin's health?

THE PRESIDENT: I think it's a case of pneumonia. That's what they said. I checked on it yesterday, and they believe that he'll be all right.

Q Mr. President, the Mexican Attorney General is reportedly saying that 22 Americans are among those found in the mass graves. Have you received any official word?

THE PRESIDENT: No. I asked about it just before I came out here, actually, and I haven't. It's a horrible example, apparently, of the excesses of the drug dealing cartels in Mexico, and I think it reenforces the imperative of our not only trying to protect our border, but to work with the Mexican authorities to try to combat these.

You know, we had a lot of success a few years ago in taking down a number of the Colombian drug cartels, and one of the adverse consequences of that was a lot of the operations were moved north into Mexico. And there are organized criminal operations there, and they are particularly vicious. You may remember that in that same area a couple of years ago, an honest and brave Mexican prosecutor was shot over a hundred times in front of his wife and child. So it's a very violent, dangerous thing, and we have to be on top of it.

Thank you.

Q Mr. President, why aren't you going to Panama? I mean, it's a major event in history.

THE PRESIDENT: Well, first of all, I have taken, and may have to take -- I've already taken, I think, a dozen foreign trips this year -- it is a major event; I think my interest in Latin America is well-known -- but I may have to take yet another trip before the end of the year, and about that time, which is why I asked President Carter and Secretary Albright to head our delegation.

I think that President Carter deserves enormous credit for his leadership in getting the Panama Canal Treaty through. It was, at the time, as you remember, very controversial, immensely unpopular. A lot of members in the Senate were -- had their seats put in peril over it. And I think it --

Q So you're not against the turnover?

THE PRESIDENT: Oh, no. I supported it at the time and I still support it. I think it's the right thing to do. I think that the new government of Panama is committed to maintaining the canal in an appropriate way and keeping it open and working with us to do so, and having good relations.

So no one in Panama or anywhere in Latin America should draw any adverse conclusion. We have a lot of things going on in the world now; I've been out of the country a lot; I need to get ready for the new Congress and the new budget, and I may have to take another foreign trip at about the same time, which is why I have not committed to make the trip. But I think --

Q What, which one?

THE PRESIDENT: I can't talk about it. (Laughter.) But I think -- I do think that Jimmy

Carter deserves to lead our delegation down there. He did an historic and great thing in advocating the Panama Canal Treaty. But the people of Panama should know that this President and our government strongly support both the treaty and the event, which will occur in a few days.

Q You're not worried about the Chinese controlling the canal?

THE PRESIDENT: I think the Chinese will, in fact, be bending over backwards to make sure that they run it in an competent and able and fair manner. This is like them, like China coming into the WTO. I think they'll want to demonstrate to a distant part of the world that they can be a responsible partner, and I would be very surprised if any adverse consequences flowed from the Chinese running the canal.

Q When are you going to Ireland?

THE PRESIDENT: I don't know. You know, I'd like to go once a month.

THE PRESS: Thank you.

END 9:35 A.M. EST



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DRAFT: CLINTON-GORE ADMINISTRATION ANNOUNCES MULTI-MILLION DOLLAR INVESTMENT TO PROTECT ELDERLY AMERICANS FROM NEGLECT AND ABUSE

January 15, 2000

Today, the White House announced that President Clinton will increase his investment to ensure nursing home quality by 29 percent in his FY 2001 budget, spending an additional \$15.9 million to strengthen Federal nursing home enforcement tools and increase oversight of nursing home quality and safety standards and proposing new legislation to tighten quality standards for these facilities. In addition, the White House also announced that this year, the Department of Health and Human Services would invest \$10 million in new efforts to educate older Americans about their long term care options. Finally, the White House announced that the implementation of provisions in the Balanced Budget Refinement Act, beginning this month, would invest over \$2.7 billion in nursing homes throughout the country to take the steps necessary to ensure that critically ill older Americans and individuals with disabilities can receive the high quality care they need. These new efforts build on the President's 1998 commitment to improve quality of care in nursing homes nationwide.

PROTECTING NURSING HOME RESIDENTS FROM ABUSE AND NEGLECT. About 1.6 million older Americans and people with disabilities receive care in approximately 16,700 nursing homes. The Clinton-Gore Administration has made the health and safety of nursing home residents a top priority – putting into effect the toughest nursing home regulations in the history of the Medicare and Medicaid programs. Most nursing homes provide high quality care to the frail and vulnerable elderly individuals they serve. However, the GAO released a report last year indicating that nearly 25 percent of the nation's nursing homes have severe quality infractions that often go unpunished, even though the conditions jeopardize the health and safety of residents. In addition, the GAO states that many states use procedures or practices that may limit the filing of complaints and fail to investigate serious complaints promptly, prolonging situations in which residents may be subject to abuse, neglect resulting in serious care problems like malnutrition and dehydration, and preventable accidents.

NEW, 29 PERCENT INCREASE IN FUNDING TO ENSURE THE DELIVERY OF HIGH QUALITY CARE IN NURSING HOMES. The President's FY 2001 budget will include an additional \$15.9 million, a 29 percent increase over last year's budget to improve Federal and state oversight of nursing homes. With these new funds, HHS will be able to:

- **Survey nursing homes during evenings and weekends.** Because of limited resources, nursing homes are often surveyed at predictable intervals, making it easy for substandard homes to ensure they are in compliance at the time of the surveyor's visit. These new funds will be used to ensure that at least 10 percent of all survey visits are conducted after traditional business hours, makes it more difficult for low-quality nursing homes to pass inspections.
- **Survey substandard facilities more frequently than other facilities.** Additional funds will be used to target at least 100 facilities with the worst records of compliance with quality standards, to ensure these nursing homes are inspected more often than currently required – at least twice a year.
- **Training surveyors in the effective inspection of nursing homes.** Additional funds will be invested to train state inspectors to use new inspection protocols to detect quality problems in nursing homes. This new system integrates quality of care data statewide and identifies areas of concern, such as bedsores, malnutrition, and abuse affecting nursing-home residents, for surveyors to focus on.

- **Ensure that states respond swiftly to resident complaints.** These new funds will be used to ensure that resident complaints of abuse or neglect placing a loved one in danger are swiftly investigated by state survey agencies.
- **Ensure swift and effective enforcement of nursing home quality standards.** The FY 2001 budget provides a 50 percent increase in funding to provide litigation support and hold hearings on nursing home enforcement cases, which will ensure that an additional ___ cases are heard over the coming year.

NEW LEGISLATIVE PROPOSALS TO STRENGTHEN QUALITY OF CARE

REQUIREMENTS FOR NURSING HOMES. Today, the White House will announce that the President's budget includes new legislative proposals to strengthen quality of care standards in nursing homes. These new proposals will: require all Medicare civil money penalties collected from deficient nursing homes to be reinvested in Federal activities to improve the quality of care, as is required for Medicaid civil money penalties; and deny Medicare and Medicaid payments for new admissions to nursing homes that have deficiencies that have caused harm to patients until the facility comes back into compliance with quality of care standards.

ANNOUNCING NEW \$100 MILLION INVESTMENT IN SKILLED NURSING FACILITIES BEGINNING THIS MONTH. The passage of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 enhances Medicare beneficiaries' access to high-quality health care by addressing many of the problems with the BBA raised by the Administration and Congress. This landmark legislation: provides new funds: provide immediate increases in payment for high-cost nursing home patients; provides nursing homes with the option to elect to be paid at the full Federal rate for skilled nursing facilities rather than through the PPS blend; increases payment rates across the board for skilled nursing facilities; imposed two-year moratorium on payment caps for physical, speech, and occupational therapy to \$1,500 each per beneficiary. Today, the White House announced that this month, nursing homes throughout the country will begin to receive new funds – approximately \$100 million this year – this month for those nursing homes choosing to be paid at the full Federal rate. In addition, this month, HCFA will send a letter to all nursing homes informing them of this new option, advising homes of the potential benefits of this choice, and outlining the effective dates and implementation schedule of other components of the BBRA that affect nursing homes.

EDUCATING OLDER AMERICANS ABOUT LONG TERM CARE OPTIONS. Beginning next month, HHS will launch a new, \$10 million campaign to provide all 39 million Medicare beneficiaries with critical information about long-term care options, including: what long-term care Medicare covers; how to find out about Medicaid long-term care coverage; what to look for in a quality private long-term care policy; and how to access information about home-and community-based care services that best fit beneficiaries' needs. This information will be presented in an easy to understand format specifically targeted to caregivers and older Americans and will include activities such as: be distributed nationwide through the Medicare and You handbook, the Guide to Health Insurance, and state organizations devoted to health insurance as well as public service announcements for television and radio. In addition, the FY 2001 budget invests over \$2.5 million in the Nursing Home Compare website, which provides prospective consumers effective information about choosing a nursing home, including facility specific information to evaluate the quality of care and educate individuals about residents' rights, abuse, and issues related to proper nutrition and hydration.

BUILDING ON THE CLINTON GORE ADMINISTRATION'S COMMITMENT TO ENSURING HIGH QUALITY OF CARE IN NURSING HOMES NATIONWIDE.

Protecting patients in nursing homes has been and will continue to be a priority of the Clinton-Gore Administration. In 1995, the President threatened to veto legislation pending before the Congress that would eliminate Federal enforcement of nursing home quality standards, and issued the toughest nursing home regulations in the history of the Medicare and Medicaid programs, leading to measurable improvements in quality of care for nursing home residents. In July of 1998, the Clinton-Gore Administration initiated a new nursing home quality initiative that ensures swift and strong penalties for nursing homes failing to comply with standards, strengthened oversight of state enforcement mechanisms, and implemented unprecedented efforts to improve nutrition and prevent bed sores. Finally, the Administration recently instructed states to impose immediate sanctions, such as fines, against nursing homes any time that a nursing home is found to have caused harm to a resident on consecutive surveys, in order to put additional pressure on nursing homes to meet all health and safety standards.



PRESIDENT'S ADVISORY COMMISSION ON **Consumer Protection AND Quality IN THE Health Care Industry**

Improving Quality in a Changing Health Care Industry

Chapter One The State of Health Care Quality: How Good Is Care?

Across the Nation, skilled practitioners and high-caliber institutions help to maintain or restore Americans' health and ability to function. While most Americans receive high-quality health care, too many patients receive substandard care. Quality problems have been identified, including (1) avoidable errors, (2) underuse of health care services, (3) overuse of services, and (4) variation in services. These shortcomings endanger the health and lives of all patients, add costs to the health care system, and reduce productivity. Efforts by public and private sector stakeholders have helped to identify problems and begin the process of finding solutions. What is needed now is a national commitment to measure, improve, and maintain quality care for all citizens.

The Best of Care, The Worst of Care

Every day, millions of Americans have access to the best quality health care available in the world. Skilled practitioners, high-caliber institutions, and top-flight researchers continue to advance the science and practice of health care. Yet many Americans increasingly are concerned about the quality of the care they receive and the ability of the health care industry to provide high-quality care on a consistent basis.

Exhaustive research documents the fact that today, in America, there is no guarantee that any individual will receive high-quality care for any particular health problem. The health care industry is plagued with overutilization of services, underutilization of services, and errors in health care practice.

These quality problems are not new, nor are they unique to any particular type of arrangements through which health care is financed and delivered. The term "managed care" denotes a wide spectrum of health care arrangements, including health maintenance organizations, preferred provider organizations, and point-of-service arrangements. Both the best and the worst health care our system has to offer can be found in managed care plans, as it can in traditional fee-for-service (or indemnity) arrangements (Miller and Luft, 1997).

Key indicators of the quality problems we face include:

- **Avoidable errors.** Many Americans are injured during the course of their treatment, and some die prematurely as a result. A study of 30,121 randomly selected records from patients treated in New York hospitals found that adverse events occurred in 3.7 percent of hospitalizations and adverse events attributable to negligence in 1 percent of hospitalizations (Brennan et al., 1991). About 70.5 percent of the adverse events gave rise to disability lasting less than 6 months, 2.6 percent caused permanently disabling injuries, and 13.6 percent led to death. A national study found that from 1983 to 1993, deaths due to medication errors rose more than twofold with 7,391 deaths attributed to medication errors in 1993 alone (Phillips et al., 1998).
- **Underutilization of services.** Millions of people do not receive care they need and suffer needless complications that add to health care costs and reduce productivity. For example, a study of Medicare patients with myocardial infarction found that only 21 percent of eligible patients

received beta blockers, and that the mortality rate among recipients was 43 percent less than that for nonrecipients (Soumerai et al., 1997). An estimated 18,000 people die each year from heart attacks because they did not receive effective interventions (Chassin, 1997).

- **Overuse of services.** Millions of Americans receive health care services that are unnecessary, increase costs, and often endanger their health. For example, an analysis of hysterectomies performed by seven health plans estimated that one in six was inappropriate (Bernstein et al., 1993).
- **Variation in services.** There is a continuing pattern of wide variation in health care practice, including regional variations and small-area variations (Wennberg and McAndrew, 1998). This is a clear indicator that the practice of health care has not caught up with the science of health care to ensure evidence-based practice in the United States.

Despite this growing body of evidence, the American health care industry still does not have the ability to systematically measure and report on the quality of health care that is delivered to patients. What is known, however, indicates that there are substantial areas for improvement in the quality of care.

The lack of comprehensive information on the quality of American health care is unacceptable in an industry that accounts for more than \$1 trillion in annual expenditures and comprises nearly one-seventh of the U.S. economy.

These problems with the quality of American health care present a clear and compelling argument for national action. Recent advances in the science of medicine, the measurement of quality, and the public and private commitment to accountability in the health care industry provide the Nation with a tremendous opportunity to improve the quality of health care in the United States. To achieve this necessary progress, we will need a national commitment to quality improvement, beginning with leadership from the highest levels of government, industry, labor, and the health care professions.

Evidence of Quality Problems

Quality of care has been defined by the Institute of Medicine as "the degree to which health services for individuals and populations increase the likelihood of desired health care outcomes and are consistent with current professional knowledge" (Lohr, 1990). Researchers have documented a tremendous amount of unevenness in the quality of health care services rendered in the United States. These problems fall into four distinct categories: avoidable errors, underuse of services, overuse of services, and variation in practice.

Evidence of Errors in Health Services

A review of the literature provides estimates of unacceptably high error rates in the United States (Leape, 1994). One study of 30,121 randomly selected records from 51 randomly selected hospitals in New York State found that adverse events occurred in 3.7 percent of hospitalizations and 27.6 percent of the adverse events were due to negligence (Brennan et al., 1991).

There are a variety of types of error that occur in the delivery of health services, including missed diagnoses, errors in the interpretation of laboratory or imaging studies, medication administration or prescribing errors, surgical errors, and errors in the care furnished by doctors, nurses, and other health care professionals.

- Missed or delayed diagnoses can significantly affect patient outcomes. A study in a rural trauma center found that about 3 percent of patients experienced a delay in diagnosis (Aaland and Smith, 1996).
- Errors in the interpretation of laboratory tests can contribute to missed or delayed diagnoses. One study reported that 10 percent to 30 percent of test results were inappropriately classified as normal based on rescreening reviews (Wilbur, 1997).
- Surgical pathology errors can contribute to missed diagnoses. One study found major errors (those likely to affect patient care management) in 1.2 percent of the pathology cases

examined prospectively (Lind et al., 1995).

- o Medication errors are a major example of misuse of health care services. One study conducted in a teaching hospital found about four errors per 1,000 medication orders; 70 percent of these errors were classified as those with the potential for serious adverse outcomes (Lesar, Briceland, and Stein, 1997). The most common type of error is related to knowledge and the application of that knowledge to the use of the medication.

Another study found that antibiotics, cardio-vascular agents, gastrointestinal agents, and narcotics were the most common medications involved in errors (Lesar, Lomaestro, and Polh, 1997). A study that examined the preventability of adverse reactions to medications found that about 28 percent were preventable overall and 42 percent of the life-threatening events were preventable (Bates et al., 1995). Studies of medication errors have evaluated the processes by which errors occur. One such study in pediatrics found lower rates of error associated with verbal orders (2.6 per 1,000) compared with handwritten or computer-entered orders (8.5 and 6.3 per 1,000, respectively) (West et al., 1994).

Preventable deaths represent another view into the prevalence of errors in practice. An assessment of deaths from stroke, pneumonia, or heart attack in 12 hospitals indicated that 14 percent could have been prevented if adequate diagnosis and treatment had been provided (Dubois and Brook, 1988). An evaluation of fetal and maternal outcomes following emergency cesarean section found that 60 percent of the infant deaths (5 infants out of 20 that had fetal heart tones) could have been prevented with earlier diagnoses and by performing cesarean sections (Morris et al., 1996).

Evidence of Underuse of Services

Underuse of health care services occurs when there is evidence that a patient did not receive a service or procedure whose benefits exceeded its risks. Underuse may occur in the provision of preventive, acute, and chronic care. When underuse occurs in preventive care, opportunities to prevent the development of disease are forgone. In acute care, underuse may result in excess days in bed or the development of serious complications. And underuse in the provision of chronic care services may have serious consequences for functioning and quality of life and may result in premature death. Americans who have no health insurance or who are underinsured experience particularly high rates of underuse of all three types of services. Further, underuse of services plays a role in the large and widening gap in health status observed between racial minorities and other Americans (see Chapter 8).

Preventive care. A classic example of underuse of services in the United States is childhood immunizations. Immunizations have virtually eliminated the incidence of polio, diphtheria, tetanus, and whooping cough from the set of infectious diseases of childhood. Vaccines for other conditions, such as haemophilus influenzae type B, measles, mumps, rubella, chicken pox, and hepatitis type B, offer the same potential. Yet a nationally representative survey of parents in 1995 estimated that only 76 percent of children had received the appropriate set of immunizations by 18 months of age (CDC, 1997). Recent data from the Health Plan Employer Data and Information Set (HEDIS) indicate that only 66 percent of children enrolled in 330 managed care plans had received appropriate immunizations by age 2 (NCQA, 1997). The range among individual health plans was from 20 percent to 95 percent.

Among adults, the two key immunizations are influenza vaccines, recommended annually for those over age 65 and for those with selected chronic health problems, and pneumococcal vaccines, recommended once for persons over age 65 and for those at increased risk of serious complications from pneumonia. A nationally representative survey of adults age 65 and older conducted in 1993 found that only 52 percent had received an annual influenza vaccine and only 28 percent had received a pneumococcal vaccine (CDC, 1995a).

Another type of preventive service is routine screening of persons without symptoms to

detect the presence of disease at an early stage. Studies have found room for improvement in screening rates. For instance, a nationally representative sample of women age 50 and older found that 45 percent had a mammography in the previous year (CDC, 1993a). A survey of women age 18 and older found that 67 percent had received a pap smear in the previous 3 years (CDC, 1995b). Finally, a national study of persons 40 and older found that just 14 percent of men and 27 percent of women had received a fecal occult blood test to screen for colorectal cancer in the past year (CDC, 1995b). More recent data from National Committee for Quality Assurance show that managed care plan enrollees obtained screening services at higher rates than these national averages (NCQA, 1997).

Another type of preventive care is characterized by counseling or other interventions to prevent behaviors that are known risk factors for the development of serious chronic conditions. Smoking causes 19 percent of deaths annually (McGinnis and Foege, 1993), and advice from a practitioner to quit smoking has been demonstrated to be an effective intervention (USPSTF, 1996). Yet a survey of smokers age 18 and older indicated that 37 percent had been advised to quit smoking in the past year by a health professional (CDC, 1993b), again with significantly higher rates of such advice among smokers in managed care plans (NCQA, 1997).

Acute care. A leading indicator of the quality of acute care is the proportion of pregnant women initiating prenatal care in the first trimester. In 1992, about 78 percent of women nationally initiated prenatal care in the first trimester (PHS, 1995). The rate was 85 percent among women enrolled in managed care plans reporting HEDIS data (NCQA, 1997).

Care for heart attacks provides another important example of underuse of potentially effective care:

- In a study of Medicare patients in four States who had experienced heart attacks, 61 percent received aspirin within the first 2 days of hospitalization; 83 percent received aspirin at some point during the hospitalization; and 77 percent received aspirin at discharge (Krumholz et al., 1995; Ellerbeck et al., 1995).
- Thrombolytic therapy, which can reduce mortality among heart attack patients by as much as half if administered within a few hours of symptom onset, was given to 70 percent of ideal candidates (Soumerai et al., 1997).
- Among Medicare patients in New Jersey, only 21 percent of heart attack patients received beta blockers within 90 days of their heart attack; those receiving beta blockers had a 43 percent lower rate of mortality than those who did not (Soumerai et al., 1997).

Chronic care. Assessing quality of care for chronic conditions tends to be complex because multiple processes are required, stratification by severity may be necessary, the need for clinical detail from health records is greater, and the settings of care are varied. However, failure to receive high-quality care for chronic conditions may have the greatest potential consequences for the health and functioning of the population.

Chronic illness has replaced infectious diseases as the number one source of death in the world. Approaches for treating chronic conditions are growing, from high-tech treatments such as coronary artery bypass graft surgery or angioplasty to low-tech solutions such as home care and assistive devices. Yet knowledge about the quality of care for chronic illness or the efficacy of many treatments for producing desirable outcomes is in its infancy. For example, hip fractures and strokes -- the two most common disabling conditions in older people -- often result in profound functional losses. Among hip fracture patients, between 55 percent and 75 percent lose their ability to perform basic activities of daily living. Among stroke survivors, about 40 percent have moderate functional impairments 6 months later and 10 to 15 percent remain severely disabled. Despite such impacts, the effectiveness of different rehabilitation options for restoring function and preventing long-term nursing home placement is largely unknown (Kramer et al., 1997).

In other cases, knowledge of the most efficacious treatment of chronic conditions does exist, yet treatment approaches are unevenly applied. Care for persons with diabetes provides an example. In 1989, 49 percent of people with diabetes in the United States had received a dilated eye examination in the past year and 66 percent had received one in the past 2 years (Brechtner et al., 1993). A study of Medicare patients in Alabama, Iowa, and Maryland reported that 46 percent had an eye examination and 16 percent had received a glycosylated hemoglobin test, a marker for glucose control in diabetes (Weiner et al., 1995).

Similar findings have been demonstrated for mental health conditions. One study found that only 20 percent to 30 percent of general medicine patients with depression were prescribed antidepressant medications; among those prescribed medication, 30 percent received a subtherapeutic dose (Wells et al., 1994). A recent consensus panel on the undertreatment of depression concluded that "there is overwhelming evidence that individuals with depression are being seriously undertreated" (Hirschfeld et al., 1997).

Evidence of Overuse of Services

Overuse occurs when a health service is provided that poses substantially greater risks than potential benefits to the patient. Overuse of services is found in all areas of medicine and in all settings of care although the magnitude of overuse varies widely from procedure to procedure. Examples include:

- A study of appropriate use of coronary artery bypass graft (CABG) surgery among the Medicare population in the early 1980's found that about 14 percent of procedures were inappropriate and an additional 30 percent were of uncertain clinical value (Winslow et al., 1988). A more recent study in New York found that just 2 percent of CABG procedures were inappropriate and about 7 percent were of uncertain value (Leape et al., 1993).
- A study on the appropriateness of carotid endarterectomy found that 18 percent were inappropriate, 49 percent were of uncertain clinical value, and 33 percent were appropriate (Wong et al., 1997).
- A study of cataract surgery in 10 academic health centers found this procedure to be appropriate most of the time, with just 2 percent of procedures being judged clinically inappropriate (Tobacman et al., 1996).
- A study of appropriateness of hysterectomy use in different health plans found that about 16 percent of women underwent hysterectomy for reasons judged to be clinically inappropriate (Bernstein et al., 1993). Nationwide, over 510,000 hysterectomies were performed in 1994 (Agency for Health Care Policy and Research, 1997).
- One study found that 23 percent of requests to insert tympanostomy tubes in children with chronic ear infections were clinically inappropriate and an additional 36 percent were of questionable clinical utility (Kleinman et al., 1994).

Another significant area of overuse of health services lies in the use of medications. Treatment of respiratory infections (common cold, influenza, sore throat, sinus infections, bronchitis, and pneumonia) is the most common reason for Americans visiting a physician, representing about 10 percent of all visits among adults and 13 percent of visits for children (NCHS, 1994a; NCHS, 1994b). The cause of many upper respiratory infections is a virus, and antibiotics are not an effective treatment for viral illnesses. Yet several studies have reported high rates (30 to 70 percent) of inappropriate prescription of antibiotics for viral infections (Mainous et al., 1996; McCaig and Hughes, 1995; Dowell and Schwartz, 1997). Another study found that unnecessary prescriptions for nonsteroidal anti-inflammatory drugs were written in 42 percent of visits; this pattern of overprescribing can increase risk for hospitalization and death from gastrointestinal bleeding and perforation (Tamblyn et al., 1997).

The appropriateness of hospitalization has been examined in several different studies:

- One study of hospitalization rates in six communities found inappropriate admissions ranging from 10 percent to 35 percent (Siu et al., 1986).
- A study of internal medicine admissions in one hospital found 15 percent of admissions were inappropriate (Perneger et al., 1997).

- An examination of the appropriateness of admission for patients with community-acquired pneumonia found that 61 percent of admissions were medically inappropriate (Porath et al., 1996).

Evidence of Variation in Services

A clear sign of quality problems is the tremendous variation in the delivery of health care services, including sharp regional differences and significant variation even within small areas. Although some variation in services is expected due to differences in health status, available resources, and ambiguity in clinical knowledge, variation of the magnitude observed is not scientifically defensible (Chassin, 1997).

The first evidence of small-area variation in the rates of common surgical procedures was published in the early 1970's (Wennberg and Gittelsohn, 1973). A 1981 study of 123 medical and surgical procedures performed on Medicare beneficiaries in 13 metropolitan areas in the United States found threefold or greater differences for 54 percent of the procedures. A review of the literature in 1987 demonstrated variations at every level (e.g., regional, State, hospital area) and for a variety of utilization dimensions (e.g., length of stay, discharge rates, surgical procedure rates) (Paul-Shaheen et al., 1987).

Regional variation is quite apparent in the use of inpatient hospital services. In 1994, for example, overall hospital discharge rates were 49 percent higher in the Northeast than in the West and lengths of stay were 40 percent higher (Graves and Gillum, 1997). These variations also are apparent among specific conditions. Rates of hospital discharges for diabetes mellitus were 85 percent higher in the South than in the West and discharges for pneumonia were 76 percent higher in the South than in the West. Discharge rates for psychoses were 160 percent higher in the Northeast than in the West and 107 percent higher for asthma (Karuza et al., 1995).

Utilization rates also have been shown to vary within States and regions. A study of hysterectomy rates in Massachusetts between 1982 and 1989 found a fivefold variation (Haas et al., 1993). Hospitalization rates among children with asthma also varied, with children in Boston having a 3.8 percent risk of hospitalization compared with a 2.3 percent rate for children in New Haven, Connecticut. Researchers even found variations in utilization within Los Angeles County (Carlisle et al., 1995).

Variation in utilization is not limited to hospitals. A recent study of the use of hormone replacement therapy (HRT) found that HRT was prescribed in 13.7 percent of visits by women age 40 and older in the West compared to 3.9 percent of visits by women in the Northeast (Stafford et al., 1997). Women living in metropolitan areas were more likely to receive HRT than those residing in nonmetropolitan areas. A study of diabetes care among Medicare beneficiaries in three States found more than a twofold variation in care (Weiner et al., 1995).

Variations also have been demonstrated among individual practitioners. A study of the intensity of treatment provided by psychiatrists and psychologists found that the average time in face-to-face treatment per patient per month varied 244 percent among psychiatrists and 128 percent among psychologists nationally (Knesper et al., 1989). Cesarean section rates were shown to vary from 19.1 percent to 42.3 percent in a study of affluent women cared for by obstetricians practicing at a single community hospital (Goyert et al., 1989). A study of physician differences in the management of low back pain in a single managed care organization found variation in the frequency of prescribing pain medication and bed rest resulting in cost differentials of 79 percent between the high- and low-use groups (Von Korff et al., 1994).

Are Things Getting Worse?

In medicine, as in many other fields of study, as we get better at detecting problems, we find more of them. This is true both in clinical practice and in quality assessment. While we have made advances in our ability to detect problems, it also is quite likely that the rapidly expanding base of knowledge,

coupled with changes in technology, is contributing to an ever-widening gap between the best care possible and the care that is actually delivered.

Every year brings advances in the interventions available to screen for diseases, prevent diseases from developing, make diagnoses, treat conditions, and monitor the progress of disease. For example:

- The reliability of fecal occult blood testing to screen for colorectal cancer has improved sufficiently for the U.S. Preventive Services Task Force to recommend regular screening for adults age 50 and older (PSTF, 1996).
- Immunizations for chicken pox and hepatitis B recently have been introduced.
- Thrombolytic therapy has had a major influence on the treatment of persons with heart attacks.
- Laparoscopic surgery has dramatically changed the functional impact of many procedures, such as cholecystectomy.
- Home glucose monitoring makes it possible for persons living with diabetes to more carefully monitor their treatment and make appropriate adjustments to maintain health.

While these innovations in medicine have significantly, and positively, affected the health of the population, they also pose a challenge for health care practitioners to keep their skills up-to-date. Just reading about advances (as compared to active training in or experience with new techniques) is a daunting task. For instance, according to an analysis of MEDLINE entries, the number of citations reporting on randomized controlled trials has increased from an average of 509 annually between 1975 and 1980 to 8,636 annually from 1993 through 1997 (McGlynn, 1998). Although no practitioner needs to follow advances across all areas of medicine and surgery, rapid expansion of knowledge is occurring even within specific areas. Randomized controlled trials published on coronary artery disease increased from about 6 per year between 1975 and 1980 to 149 per year between 1993 and 1997. For diabetes, the growth was from about 6 per year to about 176 per year in the same time periods. For asthma, citations increased from 13 to 200 annually. And, while there were no randomized trials reported in the literature on laser surgery between 1980 and 1985, about 30 were published per year between 1993 and 1997.

Randomized trials represent only one type of study report that practitioners are expected to track. Large observational studies also contribute new insights into the science of medicine. Considerable attention is being paid to methods for making information more readily available to practitioners, such as through the Internet and information systems within health plans. Meta-analysis, a technique that summarizes findings across multiple studies, is another mechanism that may assist practitioners in understanding the "bottom line" message from the literature. Only one citation classified as a meta-analysis appeared between 1985 and 1990, compared with 416 annually between 1993 and 1997.

There also has been an explosion in the availability of practice guidelines, which increasingly are viewed as mechanisms for communicating information about best practices. Between 1975 and 1980, about 1 publication annually was classified as a practice guideline, compared to 454 annually between 1993 and 1997. Initial resistance among practitioners to guidelines has given way to active participation in constructing such guidelines (Hoyt, 1997). The *Directory of Clinical Practice Guidelines*, published by the American Medical Association (AMA), currently lists 1,700 clinical practice guidelines. A survey of physician medical groups and independent practice associations found that 87 percent were developing or implementing guidelines to accomplish either cost containment or quality improvement goals (Fang et al., 1996).

The proliferation of guidelines and concerns about the scientific basis for guidelines in general led the AMA to create the Clinical Practice Guidelines Recognition Program, which will identify evidence-based guidelines meeting a set of criteria developed by a partnership among the AMA, national medical specialty societies, the Agency for Health Care Policy and Research (AHCPR), the American Hospital Association, and the Joint Commission on Accreditation of Healthcare Organizations. In addition, the AHCPR, the AMA, and the American Association of Health Plans are working jointly to develop a comprehensive, Internet-based source of clinical practice guidelines. The initiative, known as the National Guideline Clearinghouse (NGC), will make available a full range of current guidance on treatments for specific medical conditions. The NGC will make full-text clinical practice guidelines, abstracts, summaries, and comparisons available to every physician, health plan, provider, purchaser,

and consumer with access to the Internet. It is anticipated that the NGC will be launched on the Internet in the fall of 1998.

While the "science" of health care advances, increasing attention is being paid to the "art" of health care as reflected in patient evaluations of their experiences with care. While there is a growing emphasis in health care on patient-provider partnership efforts, patients and their health care providers do not always agree on the importance of different elements of care. One study found differences between doctors and their patients on the importance of 73 of 125 elements of care (Laine et al., 1996). Patients ranked provision of information as the second most important aspect of care (behind clinical skill), whereas physicians ranked information sixth. Communication can affect health outcomes. A review of 21 studies found that in 16 a positive relationship between good doctor-patient communication and health outcomes was documented (Stewart, 1995). Outcomes that were positively influenced included emotional health, symptom resolution, function, clinical outcomes, and pain control.

Poor communication can lead to patient failure to adhere to recommended treatment regimens. A study in five urban teaching hospitals in the Northeast found that dissatisfaction with discharge instructions was a key factor that resulted in 12 percent of patients not filling their prescriptions (Thomas et al., 1996). A study conducted in Canada found that 20 percent of hospitalized patients reported that they were not told about important side effects of medications they were taking and 20 percent of patients undergoing tests indicated that results were not explained (Charles et al., 1994).

In summary, we know enough from the results of studies of variability, overutilization, underutilization, and errors to draw some conclusions about the level of quality. We know that there is a gap between best practices and actual practices. We know that even highly trained health professionals make mistakes from time to time. And we know that the likelihood that any one of us will get the best care possible varies considerably.

Quality Improvement Techniques

While a substantial amount is unknown about how to change behavior of patients and practitioners, we are learning more every day, and a wide range of effective techniques are already available to improve the delivery of health services. Much is being learned about effective techniques used in other industries. A key step in designing effective quality improvement interventions is identifying likely reasons for suboptimal performance and tailoring the interventions to address those deficiencies. Three main targets of intervention are the health professional, the patient, and the health service delivery system. Many interventions are directed at a combination of these targets.

Provider-Oriented Interventions

One explanation for identified quality of care problems is that the health care practitioner has erroneous, outdated, or absent information or skills. Given the rapid increase in new information, this problem is hardly surprising. The traditional approach to keeping practitioners up-to-date is continuing professional education. A review of 99 education strategies designed to improve practitioner performance found that the traditional continuing medical education (CME) conference was not, by itself, an effective mechanism of change (Davis et al., 1995). More individualized outreach educational efforts involving leaders, often referred to as academic detailing, are more effective than traditional educational interventions (Soumerai and Avorn, 1990). A randomized trial in four hospitals in Massachusetts to improve the appropriateness of blood product utilization employed a combination of a departmental lecture, printed guidelines, and a 30-minute, one-on-one visit with each practitioner (Soumerai et al., 1993). The proportion of transfusions in compliance with guidelines 6 months after the intervention increased from 60 percent to 76 percent in the intervention group compared to a decrease from 60 percent to 56 percent in the control group. A trial designed to improve the likelihood that new practice guidelines for influenza immunizations would be adopted tested a small-group discussion and consensus process. Practitioners in the intervention group increased vaccination rates by an average of 34 percent compared to those in the control group (Karuza et al., 1995). Furthermore, all practitioners in the intervention group, compared to 54 percent in the control group, increased

their individual vaccination rates.

Another method for improving care is structured encounter forms that serve to prompt practitioners to provide certain processes during single or multiple encounters. Prenatal care forms are one example. A randomized trial involving pediatric house staff found that the group using a structured form that included key developmental milestones had greater adherence to standards of developmental screening than the group without the form. Parent satisfaction also was higher (Zenni and Robinson, 1996).

Feedback to practitioners about their performance relative to expectations is another method that has been used to improve quality. New York State's Cardiac Reporting System is one of the best known examples of successful public feedback of results. Risk-adjusted mortality rates following coronary artery bypass graft surgery are published for individual hospitals and physicians in the State. Between 1989 and 1992, a 41 percent decrease in risk-adjusted mortality in the State was documented (Hannan et al., 1994). Private feedback to practitioners about performance is more common. For example, a combined strategies trial using an evidence-based protocol, an opinion leader, CME rounds, and feedback demonstrated a reduction in the use of superficial cultures to evaluate sepsis in neonates from 50.5 percent to 6.9 percent (Paes et al., 1994).

Patient-Oriented Interventions

Patient refusal to participate in recommended interventions, such as routine screening, frequently is cited as a problem. Thus, some interventions have focused on patients, most commonly to enhance rates of preventive service use and to improve management of chronic conditions. In the review of the literature on changing practitioner performance, patient-mediated strategies were identified as one of the successful approaches. For example, a trial designed to improve the effectiveness of management for persons with depression included patient education materials (both video and written), along with increased intensity and frequency of visits and ongoing medication management. Patients with major depression in the intervention group were more compliant with medication dose and duration, rated the quality of care higher, believed that medication had helped their condition, and showed a significant reduction in symptoms and disease severity (Katon et al., 1995). Patients with minor depression also adhered more closely to medication regimens and believed that medication was helping them, but did not demonstrate significant improvement in symptoms, severity, or satisfaction relative to the control group.

Reminder systems have been used to help both patients and practitioners increase adherence to preventive service recommendations. A study of patient-directed methods for improving mammography rates compared three strategies: (1) mailed birthday card reminders; (2) a personalized letter from the medical director with educational materials enclosed; and (3) phone calls that included reminders, counseling, and appointment scheduling. Although overall rates of adherence were small, the most effective strategy was phone calls (28 percent), followed by birthday reminders (15 percent), and then mailed materials (9 percent) (Davis et al., 1997).

As with health care practitioners, consumer education strategies alone do not appear to be effective. For example, a randomized trial of a patient education program designed to reduce emergency room use for persons with asthma found no difference between the control and intervention groups in the first year following the intervention (Shields et al., 1990). A study of methods for improving influenza vaccination rates among the elderly combined community-based education with making the shots available for free. The educational intervention alone improved rates from about 41 percent to 54 percent; the addition of free shots increased rates from 41 percent to 64 percent (hospital-based) and 69 percent (physician-based) (Ives et al., 1994).

Systems-Oriented Interventions

Perhaps the most important innovation in quality improvement has been the increased focus on system-related problems. Continuous quality improvement (CQI) and total quality management (TQM) programs have demonstrated the importance of examining multiple steps in the process of

delivering care to identify opportunities for system redesign.

One starting point for quality improvement programs may be to examine the factors contributing to errors in processes or outcomes of care. For example, an assessment of factors contributing to errors in an intensive care unit found that human error was a factor in 55 percent of incidents and that violations of practice standards were a factor in 28 percent (Buckley et al., 1997). Both direct observation and monitoring systems were used to detect errors. A prospective observational study of the causes of adverse events in the hospital found that about 18 percent of patients experienced an adverse event and that 38 percent of these were caused by an individual, 16 percent were the result of systems factors, and 10 percent were due to administrative decisions (Andrews et al., 1997).

A related approach is to examine the processes by which certain interventions are provided, particularly those that require several steps to accomplish a goal. For example, staff in a health maintenance organization (HMO) examined the processes by which complete blood counts, mammograms, and surgical consultations were ordered and provided across nine clinics in the system. Variations in both the intent and successful implementation of steps in each of these interventions were noted; enhanced information systems were identified as one potential solution to some of the problems identified (Banks et al., 1995).

System redesign has been used frequently to improve the use of preventive services, particularly by reducing missed opportunities to provide the intervention. For example, to improve rates of mammography, medical assistants and licensed practical nurses were trained to determine if a woman visiting the clinic was due for a mammogram and, if so, were allowed to offer and order the test. The proportion of visits in which women were up-to-date on mammography screening increased in the intervention clinic from 68 percent to 77 percent compared with a 1 percentage point increase in one control clinic and a 2 percentage point decline in another control clinic (McCarthy et al., 1997).

Large-scale systems redesign has been shown to be effective in improving adherence to preventive service recommendations. For example, at Group Health of Puget Sound, a combination of strategies has demonstrated effectiveness. Eighty-nine percent of enrolled children have complete immunizations, the proportion of smokers has declined from 25 percent to 17 percent, bicycle helmet use among children has increased from 4 percent to 48 percent, and head injuries for this group decreased 67 percent (Thompson et al., 1995).

Quality improvement programs are designed around a team model, and the effective functioning of the team is likely to be critical to the success of the enterprise. A study of quality management teams in Veterans Administration hospitals found that commitment to total quality management by the facility and practitioners along with the number of teams involved in active quality improvement projects explained a substantial portion of the variation in quality improvement realized across the hospitals (Lammers et al., 1996). Inappropriate prescribing of medications for elderly outpatient veterans on multiple drug regimens was significantly reduced by adding a clinical pharmacist to the treatment team (28 percent decline in the intervention groups vs. 5 percent in the control group at 12 months) (Hanlon et al., 1996).

A National Commitment Is Needed

Quality of care in the United States varies considerably within and across communities, hospitals, practitioners, patients, delivery systems, geographic areas, and health problems. This variation is itself inconsistent -- meaning that the same groups do not always perform best or worst, making it difficult to develop programs to improve quality based on current knowledge. The real level of quality in most areas of the country is unknown, but what we do know suggests that we can no longer afford the luxury of ignorance.

What is needed to move forward? Significant advances have been made in the methods of quality measurement so that it is possible to assess the quality of care for diverse conditions in a variety of

settings. We need to implement such measurement activities systematically, and on a broad national scale. This will require investment in people, methods, and data systems. We also need to find mechanisms for making the lessons of quality improvement available to all participants in the health care industry. The quality of services can be improved, but doing so requires an understanding of the extent of the gap between standards and actual practice, the likely causes of the gap, effective tools for closing the gap, and a cultural change that values engaging in ongoing quality improvement.

To accomplish these vitally important aims, the United States needs a national commitment to the measurement, improvement, and maintenance of high-quality health care for all its citizens. The body of this report lays out a series of steps that must be taken by all sectors -- public and private -- to achieve the goal of a quality health care system for all Americans.

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DUE TO MEDICAL ERRORS*****MDPad Solves Critical Problems Raised in Institute of Medicine Study***

EAST BRUNSWICK, NJ—November 30, 1999—The large number of unnecessary deaths caused by medical errors will be significantly reduced through an innovative technology under development by a new company, according to the founder of MDPad. Dr. Pankaj Merchia, a physician with additional training in biomedical engineering and computer science, has created a hand-held tool for physicians to write error-free prescriptions.

Yesterday, an expert panel of the Institute of Medicine released a study indicating that 98,000 Americans die each year as the result of medical errors. The study reported that medication errors were the largest single cause of these deaths.

"Patients have a right to the best care a physician can provide," said Dr. Merchia. "We are developing a new technology for physicians to increase the safety and efficacy of their patients' care. There is a need for products and services that will help to eliminate the all too common occurrence of medication errors and MDPad will eliminate these errors and save lives," said Dr. Merchia.

It is becoming increasingly difficult for physicians to maintain effective continuing medical education and patient care due to a variety of time constraints. Cutting-edge advances in science and technology today have enabled a great deal of progress in the healthcare industry. Physicians are often overwhelmed by the multitude of new advances accessible to them. Many of the new tools that are available to improve patient care and ensure safety are not utilized due to lack of time or availability of necessary training.

MDPad is an innovative hand-held device that serves as an easy-to-use electronic prescription pad offering real-time medical education focused on the individual patient visit. MDPad was founded by a group of physicians at Harvard Medical School and Massachusetts General Hospital. MDPad is currently testing its new technologies with a national panel of expert physicians and will be available to physicians free-of-charge in the first quarter of next year.

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Clinton says technology could reduce medical errors

WASHINGTON, Nov 30 (Reuters) - Health care reform and better uses of technology are necessary to prevent the high number of U.S. deaths and injuries caused through medical errors, President Bill Clinton said on Tuesday

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"We know that otherwise competent people are making a lot of these mistakes," Clinton told a news briefing. "We've got to work through how we can use technology and how we can maybe even slow some of the actions to make sure that mistakes like this aren't made."

Clinton was responding to National Academy of Sciences report that said the errors of U.S. physicians, pharmacists and other health care providers cause the deaths of between 44,000 and 98,000 people every year -- more than highway accidents, breast cancer and AIDS.

More than 7,000 of those deaths occur as a result of "medication errors," which include the prescribing or dispensing of the wrong drugs.

"Health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety," the academy's Institute of Medicine said in the report.

The academy is lobbying Congress to create a patient safety center within the U.S. Department of Health and Human Services to improve health care and track medical errors. They said the government should strive to reduce medical errors by at least 50 percent in the next five years.

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11/30/1999

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American Medical Association

Physicians dedicated to the health of America



Statement

FOR IMMEDIATE RELEASE

November 30, 1999

AMA ON IMPROVING PATIENT SAFETY

Statement attributable to:

Nancy W. Dickey, MD
AMA Immediate-Past President

"The AMA is pleased the Institute of Medicine is taking a serious look at patient safety and is recommending a plan to improve the best medical care in the world.

"Any error that causes harm to a patient is one error too many. In general, medicine is very safe, but medicine is also very complex and is not without risk.

"While we may never achieve perfection, we must continue to strive for it. In its continuing effort to improve patient care, the AMA and other organizations launched the National Patient Safety Foundation in 1997 to acknowledge and address error in the health care system.

"NPSF is taking a new approach to reducing errors and accidents in health care that emphasizes a systems-learning approach, as opposed to methods that focus only on blame and punishment. The health care system is in place to heal not harm. But when an error occurs, it's important to learn from it so as not to repeat it.

"As the IOM report says, the majority of medical errors do not result from individual recklessness, but from basic flaws in the way the health system is organized.

"Medical science can do more to prevent and cure illness than ever before, but we cannot be satisfied with good when we can do even better. The AMA and the National Patient Safety Foundation will continue to lead the effort to improve patient safety."

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 13, 1998

PRESIDENT ENDORSES QUALITY COMMISSION'S FINAL REPORT
AND ISSUES EXECUTIVE MEMORANDUM
TO IMPROVE HEALTH CARE QUALITY

March 13, 1998

Today, the President accepted the final report from his Advisory Commission on Consumer Protection and Quality. The report calls for a health quality council to develop unprecedented national quality improvement goals and a privately-administered forum to develop new tools to empower consumers and businesses to purchase quality health care. The President praised the Commission's work and endorsed its new recommendations for a national effort to improve quality throughout the health care system.

Hundreds of thousands of Americans each year are injured and even die from avoidable medical errors in the health care system, and millions more receive unnecessary services or substandard care that cause needless health complications and increase health care costs. Establishing uniform standards will help ensure that health plans finally begin to compete on the basis of quality -- not just costs and benefits.

To implement these new recommendations, the President also issued an Executive Memorandum that directs five Federal agencies to establish immediately an interagency task force to ensure the Federal government takes the lead on improving health care quality. The President also asked the Vice President to hold a blue ribbon planning meeting this June, to kick off the work of the health care forum recommended by the Quality Commission.

The President created the 34-member Advisory Commission on Consumer Protection and Quality in the Health Care Industry on March 26, 1997, charging it with "recommend[ing]" such measures as may be necessary to promote and assure quality and value and protect consumers in the health care industry. In November, the Commission recommended to the President a "Consumer Bill of Rights." The President endorsed these protections and directed the Federal Government to come into compliance with this bill of rights and called on Congress to pass legislation to make these protections real for all Americans.

NUMEROUS INCONSISTENCIES AND AVOIDABLE ERRORS IN THE NATION'S HEALTH CARE SYSTEM COST LIVES AND UNDERMINE HEALTH. Too many Americans receive substandard health care, causing avoidable injuries and death, needless complications, and increased health care costs, including:

Avoidable errors: Hundreds of thousands of Americans are injured each year with tens of thousands dying as a result of avoidable errors in hospital care.

Underutilization of services: Millions of Americans do not receive necessary care and suffer needless complications that can add to health care costs. For example, far too many Americans do not get the preventive care they need.

Overuse of services: Others receive unnecessary health care that can increase costs and even endanger a patient's health. For

example, 80,000 women every year undergo unnecessary hysterectomies.

Wide variation in health care quality: There is tremendous variation in health care services including wide regional disparities and different hospitalization rates for similar conditions.

ENDORSED COMMISSION'S NEW RECOMMENDATIONS TO IMPROVE QUALITY HEALTH CARE. The President endorsed the Commission's recommendations which call for:

Creating an Advisory Council for Health Care Quality. This public advisory panel would establish, for the first time, national goals to improve health care quality and develop strategies to achieve them. The Council would emphasize areas such as ensuring consumers have access to clear information to make decisions about health plans and professionals, identifying strategies to reduce avoidable medical errors, reducing variation in health care services, and promoting evidence-based medicine. Such a council, which would include representatives from both the public and private sector, would make an annual report to Congress on the nation's progress in improving health care quality.

Creating a Health Care Forum and Asking the Vice President to Hold the First Planning Meeting This June. The absence of uniform quality standards means that consumers do not have the necessary information to choose health plans based on quality. The forum would bring together the public and private sectors to identify a core set of measures to be adopted by health plans across the country. This would ensure that, for the first time, consumers have a consistent set of standards so they can choose health plans based on quality -- not just on cost. The President asked the Vice President to hold a blue ribbon planning meeting this June to kick off the work of the health quality forum as recommended by the Commission.

ISSUED A PRESIDENTIAL MEMORANDUM DIRECTING AGENCIES TO DEVELOP A FEDERAL TASK FORCE TO COORDINATE AND IMPROVE HEALTH QUALITY. The President directed the Departments of Health and Human Services, Labor, Veterans Affairs, Defense, and the Office of Personnel Management to establish the "Quality Interagency Coordination" (QuIC) task force. He directed this task force to ensure better collaboration and coordination across the Federal government, through initiatives such as developing consistent goals, models, and timetables; sharing information about evidence-based medical research and quality outcomes, and coordinating Federal programs' quality reporting and compliance requirements.

RENEWED HIS CALL ON CONGRESS TO PASS A PATIENTS' BILL OF RIGHTS THIS YEAR. Following his speech earlier in the week to the American Medical Association, the President urged Congress to step up its efforts to pass a Patients' Bill of Rights this year. He also asked Congress to ensure that the Patients' Bill of Rights includes the health care quality council the endorsed today. With fewer than 70 working days in this legislative session, the President urged Congress not to adjourn without passing a Patients' Bill of Rights that includes important protections for patients such as: access to the specialists they need, access to emergency room services, and an external appeals process to address grievances with their health plans.