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DETERMINED TO BE AN
ADMINISTRATIVE MARKING

THE HMO GROUP

INITIALS: MA DATE: 7.6.05

PRINCIPLES FOR PATIENT PROTECTION AND HEALTH PLAN RESPONSIBILITIES

Accessibility of Services

An adequate health plan delivery system is essential to ensuring that the patient's health care needs can be met in a timely and appropriate manner. Access includes:

- The timely provision of medically necessary services;
- Efficient administrative procedures for specialty care;
- Ensuring that written materials and member services are understandable and responsive to members' language needs; and
- An adequate number of physicians, other health care professionals and facilities and their locations.

To ensure access to quality care, health plans should:

- Have enough primary care physicians, specialists, and other providers to provide timely, appropriate care;
- Provide women with direct access to routine obstetrical and gynecological services by participating obstetricians and gynecologists or other participating physicians or practitioners qualified to provide obstetrical and gynecological services;
- Provide access to specialists and specialty care centers affiliated with the health plan as needed for treatment, including standing referrals to specialists when appropriate;
- Provide out-of-network referrals at no additional cost to the member when the health plan does not have a network physician with the appropriate training or experience or when the health plan does not have an affiliation with a recognized specialty care center to meet a member's covered medical needs; and
- Health plans should make reasonable efforts to provide health care plan information in a culturally and linguistically competent cost effective manner.

Choice

Consumer satisfaction is enhanced in an environment that includes choices among health plans care systems and providers. Choices of providers include the option of changing personal primary care physicians at any time.

- Members should have available to them a choice of health plans or a choice of physicians within an organized system of care offered by a health plan;
- Health plan participation in appropriate health care purchasing cooperative arrangements should be encouraged.

Confidentiality of Health Plan Information

Consumers should be assured that their health care information will remain confidential. Health plans, purchasers and providers should safeguard against improper release of patient specific information by developing and monitoring policies and procedures protecting patient records and reports.

- There should be strong protections against improper disclosure of patient-identifiable medical information by health plans. Health plans must have written policies and procedures protecting the confidentiality of patient information and records;
- Health plan staff with access to patient-identifiable information should be trained in the plan's confidentiality policies;
- Contractors, sub-contractors or individuals with access to patient-identifiable health information should be informed of the health plan's confidentiality policies and required to adhere to them.

Continuity of Care

To ensure that care is continuous and coordinated the health plan should have arrangements that encourage the member to select a regular source of care. For in-network services, the health plan or its provider network should:

- Coordinate the provision of health care services to members and monitor their overall health status;
- Promote the achievement of needed preventive health services for all members
- Ensure that members have timely access to their medical records and that the records are complete and consistently maintained.

To further promote care transitions, health plans should:

- facilitate a smooth transition to a new health care professional in the plan's network, at the member's request, including providers or the health plan as appropriate making a copy of the medical records available, as authorized by the member, to all health care professional that provide care to the member;
- have policies and procedures to facilitate the transfer of care from one provider to another for members who are undergoing an active course of treatment for a life-threatening disease or condition or a degenerative and disabling disease or condition, or if a patient is in the second or third trimester of pregnancy.

Note:

These members should be able to continue to receive medically necessary care from their treating providers for a defined period of time e.g., up to 60 days (or through post-partum for care related to delivery) when:

- 1) a new member to the health plan does not have the option of continuing with their previous physician specialist because their former health plan was replaced; or*
- 2) in the case of existing health plan members, their previous physician specialist's contracts were terminated by the health plan for reasons other than unacceptable quality, fraud, patient abuse, incompetence or loss of licensure.*

In either instance the previous provider agrees to the health plan's conditions of care, including the health plan's protocols with respect to quality of care, transition rules and payment terms applicable to similar providers with the health plan's network for such services and to provide the health plan with necessary medical information related to the member's care.

Disclosure of Information to Consumers

Consumers should receive adequate information to assist them in deciding about joining a health plan. This information should be current, accurate and reliable. Additional, more detailed information should be provided by health plans upon request including such details as training and qualifications of specific physicians.

Health plans should provide consumers with a description of:

- coverage and exclusions;
- cost sharing;
- referral, emergency room and utilization management procedures;
- access to out-of-plan care;
- accessibility of services for consumers with special needs;
- credentials of physicians;
- general information on reimbursement methodologies used to pay providers;
- formularies;
- appeals procedures; and
- contacts for consumer organizations, such as ombudsman programs or government agencies regulating the health plan.

Coverage of Emergency Care

Patients should have access to and coverage for medically necessary emergency care. Health plan coverage should include emergency services, including services provided when a prudent layperson reasonably believes he or she is suffering from a medical emergency (including severe pain).

- Emergency departments should be required to contact health plans or the designated primary care physician within 30 minutes after screening and/or stabilization to obtain authorization for any medically necessary post-stabilization services and the health plan should respond to the emergency room within 30 minutes, unless this process is waived by the health plan.

Determinations of When Coverage is Excluded Because Care is Experimental or Investigational

Exclusions of treatments determined to be experimental should be based on objective and scientific processes for reviewing new drugs, devices, procedures and therapies. These processes should be disclosed to consumers and providers. When coverage for experimental treatments is denied by the health plan and the member has a condition that has a high probability of causing death within two years the decision should be subject to an external review by a panel of impartial and independent experts.

- Health plans should be able to voluntarily select an external, independent review process to examine the cases of seriously ill patients who are denied coverage for experimental treatments. The external process should be subject to review by the appropriate authority and accrediting body.

Development of Formularies

Health plans that utilize a formulary should have a process to evaluate and revise the extent of the prescription drugs that are included on an ongoing basis based on the recommendations of physicians and the needs of the patient population served.

- Health plans that cover prescription drugs and use closed formularies should ensure physician participation in the development of the formularies and provide for an exception process when non-formulary alternatives are medically necessary;
- Health plans should disclose their formularies, including informing a member, upon request, about whether a specific prescription drug is included in the formulary.

Grievances and Appeals

Timely and responsive actions by health plans to resolve members' complaints and grievances are integral to consumer satisfaction and should be a well organized internal component of the health plan. These internal processes should be subject to oversight by regulatory agencies and accrediting bodies. Independent external review processes should be available under appropriate circumstances as defined below. Health plans should provide information concerning a members' appeal rights at the time of enrollment, and when requested by the patient or an ombudsman.

Internal Review of Member Grievances and Appeals

Health plan members may submit appeals to their health plan regarding denials of coverage or care (including termination and reduction of inpatient services) made by the health plan or its

agents, as well as grievances concerning waiting times and other services issues. A health plan's internal procedure should:

- Include the option of the patient obtaining a second opinion of a treating physician's diagnosis or treatment recommendations from another plan physician in the same specialty of the patient's choice;
- Provide timely notice of a denial of coverage or care made by the health plan or its agents (including a notice of appeal rights in advance of reduction or termination of inpatient services). This should include information on how to file grievances and appeal health plan decisions;
- Include a process for an initial decision and a final determination. This process should preclude the involvement of persons who have a direct financial stake in the outcome of the decision;
- Provide for issuance of all final determinations in a timely manner, within no more than 60 days for receipt of all necessary information from the member for non-expedited reviews;
- Provide an expedited process for review of denials of coverage or care which involve the threat of imminent and serious harm to the member's health;
- Ensure that disputes regarding significant issues of medical appropriateness are resolved within the health plan through a formal process which includes disclosure to members of the basis for decisions;
- Provide that, in the case of appeals, where the health plan has determined that a service or treatment is not otherwise covered under the terms of the contract with the member, that the member have the right to appeal to the appropriate state regulatory body to review whether the health plan has properly followed its procedures;
- The appropriate regulatory authority should review the health plan's grievance and appeals procedures to ensure that they are fair and that appropriate procedures have been followed. Health plans should collect data and issue periodic reports to the regulatory authority on the nature and frequency of grievances and appeals.

External Review of a Health Plan's Grievance and Appeals Procedure

- If a health plan has overturned a treating physician's finding of medical necessity (when the treating physician's services are a covered benefit), including by terminating or reducing covered inpatient services that the physician believes are medically necessary other than on the basis that a treatment is experimental or investigational, or if an item or service is contractually excluded as a covered benefit), the health plan should be required to submit, at a member's request after the member has exhausted the plan's internal appeals or grievance process, a final determination regarding an appeal to an independent panel of medical experts for a binding opinion. In addition, a similar right to an external appeal (after exhaustion of the internal process) should be allowed for any other decision regarding medical necessity and appropriateness (other than on the basis that a treatment is experimental or investigational, or if an item or service is contractually excluded as a covered benefit) not supported by a treating physician if the proposed service or treatment would require the plan to provide or cover services (a) when the value of

those services exceeds a significant threshold and the member's health is jeopardized, or (b) when the member's life is jeopardized.

- The panel should be organized by a recognized, impartial independent entity that is under contract with the health plan. The panel should follow a standard of review that promotes evidence-based decision making and relies on objective evidence regarding medical necessity and appropriateness. The medical professionals on a given panel should be independently accredited in the appropriate specialty areas and should not have any conflicts of interest;
- The costs for an external review should be divided equally between the health plan and the member.

Ombudsman Programs

Well-informed consumers are more likely to be satisfied with their choices of health plan and providers and the care that they receive. Patients who are well informed about their health options are more likely to participate in their care and to assume responsibility for complying with treatment plans thereby improving the effectiveness of the health care services.

Health plans should cooperate with independent, recognized ombudsman programs that would:

- assist consumers in understanding the health plan's marketing materials and coverage provisions,
- educate members about their rights within health plans,
- help to identify and evaluate member complaints, and
- assist members in filing formal grievances and appeals and report to appropriate regulatory bodies on issues of concern to consumers.

Out-of-Area Coverage

Consumers with urgent or emergent medical care needs should be covered by their health plan when they are traveling outside the plan's service area.

- Health plans should cover unforeseen emergency and urgent medical care for members traveling outside the plan's service area.
- Members who need to live outside the health plan's service area for extended periods of time, e.g., international travelers, should obtain separate coverage for their non-emergent out-of-area medical needs.

Participation in Treatment Decisions

Improvements in the patient's health status and consumer satisfaction in general can be enhanced in an environment of open communication between patients and providers. Health care professionals should be able to help patients understand their treatment options and the benefits and risks of the alternatives. Health plans should support and facilitate this exchange of information.

- Patients have the right and responsibility to fully participate in all decisions related to their health care. Patients who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members or other conservators. Physicians, with participation of their patients, and where appropriate, in consultation with their peers, should make treatment decisions, consistent with the patient's coverage, based upon the best available scientific evidence. In the absence of scientifically derived/evidence-based standards for medical necessity, health plans should work closely with medical professionals and their patients to provide or arrange for high quality cost-effective care in accordance with covered benefits;
- To ensure patient participation in treatment decisions, health care professionals should provide patients with easily understood information and opportunities to decide among treatment options consistent with the informed consent process;
- Health care professionals should discuss all risks, benefits and clinical consequences of treatment or non-treatment. Patients have the right to refuse treatment and to express preferences about future treatment decisions.

Performance Measurement and Data Reporting

Comparable national standards which are developed cooperatively by consumers, providers, purchasers, health plans and regulators will assist consumers with the process of choosing a health plan or provider. The standards should be relevant to all parties, scientifically sound, feasible to produce, subject to independent verification for accuracy and should protect individual privacy and the confidentiality of medical information. Consumers will benefit from the measurement process as the data stimulate quality improvement activities by health plans:

- Health plans should meet national standards for measuring and reporting performance in areas such as quality of care, access to care and patient satisfaction.

Provider Communication with Patients

Interactions between consumers and health care professionals as well as clinical outcomes are enhanced in an environment of open communication that is unhindered by third parties. Contractual provisions between health plans and providers should not restrict communication of medical advice to patients or include policies or procedures which could penalize providers for advising patients about medically necessary treatment options.

- Health plans should not restrict exchange of information between providers and patients regarding the patient's condition and treatment options. Health plans should not prohibit or otherwise hinder physicians from discussing possible treatment options with the patient or a patient's representative. Health plans should not impose contractual terms or conditions of payment that would interfere with a physician advocating on a patient's behalf or meeting all duties owed a patient; and
- Health plans, their contractors and subcontractors should be prohibited from retaliating against providers or health care workers if they report patient-related concerns to state or federal authorities or to management officials.

Provider Credentialing

The process of health plans evaluating and verifying the qualifications of health care professionals and facilities protects consumers. The credentialing standards should be objective and supervised by appropriate health and medical professionals. The standards and verification procedures should be freely and easily available to consumers, health plan members, and providers who are subject to the review process.

- Health plans and provider groups should develop written standards similar to those used by NCQA for hiring and contracting with physicians, other providers and health care facilities. These standards should be made available to consumers as part of the process of disclosure of information.

Prohibitions Against Discrimination

Health plans and participating providers and facilities have an obligation to ensure that all consumers who wish to enroll in the health plan or members who want to use the providers services are treated in a respectful and appropriate manner regardless of their characteristics, circumstances or values.

- Health plans should not discriminate in the provision of health services on the basis of age, gender, race, national origin, language, religion, socio-economic status, sexual orientation, disability, genetic make-up, health status, or source of payment;
- Health plans should utilize recruitment, retention and contracting policies and practices designed to help assure a health care provider network that is responsive to the cultural needs of the various communities it serves.

Provider Reimbursement Incentives

The purpose of incentive arrangements is to ensure that treatment patterns either improve the quality of care or reduce medically unnecessary costs of care. Incentive arrangements and provider payment methodologies should not result in the creation of barriers to care, or in the under-utilization or over-utilization of health care services. Consumers should be provided descriptive information about the types of provider reimbursement incentives employed by the health plan.

- Neither health plans nor provider groups should use payment methodologies that directly encourage providers to over-treat patients or to limit medically necessary care. Health plans should prohibit at-risk capitation arrangements to individual physicians for services of other providers. If individual providers or small groups of providers are capitated, or if providers are placed at substantial financial risk, then safeguards such as reinsurance or stop-loss coverage should be employed.

Quality Assurance

Comprehensive national standards for quality assurance and quality improvement should be applicable to all health plans. The standards should be evidence-based objective and should enhance the ability of consumers to make more informed decisions about different health plans.

- All health plans should be subject to comparable comprehensive quality assurance requirements. Standards should provide for external review of the quality of care, be conducted by qualified health professionals who are independent of the health plan and accountable to the appropriate regulatory agency;
- External review by a private accrediting body should not be deemed to be sufficient to meet requirements unless an appropriate regulatory body has confirmed that the review is consistent with the national standards for quality assurance.

Utilization Management

Determinations about treatment protocols, patient length of stay, and hospital discharge should be made by the patient's attending physician in consultation with the patient. Health plans should utilize scientifically derived/evidence-based clinical standards of care involving participating physicians in the development and local promotion of the standards. These measures can be used by health plans for the purpose of utilization management consistent with covered benefits. The implementation of such standards should be managed by physicians.

- Utilization management activities should be subject to appropriate regulation, including requirements to use appropriately licensed providers in conducting utilization management activities. Health plans should make timely and, if necessary, expedited decisions;
- Health plans should provide members with written notification of an adverse determination, which should include the principal reason for the determination and instructions for initiating an appeal;
- Health plans should be prohibited from compensation arrangements which include incentives to make review decisions adverse to the patient.

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TECHNOLOGY LIST

REDUCING MEDICATION ERRORS

1. Barcoding medications to match patient identifiers (idea initiated at VA based on the system used to check in car rentals)
2. Creating automated order entry systems that eliminating confusion caused by sloppy handwriting

REDUCING TRANSFUSION ERRORS

1. Barcoding blood transfusions to match patient identifiers

USING COMPUTERIZED MEDICAL RECORDS

1. Hospitals in Indianapolis are using computerized medical records that automatically provide physicians with information from the electronic medical record of the patient and show the physician the results of previous laboratory tests on the patient when they order a new complete blood count or other laboratory test on a patient. The system also shows the physician the time when the last test was ordered, information about cost effective testing and treatment, and information about potential drug interactions and allergies.

TRAINING HEALTH CARE PROFESSIONALS

1. Using "patient simulators" that provide a team of medical students with the experience of treating a critically ill patient in a crisis situation to help them prevent common medical mistakes made under pressure (they are doing this at Harvard)

- Barcoding medications and blood transfusions
to match patient identifiers (Rental cars)

- Automated order entry systems

- Computerized medical records

- Patient simulators (Harvard)

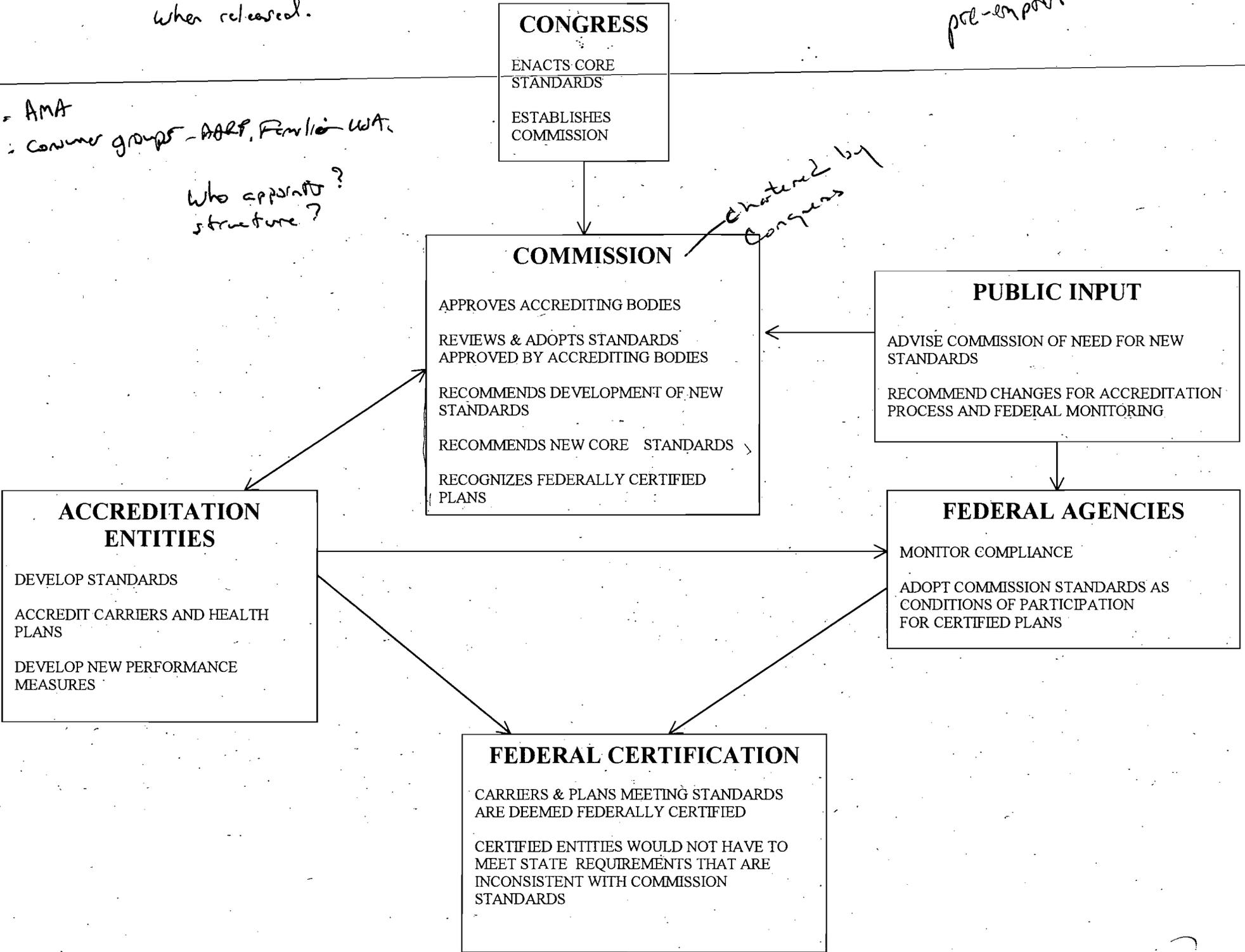
when released.

pre-emptive

- AMA
- consumer groups - AARP, Family USA

Who appoints?
structure?

Chartered by
Congress



CONGRESS

ENACTS CORE STANDARDS

ESTABLISHES COMMISSION

COMMISSION

APPROVES ACCREDITING BODIES

REVIEWS & ADOPTS STANDARDS APPROVED BY ACCREDITING BODIES

RECOMMENDS DEVELOPMENT OF NEW STANDARDS

RECOMMENDS NEW CORE STANDARDS

RECOGNIZES FEDERALLY CERTIFIED PLANS

PUBLIC INPUT

ADVISE COMMISSION OF NEED FOR NEW STANDARDS

RECOMMEND CHANGES FOR ACCREDITATION PROCESS AND FEDERAL MONITORING

ACCREDITATION ENTITIES

DEVELOP STANDARDS

ACCREDIT CARRIERS AND HEALTH PLANS

DEVELOP NEW PERFORMANCE MEASURES

FEDERAL AGENCIES

MONITOR COMPLIANCE

ADOPT COMMISSION STANDARDS AS CONDITIONS OF PARTICIPATION FOR CERTIFIED PLANS

FEDERAL CERTIFICATION

CARRIERS & PLANS MEETING STANDARDS ARE DEEMED FEDERALLY CERTIFIED

CERTIFIED ENTITIES WOULD NOT HAVE TO MEET STATE REQUIREMENTS THAT ARE INCONSISTENT WITH COMMISSION STANDARDS

Andree Walsh - central Parkway -

P6/b(6)

H

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- Payer?

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②

Nancy Ann ③ - 600

Meredith - Oliva ④

Sarah will get → Joe Kodak ⑤
Lehman

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Executive Summary and Actions (DRAFT)

Doing What Counts for Patient Safety: National Action to Reduce Medical Errors and Their Impact

To Err is Human: Building a Safer Health System, a report released late last year by the Institute of Medicine (IOM), shocked the nation by estimating that up to 98,000 Americans die each year as a result of preventable medical errors. The report concludes that the majority of these errors are the result of systemic problems rather than poor performance by individual providers, and outlined a four-pronged approach to prevent medical mistakes and improve patient safety.

On December 7, President Clinton directed the Quality Interagency Coordination Task Force (QuIC) to evaluate the recommendations in *To Err is Human* and to respond with a strategy to identify prevalent threats to patient safety and reduce medical errors. This report responds to the President's request and provides an action plan to implement Administration initiatives designed to help prevent mistakes in the nation's health care delivery system.

A National Epidemic

It is clear that, although the United States provides some of the best health care in the world, the numbers of errors in health care are at unacceptably high levels. The Institute of Medicine's report estimates that more than half of the adverse medical events occurring each year are due to preventable medical errors, causing the death of tens of thousands. The cost associated with these errors in lost income, disability, and health care costs is as much as \$29 billion annually. The consequences of medical mistakes are often more severe than the consequences of mistakes in other industries – leading to death or disability rather than inconvenience on the part of consumers – underscoring the need for aggressive action in this area.

A wide body of research, including many studies funded by AHRQ, supports the IOM conclusions. In a study of intensive care units, the correct medical intervention was taken 99 percent of the time, translating to 1.7 errors per day. One out of five of these errors were serious or potentially fatal. If performance levels of 99.9 percent – substantially better than those found in the ICU – applied to the airline and banking industries, it would equate to two dangerous landings per day at O'Hare International Airport and 32,000 checks deducted from the wrong account per hour (Leape, 1994). A 1999 study of hospital admissions in Colorado and Utah demonstrated that in some health care systems, the number of errors is even higher. In these hospitals, the correct action was taken only 96.3 percent of the time – an alarmingly high prevalence of adverse events (Thomas, 1999).

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Many of these adverse events are associated with the use of pharmaceuticals, and are potentially preventable. The IOM estimates the number of lives lost to preventable medication errors alone account for over 7,000 deaths annually – more than the number of Americans injured in the workplace. In addition, preventable medication errors are estimated to increase hospital costs by about \$2 billion nationwide. A 1995 study estimated that problems related to the use of pharmaceutical drugs account for nearly 10 percent of all hospital admissions, and significantly contribute to increased morbidity and mortality in the United States (Bates, 1995). A 1991 study of hospitals in New York State indicated that drug complications represent 19 percent of all adverse events, and that 45 percent of these adverse events were caused by medical errors. In this study, 30 percent of the individuals with drug-related injuries died (Leape, 1991).

Clinton-Gore Administration's Commitment to Improving Patient Safety

In early 1997, the President established the Advisory Commission on Consumer Protection and Quality in the Health Care Industry (Quality Commission) and appointed Health and Human Services Secretary Shalala and Labor Secretary Herman as co-chairs. The Quality Commission released two seminal reports focusing on patient protections and quality improvement. Subsequent to the Commission's second report on patient safety and quality improvement and consistent with its recommendations, the President established the Quality Interagency Coordination Task Force (QuIC), a umbrella organization also co-chaired by Secretary Shalala and Secretary Herman, to coordinate Administration efforts to improve quality. As he established the QuIC, the President stated that "For all of its strengths, our health care system still is plagued by avoidable errors."

Also consistent with the Quality Commission's recommendations, Vice President Gore launched the National Forum for Health Care Quality Measurement and Reporting. The "Quality Forum" is a broad-based, widely representative private advisory body that develops standard quality measurement tools to help all purchasers, providers, and consumers of health care better evaluate and ensure the delivery of quality services. In addition to the work and significant potential of the QuIC and Quality Forum, other Federal agencies have made significant efforts to reduce medical errors and increase attention on patient safety.

The Agency for Healthcare Research and Quality (AHRQ) is the lead coordinating agency for the QuIC. It sponsors research examining the frequency and cause of medical errors and tests techniques designed to reduce these mistakes. It also examines issues generally related to health care quality, including over and under-use of services.

The Departments of Defense (DOD) and the Department of Veterans Affairs (VA), serving over 11 million patients nationwide, have begun to implement computerized physician order entry systems, proven effective in reducing medical errors. In addition, the Veterans Affairs has implemented a computerized medical record in all their 172 hospitals, making it possible to reduce errors by providing complete information about patients at the point of care. Over the past 3 years, the VA created an error reporting system, established four Centers of Inquiry for Patient Safety, and began to use barcode technology to reduce medication errors.

The Health Care Financing Administration (HCFA) through its Peer Review Organizations (PROs), is working to reduce errors of omission for the 39 million Medicare beneficiaries. Under their current performance-based contracts, the PROs are working to prevent failures and delays in delivering services for breast cancer, diabetes, heart attack, heart failure, pneumonia, and stroke. These efforts have already decreased mortality for heart attack victims.

The Centers for Disease Control and the Food and Drug Administration collect data on adverse events that are the result of treatment, such as hospital acquired infections and the unintended effects of drugs and medical devices. CDC's National Nosocomial Infections Surveillance (NNIS) system is a hospital-based reporting system that monitors hospital-acquired infections afflicting more than two million patients every year. Among participating hospitals, bloodstream infection rates have decreased by more than 30 percent since 1990 and wound infections following surgery have decreased by 60 percent among high risk patients. FDA receives approximately 100,000 reports per year of adverse events associated with medical devices and over 250,000 reports associated with pharmaceuticals. FDA estimates that over one-third of the adverse events associated with medical devices and pharmaceuticals are preventable.

In all of these efforts, the Administration has worked closely with the private sector and the states, which are moving ahead with actions to reduce the number of medical errors. Currently, almost 20 states have implemented mandatory reporting systems to improve patient safety and hold health care organizations responsible for the quality of care they provide. The private sector has also taken strong strides to address the issue of patient safety, most recently with the creation of the Leapfrog Group by eight executives of some of the nation's biggest companies, including General Motors and General Electric. This group encourages all employers to make safe medicine a top priority of the health insurance they provide and to steer workers to hospitals that make the fewest mistakes.

While both the public and private sectors have made notable contributions to reducing preventable medical errors, additional and aggressive efforts are needed in and outside of the Federal government to reduce these mistakes.

Institute of Medicine Recommendations

The IOM report recommends the establishment of a national goal of reducing the number of medical errors by 50 percent over 5 years. To that end, it outlined a four-tiered approach to reduce medical mistakes nationwide, including actions to:

- Establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety;
- Identify and learn from medical errors through both mandatory and voluntary reporting systems;
- Raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- Implement safe practices at the delivery level.

A Road Map for Action: The Federal Response

The QuIC agencies join the IOM's call for action to reduce errors, implement a system of public accountability, develop of a robust knowledge base about medical errors, and change the culture in health care organizations to promote the recognition of errors and improvement in patient safety. This report describes the actions that the QuIC agencies will take to build on current programs and develop new initiatives to reduce errors.

The QuIC fully endorses the IOM's goal of reducing the number of medical mistakes by 50 percent over 5 years and has developed a strategy that builds on the IOM recommendations and, in some cases, goes beyond them. This strategy is detailed below.

Create a National Focus to Enhance the Knowledge Base on Patient Safety

IOM Recommendation: Creating a Center for Patient Safety. The IOM recommends that Congress fund a Center for Patient Safety within the Agency for Healthcare Research and Quality (AHRQ) that will set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety. The Center should also enhance the current knowledge base on patient safety by developing a research agenda, disseminating grants for research on patient safety, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

QuIC Response. The Administration endorses the IOM recommendation and is pleased that the President has included \$20 million in the FY 2001 budget to support a Center for Quality Improvement and Patient Safety at the AHRQ as part of the agency's broader quality agenda. The Center will, principally through extramural grants and contracts, fund research on medical errors. It will work with private sector entities and public sector partners, including the Quality Forum, to develop national goals for patient safety; issue an annual report on the state of patient safety nationally; promote the translation of research findings into improved practices and policies; and educate patients, consumers, and health care providers about patient safety.

Within the next year, AHRQ will hold a national conference on patient safety to set coordinated research agendas across the field and lay the groundwork for future action to develop and encourage the expansion of error reporting systems. The Center will also develop a national clearinghouse for the data collected by voluntary and mandatory reporting systems that currently exist and make this information available to researchers in both the public and private sectors in a manner that protects privacy. Over the next year, together with the CDC and other QuIC agencies, the Center will develop an annual National Quality Report that will include information on medical errors.

Identifying and Learning From Errors

IOM Recommendation: Establishing reporting systems nationwide. The IOM recommends that the Administration and the Congress move to establish a nationwide system of error reporting that includes both mandatory and voluntary components.

Mandatory Reporting Systems. The IOM recommends the development of a nationwide mandatory reporting system to provide for the collection of standardized information by state governments about adverse events that result in death or serious harm. The report states that adverse event reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery systems. It recommends that this system should be implemented nationwide, linked to systems of accountability, and made available to the public. IOM concludes that if states choose not to implement the mandatory reporting system, HHS should serve as the responsible entity.

Voluntary Reporting Systems. The IOM report does not propose the establishment of a national voluntary reporting system; rather, it offers a variety of options for more limited voluntary reporting systems that function in all 50 states and build on currently existing options, including the development of systems focused on selected areas, such as medications, surgery, and pediatrics or using a sampling technique to collect the full range of information from a limited subset of health care providers. The IOM recommends that more research be conducted to determine the best way to develop voluntary reporting systems that complement proposed mandatory reporting systems and can identify potential precursors to error, preventing patient harm. It also recommends that the Congress extend peer review protections to data related to patient safety and quality improvement collected through voluntary reporting systems.

QuIC response. The Administration agrees with the IOM that error reporting systems should be established in all 50 states, and that these systems should have both mandatory and voluntary components. Such an approach should establish important complementary approaches to both learning and accountability on errors. Well designed patient safety programs include reporting systems that both hold health systems accountable for delivering high quality health care and provide important information to health care decision-makers that improves patient safety.

We agree with the IOM that individuals should have access to information leading up to and including the occurrence of a preventable error that caused their serious injury or the death of a family member. However, we believe that subsequent "root-cause" analyses undertaken to determine the internal shortcomings of the hospital's delivery system should not be subject to discovery in litigation and that appropriate legislation should be enacted in conjunction with or prior to the implementation of mandatory or voluntary reporting systems.

It is important to note the QuIC believes that any legislation or administrative intervention in this area should not undermine individuals' rights to redress for criminal activity, malpractice, or negligence. The QuIC does not support legislation that would allow safety reporting systems to serve as a shield for providers engaging in illegal or negligent behavior.

Mandatory Reporting Systems. The QuIC supports the development of state-based systems to require the collection of standardized information on preventable adverse events that result in death or serious harm, and believes that the development of these systems are ultimately in the best interests of patients. We agree with IOM that the scope of events targeted by mandatory reporting systems with public disclosure components should be limited to serious, preventable, and identifiable adverse events. By limiting required reporting systems to the most serious of errors (those causing lifelong disability or death), this approach will most effectively target these problems, allow purchasers of health care to select systems that have effective safety programs in place, and minimize the cost of oversight systems to health care organizations, ensuring resources to analyze reported events. The QuIC believes that once mandatory systems are fully implemented such information should be aggregated by health system and made public but that there should be no identification of patients or individual health care professionals in order to promote full and open disclosure. Moreover, the QuIC believes that mandatory reporting systems with public disclosure components should not be used as a tool for punitive action by state and local authorities but rather should be used as a mechanism to provide the public with information about the safety of their health systems and to highlight errors that can and should be prevented in the future.

The IOM has a set of specific recommendations for the structure of a nationwide mandatory reporting system. The QuIC believes that there are a number of issues that need to be addressed prior to determining the best mechanism to ensure the establishment of state based mandatory reporting systems. The Administration will work with the Congress to outline the appropriate Federal role in such a system. However, while these issues are being resolved, the Administration will take the following actions to demonstrate the importance of implementing mandatory reporting systems and to create an environment in which there is widespread support for their use.

- *Implementing a mandatory reporting system in the over 500 hospitals and clinics operated by the Department of Defense.* Beginning this spring, the Department of Defense will implement a new reporting system in its 500 hospitals and clinics serving approximately 8 million patients. This confidential reporting system will be modeled on the system in operation at the Department of Veterans Affairs and will be used to provide health care professionals and facilities with the information necessary to protect patient safety. This system will begin to be pilot tested in August of 2000, will collect information on adverse events, medication errors, "near misses", and other patient safety issues. DOD will implement a new policy that requires that affected patients or their families be notified when a serious medical mistake is made.
- *Expand mandatory reporting requirements for blood banks and establishments nationwide.* By the end of the year, the Food and Drug Administration (FDA) will release regulations to improve the safety of blood transfusions by requiring the over 3,000 blood banks and establishments dealing with blood products to report errors and accidents, such as mistyping blood products and adverse events affecting donors, that affect patient safety. Currently, only 400 blood banks are required to report such errors.

In addition to Federal action to integrate mandatory reporting systems into Federal agencies delivering care and strengthen the mandatory system that currently exist, there is a critical need for Federal leadership in the development of patient safety standards. To that end, the Federal government will:

- *Identify a set of patient safety measurements critical to the identification of medical errors.* The QuIC will ask the Quality Forum to identify a set of patient safety measurements that should be a basic component of any medical errors reporting system. Developing standardized measures lays the foundation for a uniform system of data collection and facilitates the development of these systems.
- *Identify a set of patient safety practices critical to prevention of medical errors.* The QuIC will ask the Quality Forum to identify patient safety practices that should be adopted by all hospitals and health systems within 12 months and undertake activities to encourage their widespread use.
- *Identifying issues related to the implementation of mandatory reporting for error reduction.* Using the Quality Forum's recommendations for medical error reporting, the Health Care Financing Administration (HCFA) will develop a pilot project through the Peer Review Organization Program (PRO) with up to 100 hospitals. These hospitals would volunteer to implement penalty-free, confidential mandatory reporting systems. These pilot projects will assist hospitals in changing their medical delivery systems to reduce or eliminate errors. This pilot project will include a rigorous evaluation component and identify issues related to the implementation of medical error reporting systems.
- *Determine the most effective way to present information on the incidence of medical errors to the public.* The QuIC will work with the Quality Forum and states with mandatory reporting systems to determine how data on medical errors can be collected, validated, and presented – and the impact of providing such information – to the general public and local policy officials. Since informing the public about the safety of their health care systems is a critical component of mandatory reporting systems, this pilot project will provide insights on presenting this information to the public.
- *Examine existing mandatory reporting systems.* The Center for Quality Improvement and Patient Safety, in collaboration with other QuIC agencies will evaluate the effectiveness of currently existing mandatory reporting systems at the Federal and state levels and develop recommendations to improve them. This information will be presented to states and other organizations considering developing systems or who currently have existing systems in order to help them design effective reporting systems likely to improve patient safety.

We hope that these actions will encourage states to begin implementing their own mandatory reporting systems for preventable adverse events, with the goal that all 50 states have mandatory reporting systems for preventable adverse events within three years. This time frame will enable the Federal government, working with the Congress and other private sector stakeholders, to conclusively resolve outstanding implementation issues.

If all states have not implemented mandatory reporting systems within three years, the QuIC will deliver recommendations to the President that assure all health care institutions are reporting serious preventable adverse events.

Although currently the QuIC believes that moving towards a mandatory reporting system is the appropriate course of action, if research conducted by AHRQ and other agencies indicates that the implementation of these systems does not enhance (or detracts from) patient safety, these results will be reported to the QuIC. Special emphasis will be placed on efforts to determine whether making information public serves to hold health systems accountable and reduce preventable errors, or whether it only stifles reporting.

Voluntary Reporting Systems. The QuIC agrees with the IOM that voluntary reporting systems are a critical component of a national strategy to reduce errors. Information from voluntary reporting systems is usually gathered by an independent entity to identify patterns of error applying to all health care systems. The QuIC proposes to integrate existing Federal voluntary reporting systems with data collection efforts by states and private organizations. The QuIC agrees with the IOM that these programs should be confidential to protect the privacy of patients, institutions, and providers reporting errors and “near misses”. Experience in other industries demonstrates that this encourages reporting. In order to encourage the development of voluntary reporting systems, the Administration will:

- *Implement a voluntary reporting system nationwide for veterans' hospitals.* The VA currently operates a mandatory reporting system. By the end of the year, the VA will implement a voluntary reporting system for both adverse events and “close calls” nationwide. Information will be collected by an independent external entity, analyzed, and disseminated to all VA health care networks to help prevent medical errors before they occur. Implementing this system is likely to lead to a richer database of information, as incidents are reported on a de-identified basis, and will allow researchers to compare the effectiveness of identified systems to de-identified ones.
- *Examine existing voluntary systems.* The Center for Quality Improvement and Patient Safety, with its QuIC partners, will evaluate the effectiveness of currently existing voluntary reporting systems at the Federal and state levels and develop recommendations to improve them. This study will demonstrate which entity or entities would be best to collect, analyze, and disseminate information on frequently occurring errors and the best interventions to prevent them.

Setting Performance Standards and Expectations for Safety

IOM Recommendation: Include patient safety in performance standards and expectation for health care organizations. The IOM recommends that regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility. Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.

QuIC response. The QuIC reviewed current Federal activities and proposed several ways to improve safety through current oversight activities. These include:

- *Assuring all hospitals participating in the Medicare program implement patient safety programs.* The Health Care Financing Administration intends to publish regulations this year requiring the over 6,000 hospitals participating in the Medicare program to have ongoing medical error reduction programs that would include, among other interventions, mechanisms to reduce medication errors. In order to comply with this new regulation, most hospitals are likely to implement automated pharmacy order entry systems and automatic safeguards against harmful drug interactions and other adverse events.
- *Requiring the all health plans in the Federal Employees Health Benefits Program to implement patient safety programs.* In their annual call letter to be issued this April, the Office of Personnel Management will announce that beginning in FY 2001, all health plans participating in the program will be required to include error reduction and patient safety techniques in provider contracts in order to improve the quality of care.
- *Working with private sector employers and employees to incorporate patient safety into purchasing decisions.* This year, the Department of Labor will include information on medical errors in the Health Benefits Education Campaign. This national effort educates employees about issues of quality and safety under their employer provided health benefits so that they can make informed health benefits decisions and educates employers in order to facilitate the provision of high quality, affordable health benefits to their employees.

IOM Recommendation: Performance standards and expectations for health professionals should focus greater attention on patient safety. Periodic re-examination and re-licensing of doctors, nurses, and other key providers should be conducted based on both competence and knowledge of safety practices. Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement.

QuIC response. The QuIC is supportive of these goals, but recognizes and agrees with the IOM that these appropriately fall under state jurisdiction and oversight. However, the QuIC agencies will provide technical assistance to state or professional agencies seeking to ensure a basic level of knowledge for health care providers on patient safety issues, promote model patient safety programs that include evidence based best patient safety practices to provider organizations, or help agencies implement the cultural change necessary to make reporting systems a success.

IOM Recommendation: FDA should increase attention to the safe use of drugs. Both pre and post-marketing processes should be improved to maximize safety in use. FDA should develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use and require pharmaceutical companies to test proposed drug names to identify potential sources of confusion with existing drug names. In addition, the agency should work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through post-marketing surveillance activities.

QuIC response. The QuIC endorses the IOM recommendation. FDA currently has a strong program of pre and post-market surveillance, and is pleased that the President is committing \$33 million, an increase of 65 percent over last year's funding level, in his FY 2001 budget to prevent medical errors associated with drugs and medical devices. It would:

- *Initiate new efforts to ensure that pharmaceuticals are packaged and marketed in a manner that promotes patient safety.* Within one year, FDA will develop new standards to help prevent medical errors caused by proprietary drug names that sound similar or packaging that looks similar, making it easy for health care providers to confuse medications. The agency will also develop new label standards by the end of the year that highlight common drug-drug interactions and dosage errors related to medications.

Implementing Safety Systems in Health Care Organizations

IOM Recommendation: Health care organizations should make continually improved patient safety a declared and serious aim. Patient safety programs should provide strong, clear, and visible attention to safety; implement non-punitive systems for reporting and analyzing errors within their organizations; and incorporate well understood safety principles.

QuIC response. The QuIC supports this recommendation, and Federal agencies will take the following actions:

The Department of Veterans Affairs. The VA is considered one of the national leaders in patient safety, having instituted patient safety programs in all of its health care facilities serving 3.8 million patients nationwide. This year, the VA will increase the requirement for patient safety training for staff from 15 to 20 hours a year, provide "VA Quality Scholars" fellowships for ten physicians, implement a patient safety awards program, and place "patient safety checklists" in operating rooms in every hospital nationwide. This summer, as part as a participant in a QuIC program to improve patient safety at the direct care level, the VA will implement a pilot project in at least 18 hospitals to reduce errors "high hazard areas" such as emergency rooms, operating rooms, intensive care units, and labor and delivery rooms.

The Department of Defense. Beginning this fall, the Department of Defense will begin the implementation of a new computerized medical record, including an automated entry order system for pharmaceuticals, that makes all relevant clinical information on a patient available when and where it is needed. It will be phased to all DOD facilities over three years. This summer, as a participant in a QuIC program to improve patient safety at the direct care level, DOD will implement a pilot project in 10 hospitals to reduce errors in "high hazard areas" such as emergency rooms, operating rooms, intensive care units, and labor and delivery rooms.

IOM Recommendation: Improve medication safety. Health care organizations should implement proven medication safety practices.

QuIC Response. The QuIC endorses this recommendation. This year, the VA will complete the implementation of an automated order entry system in all of its health care facilities along with a barcoding system for blood transfusions and medication administration. A 1999 evaluation of this system indicates that it has reduced medication errors by 67 percent since its implementation. The Department of Defense will implement an integrated pharmacy system that creates a single profile for all the medications a patient takes, even if the prescriptions were filled at military and private pharmacies serving DOD beneficiaries worldwide by the end of 2000. In addition, in order to comply with the new proposed requirement that hospitals participating in the Medicare program must have error reduction programs, hospitals are likely to implement programs such as automated pharmacy order entry systems. In addition, as highlighted in the prescription drug provisions in the President's Medicare reform initiative, any outpatient drug benefit for Medicare beneficiaries should require private contractors administering the program to utilize the latest drug utilization review, patient compliance, and counseling techniques to ensure the safe and effective use of these medications.

Additional Federal Actions to Improve Patient Safety

The President asked the QuIC to identify additional strategies to reduce medical errors and ensure patient safety in Federal health care programs. This report includes several additional recommendations, including an emphasis on the application of information systems and computer-based initiatives to improve patient safety. The President has requested \$20 million in his FY 2001 budget to develop a consistent structure for health care information technology while providing strong privacy protections for patients and providers. Investments in information technology are one of the most effective and efficient ways to improve the quality of health care. The Health Informatics Initiative will address the problem of medical errors as a part of the Administration's efforts to improve health care quality through enhanced information technology.

Conclusion

In this report, the QuIC proposes to take strong action on each and every one of the IOM recommendations to promote safer health care. While some of the recommendations of the IOM can be addressed individually by specific agencies, the majority of the proposed actions require joint effort. The QuIC and its participating agencies are eager to partner with a broad array of public, state, and private organizations in a national effort to reduce medical errors and improve patient safety.

Clinton exhorts doctors, government to report, correct thousands of errors

ASSOCIATED PRESS

Doctors and the government have a moral obligation to report and correct medical mistakes that kill or injure thousands each year, President Clinton said yesterday.

He announced steps to confront the problem — and promised more money to improve accountability.

Mr. Clinton said he doubts that better reporting of medical errors will leave doctors and hospitals vulnerable to more lawsuits.

Even if he's wrong, he said, they must feel free to reveal mistakes — or what Press Secretary Joe Lockhart called "near misses," situations when medical professionals erred but did not kill the patient.

"Once you know about a problem, you're under a moral obligation to deal with it," Mr. Clinton said. "Whatever the consequences are, we have to go forward."

For starters, each of the more than 300 private health plans that sell insurance to federal employees will be required to institute quality improvement and patient safety initiatives, Mr. Clinton said during a Rose Garden appearance.

The White House said the requirement will cover roughly 9 million federal workers, retirees

and their dependents.

He also directed federal agencies that administer health plans to evaluate and, when feasible, begin using the latest techniques to reduce mistakes. That includes plans covering veterans, the military, the elderly, children and the poor.

The plans follow last week's release of an independent report that estimated medical mistakes kill between 44,000 and 98,000 Americans each year. The Institute of Medicine said it found flaws in the way hospitals, clinics and pharmacies operate.

While lauding American medicine as the finest in the world, Mr. Clinton said the report startled a lot of people, including him.

He said he plans to propose the most money to date for medical accountability programs in his upcoming budget package.

He did not give specifics, but a White House statement said Mr. Clinton plans a "multimillion-dollar investment in research programs to improve health care quality."

He was joined by Richard J. Davidson, president of the American Hospital Association, who said doctors and nurses already are making headway in reducing er-

rors.

However, Mr. Davidson said, "We can and we must do better."

Mr. Clinton's action dovetails with similar plans on Capitol Hill, where Sen. Edward M. Kennedy, Massachusetts Democrat, is working on legislation with a similar goal.

"I believe we can have a strong bipartisan bill in the next session," Mr. Kennedy, senior Democrat on the Senate Health, Education, Labor and Pension Committee, told reporters Monday.

He said Republican senators, including the committee's chairman, Sen. James M. Jeffords of Vermont, and Sen. Bill Frist, a heart surgeon from Tennessee, were interested in holding hearings.

Dr. Nancy Dickey, immediate past president of the American Medical Association, said the doctors' organization will work with the administration in studying the causes of physician errors and working to prevent them.

However, she said the number of fatal mistakes is relatively low considering the complexity of modern medicine and that there are more than 1 million doctor-patient interactions in the United States each day.

Peru looks at giving a new trial to imprisoned American leftist

Has served 4 years of a life sentence

By Tom Carter
THE WASHINGTON TIMES

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Peruvian officials for the first time say new evidence about Lori Berenson's role in a revolutionary Marxist group is prompting them to consider a new trial for the American leftist, who has spent four years of a life sentence in Andean jails.

The comments come as a lawyer for Berenson prepares to file legal documents in Lima this week seeking a new trial with hope of a reduced sentence or even winning her release for time served.

"It is very sensitive, but we are looking at the law," a Peruvian government official said Monday. "If new evidence is introduced, it is possible that she could get a new trial."

Berenson, a former student at the Massachusetts Institute of Technology, was convicted in January 1996 by a hooded judge in a Peruvian military court for being

a leader in the Revolutionary Movement of Tupac Amaru (MRTA).

The Maoist group is best known for the Christmas 1996 takeover of the Japanese Embassy in Lima, in which 72 hostages were held for 126 days.

Clinton administration officials raised the case of Berenson, now 30, during a visit this week by Alberto Bustamante, Peru's prime minister and justice minister, a State Department official said yesterday.

Mr. Bustamante's portfolios make him responsible for the Berenson case, but several sources said civilian authorities have minimal sway over Peru's military courts.

A previous prime minister, Javier Valle Riestra, resigned in 1998 after demanding Berenson's release and complaining that the

military justice system held too much power.

"We continue to work with the government of Peru to obtain a fair civilian trial [for Berenson]," said a State Department official who spoke on the condition of anonymity.

Mr. Bustamante held meetings Monday with White House officials and yesterday with the State Department's top Latin America diplomat, Peter Romero.

Asked at a luncheon with reporters and editors at The Washington Times on Monday if there were any chance of a new trial for Berenson, Mr. Bustamante would not comment.

However, others in his entourage said that there are provisions in Peruvian law to introduce "new evidence" if someone has been wrongly convicted. If the military court accepts the new evidence, Berenson could get a trial before Peru's Council of Supreme Military Justice, the equivalent of Peru's supreme court of military justice.

Yesterday, Berenson's father, Mark Berenson, said by telephone from New York that his daughter's lawyer in Lima is preparing to submit an official document requesting that she be given a new trial.

"Witnesses have come forward and are prepared to testify that Lori was not a leader [of MRTA]. She wasn't even a member," said Mr. Berenson yesterday. "She has serious leftist social views, but being an ideological sympathizer does not mean she was involved with their methodology. She abhors violence."

At the time of her arrest, Berenson had been in Peru just nine months. To be eligible for a life sentence, according to Peruvian law, she had to be either a guerrilla leader or dealing in firearms.

"She was not dealing arms and the idea that a 25-year-old woman, after nine months in the country, could rise to become a leader in Peru's macho society is preposterous," said her father. "Anyone who knows Lori knows she would not be involved in violence."

In the last four years, Berenson has been held in two prisons. For three years, she was held at the Yamamayo maximum security prison 12,000 feet above sea level, with other leftist political prisoners. In October 1998, she was moved, because of circulation, stomach and respiratory problems, to Socabaya, at 7,600 feet, near the southern city of Arequipa, where she is in virtual isolation.

"For 23 hours a days she is in a dark cell. For an hour a day she has yard time with two or three other prisoners," said Gail Taylor, na-

tional organizer of the Committee to Free Lori Berenson, which runs the Free Lori Berenson Web page (www.freelori.org).

She said Berenson's hands are purple because of her circulation problems and that she spends her days reading Isabelle Allende novels, singing Indian songs and knitting when her swollen hands permit.

Miss Taylor said that she knows nothing about legal moves to free Berenson, and that her organization's petitioning to have her released on "humanitarian grounds."

She said a congressional resolution offered in July by Rep. Maxine Waters, California Democrat, requesting the Peruvian government give Berenson a fair trial failed, but won 180 votes.

The Berenson case is sensitive in Peru for a number of reasons. At the time of her arrest and conviction, Peru was still reeling from the trauma of two brutally violent

guerrilla movements — Shining Path and the lesser-known Tupac Amaru — which had nearly destroyed the nation's infrastructure, killing more than 30,000 people in the 1980s.

While the case is something of an albatross in U.S.-Peruvian relations, and some wish they could simply dispense with the problem, hard-line supporters of Peru's military have been adamant that Berenson face the full force of Peruvian law.

Human rights organizations, which call for Berenson to be released on humanitarian grounds or to be retried in a civilian court, contend that any trial in Peru's military courts is by definition unfair.

Moving Fast on Patient Safety

The Institute of Medicine reported last week that between about 50,000 and 100,000 patients die in hospitals each year because of medical mistakes. President Clinton responded yesterday by embracing the report and ordering his administration to take immediate action. For Washington, that is a remarkably rapid turnabout.

The institute estimated that perhaps 3 percent of hospital patients suffered injuries from treatment. About half are preventable. The problem, the report said, is not individual carelessness as much as faulty systems that fail to catch mistakes — such as administering the wrong dose of drugs — before they injure patients.

Mr. Clinton instructed a task force to report within 60 days on steps to improve patient safety. He directed federal agencies to come up with remedies in time for his next budget address. By presidential order, he instructed the agency that oversees health plans for federal employees to require that those plans develop systems for cutting down errors. It is expected that improvements in plans that cover nine million federal employees and their families will spread to other patients.

The institute report itself contains useful suggestions. It calls for a federal center for patient

safety to distribute information about preventing errors, as well as mandatory reporting of serious injuries and voluntary confidential reporting of less serious errors. Confidentiality, it argued, is needed to discourage doctors from hiding mistakes to save themselves professional or financial ruin.

Meanwhile, Senator Edward Kennedy of Massachusetts announced that he would introduce a bill that would put the institute's proposals into effect and require hospitals to adopt error-preventing systems or else risk losing Medicare and Medicaid patients. That would cover most hospitals in the country.

The institute's frightening statistics were known to health experts long before last week. Yet no one has figured out how to get hospitals and physicians to do better. Employers say they cannot make intelligent choices among health plans because data on the quality of these plans are unreliable. The health plans say they cannot undertake the huge cost of producing reliable data because employers do not act on them.

Even adopting the institute's recommendations in full will not completely solve this chicken-and-egg problem. But the proposals should produce better information and at the same time protect patients.

New Pressure on Gun Makers

The Clinton administration yesterday threatened a lawsuit against gun manufacturers on behalf of the three million people who live in public housing projects long plagued by gun violence. The threat followed last week's ruling by an Illinois state judge that an innovative private lawsuit against gun manufacturers could proceed, despite heavy industry pressure to kill it.

Taken together, these actions provided a positive counterpoint to yet another school shooting episode, this one in Gibson, Okla., where a seventh grader wounded four schoolmates on Monday. The attack, in which no one was killed, reaffirmed the grim fact that there are too many weapons floating around American society — one for nearly every man, woman and child — and that these weapons are all too accessible to the wrong people.

There was hope last spring that Congress would react to the massacre at Columbine High School in Colorado by approving measures aimed at keeping weapons out of the wrong hands. But Republican leaders, unwilling to buck the National Rifle Association and its sizable political donations, made sure that Congress adjourned without doing anything on gun control — creating a big issue for debate in the

coming presidential and Congressional campaigns.

However, there is now reason to believe that pending public and private litigation against the gun industry may succeed in wresting from gun makers at least some of the reforms that Congress has refused to entertain, much less pass. The central argument in the Illinois suit is that the firearms industry has created a public nuisance by negligently distributing its products. That argument makes it similar to cases brought by Chicago and other cities.

The latest ruling is not a binding precedent in any other suit. But according to David Kairys, a Temple University Law School professor, this and other recent rulings signify that the courts are not going to follow Congress's lead in exempting the gun industry from the rules of civil responsibility that apply to other consumer products.

Thus pressure is growing on gun makers to negotiate a settlement that includes steps like personalizing guns so only their rightful owner can fire them, reforming gun distribution practices and barring handgun sales at gun shows and on the Internet. That is a prospect that Americans anxious to prevent more school shootings can only applaud.

Weather
 Today: *Sunny, mild*
 High 56, Low 39
 Thursday: *Mostly sunny*
 High 54, Low 44
 Details: Page B8

The Washington Post

Friday, Dec. 8, 1999
 Today's Contents on Page A2
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WEDNESDAY, DECEMBER 8, 1999

Methods Faulted in Fatal Gene Therapy

Teen Was Too Sick For Experimentation, Federal Probe Finds

By Rick Weiss and Deborah Nelson
 Washington Post Staff Writers

Federal investigators have uncovered serious problems in the gene therapy experiment that killed a Tucson teenager in September, including new evidence that the young man should not have been allowed into the risky study because he was too sick at the time.

Jesse Gelsinger's liver was not functioning at the minimal level that regulators had required for inclusion in the study when University of Pennsylvania researchers infused trillions of genetically engineered viruses into the 18-year-old. Food and Drug Administration officials said.

Moreover, officials said, the researchers failed to notify the agency when two earlier volunteers in the experiment suffered side effects so severe that the study should have been put on immediate hold, according to rules established in advance by the scientists and the FDA.

The Penn researchers also did not tell federal regulators about the results of some crucial animal experiments that might have influenced the agency's judgment of the study's safety, officials said. Nor did the researchers tell the FDA about a key change in wording on the study's patient consent form, which ultimately left volunteers in the dark about the deaths of four monkeys that had undergone a similar treatment.

The new information is the first to emerge from an ongoing federal investigation into Gelsinger's death and raises fresh questions about the conduct of the scientists involved. It stands in stark contrast to a public statement released last week by the Penn team that attributed Gelsinger's death to the gene therapy but claimed that no "human error" had contributed to his demise.

More broadly, the discovery of so many apparent lapses at one of

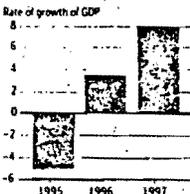
PROSPERITY'S SHADOW | Latin America's New Poor



A visit to the apartment he once occupied in a comfortable workers' village moves Horacio Hinojosa to tears.

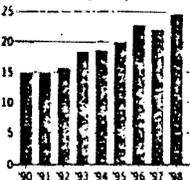
Argentina's Lost World

Argentina's economy has been healthy...



...but the income gap is widening.

In 1990, the richest 10% of the population earned 15 times as much as the poorest 10%. In 1998 that gap had grown to 24.8.



SOURCE: World Bank, Economic Commission for Latin America and the Caribbean

Rush Into the New Global Economy Leaves the Working Class Behind

By ANTHONY FAJOLA
 Washington Post Foreign Service

NUEVE DE OCTUBRE, Argentina—Horacio Hinojosa crossed a ruined tennis court, starting a stray horse grazing on tufts of wild grass pushing through cracks in the red pavement. Undeterred, he walked on through this deserted town where he had once flourished, pausing at an abandoned movie theater to pull at the branches creeping up the walls.

"I took my wife to see 'Planet of the Apes' here once," he said, and recalled a scene of desolation from the movie. "Remember all the buildings covered in vines and weeds? Well, you see we lost our world, too."

Hinojosa wandered down an overgrown path, passing a church whose ruptured doors were marked with graffiti. "Happiness and pain, for returning to the place of my best

memories," read one scrawl in heavy black paint. Hinojosa nodded, then climbed the metal staircase of a nearby apartment building, where his family used to live.

It was inside the apartment, after touching its mold-covered pink walls and wandering the floors covered in rodent droppings, that the portly, 46-year-old former truck driver began to cry.

"We had a cake for my son's first birthday on this spot," he said, weeping. "And over there, we used to move the furniture to one side and put on music for dancing."

The music stopped in 1992. That was when this workers' village, 35 miles east of San Salvador de Jujuy in far northern Argentina, was shut down by the new private owners of Aceros Zapla, the formerly state-run steel and mining

See LATIN, A29, Col. 1

U.S. Plans Role In Gun Lawsuits

'Pressure Focuses on Sales, Safety'

By CHARLES BABINGTON
 Washington Post Staff Writer

The Clinton administration plans for the first time to intervene in litigation against the gun industry, a move to pressure manufacturers to help keep guns out of the hands of criminals and to reduce accidental shootings, officials said yesterday.

The decision could dramatically strengthen the hand of numerous cities that have sued or threatened to sue firearms manufacturers, seeking redress for the public costs of gun violence. Federal officials will begin pressing the manufacturers to settle those lawsuits by making a variety of concessions, such as preventing "straw purchasers" from buying large quantities of firearms—a popular method for convicted felons to obtain new guns.

If the gunmakers don't agree, the administration says it is ready with a powerful weapon similar to one it is using against the tobacco in-

dustry: a massive lawsuit on behalf of the nation's 3,191 public housing authorities and their 3.25 million residents.

"If we cannot come up with a satisfactory resolution" through negotiations, "HUD would bring a class action suit on behalf of public housing authorities," Housing and Urban Development Secretary Andrew M. Cuomo said in an interview yesterday. "I think it's a clear signal to the manufacturers that enough is enough. The status quo is unacceptable."

To some degree, the threatened litigation could allow the Clinton administration to use the courts to achieve gun control measures that have failed in Congress. The architects of the current wave of litigation against gun manufacturers are openly seeking quasi-legislative remedies: They want gunmakers to agree to distribute their products only to dealers who will not sell at gun shows, not to sell an individual

See GUNS, A18, Col. 1



At JPL, flight operations chief Sam Thurman, left, and project manager Richard Cook listen in rain for contact with Polar Lander.

NASA Reassessing Planetary Program

Mars Loss Termed 'Wake-Up Call'

By KATHY SAWYER
 Washington Post Staff Writer

PASADENA, Calif., Dec. 7—The devastating loss of an entire generation of U.S. Mars missions has triggered a total reassessment of NASA's approach to interplanetary exploration, officials said today.

The whole program is on the table for restructuring, "space agency administrator Daniel S. Goldin said in an interview early today, adding that "there's a chance we may miss" or at least drastically change the next mission in the pipeline, slated for launch in 2001.

Missing and presumed dead are the entire \$360 million suite of robots, including the Mars Polar Lander, that were to have constituted the second wave of

planned long-term research on the Red Planet.

A number of experts in and out of NASA said the failures confirm growing fears that the program has pushed the space agency's "faster, cheaper, better" approach a bit too far, cutting costs—and therefore numbers of people—too close to the bone. Some suggest the changes were pushed through too fast for institutions involved to adapt adequately.

Where the Jet Propulsion Laboratory (JPL), which manages missions for NASA, once handled one or two huge programs that went on for a decade or more, it now spreads its staff across 10 or 20 much smaller programs that must be dis-

See MARS, A8, Col. 1

'Pay-to-Surf': A Pyramid Marketing Ploy Clicks

By ARIANA EUNJUNG CHA and LESLIE WALKER
 Washington Post Staff Writers

In April, Ron Streeter discovered a company that would pay him just for surfing around and looking at ads on the World Wide Web. It was a pittance, really—50 cents an hour—but then he learned that if he signed up his brother Tom, or anyone else, the company would pay Streeter a 10-cent commission for each hour they spent online.

And for each person his brother recruited—and for each of their friends and even their friends'

friends—Streeter would collect another nickel per hour.

The group Streeter initiated into AllAdvantage.com now numbers more than 10,000 people. His reward? He got a monthly commission check for \$2,044.43 in the mail the other day.

Streeter and millions of others are cashing in on the latest Internet marketing craze. AllAdvantage and dozens of other companies are rushing to build big audiences by handing out cash to anyone willing to let advertisers track their Web surfing and send them ads tailored to their habits.

"It takes no investment except one's own time,

and you make money even if you don't work at it," said Streeter, 44, a Syracuse, N.Y., graphic artist. "It's really the gold rush of the '90s for the average person, if you know what you're doing."

The pay-to-surf companies essentially pass on to users a portion of their revenue from selling ads. The theory is that cash payments will not only attract more "eyeballs" but also let the companies raise ad rates because surfers will respond more frequently to ads that interest them. But analysts are divided over whether the scheme is born of in-

See WEB, A20, Col. 1

INSIDE

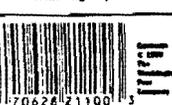
Suit for 'Truth'

The trial is nearing a close in a lawsuit brought by the family of Martin Luther King Jr. against a former Memphis cafe owner who boasted in recent years that he conspired to kill the civil rights leader in 1968.
 NATION, Page A2

Albright Hopeful

After a three-hour meeting with Syrian leader Hafez Assad, Secretary of State Madeleine K. Albright said she was "much more hopeful" about reviving peace talks between Israel and Syria.
 WORLD, Page A25

The Post on the Internet:
 www.washingtonpost.com



Bonus Plan Fails

D.C. Council members rejected Mayor Anthony A. Williams's plan to pay worker bonuses with money from the District's tobacco settlement. Members endorsed the bonuses but said the money must come from the budget.
 METRO, Page B1



A Nice Twist

The twisted history of neckties, the science of sticky stuff, the origin of the musical scale and the inside story on time capsules.
 HORIZON, behind Food

For Foster Children, a Long Way Home

With Need Increasing, Area's Recruiters Struggle to Find Temporary Parents

By SARA HORWITZ
 Washington Post Staff Writer

Paulette Saunders is asking people to do something very hard: take children they don't know—children who may be hard to handle; physically ill—into their homes and care for them as their own. And they must do it knowing that at some point they will have to say goodbye.

Saunders, a foster care recruiter with For Love of Children, is making her pitch on a Sunday afternoon in the basement of New Bethel Baptist Church, an 800-member congregation in Northwest Washington's Shaw neighborhood. Only nine people have stayed after services to hear her out.

Few eyes are dry when Saunders finishes her passionate speech. Yet only three people sign up even to hear more about being a foster parent—just the first step in a long process before a child is placed in a foster home. For Saunders, the response is disappoint-



Paulette Saunders speaks with members of New Bethel Baptist Church as part of her search for potential foster parents in the District.

ing. But she's getting used to it. The number of foster children in the District (now 3,334) and across the nation (about 530,000) is rising rapidly, even as fewer and fewer adults show a willingness to

take such children into their homes. As of this week, 1,034 families are home to D.C. foster kids. Today, Mayor Anthony A. Williams (D) plans to announce a year-long, high-visibility cam-

paign to persuade more District residents to become foster parents. The mayor is expected to tell the tale of his own upbringing as a foster child, hoping to inspire others to recognize the rewards involved in foster care and adoption.

In addition to the growing gap between available children and willing foster parents, the mayor and recruiters such as Saunders face another challenge: The District's child welfare system has long been notorious for poor administration, neglect and other problems that make foster parents' work more difficult.

Recently, nearly 100 parents threatened to return their foster children because the D.C. Child and Family Services Agency was several months in payments to parents and day-care providers. The problem is exacerbated by the fact that District foster children stay in the system more than twice as long as the national average.

See PARENTS, A14, Col. 1

Top of page:

Col 1: Local feature.

Cols 2-6: In the wake of the almost certain loss of the Mars Polar Lander, senior NASA officials vow a complete overhaul of the U.S. interplanetary exploration program, including postponement or even cancellation of missions already in development. (with art) (MARS-TIMES, moved.)

Above the fold:

Cols 2-3: Amid heightened concern by officials over potential terrorist acts on New Year's Eve, two militia members are arraigned here on firearms charges related to an alleged plot to blow up targets in Northern California. (TERROR, moved.)

Col 4: Police Chief Norm Stamper says he will step down, a week after his outnumbered officers watched helplessly as mobs of World Trade Organization protesters rampaged through downtown Seattle leaving behind \$19 million in damage and lost retail sales. (SEATTLE, moved.)

Col 6: Faced with mounting criticism from the West over the war in Chechnya, Russian President Boris N. Yeltsin heads to Beijing for talks with Chinese leaders aimed at balancing what both countries see as global domination by the United States. (RUSSIA-CHINA, moved.)

Below the fold:

Col 3: Caving in to a derisive public outcry, a 49-year-old Mexican Cabinet minister says he will give his monthly early retirement pension a substantial sum to charity for as long as he keeps working in government. (MEXICO, moved.)

Cols 5-6: State political story.

Bottom of the page:

Cols 1-2: Local feature.

Cols 5-6: Local story.

Hospital Leaders Move to 'X'-Out Medical Errors

Robert A. Rosenblatt

Los Angeles Times

WASHINGTON Hospital leaders on Tuesday announced a nationwide campaign to reduce the number of fatal mistakes made by medical personnel including steps such as putting an "X" on a patient's body where a surgeon is supposed to cut and using special colored labels on bottles of lethal drugs.

President Clinton also ordered the federal health programs that cover senior citizens, the poor and the military to use the latest techniques available to avoid errors.

The wave of attention to medical error comes one week after an Institute of Medicine report found that preventable mistakes kill 44,000 to 98,000 people a year and add \$17 billion to \$25 billion to the nation's health bill.

But the issue "is about far more than dollars or statistics, it's about the toll that such errors take on people's lives and on their faith in our health care system," Clinton said.

The president ordered the 300 private health plans covering federal workers to seek ways to improve patient safety, and promised to ask Congress next year for additional research funds to find techniques to reduce the frequency of medical mistakes.

He also directed government-run health plans Medicare for senior citizens; Medicaid for the poor; and the Defense Department and the Department of Veterans Affairs for active and retired military personnel and their families to adopt methods to reduce errors by doctors, nurses and pharmacists.

Clinton was joined Tuesday in his call for medical safety by Dick Davidson, president of the American Hospital Association, who said that personnel would be more willing to report mistakes if they were assured that they would not be punished or sued.

This approach is used successfully in the airline industry, where pilots are not punished if they report near collisions within 48 hours, said Gordon M. Sprenger, president of the Allina Health System, based in Minneapolis.

Manufacturing firms also successfully record their near-mistakes to devise better working procedures.

In the hospital industry, major incidents such as a patient's severe illness or death because of a medical mistake are formally reported. But it is the much more numerous mistakes that are caught just in time that could lead to systemic improvements, ultimately reducing the frequency of illness and death, Sprenger and Davidson said.

For example, some drugs have very similar labels, making potentially deadly mistakes possible when a rushed nurse or doctor grabs a bottle from the shelf. Sprenger said his hospitals now store the lethal drugs in bins. And he said he is going to ask manufacturers to consider different colored labels for certain types of drugs.

In some rooms, a sign is placed above the patient's bed, reading: "This patient is not ambulatory." That tells the nurse or attendant or technician coming into the room that the person shouldn't get out of bed to go to the bathroom without assistance, Sprenger noted.

Hospital surgery teams now meet beforehand, he said, to review a long checklist of tasks and to make clear what each person in the operating room will do.

"It is going to take all of us working together to continue to improve the safety of our medical system," Davidson said.

The hospital group will work with a research organization that reviews medical errors the Institute for Safe Medication Practices to develop a list of successful procedures, Davidson said. Doctors, nurses and other health care professionals can report actual and potential errors with medication by calling (800) 23-ERROR.

Meanwhile, Sen. Edward M. Kennedy, D-Mass., said he will work with members of the Republican majority in Congress to create a new National Center for Patient Safety.

Kennedy said he was "amazed and enormously distressed" by the Institute of Medicine report.

Shocking Street Attack Puts Senate Race in Focus

By Josh Getlin

Los Angeles Times

Again a Mars probe is lost and questions begin

With the apparent loss of the Mars Polar Lander, NASA has been forced to concede the failure of two missions, worth \$300 million, since September. Plainly something is wrong. But the quick target of attack — NASA's famous "faster, better, cheaper" management mantra — is neither the most appropriate place to lay blame nor the most productive.

The loss of the two missions pales against earlier losses, including the \$1-billion Mars Observer mission in 1993, that were produced before NASA embraced its new themes. Interplanetary exploration is tricky business no matter how much you spend.

There are risks in faster-better-cheaper, of course. The cause of the loss of the \$125-million Mars Climate Orbiter was a simple failure to calculate the spacecraft's path accurately. This was caused in part because the probe's navigation team had only two members, a direct consequence of the management imperative to launch numerous smaller missions quickly and inexpensively. NASA officials now admit they may have been too aggressive and suggest they might reconfigure some of the pending eight missions.

Such humility is essential. A blistering external review of the orbiter's loss listed overconfidence, miscommunication and a lack of training and oversight as contributing factors.

Given the hubris that suffuses space science, it's no surprise that NASA is guilty of overconfidence. But attitude isn't the agency's only problem. Its budget and its congressional mandate are part of the loss equation, too. At \$13.6 billion, its budget essentially has been flat for the past decade and has lost value adjusted for inflation. Yet for less than 1% of the federal budget, NASA is supposed to operate the space shuttle fleet, build a space station,

Missed missions

Since October 1960, NASA has launched 30 missions to Mars, of which only 40% have been even partially successful. So far in this decade, there have been seven launches from three nations, with two outright successes, four outright failures and a Japanese mission still orbiting the sun with propulsion problems. The record, by decade:

Decade	Successful missions	Unsuccessful missions
1960	3	7
1970	7	4
1980	0	2
1990	2	5

Source: NASA

explore the universe and conduct research of Earth.

Congress is bound to hold hearings into the agency's latest failures, and so it should. But that review needs to focus both on management issues within the agency and on the constraints Congress itself imposes. Faster-better-cheaper isn't the sole problem, and it may be the only solution to modern realities.

Truth is, NASA isn't going to return soon to the billion-dollar space probes of old. There isn't the money. And it makes sense to conduct multiple smaller missions. The losses are less damaging when they occur, as they always have, and as they surely will in the future.

The question is how, within the constraints of politics and money, to go faster-better-cheaper more wisely.

CLINTON-GORE ADMINISTRATION TAKES STRONG NEW STEPS TO IMPROVE HEALTH CARE QUALITY AND ENSURE PATIENT SAFETY

December 7, 1999

Today, President Clinton will meet with representatives of the Institute of Medicine (IOM), health care consumers, providers, purchasers, and members of the business and labor communities, and sign an executive memorandum directing the Federal Quality Interagency Coordination (QuIC) Task Force to report back within 60 days, through the Vice President, with recommendations to improve health care quality through the prevention of medical errors and enhancements in patient safety. The President will also: announce that each of the over 300 private health plans participating in the Federal Employee Health Benefits Program will be required to institute quality improvement and patient safety initiatives; instruct Federal agencies administering health plans to evaluate and, where feasible, implement the latest error reduction techniques; direct the Office of Management and Budget, the Domestic Policy Council, and other agencies throughout the government to develop meaningful health care quality and patient safety initiatives for the FY 2001 budget; and announce his signing of the reauthorization of the Agency for Healthcare Research and Quality, ensuring a new, multi-million dollar investment in research programs to improve health care quality. In addition, the President will praise the American Hospital Association for its landmark announcement of a multi-faceted campaign to prevent unnecessary, harmful, and expensive medication errors in 5,000 member hospitals.

INCONSISTENCIES AND AVOIDABLE ERRORS IN MEDICAL PRACTICE COST LIVES AND UNDERMINE HEALTH. Inappropriate utilization of services, unnecessary variations in the delivery of health care, and preventable medical errors are responsible for tens of thousands of deaths, unnecessary illnesses, and instances of prolonged disability each year. In addition to these severe health consequences, these variations in medical practice increase national health care spending by billions of dollars annually.

- **Preventable medical errors.** A study released last week by the Institute of Medicine estimates that more than half of the adverse medical events occurring each year are due to preventable medical errors, placing as many as 98,000 Americans at unnecessary risk. The cost associated with these errors in lost income, disability, and health care costs is as much as \$29 billion annually. The financial cost of these errors are far outweighed by the impact they have on the lives of patients and the trust of patients in the quality of the care they receive.
- **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, the overuse of antibiotics creates unnecessary health care costs and contributes to the emergence of antibiotic-resistant pathogens, resulting in as much as \$7.5 billion in unnecessary expenditures 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, hospital discharge rates and lengths of stay in the Northeast were over 40 percent higher than in Western states.

NEW ACTION TO IMPROVE HEALTH CARE QUALITY AND ENSURE PATIENT SAFETY.

Today, President Clinton will:

- **Issue an Executive Memorandum directing the Quality Interagency Coordination Task Force (QuIC) to develop new strategies to improve health care quality and protect patient safety.** Today, President Clinton will sign an executive memorandum directing the QuIC to report back recommendations to him, through the Vice President, within 60 days that: identify prevalent threats to patient safety and reduce medical errors that can be prevented through the use of decision support systems, such as automated patient monitoring and reminder systems; evaluate the feasibility and advisability of the recommendations of the Institute of Medicine on patient safety; develop additional strategies, including the use of information technology, to reduce medical errors and ensure patient safety in Federal health care programs; evaluate the extent to which medical errors are caused by misuse of medications and medical devices and consider steps to further strengthen FDA's response to this challenge; and identify opportunities for the Federal government to take specific action to improve patient safety and improve health care quality through collaboration with the private sector, including the newly constituted National Forum for Health Care Quality Measurement and Reporting.
- **Announce that each of the more than 300 private health plans participating in the Federal Employee Health Benefits Program will be required to institute quality improvement and patient safety initiatives.** Today, the President will announce that the Office of Personnel Management, which oversees plans serving 9 million Americans, will include in its annual call letter to be issued next spring a requirement that FEHBP plans use error reduction and other patient safety techniques in order to improve the quality of care in the program. In addition, OPM will supplement this initiative using workplace campaigns to improve mammography and medical screening rates among Federal employees, retirees, and their families. Finally, OPM will initiate new ways to measure and report on the quality of care that plans deliver to enrollees.
- **Instruct Federal agencies administering health plans to evaluate and, where feasible, implement the latest error reduction techniques.** The President will request that the Departments of Health and Human Services, Veterans Affairs, and Defense, and the Office of Personnel Management evaluate and, where feasible, implement the latest error reduction techniques in a manner consistent with the Administration's recently released draft regulations on patient privacy. These agencies administer Medicare, Medicaid, CHIP, the Federal Employees Health Benefits Program, the nationwide network of veterans hospitals and outpatient clinics, and the military health care system, serving over 85 million Americans.
- **Announce the reauthorization of the Agency for Healthcare Research and Quality, ensuring a multi-million dollar investment in research programs to improve health care quality.** President Clinton will announce that he signed legislation yesterday reauthorizing the Agency for Healthcare Research and Quality (AHRQ). To achieve the goals of this legislation, which is the result of the bipartisan efforts of Senators Frist and Kennedy and Congressmen Bliley and Brown, the FY 2000 budget increases the agency's resources by 16 percent over FY 1999 funding levels, for a multi-million dollar investment in health care quality. These new funds will be used for important quality improvement research, including the over-and-under utilization of services, variation in the delivery of services, and efforts to prevent medical errors. In recognition of the critical role that states do and will play in assuring and improving health care quality, AHRQ will hold a nationwide conference this March with senior state health officials to promote best medical practices, to prevent medical errors and improve patient safety, and to better develop a working relationship between the Federal and state governments in this area.

- **Direct the Office of Management and Budget, the Domestic Policy Council, and other agencies to develop additional health care quality and patient safety initiatives for the FY 2001 budget.** The President will direct the Office of Management and Budget, the Domestic Policy Council, and the Office of the Vice President to work with the Department of Health and Human Services and other agencies to develop additional initiatives within the context of the FY 2001 budget that build on our current error prevention, quality improvement, and patient safety initiatives.
- **Praise the American Hospital Association for launching a new medication safety campaign.** The President will praise the American Hospital Association for launching a new partnership with the Institute for Safe Medication Practices to prevent patient medication errors. Today, the AHA will send a list of "best practices" on prevention medication errors to all 5,000 of their member hospitals. In the coming months, they will also begin to: develop a medication safety awareness test that surveys hospitals' medication error prevention systems; track implementation by the hospital and health system field of the practices for reducing and preventing errors; and working with national experts to develop a model medication error reporting process. By taking these actions today, the AHA joins numerous other health care organizations making an important commitment to this area, including the American Medical Association's initiative to establish the National Patient Safety Foundation.

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 promoting advances in health care quality nationwide. The President also asked the Vice President to help launch the National Forum for Health Care Quality Measurement and Reporting, a broad-based, widely representative private advisory body that develops standard quality measurement tools to help all purchasers, providers, and consumers of health care better evaluate and ensure the delivery of quality services. In addition to the work and significant potential of the QuIC and Quality Forum, the Departments of Veterans Affairs and Defense have been leaders in patient safety and quality improvement programs. The Department of Veterans Affairs also spearheaded the development of the National Patient Safety Partnership to address issues related to adverse medical events. Finally, the Health Care Financing Administration has implemented new quality improvement initiatives through its peer review organization efforts, and the Food and Drug Administration is working to implement new reporting systems that allow for a rapid response to medical errors causing patient injury.

Revised Final 12/7/99 10:00 am
Sam Afridi

PRESIDENT WILLIAM J. CLINTON

REMARKS ON HEALTH CARE QUALITY

AND PATIENT SAFETY

THE WHITE HOUSE

December 7, 1999

Acknowledge: Secretary Herman, other officials from the federal government; leaders representing consumers, health care providers, business, labor and quality experts.

Last week, the Institute of Medicine released a disturbing report about patient safety and medical errors in our nation's health care system. According to its study, as many as 98,000 Americans lose their lives each year as a result of preventable medical errors. Up to 7,000 Americans die because of errors in prescribing medicine. And the costs of all of these medical errors add as much as \$29 billion to America's health care bill.

But this is about more than dollars or statistics. It's about the toll that medical errors take on people's lives and on their faith in the health care system. I just finished a good meeting with the leaders here to talk about what we can do together to save lives, prevent medical errors and promote patient safety.

We have the finest health care system in the world—and the best professionals to deliver that care. But too many families have been the victims of medical errors that are avoidable, mistakes that are preventable and tragedies that are unacceptable. Everyone here with me agrees: America's health care system does wonders, but first it must also 'do no harm'.

No American should ever have to fear that their health care could jeopardize their health.

Now, I want to be clear. Ensuring patient safety is not about fixing blame, it's about fixing problems in a complex system. It's about creating a culture of safety—and an environment where medical errors are not tolerated. In short, it's about working together to zero in on patient safety and zero out preventable medical errors.

This morning's meeting builds on our Administration's long-standing record to improve health care quality.

Almost three years ago, I established the Commission on Consumer Protection and Quality Health Care—chaired by Secretary Shalala and Secretary Herman. That Commission produced a landmark report and led to my own executive action to provide patient protections to the one out of three Americans enrolled in federal health plans. It also set the stage for the Congress to pass a strong, enforceable Patients’ Bill of Rights.

But—as the Commission’s work has made clear—the challenge goes beyond patient protections for all Americans in all plans. We also must improve the quality of care that patients receive.

That's why I created an interagency Task Force to coordinate Administration efforts in this area. And it's why I asked the Vice President to launch the Quality Forum, a private advisory panel to develop uniform quality standards--so that health plans can compete on quality, not just cost—and consumers and businesses have better tools to judge what plan is best for them.

In a few moments, I'm going to announce new steps our Administration is taking to promote quality and reduce medical errors. But first I want to turn it over to one of our partners in that effort.

If there's one thing we have learned, it is that effectively managing the prescribing and dispensing of drugs is one of the best ways we can improve quality and hold down costs. The President of the American Hospital Association, Dick Davidson, is here this morning to announce a major new medical safety campaign that they're launching with the Institute for Safe Medication Practices. It is truly a prescription for better health for all Americans. I'd like to ask President Davidson to tell you about it.

(President Davidson makes remarks. Following his remarks, you return to the podium)

Thank you Dick for your words and your leadership in this new campaign. Now I'm proud to announce new executive action I'm taking at the federal level to target medical errors and promote patient safety.

First, I'm signing an Executive Memorandum this morning directing our Health Care Quality Task Force to analyze the Institute of Medicine's landmark study—and to report back to me through the Vice President within 60 days about the ways we can implement their recommendations. I'm also calling on the Task Force to evaluate the extent to which medical errors are caused by the misuse of medications and medical devices and to develop additional strategies to reduce these errors.

Second, I want the federal government to lead by example. So I'm instructing government agencies that administer health plans for 85 million Americans to take an inventory of the good ideas out there to reduce medical errors. They should apply those techniques to the health programs that they administer—and do so in a way that protects patient privacy.

As a first step, I'm announcing today that each of the more than 300 private health plans participating in the Federal Employee Health Benefits Program will now be required to institute quality improvement and patient safety initiatives.

Third, ongoing research to enhance patient safety and reduce medical errors is critical—so we're increasing our investment in this area. Yesterday, I signed legislation reauthorizing the Agency for Health Care Quality and Research and providing \$25 million for research to improve health care quality and prevent medical errors. Through the work of the Agency, we are also engaging our partners at the state level. In March, we will convene the first national conference with state health officials to promote best practices in preventing medical errors.

Finally, I'm directing my budget and health care teams to develop quality and patient safety initiatives for next year's budget to ensure that we're doing all we can to combat this problem.

I want next year's budget to provide our largest investment to eliminate medical errors, improve quality, and enhance patient safety.

The Institute of Medicine's report makes clear that a systematic approach to reducing medical errors gives us the best chance of success. Years ago, we took that approach in aviation and we've dramatically reduced errors and saved lives. By working together, we can achieve the same goals in the health care industry.

The American people deserve quality health care—through the protections we're fighting for in the Patients' Bill of Rights—and the safety measures we're putting in place today.

I'm committed to working with everyone here to do even more. And by working in partnership, we will do our part to save lives, end needless medical errors and make the best health care system in the world even better for the 21st century.

Breaking News
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December 6, 1999

Lawmakers Target Medical Mistakes[A.P. INDEXES](#) | [TOP STORIES](#) | [NEWS](#) | [SPORTS](#) | [BUSINESS](#) | [TECHNOLOGY](#) | [ENTERTAINMENT](#)**Filed at 8:44 p.m. EDT****By The Associated Press**

WASHINGTON (AP) -- Propelled by a report that medical mistakes kill thousands of Americans, President Clinton and congressional lawmakers are putting together plans to quickly cut down the number of deaths.

The president, at a White House ceremony Tuesday, will direct federal agencies that administer health plans to find ways to reduce room for errors at hospitals. Meanwhile, in Congress, Sen. Edward Kennedy, D-Mass., is putting together legislation for next year, also requiring precautionary actions.

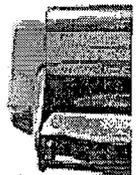
Both efforts will track suggestions made last week by the Institute of Medicine on ways to reduce mistakes at the nation's hospitals.

"I believe we can have a strong bipartisan bill in the next session," Kennedy, the senior Democrat on the Senate Health, Education, Labor and Pension Committee, told reporters. He said Republican senators, including Chairman James Jeffords, R-Vt., and Bill Frist, a doctor from Tennessee, are interested in holding hearings on the issue.

A senior White House official, who spoke on condition of anonymity, said late Monday that Clinton plans to meet Tuesday with officials from the Institute of Medicine, health care providers and hospitals to discuss initiatives that can be taken.

Afterward, the official said, Clinton will announce a series of first steps toward making mistakes less likely. They include a partnership with the American Hospital Association, which will ask its 5,000 members to produce a report on ways to cut down on errors.

Clinton also will issue an executive memorandum directing an interagency coordination task force to report back to him in 60 days on threats to patient safety. Federal agencies, too, will be required to

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put in place a system to reduce errors, the official said.

Kennedy's legislation, among other things, would create a national center for patient safety that would set safety goals, track progress in achieving them and serve as a clearinghouse for organizations seeking tips on improving medical safety.

Meanwhile, Clinton signed a bill Monday that provides \$40 million to improve health care and help train new pediatricians. The Healthcare Research Quality Act authorized a new grant program to support children's hospitals that train doctors.

"In an increasingly competitive health care market dominated by managed care, teaching hospitals struggle to cover the significant costs associated with training," Clinton said in a statement, adding that the new program would "provide much needed support for the training of these critical health providers."

The Institute of Medicine said a center like Kennedy's would cost \$35 million to set up. Eventually, the report said, Congress should spend \$100 million a year in safety research, even building prototypes of safety systems.

Still, that would be just a fraction of the estimated \$8.8 billion spent each year as a result of medical mistakes, the report calculated.

The legislation also would provide grants and contracts for research on preventing medical errors and on creating error-reporting systems.

Kennedy said that Republican senators, including committee chairman James Jeffords of Vermont and Bill Frist, a Tennessee doctor, have expressed interest in such a bill.

Both the legislation and the White House action would be based, Kennedy said, on the Institute of Medicine report and recommendations last week.

Kennedy called the institute's goal of reducing medical errors by 50 percent "optimistic," but he also said any legislation would adopt similar goals.

The institute said it found flaws in the way hospitals, clinics and pharmacies operate. It cited two studies that estimate hospital errors cost at least 44,000, and perhaps as many as 98,000, lives a year.

Some problems are familiar, it suggested: Doctors' famously poor handwriting too often leaves pharmacists squinting at tiny paper prescriptions, and too many drug names sound alike.

Also, medical science advances so rapidly that it is difficult for health care workers to keep up with the latest treatments and new dangers. Technology poses a hazard when device models change from year to year.

And most health professionals do not have their competence regularly re-tested after they are licensed to practice, the report said.

Indeed, health care is a decade or more behind other high-risk industries in improving safety, the report said.

Kennedy's other proposals include requirements for reporting errors. About 20 states now require such reports, but how much information they require and what penalties they impose for errors varies widely, the report said.

Bright lights, big cities.

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A Clinton Order Seeks to Reduce Medical Errors

By ROBERT PEAR

WASHINGTON, Dec. 6 — President Clinton will order federal agencies that provide or finance health care to take steps to reduce medical errors blamed for tens of thousands of deaths, administration officials said today.

The order would require pharmacists to take more precautions to avoid dispensing the wrong drugs and would encourage hospitals to investigate errors that cause serious injuries or deaths and report their findings to state health agencies. The standards would apply to health care providers under direct federal control, but would serve as an example for the rest of the industry.

At a White House ceremony on Tuesday, the officials said, Mr. Clinton will instruct the agencies, which deal with the health care of 85 million people, to adopt all feasible techniques for reducing medical errors. In so doing, the officials said, Mr. Clinton is recognizing medical mistakes as a serious problem in the health care system.

In effect Mr. Clinton has decided to accept major recommendations from a report issued last week by the National Academy of Sciences. The report said that the medical mistakes that cause tens of thousands of deaths each year could be reduced by half in the next five years if health care providers collected and analyzed data on unsafe practices, as the aviation industry does.

Some health care providers already investigate errors, and about 20 states require that they report their mistakes. But compliance is uneven, and many states have no such requirements.

The federal government has immense leverage over the health care

Continued on Page A17

probes that were supposed to penetrate the Martian ground at about the same time of the lander's arrival. They were designed to examine the subsurface for signs of water ice.

The search for water by both the probes and the lander was an effort to answer the consuming question about Mars: Could life have arisen there in the past? Water is considered essential for life, and other research has shown that some water ice and vapor exists on Mars and might have been more abundant and in liquid form earlier.

The mission's apparent failure has been acutely painful for Mr. Zimmerman and others who have invested years, sometimes decades, in

Continued on Page A19

Airline Contractor Is Guilty in Jet Crash

An airline maintenance company was convicted in a Miami federal court of mishandling hazardous materials in the crash of ValuJet Flight 592, which killed 110 people in 1996. The company's chief of hangar operations and a mechanic were acquitted of lying on repair records. The company was accused of failing to install safety caps on oxygen generators that started a fire in a hold.

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Clinton Will Order Agencies To Reduce Medical Errors

Continued From Page A1

industry because it buys or subsidizes large amounts of health care and regulates hospitals, nursing homes and many other health care providers.

President Clinton has the authority to make some changes unilaterally. Thus, White House officials said, any health insurance plan that wants to cover federal employees in 2001 will have to take steps to reduce medical errors and protect patients, as recommended by the National Academy of Sciences.

This directive will affect more than 300 private health plans that insure nine million Americans through the Federal Employees Health Benefits Program.

Mr. Clinton will order other federal agencies that provide or finance health care to "evaluate and, where feasible, implement the latest error-reduction techniques," a White House document says.

This instruction will be addressed to the Department of Health and Human Services, which runs Medicare and Medicaid; the Department of Veterans Affairs, which provides medical care to millions of veterans, and the Defense Department, which provides health care to military personnel.

Chris Jennings, the health policy coordinator at the White House, said the federal government would try to use its leverage as the nation's biggest purchaser of health care to improve the quality of care for all Americans.

In March 1998, Mr. Clinton created a task force of federal agencies to find ways of measuring and improving the quality of health care. On Tuesday, officials said, Mr. Clinton will order this group to report within 60 days on ways to carry out the recent recommendations from the National Academy of Sciences.

The interagency group will develop proposals that can be included in the president's next budget, which he intends to submit to Congress in late January or early February, administration officials said.

White House officials said they had not figured out how Mr. Clinton's new initiative would deal with the concerns of health care providers who fear they will be more exposed to malpractice lawsuits if they acknowledge more of their mistakes. The Clinton administration has generally opposed efforts by health care providers to limit the damages they might be required to pay in such cases.

President Clinton today signed a bill expanding the mission of the Agency for Health Care Policy and Research, a unit of the Public Health Service. One of the agency's new roles is to "identify the causes of preventable health care errors" and to find ways of curtailing such mistakes.

Representatives of the health care industry, including leaders of the American Hospital Association, will meet with the president on Tuesday, to signal their support for some of the academy's recommendations.

The hospital association is sending a list of error-reduction techniques to

each of its 5,000 hospitals. Richard H. Wade, senior vice president of the association, said his group was forming a partnership with the Institute for Safe Medication Practices, a non-profit organization based in Huntingdon Valley, Pa., to reduce errors in the prescribing and dispensing of medicines.

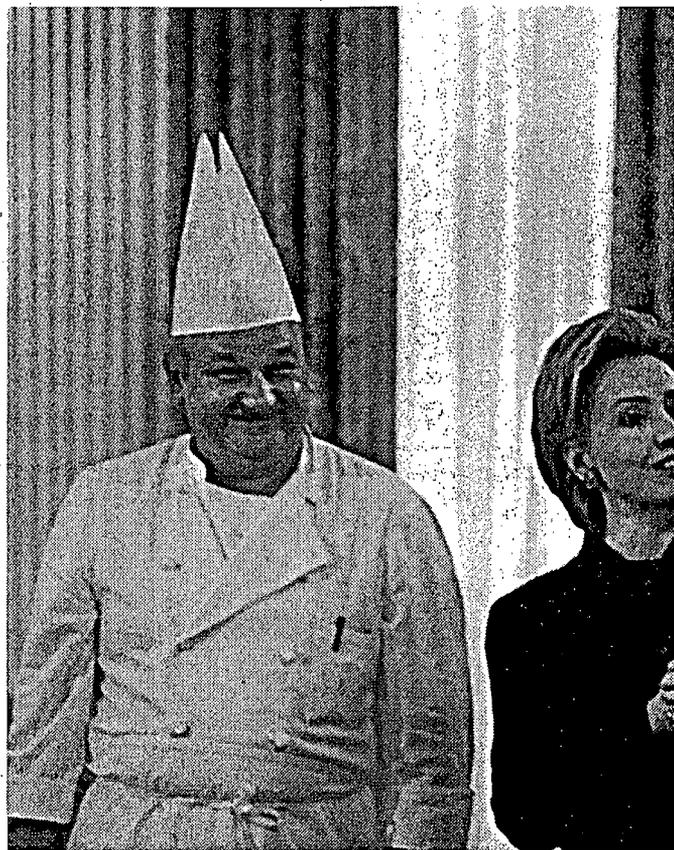
The institute reviews medication errors reported by doctors and nurses across the country, and it advises drug companies how to change the labeling or packaging of products to prevent such errors.

Senator Edward M. Kennedy, Democrat of Massachusetts, said today that he would introduce a bill to carry out all the recommendations of the National Academy of Sciences, including mandatory reporting of serious errors and creation of a new Center for Patient Safety in the federal government. The center would have an annual budget of \$30 million, rising to \$100 million in five years.

Senator Kennedy said his effort would be bipartisan; he intends to work with two Republican senators, James M. Jeffords of Vermont and Bill Frist of Tennessee, as well as with Senator Joseph I. Lieberman, Democrat of Connecticut.

Mr. Kennedy's bill would require hospitals and nursing homes to adopt policies to reduce errors as a condition of participating in Medicare or Medicaid, just as many Clinton administration officials want to do.

Medicare, which finances health care for 39 million people who are elderly or disabled, and Medicaid, which insures a similar number of low-income people, provide more than 40 percent of the revenue for hospitals and nursing homes. So standards for these two programs become virtual mandates for the entire health care industry.



Hillary Rodham Clinton supervised the decorating yesterday the White House pastry chef, Roland Mesnier, who created

Start Spreading the News, S

By MARIAN BURROS

WASHINGTON, Dec. 6 — Between about a dozen holiday parties at the White House, the elaborate plans for the millennium celebration and a full campaign schedule in New York, Hillary Rodham Clinton is sneaking in a little packing.

At the annual unveiling of White House Christmas decorations (this year's theme reflects times past), the first lady said today that the timing of her move into the Dutch Colonial house in Chap-

paqua, N.Y., that she and the president bought for \$1.7 million depended on the Secret Service. "I don't know if we'll be home before the end of the year," she said.

But she added, "While I'm packing, I'm trying to get everything ready. We are pulling things out of storage to see what has been covered."

There will not be any further shopping for the moment, she said, because "We are moving to use what we have."

Embattled Head of Laborers Union Annou

By STEVEN GREENHOUSE

Arthur A. Coia, the embattled president of the laborers' union, announced his retirement yesterday, two months after several union and federal officials said he would soon step down as part of a deal in which he would plead guilty to fraud charges.

Mr. Coia, 56, one of President Clinton's biggest labor supporters, said he was retiring because of illness and because he and his family thought it was time for him to step down. Officials with the Laborers' International Union of North America, one of the nation's largest building trades unions, insisted that his retirement had nothing to do with a deal with federal prosecutors.

Justice Department officials declined to comment.

In October, Mr. Coia angrily accused the department of leaking incriminating information about him. Those attacks came after newspapers reported that he would soon resign and would later plead guilty to charges involving his purchase of a \$450,000 Ferrari from a supplier to

the 750,000-member union.

In October, a government official and a union official said the plea would not result in a prison term but would bar Mr. Coia from future contacts with the union, which a president's commission described in 1985 as one of the nation's most corrupt.

In its announcement yesterday, the union said Mr. Coia would become president emeritus. He would stop serving on the union's board, but would receive part of his salary.

In March, after a five-year investigation, an independent union hearing officer cleared Mr. Coia on charges that he had ties to organized crime. But the officer fined Mr. Coia \$100,000 for an ethics violation concerning his purchase of the Ferrari.

In a statement, Mr. Coia said, "For too many years, my position in the union has caused me to be investigated nonstop, top to bottom and inside out. For far too many years, my entire life has been scrutinized — every action reviewed, every motive analyzed, every decision questioned, every good deed doubted."

Mr. Coia, who has largely recov-

ered after bouts of Hodgkin's and prostate cancer, said it would be to retire rather than continue his family in a secondary role.

Mr. Coia was a co-chairman of several fund-raisers for Mr. Clinton and Republicans pushed for an investigation of whether the president asked prosecutors to go easy on Mr. Coia and his union. Administration officials have denied Clinton asked any such favors, but they went easy on Mr. Coia.

Mr. Coia has long been one of the nation's most flamboyant union officials. He drove a Ferrari and owned luxury cars, he had a large home in his native Rhode Island and he loves to golf.

At the same time, he made his union, making it more on organizing additional members and improving health and safety programs.

Mr. Coia's father was once a party-treasurer of the union and a court reporter, associated with Raymond Patriarca Jr., New England's longtime crime boss.

The union said yesterday

outside the U.S. Interests Section. "I have two children, and as a mother you want to see the best for the child."

The White House takes a "dim view" of the threat posed by anti-U.S. demonstrations, spokesman Joe Lockhart said. "We take the safety of our diplomats and American personnel very seriously, and we expect Cuba to live up to the obligations they've undertaken to keep those Americans safe," he said.

The political pressures continued to mount for the administration, as a three-day deadline granted by a furious Castro was set to lapse Tuesday evening. Asserting that the boy had been kidnapped by U.S. officials and his exile relatives in Miami, Castro vowed to unleash "a battle of public opinion that will move heaven and earth" to return him to his father in Cuba.

In Havana on Monday, a government crane installed a reviewing stand in front of the U.S. mission while government workers delivered portable toilets, refreshment stands and loudspeakers, sparking speculation that Castro would speak there in the next few days.

The confrontation comes just days before U.S. and Cuban officials are set to meet for regularly scheduled migration talks on Monday. Those talks monitor the status of two historic accords reached between Havana and Washington in 1994 and 1995, which curtailed a raftier exodus by allowing the repatriation to Cuba of illegal migrants and facilitating the orderly outflow of more than 20,000 Cubans a year to the United States.

Cuban officials have made plain that they believe the decision not to repatriate Elian Gonzalez immediately was a violation of those accords. Over the weekend, National Assembly President Ricardo Alarcon hinted that the talks might be scrapped because "it is very hard to imagine that we could have any type of constructive discussion" while the controversy over the child simmers.

But as far as U.S. government officials are concerned, the talks will be held on schedule and preparations are proceeding accordingly.

With the prospect of a renewed Cuban exodus never far from the minds of U.S. policy makers, Foley said it was the State Department's view that the migration talks were in the "mutual interest" of both nations.

U.S. officials noted that Castro's angry outburst Sunday, when he branded the U.S. decision to let Florida courts handle Elian's case a "kidnapping," was the fourth strong attack he has launched against U.S. policies over the past few weeks.

"Castro is clearly orchestrating a major anti-American campaign with all this, and now the child," one U.S. official said. "The question is, where is he going with all this? We just hope it doesn't get out of control."

Clinton to announce strategies to reduce medical errors

By Andrea Gerlin

Knight Ridder Newspapers

PHILADELPHIA President Clinton is expected to sign an executive order Tuesday directing a task force to find new strategies to reduce medical errors and instructing government agencies to evaluate and implement error reduction techniques.

White House officials said Clinton will announce the measures in the Rose Garden after a planned morning meeting with representatives of health-care providers, consumers, purchasers, lawmakers and the Institute of Medicine.

"The President believes we should move quickly in this area and is unveiling a series of initiatives to reduce medical error and improve patient safety," said Christopher C. Jennings, deputy assistant to the president for health policy.

The executive order will direct the Quality Interagency Coordination Task Force to report, through Vice President Gore within 60 days, its recommendations for preventing medical errors. The federal Office of Personnel and Management will be ordered to require 300 private health plans that cover government employees to institute patient safety standards.

In making the announcement, Clinton is expected to direct the Office of Management and Budget, the Domestic Policy Council and other agencies to develop initiatives for combating errors and include them in the 2001 fiscal year budget. He is expected to highlight the American Hospital Association's plan to

American Hospital Association president Dick Davidson said the group looked forward to working with Clinton. The AHA said it would work with the Institute for Safe Medication Practices, based in Huntingdon Valley, Pa. The non-profit institute collects 50 to 60 confidential reports of drug errors each month and sends weekly alerts to 5,800 hospital pharmacies around the country.

In September, The Inquirer published a four-part series about medical mistakes. Based on internal hospital records, the articles described cases in which patients suffered injuries and deaths caused by errors in their care. In some cases, the patients or their survivors were never told about the mistakes.

Clinton is expected to review a new law, which he signed Monday, reauthorizing the Agency for Health Care Policy and Research and renaming it the Agency for Health Research and Quality. That agency, whose focus already includes health-care quality, may ultimately play a significant role in a rapidly developing national effort to reduce medical errors.

In a report issued Nov. 29, a panel of experts convened by a division of the National Academy of Sciences estimated that as many as 98,000 people die as a result of mistakes made in care at U.S. hospitals alone more than auto accidents, breast cancer and AIDS. The panel concluded that the number of deaths due to medical errors could be cut in half within five years.

The report, from a committee of the Institute of Medicine, recommended that Congress establish a center for patient safety within the Agency for Health Research and Quality at an initial cost of \$30 million to \$35 million a year, which is anticipated to grow to \$100 million a year. It also recommended that national guidelines be developed for mandatory public reporting of errors that kill or injure patients, and that Congress extend confidentiality protections to voluntarily report errors that do not harm patients.

Jennings said the executive order does not obviate the need for legislation. Sen. Edward M. Kennedy, D., Ma., Monday proposed legislation that would implement the recommendations for Congressional action suggested by the Institute of Medicine panel.

Kennedy is the ranking minority member of the Senate Health and Education Committee. The committee chairman, Sen. James Jeffords, R., Vt., said last week that it would hold hearings when Congress reconvenes on Jan. 24.

Kennedy's spokesman, Jim Manley, said, the senator "would rather lay this legislation down before going into hearings."

Although Congress is not in session, there has been a flurry of activity in the last week, with lawmakers' staffs racing to take action on an issue likely to be popular with voters in the upcoming election year. Sen. Arlen Specter, R., Pa., chairman of the Senate Appropriations subcommittee on labor, health and human services, and education, also said last week that the subcommittee would hold hearings on the matter.

Specter's chief of staff, David Urban, said Monday that those hearings might be held as early as Dec. 13 if subcommittee members and witnesses are available then. "We're moving pretty quickly," Urban said.

In the House, representatives and officials continue to study the Institute of Medicine report. Peter Sheffield, a spokesman for the House Committee on Commerce, said the committee is "holding open the option to hold hearings next year."

One of the first members of the House to address medical errors, Rep. Bruce Vento, D., Minn., met Monday with Agency for Health Research and Quality administrator John Eisenberg. Vento said he wrote to Eisenberg in September after he read The Inquirer's series, reprinted in his hometown newspaper, and became interested in the issue. He said a sister who had been hospitalized was mistaken for another patient and nearly received a hysterectomy not intended for her.

Vento, a biologist, raised the medical error issue on the floor of the House during a subcommittee on health and environment debate of the agency's reauthorization bill on Sept. 28. He asked then if the agency could compile state-by-state statistics on the number of injuries and deaths from medical errors to better monitor and reduce them.

He said Eisenberg told him Monday that the agency has the authority to assess quality and house a patient safety center but has only \$2 million in its budget for a program to address medical errors this year. Vento said he agreed with the Institute of Medicine's recommendations to Congress.

"We're going to have to respond to this," Vento said. "We know a lot of this happens. This is not something that can be pushed aside."