

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. note	re: phone numbers (1 page)	n.d.	P6/b(6)
002. fax	Caroline Stein to Chris Jennings (7 pages)	02/22/2000	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
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FOLDER TITLE:

Errors [Folder 2]

2012-0463-S

rc749

RESTRICTION CODES

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

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

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

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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**DETERMINED TO BE AN
ADMINISTRATIVE MARKING**

INITIALS: RLC DATE: 06/14/12

2012-0463-S

**I. LETTER OF INTRODUCTION
(December 20, 1999)**

*DeVora
Business
HC Quality Unit*

DATE

Dear _____:

I am writing to ask you to join other Fortune 50 employers in a simple effort to accelerate the safety and value of American health care. If you join us, the limits of your obligation would be to attend a single day's planning meeting and then self-certify that you will adhere to the attached purchasing principles.

Our effort is rooted in these five foundational ideas:

- That American health care remains **very far below obtainable levels** of basic safety and overall customer value. For example, the Harvard Medical Practice study shows that our chances of dying from avoidable human error is more than 10,000X greater during a hospitalization than during a commercial airline flight. Dr. Donald Berwick estimates that better quality management in American health care would allow a 30% reduction in cost *and* an improvement in quality. The National Academy of Science's 1998 IOM Round Table Report cited "serious and widespread" quality flaws resulting in a "great burden of harm" on Americans.
- That the health industry would much more rapidly obtain these large improvements if purchasers better recognized and rewarded superior safety and overall value. Most providers and insurers **do not perceive a strong business case** for safety and quality, or for the necessary information systems and quality management resources.

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- That voluntary, publicly salient adherence to thoughtfully crafted purchasing principles by a majority of America's Fortune 50 employers, would provide a **large jump start** for making the missing business case and encourage other purchasers to join us.
- That to maximize media/consumer support and adoption by other purchasers, the principles should not only champion superior overall value, but specifically focus on a handful of specific innovations offering "**great leaps**" in basic patient safety. After consultation with national quality experts, we selected for initial focus (1) computer physician order entry (CPOE) in hospitals and (2) evidence-based hospital referral (EHR) to hospitals offering the best survival odds (based on scientifically valid criteria such as the hospital's volume of experience in treating a given condition). CPOE has been shown to reduce serious prescribing errors in hospitals by over 50%, yet fewer than 1% of hospitals use it. EHR for the roughly 19 conditions showing strong statistical relationships between patient survival and a hospital's annual volume of such procedures or teaching status, could prevent over 7,000 American deaths annually, based on estimates by researchers at UCSF.
- That consumer understanding of and support for the safety leaps and other critically needed improvements in health care value are pivotal to our success. Accordingly, we will ground our efforts in consumer activation.

I have attached several brief documents that explain our reasoning and intended path. I've also enclosed a checklist by which you can assess what it would mean for you to adhere to these "leapfrog" purchasing principles.

I will call shortly to ask for your help. Many thanks for considering this.

Best regards,

Bruce Bradley
Committee Chair

White Paper on Value-based Purchasing
"When in the Course of Human Events..."

Preamble: This document addresses purchasers' unique opportunities to accelerate critically needed improvement in the value of American health care. Purchasers' roles in health care performance breakthrough carry important distinctions from the roles of government regulation, accreditation, and health care professional ethics. Many of these distinctions are elaborated in section V; the most important is an obligation to support the knowledge and autonomy of consumers for whom health care is a highly personal service. Accordingly, the bedrock in which this initiative is anchored is purchaser support for consumer discernment of, and access to, safer, higher value services. We place our faith and the fate of value breakthrough in their capable hands.

A. The Goal

"...to assume the station which the Laws of Nature entitle..."

Trigger a giant leap forward in quality, customer service, and affordability of health care of *all types* through (1) bringing into mainstream American public awareness a small number of highly compelling and easily understood advances in patient safety; and (2) specifying a simple set of purchasing principles designed to power these discrete safety advances, as well as overall customer value, broadly defined.

B. Foundational Assumptions

"Such has been patient suffering, let facts be submitted..."

1. Current levels of quality, customer service and cost in the health industry as a whole fall far short of best achievable.
2. The performance shortfall reflects a history of purchaser failure to incent the pursuit of superior value by both employees/beneficiaries and the health industry; it also reflects failure by the health industry to adopt modern methods of quality management.
3. The consequences of the shortfall are needless morbidity, mortality, dissatisfaction and uninsurance rates, as well as loss of international competitiveness of American workers and their employers.
4. Among the most disturbing consequences is lack of basic patient safety, documented in multiple scientific publications. Harvard and RAND researchers have documented *avoidable harm* to 3% of American inpatients and 11% of chronically ill outpatients.
5. The gross magnitude of the performance shortfall and its consequences are under-appreciated by health care buyers, sellers, and the public.
6. The most expedient route to rapid improvement originates with changing the behavior of American health purchasers and consumers.
7. The linchpin of required purchaser behavior change is rigorous identification and reward of superior health care value and four critical ingredients: reliable use of proven methods to assure basic patient safety; improved health information systems; routine use of industrial quality improvement methods in managing and delivering clinical services; and routinely involving consumers as active participants in health care decision-making.
8. Both the likelihood and effect of purchaser behavior change can be dramatically increased, if it is reinforced by mainstream public awareness of the health industry's progress in eliminating salient safety threats.

C. Operational Blueprint

"We therefore assembled and declare...the full power to levy War, conclude Peace, contract Alliances and do other...Things..."

1. Develop, disseminate and steadily elevate a set of common Purchasing Principles designed to strongly incent superior health care value.
2. Subscription to Purchasing Principles would be voluntary, documented by completion of the attached checklist, propagated by social norms among purchasers analogous to subscription to ISO 9000 manufacturing norms.
3. Purchasing Principles will be flexible to accommodate member differences in geographic, demographic, organizational and market factors.
4. Purchasing Principles will be structured in stepwise fashion (see attached checklist), so that purchasers can benchmark themselves against the most exacting standard and ascertain how they can advance.
5. In partnership with the health industry, select for special focus the rapid, industry-wide adoption of 2-4 discrete improvements likely to yield the largest gain in patient safety.
6. Transform these discrete improvement and their corresponding dangers into simple, compelling concepts that will "stick" in the awareness of all stakeholders (e.g., hospitals without computer physician order entry are unnecessarily risky)
7. Use the public stature and contacts of the founding purchasers to catalyze wide adoption of the purchasing principles by other purchasers and establish the concepts in the common language of the American public.
8. Rely on the power of the American public to drive health care improvement by centering our efforts on strengthening their ability to discern and access safer and higher value health care.

- Fifth Draft prepared by Arnold Milstein MD and Robert Galvin MD
- Quotations from T. Jefferson, B. Franklin, et al, The Declaration of Independence, July 1776

III. PRINCIPLES

Purchasing Principles

- A. **Use of Comparative Rating.** Purchasers will aggregate available valid performance information into *comparative value ratings* of their largest delivery systems, irrespective of the associated insurance mechanism. Whenever available, the performance measurement approach will be based on nationally recognized sources such as NCQA which assures the validity of performance comparisons.

Rationale: Comparative value ratings will make more straightforward to the health industry how variations in performance cause variations in comparative value perceived by customers. Nationally recognized information sources will promote consistency and validity of comparisons.

- B. **Use of Substantial Incentives.** Purchasers will use two or more of the following three methods to commercially reward delivery systems with higher value ratings; and will annually increase their intensity until that they prove sufficient to motivate widespread and substantial annual performance improvement among network providers.
- **Patient Volume.** Support consumers' selection of higher value delivery systems via robust (i) promotion (such as "blue ribbon" designation, selection/deselection of plans/providers and enrollment freezes) (ii) consumer economic incentives (such as Enthoven's model of price-conscious enrollee choice applied to plans or delivery system or other methods of varying consumer out-of-pocket costs) and (iii) consumer decision support (such as easily accessed and interpreted performance comparisons).
 - **Price.** Vary prices which purchasers pay to delivery systems based on comparative value (such as value-based bonuses or rebates and/or incorporating risk-adjustment into negotiation of cost targets or premiums/prices, whenever feasible).
 - **Public Recognition.** Publicly disseminate and recognize superior performance.

Rationale: To motivate delivery systems to stretch for major breakthroughs in customer value, purchasers must build much more robust market rewards for higher value.

- C. **Focus on Discrete Forward Leaps in Patient Safety.** In implementing the two basic Purchasing Principles of comparative rating and substantial incentives, purchasers will highlight a common set of 2-4 discrete delivery system improvements likely to yield the largest safety gains ("safety leaps"). These will be earmarked for special visibility in purchasers' interaction with their delivery systems, insurers/administrators, and consumers. For example, purchasers will use common RFP questions to rate for each delivery system the implementation status of the safety leaps and explicitly integrate such status information into every method utilized to reward superior value (patient volume, price and/or public recognition). Using expert input, we identified the following two initial safety leaps, which have been transformed into safety standards in section V. A third safety leap in physician ICU staffing is under consideration and also included in section V.

- **Computer Physician Order Entry:** Physician order entry in hospitals should be computerized. Adverse drug events are the leading cause of avoidable death and disability in American hospitals. As documented in research by Dr. David Bates at Brigham and Women's Hospital, computer physician order entry (CPOE) is a highly effective discrete remedy. In well managed installations, its costs are likely to be substantially offset by savings from avoided costs of treating complications.
- **Evidence-Based Hospital Referral:** Elective treatment should be routinely guided by providers to hospitals and clinical teams (1) meeting evidence-based service credentialing criteria, such as the American College of Cardiology's minimum volume thresholds for CABGs and angioplasties; or (2) with clearly superior outcomes, when valid comparative outcome measurement systems exist. For 19 conditions and treatments, the scientific literature documents significantly superior patient outcomes in hospitals with higher volumes or with teaching programs. In some regions, risk-adjusted outcome information for individual hospitals is available. For example, in California, Dr. Adams Dudley at UCSF's Institute for Health Policy projects that 500 to 1,000 deaths could be prevented annually through such evidence-based hospital referral in California alone. If the current California equilibrium reflects the nation, it implies a national opportunity to save over 7000 lives annually.

To maximize initial safety gains and minimize legitimate concerns about unintended consequences, initial efforts to implement these two safety leaps should focus on urban areas.

Rationale: Of all potential topics for improvement, basic safety, as well as strongly motivating providers to support enhanced safety, are likely to garner the widest support from the public, the media, regulators, accreditors, other purchasers and the health industry.

- D. Hold Health Plans Accountable for Leapfrog Implementation.** In advancing these principles, purchasers who utilize health plans as their intermediaries may delegate responsibility to plans for applying the principles to their network providers. If so, purchasers would hold their health plan(s) accountable via nationally standardized leapfrog questions in health plan RFPs, heavily weighted scoring criteria, robust health plan performance incentives, and other methods of assuring health plan application of leapfrog principles. Purchasers would annually intensify these incentives until their largest health plans fully meet their delegated responsibility for applying Principles A, B and C.

Rationale: Many purchasers utilize health plans as their intermediaries to delivery systems. Health plan application of leapfrog principles in their provider relationships for their whole book of business will exert an even stronger effect on delivery systems.

- E. Encourage the Support of Consultants and Brokers.** In selecting benefits consultants and brokers, purchasers will strongly incent them to incorporate leapfrog principles (1) in their advice to other purchaser clients; and (2) in their standard tools for assessing health plans and delivery systems.

Rationale: The purchasing principles advocated and utilized by these purchaser advisors profoundly shape the market experience of insurers and delivery systems. As major customers of these advisors, purchasers can motivate them to advocate these principles on behalf of all of their clients.

IV. IMPLEMENTATION PLAN
(December 20, 1999)

Summary Purchaser-Driven Implementation Plan

A. Pre-Market:

Pre-market the Leapfrog Purchasing Principles by: (1) Using personal contacts of Leapfrog founders, obtain the commitment (via satisfactory completion of the attached self-rating checklist) of a majority of Fortune 50 employers, OPM, HCFA, the largest network-based health plans, and the largest benefit consulting firms/brokers to implement the Principles; (2) Attempt to arrange the support for the Principles of the following groups: MHCA, WBGH, major employer health care coalitions, BRT, NAM, USCOC, HCFA, AARP, the AFL-CIO and AAHP; and (3) Explain the principles to the national "idea-leading" press (WSJ, NYT, WP, LAT and selected others).

B. Launch:

As soon as we have finalized the self-rating checklist and obtained the commitment of 26 of Fortune 50 employers, we will hold a professionally-arranged Leapfrog leaders press conference to unveil the Leapfrog Purchasing Principles publicly and identify computer physician order entry in hospitals and evidence-based hospital referral as the initial primary "leaps." Use the Harvard Medical Practice study results, David Bates' results, Adams Dudley's findings and national hospital discharge data to derive (and use in the press conference) a conservative estimate of how many American lives would be saved annually if the first two safety leaps were fully implemented. Anchor the announcement in a Leapfrog commitment to use the Leapfrog Purchasing Principles of rating and reward aggressively to advance both safety leaps. If development of a third safety leap directed at encouraging closed ICU physician staffing is complete, it will be included in the launch.

C. Propagate:

Develop a coherent strategy for wide dissemination and uptake by other purchasers and consumers, using (1) large purchasers' customer relationships with insurers, administrators, benefits consultants and brokers and (2) advice from professional marketing specialists with experience in promoting health consumerism and/or public health programs. The essence of our strategy is to use a cadre of highly visible companies to advance health care safety and value and pull many smaller purchasers forward by our example.

D. Steadily Reinforce:

Develop a tracking system for national progress in achieving computer order entry and evidence-based hospital referral. Use press contacts to publicly disseminate quarterly estimates of lives saved, using a contract health services research center. (Similar to MCI tracking of how much money America saved via MCI.)

E. Expand:

Continuously refine and expand Purchasing Principles, with special focus on new safety leaps.

F. Support Implementation:

This would include standard Leapfrog-specific questions for RFPs to health plans, delivery systems and consultants/brokers; a suggested menu of Leapfrog-specific performance targets and rewards; samples of well crafted Leapfrog-specific performance measures for consumer scorecards and other consumer education materials; and suggested alliances with purchaser, regulatory, accrediting and consumer organizations.

**V. Safety Standards
(December 20, 1999)**

Leapfrog purchasers will advance the following three initial methods to improve patient safety. The selection of these standards does not imply lack of support for the many other important methods of improving or assuring patient safety. Rather, it reflects our view that these three methods are well suited to purchasing standards because: they are highly tangible; their presence or absence is readily discernable by purchasers; their beneficial effect is easy for consumers to grasp; there is reasonable scientific evidence that they are effective; and the magnitude of their likely effect on patient safety is large. We intend to expand this list as we identify other safety improvement with these features.

Leapfrog purchasers specifically commit to (1) identifying for their enrollees which providers publicly warrant on a leapfrog-designated website their fulfillment of each of these safety standards by 12 months prior to the target dates indicated below; (2) proactively providing this information at an 8th grade literacy level to all enrollees who are at increased risk of hospitalization; (3) including a clear statement of the limitations of each safety standard; (4) assuring that all enrollees in urban areas have access to providers which warrant they meet the standards; and (5) working toward a goal that by 12/31/04 more than half of urban hospitalizations of their enrollees will occur in hospitals which offer such a warranty.

- A. Computer Physician Order Entry (CPOE):** Hospitals (1) require physicians to enter medication orders via computer linked to prescribing error prevention software; (2) demonstrate that their CPOE system intercepted at least 50% of common serious prescribing errors, utilizing test cases and a testing protocol specified by the Institute for Safe Medication Practices (ISMP); (3) require documented acknowledgment by the prescribing physician of the interception prior to any override; and (4) post the test case interception rate on a leapfrog-designated website. Target date 12/31/02

- B. Evidence-based Hospital Referral (EHR):** For elective hospitalizations in urban areas, the following treatments will be provided in hospitals which both meet the favorable hospital volume characteristics listed below and demonstrate unadjusted mortality rates below regional norms. In geographies where scientifically rigorous risk-adjusted hospital outcome comparisons are publicly reported, these treatments will be provided in hospitals with favorable comparative outcomes. Target date: 12/31/02

Condition/Procedure	Minimum Hospital Volume Characteristics
Coronary artery bypass	Volume $\geq$ 500/year
Coronary angioplasty	Volume $\geq$ 400/year
Abdominal aortic aneurysm repair	Volume $\geq$ 30/year
Carotid endarterectomy	Volume $\geq$ 50/year
Esophageal cancer surgery	Volume $\geq$ 7/year
Delivery with expected birthweight <1500 grams or gestational age < 32 weeks; or	Regional neonatal ICU ² with average daily census $\geq$ 15
Delivery with pre-natal diagnosis of major congenital anomalies. Diagnosis ² codes 741.XX, 742.0X, 742.2-742.9, 745.XX, 746.00-746.85, 747.1X-747.9, 748.0, 748.2-748.8X, 750.16, 750.3, 750.4, 750.6, 751.XX, 752.7, 753.1X, 753.3, 753.6, 756.4, 756.51, 756.55, 756.59, 756.6, 756.7X, 756.89, 756.9	Regional neonatal ICU ³ with average daily census $\geq$ 15

¹Consumer information will also explain the benefits obtainable above lower volume threshold(s)

²Applies in states in which hospital licensing agency makes such a designation

³This code list is in the process of expert peer review and refinement

- C. ICU Physician Staffing (IPS):** Hospital ICU care is managed by a physician certified (or eligible for certification) in critical care medicine, who (1) during daytime hours is present and provides clinical care exclusively in the ICU; (2) at other times, returns more than 95% of ICU pages within five minutes; and can rely on an FCCS certified "effector" (physician or physician extender) who is in the hospital and able to reach ICU patients within 5 minutes in more than 95% of cases. Target date: 12/31/03

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INITIALS: RUR DATE: 06/14/12

2012-0463-5

VI. CHECKLIST
(December 20, 1999)

Checklist for Fulfillment
of Leapfrog Purchasing Principles

Please complete this checklist. Note that fulfillment requires that you circle YES at least once for each question. If you are fulfilling by requiring that your major health plans apply the purchasing principles to their network providers, please describe how your largest plan(s) comply.

	<u>Currently</u>	<u>By Dec 2000</u>	<u>By Dec 2001</u>	
A. I will aggregate valid comparative performance information into annual comparative value ratings that span quality, customer service and cost for my largest delivery systems.	Circle Y or N. If yes, describe:	Circle Y or N. If yes, describe:	Circle Y or N. If yes, describe:	For Health Plans
				For Hospitals
				For Physicians (or Groups)

B. I will use two of the following three methods (1-3) to reward higher value delivery systems; and will annually intensify them until they prove sufficient to motivate widespread and substantial annual performance improvement among network providers.

1(a) Channeling of patient volume (e.g., promotion in plan selection materials/provider directories or selection/deselection/freezing)

	Circle Y or N. If yes, describe:	Circle Y or N. If yes, describe:	Circle Y or N. If yes, describe:	
				For Health Plans
				For Hospitals
				For Physicians (or Groups)

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Currently

By Dec 2000

By Dec 2001

- (b) Consumer economic incentives (e.g., varying levels of purchaser contribution to monthly plan cost or out-of-pocket costs)

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

			For Health Plans
			For Hospitals
			For Physicians (or Groups)

- (c) Consumer decision support (e.g., easily accessed and interpreted performance comparisons)

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

			For Health Plans
			For Hospitals
			For Physicians (or Groups)

2. Variation in prices paid to delivery systems (e.g., bonuses, rebates, penalties, risk-adjusted premiums or cost targets)

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

			For Health Plans
			For Hospitals
			For Physicians (or Groups)

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3. Public recognition
(e.g., publicly disseminate
and congratulate superior
performance)

Currently

By Dec 2000

By Dec 2001

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

			For Health Plans
			For Hospitals
			For Physicians (or Groups)

- C. I will fulfill the Leapfrog
purchaser commitment stated in
section V to advancing Leapfrog
safety standards.

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

Circle Y or N.
If yes, describe:

			For Health Plans
			For Hospitals

- D. I will limit the award of new
assignments to benefits consulting
firms and brokers which
vigorously advocate principles A-
F with their clients

Circle Y or N
If Yes, describe.

Circle Y or N
If Yes, describe.

Circle Y or N
If Yes, describe.

			For Benefits Consulting Firms
			For Brokers

GM HMO PERFORMANCE EXPECTATIONS

2000

Patient Safety/Medical Errors

- 1.0** The HMO fosters an approach to patient safety (e.g., error reduction) that emphasizes root cause identification rather than individual performance and blame. The HMO works with the delivery system to improve systems and processes that impact safety.
- 1.01** The HMO will develop and implement patient safety standards in three key areas that have been documented to be effective in hospitals at reducing medical errors and/or improving patient outcomes:
- a. Computer Physician Order Entry (CPOE) for non-rural¹ network hospitals
 - b. An ICU Physician Staffing Standard for non-rural network hospitals
 - c. An Evidence-based Hospital Referral Standard for non-rural, elective hospitalizations
- 1.02** The HMO will meet the following standards and timelines for implementation of Computer Physician Order Entry in non-rural network hospitals:
- 1.02.01** By 12/31/00, the HMO will have a written plan, including goals, implementation plan, measurable implementation milestones with target dates, and identified indicators of successful implementation (e.g., number of orders that were flagged and percent of flagged orders that were modified).
- 1.02.02** By 12/31/01, the HMO will ensure that 30% of their non-rural contracted hospitals will have implemented a computer physician order entry system. Further, these hospitals will have tested their system by using the Institute for Safe Medication Practices' (ISMP²) testing protocol and documented, by posting to a specified website³, that at least 50% of common serious prescribing errors have been intercepted. Demonstration of a successful interception must include documented acknowledgement of the intercept by the prescribing physician prior to any override.
- 1.02.03** By 12/31/02, the HMO will ensure implementation, testing, and documentation of a 50% interception rate by the mandatory computer physician order entry systems in 90% of its contracted non-rural network hospitals. All compliant hospitals will report the results of identified indicators to the HMO and to GM on an annual basis as of this date.
- 1.03** The HMO will meet the following standards and timelines for implementation of mandatory coverage of non-rural network hospital ICUs by physicians certified in critical care medicine who (1) during daytime hours are present and provide clinical care exclusively in the ICU; (2) at other times return more than 95% of ICU pages within five minutes; and can rely on a physician or physician extender

¹ Non-rural -- within a SMSA

² The Institute for Safe Medication Practices (ISMP) is a nonprofit organization focused on educating the healthcare community about safe medication practices. ISMP is partnering with the American Hospital Association on a national initiative on medication safety. More information is available at www.ismp.org.

³ This website will be determined by ISMP within the next 6-12 months.

(the "effector") who is in the hospital and able to reach ICU patients within 5 minutes in more than 95% of cases (effectors must be FCCS⁴ certified):

1.03.01 By 12/31/00, the HMO will have a written plan, including goals, implementation plan, measurable implementation milestones with target dates, and identified indicators of successful implementation (e.g., >95% of ICU after-hours pages are answered within 5 minutes).

1.03.02 By 12/31/01, the HMO will have ensured full implementation of the standard in 10% of applicable hospitals.

1.03.03 By 12/31/02, the HMO will have ensured full implementation of the standard in 40% of applicable hospitals.

1.03.04 By 12/31/03, the HMO will have ensured full implementation of the standard in 90% of applicable hospitals.

1.04 The HMO will meet the following standards and timelines for implementation of evidence-based hospital referrals:

1.04.01 By 12/31/00, the HMO will have a written plan, including goals, implementation plan, measurable implementation milestones with target dates, and identified indicators of successful implementation (e.g., elective hospitalizations in hospitals with favorable characteristics) for a program to encourage referral of patients with specified conditions to hospitals that meet specified annual volume thresholds as listed in the table below.⁵

Condition/Procedure	Favorable Hospital Characteristics
Coronary artery bypass	Volume $\geq$ 500/year
Coronary angioplasty	Volume $\geq$ 400/year
Abdominal aortic aneurysm repair	Volume $\geq$ 30/year
Carotid endarterectomy	Volume $\geq$ 50/year
Esophageal cancer surgery	Volume $\geq$ 7/year
Expected birthweight <1500 grams or gestational age <32 weeks	Regional neonatal ICU ⁴ with average daily census $\geq$ 15
Surgical correction of major congenital anomalies. Diagnosis codes 741.XX, 742.0X, 742.2-742.9, 745.XX, 746.00-746.85, 747.1X-747.9, 748.0, 748.2-748.8X, 750.16, 750.3, 750.4, 750.6, 751.XX, 752.7, 753.1X, 753.3, 753.6, 756.4, 756.51, 756.55, 756.59, 756.6, 756.7X, 756.89, 756.9	Regional neonatal ICU ⁴ with average daily census $\geq$ 15

⁴ "Fundamental Critical Care Support" is a certification course offered by the Society for Critical Care Medicine.

⁵ In regions where scientifically rigorous risk-adjusted hospital outcome comparisons are publicly reported, the basis of hospital referrals will convert from these characteristics to favorable comparative outcomes. In regions where scientifically rigorous risk-adjusted hospital outcome comparisons are publicly reported, the bases of hospital referrals will convert from volume thresholds to favorable comparative outcomes.

¹Applies in states in which hospital licensing agency makes such a designation

1.04.01.1 By 12/31/01, the HMO will ensure that 50% of its non-rural relevant elective hospitalizations occur in hospitals that meet the standard.⁶

1.04.01.2 By 12/31/02, the HMO will ensure that 90% of its non-rural relevant elective hospitalizations occur in hospitals that meet the standard.¹

⁶ Patients who choose a hospital with unfavorable characteristics shall be excluded from the calculation if the HMO can document that they received an advance written explanation (geared to the eighth grade reading level) of the estimated reduction in survival odds associated with their choice.

*Carmela
Boccino*

*Call
Janet
Conigan*

Sentinel Event Questionnaire Responses

1. Do you have a law that requires reporting of health care sentinel events to the state?

STATE	Yes	No	Comments
Alabama	✓		
Alaska	✓		
Arizona		✓	
Arkansas			Wouldn't share information.
California		✓	
Colorado			
Connecticut			
Delaware			
District of Columbia	✓		
Florida	✓		
Georgia			
Hawaii		✓	
Idaho	✓		
Illinois			
Indiana			
Iowa	✓		
Kansas			
Kentucky		✓	
Louisiana	✓		
Maine			
Maryland			
Massachusetts	✓		
Michigan			
Minnesota	✓		
Mississippi		✓	
Missouri		✓	
Montana		✓	
Nebraska			
Nevada	✓		
New Hampshire		✓	
New Jersey	✓		
New Mexico		✓	
New York	✓		
North Carolina			
North Dakota		✓	
Ohio			
Oklahoma		✓	
Oregon		✓	
Pennsylvania	✓		
Rhode Island			
South Carolina			
South Dakota	✓		

STATE	Yes	No	Comments
Tennessee	✓		
Texas	✓		
Utah		✓	
Vermont		✓	
Virginia			
Washington	✓		
West Virginia		✓	
Wisconsin	✓		
Wyoming		✓	
Puerto Rico		✓	
Totals	18	17	

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001. note	re: phone numbers (1 page)	n.d.	P6/b(6)

COLLECTION:

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

FOLDER TITLE:

Errors [Folder 2]

2012-0463-S

rc749

RESTRICTION CODES

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

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

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

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

2. What kinds of events are reported?
(Check all that apply)

severe
not to minor
extraordinary

STATE	Unexpected patient deaths (including suicide and restraint deaths)	Wrong site surgery	Infant abduction or wrong infant discharge	Rape of a patient	Hemolytic transfusion reaction	Major loss function due to treatment or surgery	Others
Alabama	✓			✓			serious injuries, burns
Alaska							abuse/neglect for vulnerable adults
Arizona							
Arkansas							
California			✓				
Colorado							
Connecticut							
Delaware							
District of Columbia	✓		✓	✓	✓	✓	
Florida	✓	✓			✓	✓	wrong pt surg/surg repair
Georgia							
Hawaii	✓						allegations of abuse, neglect, misappropriation of funds
Idaho	✓			✓			patient abuse/ neglect/ exploitation
Illinois							
Indiana							
Iowa	✓						elopement
Kansas							
Kentucky							
Louisiana	✓			✓			abuse, injuries of unknown origin
Maine							
Maryland							
Massachusetts	✓	✓	✓	✓	✓	✓	* We have circular letters for hospitals and nursing home reporting-call if you want copies.*
Michigan							
Minnesota	✓			✓			abuse, neglect exploitation (financial)
Mississippi							

10M
10M
10M

10M

called

called
10M

10M

10M

STATE	Unexpected patient deaths (including suicide and restraint deaths)	Wrong site surgery	Infant abduction or wrong infant discharge	Rape of a patient	Hemolytic transfusion reaction	Major loss function due to treatment or surgery	Others
Missouri							
Montana							
Nebraska							
Nevada							abuse, exploitation, neglect
New Hampshire							
New Jersey	✓	✓	✓	✓	✓	✓	anesthesia related events; disasters related to interruption of service
New Mexico							Abuse, neglect, exploitation
New York	✓	✓	✓	✓	✓	✓	(serious occurrence warranting DOH/DMH notification)
North Carolina							
North Dakota							
Ohio							
Oklahoma							
Oregon							
Pennsylvania	✓	✓	✓	✓	✓		serious compromise patient care
Rhode Island							
South Carolina							
South Dakota	✓			✓	✓		Patient elopement
Tennessee							unusual occurrences or events (left to org. discretion)
Texas							abuse and neglect
Utah							
Vermont							
Virginia							
Washington	✓	✓	✓	✓	✓	✓	
West Virginia							
Wisconsin	✓						suicides, restraint, isolation and psychotropic medication deaths
Wyoming							
Totals	13	5	6	9	6	5	

10M

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10M

joint commission

chuck mowll
exec VP

630 7925656

Sentinel Event Questionnaire Responses

1. Do you have a law that requires reporting of health care sentinel events to the state?

STATE	Yes	No	Comments
Alabama	✓		Elva Goldman 334.206 5077
Alaska	✓		Shelbert Larsen 907.561 8081
Arizona		✓	LINDA PRUMER 602.674 4200
Arkansas			Wouldn't share information.
California		✓	Brenda Klutz 916.445
Colorado			
Connecticut			
Delaware			
District of Columbia	✓		
Florida	✓		
Georgia			
Hawaii		✓	
Idaho	✓		
Illinois			
Indiana			
Iowa	✓		
Kansas			
Kentucky		✓	
Louisiana	✓		
Maine			
Maryland			
Massachusetts	✓		Nancy Riordy
Michigan			
Minnesota	✓		
Mississippi		✓	
Missouri		✓	
Montana		✓	
Nebraska			
Nevada	✓		
New Hampshire		✓	
New Jersey	✓		
New Mexico		✓	
New York	✓		Fred Heigel
North Carolina			
North Dakota		✓	
Ohio			

LEAD 10 00 00:26 PM NHSHF
 KATO '98
 deta -
 NASHF is in the field now with a more detailed survey

See attached list with Ph. #

Says no -

STATE	Yes	No	Comments
Oklahoma		✓	
Oregon		✓	
✗ Pennsylvania	✓		
Rhode Island			
South Carolina			
South Dakota	✓		
→ Tennessee	✓		
Texas	✓		
Utah		✓	
Vermont		✓	
Virginia			
Washington	✓		
West Virginia		✓	
Wisconsin	✓		
Wyoming		✓	
Puerto Rico		✓	
Totals	17	16	

trialquest1.lwp

Sentinel Event Respondents

FstName	LstName	State	BusPhone
Shelbert	Larsen	AK	907-561-8081
Ellva	Goldman	AL	334-206-5077
Charles	McGrew	AR	501-661-2771
Linda	Palmer	AZ	602-674-4200
Brenda	Kluz	CA	916-445-3054
Paul	Daraghy	CO	303-692-2819
Cynthia	Derine	CT	860-509-7400
Geraldine	Sykes	DC	202-727-7190
Ellen	Reap	DE	302-577-6666
Anna	Polk	FL	850 487 1709
Martin	Rotter	GA	404-657-5700
Helen	Yoshimi	HI	808-586-4080
J.	Bennett	IA	515-281-4233
John	Hathaway	ID	208-364-1864
William	Bel	IL	217-782-2913
Gerald	Colaman	IN	317/233-7022
Joseph	Kroll	KS	913-296-1240
Timothy	Verio	KY	502-564-2888
Lilly	McAllister	LA	504-342-0415
Nancy	Ridley	MA	617 624 5280
Carol	Beriner	MD	410-402-8018
Louis	Dorogl	ME	207-624-5443
Gladys	Thomas	MI	517-241-2637
Linda	Sutherland	MN	651-215-8715
Darrell	Hendrickson	MO	573-751-6302
Vanessa	Philips	MS	601-354-7300
Linda	Sandman	MT	406-444-2037
Stephen	White	NC	919-733-7461
Darleen	Bartz	ND	701-328-2352
Helen	Meeks	NE	402-471-0179
Ray	Rusin	NH	603-271-4592
Catherine	Morris	NJ	609-633-8980
Matthew	Gervose	NM	505-827-4200
Richard	Panelli	NV	702-687-4475
Fred	Heigel	NY	516 402 1003
Rebecca	Maust	OH	614-466-7857
Brent	VanMeter	OK	405-271-4200
Dan	Barker	OR	503-945-6456
John	Hair	PA	717-787-8015
Wayne	Farrington	RI	401-222-2566
Karen	Price	SC	803-737-7205
Joan	Bachman	SD	605-773-3356 or 7205
Marie	Fitzgerald	TN	615-741-7221 615
Jim	Lehrman	TX	512-438-2625
Allan	Elkins	UT	801-538-6559
Nancy	Hofheimer	VA	804-367-2102
Laine	Luccenti	VT	802-241-2345
Kathy	Stout	WA	206-705-8655
Susan	Schroeder	WI	608-267-7185
John	Wilkinson	WV	304-558-0050
Jerry	Bronnenberg	WY	307-777-7121

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002. fax	Caroline Stein to Chris Jennings (7 pages)	02/22/2000	P6/b(6)

COLLECTION:

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

FOLDER TITLE:

Errors [Folder 2]

2012-0463-S

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RESTRICTION CODES

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To: Devora

From: Bill Hubbard/FDA

12/3/99 TO: Devora Adler FROM: Bill Hubbard

As you requested, here are a couple of additions we suggest to the executive memorandum.

- On page 1, 3rd line from bottom, after "In addition," add "The Food and Drug Administration has been developing a state-of-the-art reporting system that will enable FDA to identify and react to injuries and deaths to patients from "misadventures" in the use of medications and medical devices."
- On page 2, add a bullet among those after "This report shall:" "Evaluate the extent to which medical errors are caused by misuse of medications and medical devices and how the FDA's surveillance and response system can be strengthened to reduce their incidence."

For your background information, FDA scientists have recognized for some time that a large number of deaths and injuries, amounting to huge health care costs, are caused by "misadventures" in the use of drugs and medical devices. Indeed, the IOM report finds that perhaps 80% of medical errors are associated with products regulated by FDA.

Although the research, data collection, partnering, etc. called for in the IOM report are important, we at FDA are concerned that the developing response downplays significant programs in HHS already in effect or identified as being needed to address this problem. For example, from FDA's admittedly parochial view, we've been trying for years to make the point that relatively modest investments in these programs can return very significant savings in patient injury and health care costs. There are many things that FDA has been trying to do for which there is evidence that intervention can be successful, e.g., identifying and reacting to adverse reactions rapidly, giving patients and physicians better labeling information for drugs and devices, eliminating name confusion with drugs, and communicating to health professionals about emerging product risks before those risks multiply.

A recommendation of the IOM is to develop a mandatory nationwide adverse reaction reporting system for hospitals and a voluntary one for others. Yet FDA already has such systems. But that program has not been maximally utilized. For example, FDA receives 250,000 adverse injury reports for drugs alone each year, but the data is not adequately sorted and analyzed in a timely fashion because of lack of funding. Similarly, automation can be used to make this system more effective, but the funds to invest in a state-of-the-art system do not exist. The Administration requested an initial funding of \$15M for 2000 to begin modernizing the program, but Congress appropriated no funds.

Attached is a brief outline of how FDA's current programs to reduce medical errors work, what the FY 2001 request to OMB would provide for, and what additional ideas could be pursued if funding were made available.

I. FDA's Current Programs that Address Medical Product Safety

Evaluation and management of the risks of medical products both during product development and after marketing is a central part of the Food and Drug Administration's (FDA's) mission. FDA addresses sources of error in medical product use through programs that:

- Assure safety is designed into products before they get on the market by setting safety and quality standards and assuring that the standards are met.
- Minimize certain risks for medical products by assessing:
 - potential name confusions
 - potential interactions with other medications and foods
 - packaging, labeling, and other potential sources of error
 - information designed for consumers.
- Maintain safety surveillance programs to capture and analyze medication error and medical device experience/adverse event reporting. These programs include: an electronic reporting system for drugs and biologics that receives and analyzes over 250,000 reports annually; error and accident reporting for blood; and adverse experience reporting for devices. In addition FDA maintains co-operative agreements that provide access to databases linking drug use and patient outcomes so the agency can understand what is actually happening in medical practice.
- Require industry to re-label products, communicate problems, and in some cases to cease marketing or recall a product based on emerging safety problems.
- Communicate about emerging health risks and safety information with health professionals, patient groups, consumers, and industry in the U.S, and with regulatory authorities in other countries.
- Collaborate with other public health agencies and private organizations, e.g. National Patient Safety Foundation (NPSF), to raise awareness about safety issues.

II. Enhancements Requested in FDA's FY 2001 Budget

FDA believes that its programs can a substantial impact on public health by reducing patient risk from drugs and medical device errors. However, in recent years, the agency's programs have been insufficiently funded. For example, FDA's FY 2000 budget requested \$15 million to begin the development of a state-of-the-art risk management system, but Congress appropriated no funds.

FDA's FY 2001 request to OMB includes a number of actions that will address concerns raised in the IOM report. Such actions are described below.

FDA will develop data that define the nature and scope of the medical product safety problem by:

- Creating a pilot hospital-based medical device injury reporting system. The country needs reliable health statistics related to this problem. This will form the basis for an expanded medical product reporting system.

- Finishing FDA's on-line reporting system for adverse events for drugs and biologics to provide rapid assessment of emerging medical errors related to those products.
- Improving the speed and accuracy of our evaluation of error reports so that this knowledge can prevent further harm.
- Initiating an agency-wide adverse event reporting system (across product types) and link to more external data sources to create an integrated comprehensive picture of patient safety in the various health care settings.
- Conducting research to improve early detection of safety problems
- Improving accessibility to and ease of adverse event reporting to increase the rate and quality of reports

FDA will enhance communications by:

- Redesigning product labels to make them more useful and consistent because we know they can be greatly improved.
- Expanding educational programs for health care providers to promote the safe use of medical products
- Partnering with national organizations to address product safety
- Conducting scientific exchange programs with academia, other agencies, health care professionals, and industry to leverage safety information

FDA will develop standards for manufacture, testing, and use of medical products to promote safety and reduce human error, including standards for:

- Reuse of single-use medical devices
- Reducing name confusion
- Labeling and packaging

III. Actions FDA Can Take with Additional Funding

Form a national surveillance network

- Invest in a fully integrated national surveillance network for medical errors. This network should include funding for hospitals and health care systems to detect, investigate and report medical product errors and to take corrective actions. The federal component should be integrated across health agencies to enhance each agency's capacity to respond in its respective areas of expertise. The system should further link to international injury-reporting systems.

Improve communication and education on safety

- Develop effective product-safety communication channels with health-care providers. Provide electronic links to regional surveillance centers, researchers, and collaborating organizations, including government, licensing and professional groups.

Expand product-related safety research

- Identify behavior that leads to errors in the use of medical products.
- Conduct communication research to promote safe product use by health care professionals and consumers.
- Conduct research on human factor aspects of medical product use.
- Characterize and quantify patterns of current use and degree of under-reporting of medical errors.

ASSISTANT SECRETARY FOR FINANCIAL
MANAGEMENT

DEPARTMENT OF VETERANS AFFAIRS

FACSIMILE TRANSMITTAL SHEET

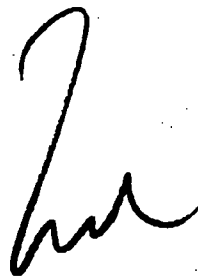
TO:	FROM:
David Beier	Ned Powell
COMPANY:	DATE:
Office of the Vice President	12/06/99
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
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Patient Safety and the VA	

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

David,

The President will be making a speech tomorrow on the issue of patient safety. The VA has been a leader, by any measure in this effort. We have had some difficulty breaking through the staff on this issue. The attached information offers a great story for the Administration, and especially the VP, on this issue and provides an opportunity to highlight the Administration's efforts on behalf of Veterans. If you desire more information, please let me know. Thanks.



[CLICK HERE AND TYPE RETURN ADDRESS]

VA Leads Nation In Patient Safety

WASHINGTON, D.C. – The Acting Under Secretary for Health for the Department of Veterans Affairs (VA), Dr. Thomas L. Garthwaite, offered evidence demonstrating successful systematic approaches to patient safety for eliminating problems highlighted in a recently released *Institute of Medicine* (IOM) report.

"VA's emphasis upon patient safety and ensuring consistently reliable, high-quality care has already resulted in improvements that meet or exceed national standards," said Dr. Garthwaite. "One far-reaching action was taken by the former Under Secretary, Dr. Kenneth W. Kizer, in 1997 when he convened the National Patient Safety Partnership which provided insights from some of the nation's leading healthcare safety and quality scholars, some of whom participated in the IOM study."

VA activities already address many of the recommendations made in the national report. VA's commitment to advancing patient safety and quality care is demonstrated by astronaut and physician, Jim Bagian, M.D., who directs VA's National Center for Patient Safety, and is a catalyst for bringing the perspective of flight safety to the healthcare environment. Dr. Bagian is credited with being one of the leaders in developing the escape system NASA uses today on the Space Shuttle, and now brings the same kind of eye for detail to the issue of patient safety. VA created four Patient Safety Centers of Inquiry to develop innovative solutions to critical patient safety challenges. "There are many examples of how the VA now sets the standard for error prevention and quality improvement through application of new technologies and process redesign," states Bagian.

One of the most prominent opportunities for systematic improvements through technology and process redesign is in medication administration. Medication errors, as noted, in the IOM study, are far too common in healthcare. Over four years ago, the VA began using a "bar-code" system on medications, similar to the computerized codes used in stores. This system helps assure that the right medication is given to the right patient at the right time, cutting medication errors by two-thirds. Plans call for the system to be fully operational next year throughout all of VA's medical centers, making VA the first healthcare system to use bar-coding nationwide. Bar-coding is also in use for prevention of errors associated with transfusion of blood products.

"Bar-coding is unequivocally successful in preventing errors. In healthcare, like aviation, it is imperative to investigate not only the crashes, but to understand the near-misses. Near-misses are more common than actual errors and their analysis allows learning and improvement to occur without first having to experience a tragedy," according to Dr. Bagian. Systematic understanding of error-prone processes and systematic solutions are among the strongest recommendations of the national study and endorse VA's approach. VA's coordinated approach to safety is facilitated by systemwide use of its recently revised Patient Safety Handbook which is coupled with extensive patient safety training.

"Poor outcomes arise not only from errors-of-commission or doing the wrong thing, but also from errors-of-omission or not doing the right thing," said Dr. Jon Perlin, Chief of the VA's Office of Quality and Performance. VA has been one of the nation's most

successful healthcare organizations in systematically changing clinical practice to ensure that the right care is delivered. Clinical Practice Guidelines bring the best scientific evidence to day-to-day practice, serving to reduce unfavorable variations in care.

To aid its caregivers in following complex and evolving guidelines, VA actively uses advanced technology, such as one of the nation's most sophisticated healthcare computer systems, to support patient safety and quality healthcare. VA's computerized patient record increasingly provides reminders for appropriate healthcare maintenance services such as immunizations and cancer screening. Electronic entry of prescriptions also eliminates mistakes arising from illegible handwritten prescriptions.

In 1991, VA established the National Surgical Quality Improvement Program to provide systematic insight into surgical care and enhance surgical outcomes. This program has led to a 10% reduction in mortality and a 30% reduction in post-operative complications over the last five years.

In 1995, an innovative Performance Measurement System was implemented that encourages and rewards the provision of consistent, predictable high-quality care across VA. Adherence to Clinical Practice Guidelines is monitored and the clinical outcomes are measured. Moreover, managers are accountable for the success of these programs. The Performance Measurement System has achieved changes in healthcare practice that ultimately led to exceeding the benchmarks established by the U.S. Government's *Healthy People 2000* goals and the private sector. Consider the following example:

- Elderly patients who receive medications known as "beta-blockers" following a heart attack are 43 percent less likely to die in the subsequent two years and are rehospitalized for heart ailments 22 percent less often. A goal of providing this therapy to 80 percent of eligible patients has been set in the private sector, and recent medical literature reports rates of use as low as only 21 percent in some settings. In the VA, over 94 percent of heart-attack patients receive this life-saving medication.

Absence of timely and appropriate preventive healthcare is a significant and potentially life-threatening error of omission. It is estimated that 50% of elderly Americans and other high-risk individuals have not received the pneumococcal pneumonia vaccine increasing risk of death and hospitalization. VA's emphasis on preventive healthcare has led to achieving pneumonia vaccination rates that exceed standards set for HMO's by almost 20% and almost double published community rates. Similar accomplishments have been achieved in providing annual influenza vaccinations. Rates for annual breast and cervical cancer screening for female patients have been driven well above 90% and exceed Health People 2000 goals and private-sector standards by over 30% in some instances. The care of patients with diabetes has been similarly improved. Clinical Practice Guidelines are part of a cycle which brings the best scientific evidence to clinical practice. VA takes the same approach to maximizing patient safety actively managing and improving quality.

"Improvement in healthcare safety and quality requires honest, open communication, data, and commitment to challenge the *status quo*. VA recognizes innovative solutions to patient safety issues through its Patient Safety Awards Program," states Dr. Garthwaite. "Good enough is not good enough when it comes to patient safety. We have to strive constantly for the ideal," concludes Bagian.

National Patient Safety Partnership

For more information, contact:
VA Public Affairs, 202-273-5700

May 12, 1999

FOR IMMEDIATE RELEASE

HEALTHCARE LEADERS URGE ADOPTION OF METHODS TO REDUCE ADVERSE DRUG EVENTS

Washington, D.C. – A coalition of healthcare organizations today released recommendations for reducing the occurrence of adverse drug events.

Stressing that this is a problem that neither government nor individual healthcare organizations can solve working alone, Kenneth W. Kizer, M.D., M.P.H., U.S. Department of Veterans Affairs' (VA) Under Secretary for Health, said the public-private National Patient Safety Partnership' is urging consumers, healthcare practitioners, healthcare provider organizations and healthcare purchasing cooperatives to adopt successful methods of preventing adverse drug events.

"Treatment-related adverse drug events are a major problem in this country that exact high costs in patient morbidity and mortality as well as dollars," said Dr. Kizer. "The Partnership can make significant patient safety improvements through advocacy of best practices to reduce errors associated with prescribing, purchasing, dispensing and administering of medications."

The patient safety group encouraged healthcare practitioners and healthcare provider organizations to commit to certain best, or model, practices and work together to implement them, in partnership with consumers, patient advocacy groups, and the pharmaceutical industry. Their recommendations follow.

- more -

The NPSP is a voluntary public-private partnership dedicated to reducing preventable adverse medical events. Its members include American Hospital Association, American Medical Association*, American Nurses Association*, Association of American Medical Colleges*, Agency for Health Care Policy and Research, Food and Drug Administration, Health Care Financing Administration, Joint Commission on Accreditation of Healthcare Organizations*, Institute for Healthcare Improvement*, National Institute for Occupational Safety and Health, National Patient Safety Foundation at the AMA*, Department of Defense - Health Affairs, and Department of Veterans Affairs*.

*Charter Organizations

Adverse Drug Events -- Page 2

To reduce the occurrence of adverse drug events (events that can cause, or lead to, inappropriate medication use and patient harm),

Patients can:

- Tell physicians about all medications they are taking and responses/reactions to them
- Ask for information in terms they understand before accepting medications

Providing Organizations and Practitioners can:

- Educate patients
- Put allergies and medications on patient records
- Stress dose adjustment in children and older persons
- Limit access to high hazard drugs
- Use protocols for high hazard drugs
- Computerize drug order entry
- Use pharmacy-based IV and drug mixing programs
- Avoid abbreviations
- Standardize drug packaging, labeling, storage
- Use "unit dose" drug systems (packaged and labeled in standard patient doses)

Purchasers can:

- Require machine-readable labeling (barcoding)
- Buy drugs with prominent display of name, strength, warnings
- Buy "unit of use" packaging (aka "unit dose")
- Buy IV solutions with two sided labeling

-more-

Adverse Drug Events -- Page 3

To reduce the potential for taking a medication that was not prescribed for them or cannot be safely taken by them, patients should ask the following five sets of questions before accepting prescription drugs.

- Is this the drug my doctor (or other health care provider) ordered? What is the trade and generic name of the medication?
- What is the drug for? What is it supposed to do?
- How and when am I supposed to take it and for how long?
- What are the likely side effects? What do I do if they occur?
- Is this medication safe to take with other over-the-counter or prescription medications, or dietary supplements, that I am already taking? What food, drink, activities, dietary supplements or other medication should be avoided while taking this medication?

###

Significant Milestones in VA Patient Safety Improvement

1997 – National Patient Safety Partnership

- ♦ VA launches public-private partnership of 8 health care organizations (now 13) to address national patient safety concerns
- ♦ NPSP takes public position regarding preventable adverse drug events in May 1999

1997 – National Patient Safety Registry

- ♦ Data base designed to collect information on a nationwide basis that includes adverse patient events, their root causes, and information to guide systematic improvements to prevent future occurrences

1997 – Patient Safety Improvement Handbook

- ♦ Provides national framework for patient safety improvement efforts

1997 – Patient Safety Improvement Oversight Committee

- ♦ Multi-disciplinary headquarters committee charged with oversight of patient safety issues

1998 – VHA Expert Advisory Panel on Patient Safety System Design

- ♦ Provided recommendations on elements for reporting systems leading to nationwide improvements
- ♦ Comprehensive, non-punitive analytic approach for close calls and actual adverse events defined

1998 – Patient Safety Redesigns included in VHA Performance Measurement System

- ♦ Provided concrete targets and mechanisms to focus leadership efforts

1998 – Patient Safety Improvement Awards Program

- ♦ Mobilizes and recognizes innovations in patient safety from all levels of the organization

1998 – VHA National Center for Patient Safety

- ♦ Created to lead and integrate the patient safety effort for the entire VA
- ♦ Employs state-of-the-art human factors and safety system approaches
- ♦ Develops and nurtures a culture of safety throughout VA

1999 – Patient Safety Centers of Inquiry

- ♦ Research groups (4) charged to develop practical solutions to critical patient safety challenges

1999 – Development of National Patient Safety Reporting System (PSRS)

- ♦ National in scope; supplementary to mandatory reporting efforts
- ♦ Modeled after NASA's successful, longstanding Aviation Safety Reporting System (ASRS)

1999 – Roll-Out of Comprehensive Adverse Event and Close Call Analysis Program

- ♦ Extensive hands-on-training to truly understand a human factors and safety systems approach to close call and adverse event analysis
- ♦ Computer assisted tool to aid implementation of comprehensive event analysis
- ♦ Captures critical elements needed to ensure a thorough and effective job
- ♦ Results in preventive actions that are superior to the status quo

1999 – National Implementation of Bar Code Medication Administration

- ♦ Multi-year development at one medical center resulted in cutting medication errors by two-thirds
- ♦ National implementation in process, targeted for completion by Spring 2000

Formal Programs for Patient Safety

The National Center for Patient Safety (NCPS) is the lead for the patient safety effort at the VHA. It is currently implementing a comprehensive, system-wide Root Cause Analysis (RCA) and corrective action methodology that makes extensive use of human factors based tools and techniques. Extensive prototyping and testing occurred in FY 99. RCA is the overarching process for data collection and analysis and provides the "fuel" for the event registry -- this provides the high quality information for the system that enables improvement. This approach also employs many innovative techniques that were developed at the VHA. These approaches are currently being assessed for use by other organizations (JCAHO, AHA) for use in the private sector. Dr. Don Berwick of the Institute for Healthcare Improvement stated, "this is the most comprehensive approach I have seen", and has asked to attend a future training session.

The first wave of training and implementation for RCA and the associated handbook/process roll-out will be completed in FY 00. With turnover, training will continue at 20% pace in future years. Once trained, each facility will have one lead RCA person with an equivalent amount by RCA team members. Ongoing evaluation and mentoring will occur for all facilities. Further, RCA and registry software and hardware will be developed and operated in FY00 and FY01. Some will be off-the-shelf, and some will be tailored to the unique needs and policies of the VHA to support this innovative approach.

The NCPS also oversees four Patient Safety Centers of Inquiry, who develop and test techniques and tools for possible use VHA-wide. These techniques include operating room simulation, learning collaboratives with many VHA facilities, and identification of curriculum. We anticipate simulation will be expanded to another site dedicated to safety-related training. Research at all the Centers of Inquiry includes communication, fall prevention, and medical simulation for device design.

Prevention and safety efforts have begun for problems identified in previous years. Many include training and awareness for VHA in all facilities. Some are review and analysis of specific high risk areas, such as transplant and mammography. Tort claims are reviewed and analyzed. And, finally, scholars and fellowship programs are offered.

All VHA personnel must complete several hours of continuing education each year. The direct cost and cost of their time is calculated and increasing over the past years.

Bar-coding for Blood Transfusion and Medication Administration

Medication errors and blood transfusion mishaps mainly occur due to inadvertent errors. Most professional societies and the VHA agree that automation will play the largest role in reducing the error frequency. Use of bar codes on blood products, medications, patients' wrists, nurses' wrists, and the associated software and hardware are all necessary for this system to work. Initial purchase of the hardware, software, and implementation is occurring across FY 99 – FY 01. Ongoing costs, include replacement and upgrading of technology (i.e., depreciation). Implementation also includes changing processes of medication handling and dispensing systems that are used by pharmacists, nurses, and management.

Computerized Patient Record System (CPRS) with Safety Implications

CPRS is an integrated, comprehensive suite of clinical applications within the Veterans Health Information Systems and Technology Architecture (*VistA*) that creates an electronic medical record to assist health care providers to perform their clinical responsibilities.

CPRS provides an integrated, point-of-care view of information needed to treat problems and address patient safety issues. Alerts, notifications, orders, medications, advanced directives, future appointments, and demographic data are all available. Current estimates indicate that providers order 54% of all outpatient prescriptions using CPRS. Providers can quickly view the patient's problems, results of consultations done in other clinics, and document new information. Alerts and warnings are passed to CPRS from *VistA* packages such as Pharmacy, Laboratory, Radiology and Clinical Reminders and Alerts. Pharmacy passes alerts for duplicate drugs, drugs in the same therapeutic class, patients receiving medications from other medical centers, and drug/drug interactions. Allergy Alerts are provided from the Allergy and Reactions Package.

CPRS facilitates management of risk factors, such as patients information relating to risk factors for Hepatitis C is entered into CPRS along with vital signs.

CPRS is implemented throughout VHA health care facilities. At this time more than 100,000 VHA staff use CPRS to accomplish their day-to-day responsibilities.

Future plans to enhance the usefulness of CPRS include the provision of remote data views, allowing providers to view, in report format, clinical information from other VA sites providing care available from other VA sites. The ability to perform interfacility consults will also be provided. Improvements to Clinical Reminders/Alerts, Pharmacy Order Dialogs and Checks and User Interface are also planned.

Suicide and Violence Prevention

VHA has always had great interest in the identification, prevention and management of suicidal and violent behaviors.

More recent milestones include:

1989 – Development of treatment guidance and a uniform process for conducting psychological autopsies (Management of Suicidal and Violent Patients Program Guide, G-15, M-2, Part X).

1989 – Development of Chief Medical Director's Task Force on Prevention and Management of Suicidal and Assaultive Behavior. This group initiated a survey series used to analyze suicidal behavior, assaultive behavior and seclusion and restraint use. These surveys provided enlightening data about the diagnostic case-mix of veterans prone to suicidal and violent behaviors.

1994 – Development of slide/video training module applicable to all providers entitled "Suicide Prevention: Everyone's Concern".

1997 – Development and dissemination of clinical Practice Guidelines for Major Depressive Disorders.

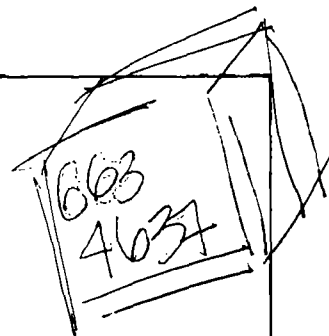
1998/99 – An array of facility, network and headquarters initiatives were developed under the umbrella concept of a "Suicide Summit". These initiatives included, but were not limited to: collaboration with DoD, NIMH, and the CDC in the development of training and research related to depression and suicide prevention and treatment; best practice surveys across all networks (and dissemination of information following survey); VISN 5 conference on suicide prevention; National Leadership Board forum on suicide prevention, and; enhanced use of electronic communication for ongoing communication and clearinghouse activity.

In the immediate future (FY 00/01), system wide educational initiatives include satellite videoconferences as well as face-to-face meetings targeted for facility providers. This training focuses on issues related to suicide awareness, assessment and treatment throughout the life cycle.

Other Patient Safety-Related Efforts

Other initiatives have begun that deal with specific patient safety issues across the VHA facilities. Many include technology solutions coupled with new training and processes to address mishaps. For example, a global positioning satellite system will be evaluated for use to assist with management of wandering patients.

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Date: 1-13-00 # of Pages to Follow: 3
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From: Melinda Murphy

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Patient Safety Program

Dollars in Millions

2000	2001
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VHA National Center for Patient Safety (NCPS)

NCPS is the leadership and driving force for patient safety efforts in VHA.

NCPS leads and integrates the initiatives described below.

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

\$ 4.7 \$ 6.3

Comprehensive Medical Error Reporting and Analysis

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

12.6 11.5

Patient Safety Centers of Inquiry

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

5.0 6.2

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

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

Field Patient Related Safety Staff

25.9

37.1

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

Comprehensive Adverse Event and Close Call Analysis Program

22.0

22.9

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

VA Quality Scholars Program

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

4.1

9.1

Mandatory Training

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

38.8

39.4

All Other

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

4.7

4.8

Total Patient Safety Program 1/

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

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

Although this is a commonly used system, it has several limitations (refer to table 1). A review of studies utilizing voluntary report incidences of medication errors between 0.01% and 0.05%.⁽⁵⁾ In contrast to the voluntary reporting program, direct observation studies have been utilized to more accurately determine medication error rates. In these studies, trained personnel work on a nursing unit and follow medication administration personnel throughout a shift, quantifying all observed medication errors. These studies have reported medication error incidences of between 0.6-24.7% and 1.7-59.1% when wrong time errors are excluded or included, respectively.^(6,7) It is difficult to compare these methods of detecting medication errors but either method would seem to indicate that the number of medication errors that are occurring are too many and drug delivery systems need to be improved.

Table 1. LIMITATIONS OF MEDICATION ERROR REPORTING SYSTEMS

MEDICATION ERROR REPORTING SYSTEM
Voluntary Reporting Program

LIMITATIONS OF REPORTING SYSTEM

1. Perceived self-incrimination and fear of disciplinary action 2. Dependence on management emphasis on reporting 3. Dependence on staff motivation to complete reporting forms 4. Interstaff variation on definition of medication error 5. Time commitment for completing the reporting form 6. Need for continual education of staff as to importance of reporting medication errors 7. Variation in the information provided on each report 8. Under-reporting of medication errors and missing serious but rare events 9. Reporting employee has to be aware that an error was made

Direct Observation Studies

1. Time commitment and labor costs for staff training in direct observation of medication delivery and administration 2. Need for consistent definitions of errors to interrecorder variation in recording data. 3. Reporting of all medication errors may result in over-reporting of clinically insignificant errors and obscure important medication errors. 4. Influence of trained observer on incidence of errors. 5. Fatigue of observer over time with a decline in documentation accuracy.

Although there are disadvantages for either type of reporting there has been no national consensus as to which reporting system is preferred.⁽⁸⁾ Furthermore, there is no consensus as to what is an "acceptable" medication error rate. What if the actual medication error rate was a very low 0.1%? To put this incidence into perspective, Shea has projected the implications of an 0.1% error rate (99.9% accuracy) to three other non-medical industries.⁽¹⁾ (refer to table 2) Clearly these error rates would not be acceptable to the public so these industries have made great efforts to further reduce the error rates.

Table 2. IMPLICATIONS OF 99.9% ACCURACY IN THREE NON-MEDICAL FIELDS

POTENTIAL ERROR	IMPLICATIONS OF ERROR RATES
Unsafe Airplane Landings	84/day
Lost Mail	16,000 pieces/hour
Bank Check Errors	32,000 errors/hour

Handwritten calculations: $84 \times 3600 = 302400$ (with a large 'X' over it), $16 \times 100 = 1600$, and $32 \times 100 = 3200$.

The University of Chicago Hospitals Experience

The University of Chicago Hospitals (UCH) has a voluntary reporting program for medication errors.

Handwritten: 34000

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PREMIER

Fax

To: Chris JenningsFrom: Herb Kuhn

Fax: _____

Pages: 5

Phone: _____

Date: 2/10/00

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CC: _____

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• Comments:

FYI

PREMIER

NEWS FROM PREMIER

**Contact: Jaime Uranga, Premier Advocacy
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FOR IMMEDIATE RELEASE – February 10, 2000

Premier Spotlights Efforts to Reduce Medical Errors

Washington, DC – As medical errors take the spotlight on Capitol Hill, Premier, Inc. is sharing the ongoing efforts of its 215 not-for-profit hospitals and health system members to remedy the unacceptable situation.

Premier has a long standing and proven commitment to safety. Nearly thirty years ago in response to public concerns, the healthcare alliance established a Clinical Technology Management program to address hospitals' needs relating to the safe use of rapidly evolving medical technology. In the early 1990s, the alliance spearheaded a program on pharmacy safety that led to significant improvements in safety-oriented labeling and packaging.

On February 17 and 18 at its corporate headquarters in Charlotte, NC, Premier will host a major industry conference on medication management. "As Congress addresses the important issue of medical errors, we aim to increase awareness of Premier's and its members' efforts to determine why medical errors occur and to develop clinical systems to prevent them," said Richard A. Norling, Premier CEO. More than 250 hospital representatives are already registered to attend and/or present at the *Medication Management Rapid Response Forum*. Tom Nolan, Ph.D.,

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internationally recognized expert with the Institute for Healthcare Improvement (IHI), will discuss how hospitals can implement innovative ways to manage the medication process. Participating hospitals will have access to a self-assessment tool that will enable them to identify the most promising opportunities for improvement based on safety experience from NASA and the aviation industry. The self-assessment tool is currently available on Premier's website, www.premierinc.com.

In addition to medication management, Premier has targeted other clinical areas for quality-of-care improvements and enhanced patient and worker safety in hospitals. Nationally recognized safety expert Gina Pugliese was chosen to head the Premier Safety Institute in an effort to create greater climates of safety for hospital workers and patients alike. The Safety Institute's diverse efforts include the promotion of special safety hypodermic syringes and latex-free gloves and the sharing of knowledge and experience among institutions. Increasing the availability of safer products and procedures in certain high-risk areas is also a priority.

Premier's broad medication management initiative is at the forefront of performance improvement efforts in the health care industry. In conjunction with IHI, a collaborative group of hospitals and 75 health systems nationwide, Premier aims to create an idealized management design with the goal of reducing medication errors within each member facility by 50 percent over a three-year period. The *Medication Management Rapid Response Forum* is just one of the early elements in this initiative.

In collaboration with Bridge Medical, Inc., Premier is also offering its members an exciting new technology designed to prevent adverse drug events. Bridge Medical, Inc. has developed an advanced medication management unit that electronically verifies--

at the patients' bedside and *before* drug administration--the **five rights**: right patient, right drug, right dose, right route of administration and right time. Bi-weekly extracts on drug interactions from Premier's Drug Intelligence Center will also prove invaluable. Through a partnership with the Institute for Safe Medical Practices, Premier members also receive the Medication Safety Alert newsletter, which gives practitioners comprehensive updates on recently reported medication errors, their causes and the preventative measures taken.

"As our innovative work demonstrates, Premier member hospitals are on the cutting edge of using new technologies to reduce the rate of medical errors," said Chip Caldwell, Premier's senior vice president. "Despite our best efforts, all humans make mistakes. Accordingly, developing systems to protect against and prevent error is the key to ensuring that patients receive the high quality health care they deserve."

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Premier is an alliance of more than 200 not-for-profit hospitals and healthcare systems across the country. Together, they comprise 957 healthcare facilities nationwide and are affiliated with more than 900 others. Premier provides hospitals and healthcare systems with products and services designed to maximize quality and safety, reduce unnecessary costs, manage technology and promote a continuum of care. The organization maintains offices in Charlotte, NC; San Diego, CA; Chicago, IL; and Washington, DC.

NEWS FROM PREMIER

**Contact: Jaime Uranga, Premier Advocacy
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FOR IMMEDIATE RELEASE – February 7, 2000

Premier Responds to Health and Human Services FY 2001 Budget and Proposed Pharmaceutical Benefit for Medicare Recipients

Washington, DC --- Today, on the heels of President Clinton's January 28th State of the Union address, Secretary of Health and Human Services Donna Shalala spelled out the specifics of the President's FY 2001 health care budget.

While Premier recognizes the relevance of a prescription drug benefit for the nation's Medicare population, it is concerned about the long term consequences of financing such a provision by further reducing payments to healthcare providers still reeling from the last round of budget cuts. To pay for such an extensive benefit, the president's budget extracts billions of dollars, in the form of Balanced Budget Act extenders, from an already constricted pool of Medicare funding.

"We are pleased that providing prescription drug coverage for elderly citizens is one of the president's priorities---we are disappointed that once again, he is considering payment reductions to caregivers as a means to finance this new benefit," Premier Vice President Herb Kuhn said. "Simply put, Clinton's approach to providing drug coverage is a mere repackaging of the same

old solution of taking money from providers to finance new benefits. It's old wine in a new bottle," Kuhn said.

"Adding prescription drug coverage to the Medicare program is a laudable goal and one that America's hospitals and hospital systems clearly recognize will improve the health of senior citizens," Kuhn said. "However, seniors also need access to affordable, high-quality health care those very hospitals are expected to provide. We are dismayed that during this time of record prosperity and federal budget surpluses, the president is aiming to finance this new benefit by slashing provider funding. We urge President Clinton and Congress to examine the surplus and other alternative means of financing a prescription benefit in a way that doesn't undermine provider resources," he concluded.

###

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Agency for Healthcare Research and Quality



Immediate Office of the Director

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FROM: John M. Eisenberg, M.D. (Director) / Nancy Foster

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COMMENTS:

TOTAL NUMBER OF PAGES INCLUDING THIS COVER SHEET:

Priority #1: Enhancing Patient Safety

ne Summary (THIS TABLE IS NOT UPDATED GIVEN THE NEW BUDGET
IL)

ne #1 Enhancing Patient Safety (\$20.0 M)			
	New Knowledge on Priority Health Issues	New Tools and Talent for a New Century	Translating Research into Practice
each to Users of Research Other Stakeholders	.250 M		2.75 M
amental and Applied earch and Demonstrations rrors and Reporting	8.25 M	.250 M	5 M
s and Training for the ic and private sector to ort efforts to enhance ent safety		3.25 M	.250 M

ground

Recent Institute of Medicine (IOM) report, *To Err is Human*, builds upon the work of President's Advisory Commission on Consumer Protection and Quality in the Health Industry, providing compelling evidence of the need to establish a national focus on patient leadership, tools, protocols, and new knowledge to enhance patient safety. As evidence of the problem has existed for some time, the IOM report succeeded in drawing the public's attention by revealing the magnitude of this medical epidemic and presenting it in a compelling fashion. Box with facts from IOM report Medical errors are estimated to cause between 44,000 and 98,000 deaths annually in the United

Using the more conservative figure, medical errors rank as the eighth leading cause of death, killing more Americans than motor vehicular accidents, breast cancer,

U.S. [box with ranking of causes of death showing where medical errors are in line with other causes]

In addition to this extraordinary human toll, medical errors have annual costs of \$17 – \$29 billion in the United States (Institute of Medicine,

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

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

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

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

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

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

Initiatives to reduce errors in health care and enhance patient safety will build upon the Agency's commitments to research in this area. Last year, AHRQ awarded four

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

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

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

in research funding for AHRQ, ramping up to \$100 million] It is striking to note that, given the magnitude of the patient safety problem documented in the IOM report, it is likely that hundreds of millions of dollars in research funding would be applied to the problem if it were an easily defined disease entity.

Development of a Substantial Research Initiative on Patient Safety at AHRQ

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

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

ific Activities to be Pursued in FY 2001

utreach to Users of Research and Other Stakeholders:

ND National Summit on Research on Medical Errors: This research agenda setting
onference (or conferences) will build upon the first conference bringing
esearchers, data collection entities, and users of the research (including and in
operation with private sector organizations such as medical specialty societies,
e JCAHO, and the Quality Forum) to review the current state of the patient safety
esearch field, to learn from its lessons about programs and policies to translate the
esearch into practice and policy, and to set new priorities for research.

utreach to Stakeholders: Develop programs to foster research dissemination to
sers of the research findings including providers and policy makers through
HRQ's ULP; providing support to the National Quality Forum to increase the
ational discussion on errors and their prevention; fund collaborative agreements
ith health care professional organizations that foster education; track patient safety
itiatives; provide input to research centers; translate, disseminate, and promote
loption of research findings; and provide important dissemination linkages for
mplementation of new practices and policies.

atient Safety Clearinghouse: Developing a clearinghouse to be an objective

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

Fundamental and Applied Research and Demonstrations on Errors and Reporting:
Fundamental Research on Errors: Exploring the role of human factors, root cause analyses, informatics, and legal and judicial issues bringing together experts in these fields with health services researchers. This research will provide a strong foundation for efforts to prevent errors following the strategy applied in other industries such as manufacturing, aviation, and banking which began their error reduction programs with a look at the factors underlying errors and the steps needed to address them.

Research on Reporting Systems: Identifying critical components for reporting systems, the data needs and structure for reporting, demonstrations programs for reporting, evaluating existing state mandatory reporting system, and the development of techniques for the analysis and dissemination of patient safety data and the impact of reporting. We will also support an evaluation of reporting systems to explore the merits, risks, and costs of reporting options including voluntary systems, de-identified mandatory reporting, and public reporting of information on medical errors.

Applied Research on Patient Safety: Evaluations of traditional efforts (e.g. incident reports) versus newer approaches (root cause analysis and systems approaches);

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

Tools and Training for the public and private sector to support efforts to enhance patient safety:

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

measures: Development and evaluation of measures for reporting on patient safety and working with the National Quality Forum and other private sector efforts on core measures for patient safety.

Data Synthesis for Research and Policy: Developing a database of de-identified information using AHRQ's Healthcare Cost and Utilization Program as a model which will facilitate comparing oneself to peer organizations and states. The database will not set standards or collect new information but instead provide a vehicle to pull together existing data from the states and private sector. In addition the Agency would provide Technical Assistance to state and private sector entities collecting, analyzing, and disseminating patient safety data.

Curricula, Tools, and Talent Development: Evaluating programs introducing health professionals to errors analysis and the realities of practicing in a technically challenging environment, evaluating the use of simulators and automation in education to prevent errors, and supporting training in errors research and evaluation which would then provide linkages with states

Patient Safety Initiatives in the Department of Defense for FY 2001

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

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

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

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

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

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

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

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

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

MTFs will enhance their patient safety programs through participation

Programs in the Military
Treatment Facilities

Defense Blood Standard
System (DBSS) 0.9M +5.8M

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

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

Deployment of the MHS
Population Health
Operational Tracking and
Oversight (PHOTO)
Capacity 0.6M +2M

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

Defense Occupational
Health Readiness System
(DOHRS) 9M 0

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

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

MHS Data Repository
(MDR) 6.1M +6M

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

Theater Medical
Information Program 14.2M 0

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

Patient Movement -- (US
Transportation Command
(TRANSCOM) Regulating
and Command and Control
Evacuation System
(TRAC²ES))

16M

+7.3M

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

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

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

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

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

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

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

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

1

on, Patient

... Hi Nancy. Happy New Year! I am attaching and including the document in this you had a great holiday.

LH SERVICE Budget Information on Error Reduction and Patient

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

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

uarters QA/QI

empt to identify funds in the FY2001 budget for technology
 annual tasks related to prescription writing and dispensing.
 y exists as provider point-of-care medication management and
 ere are also robotic prescription dispensing systems. Both
 ate manual tasks while reducing costs and dispensing errors.
 this technology at several sites in Montana and New Mexico
 nding results at these test locations, the Agency may spend an
 .45 Million in FY2000 to implement this technology.

on, Patient safety.doc>>

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INDIAN HEALTH SERVICE Budget Information on Error Reduction and Patient Safety

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

for All IHS:

Payment to JCAHO for Surveys	\$2.4 Million
Facility Maintenance and Improvement Costs	\$3 Million
QI and Risk Management Costs	\$8 Million
Safety Officers at each site	\$2.5 Million
Headquarters QA/QI	\$350,000

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

ry 3, 2000

Operating Chair, QuIC Steering Council

Administrator

ECT: Budget Information on Error Reduction and Patient Safety

onse to your request of December 27, 1999, HRSA has reviewed its Fiscal Year 2001
t submission and related materials for potential policy initiatives which might address the
ent's directive. In addition we have asked our major programs to report any "meaningful
care quality and patient initiatives" which might be forwarded to address medical error
on and improve patient safety through FY 01 budget proposals.

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

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

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

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



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

ent

obinson
A Executive Council
Donovan/Mr. Heil

Health Resources and Services Administration

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

AIDS

rent budget proposal for FY 2001:

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

Est. Cost \$450,000

roposed initiative:

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

Est. Cost \$10 M

Health Resources and Services Administration

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

PRIMARY CARE

Current budget proposal for FY 2001

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

Est. Cost \$2.8 M

Proposed initiative:

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

Est. Cost \$5.2 M

Health Resources and Services Administration

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

Health Professions

Health Professions Education and Training Initiatives

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

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

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

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

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

Estimated Cost: \$19,250M

Health Resources and Services Administration

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

Maternal and Child Health

Proposed initiative for 2001:

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

Est. Cost \$1.0 M

Proposed initiative for 2001:

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

Est. Cost \$1.0 M

Health Resources and Services Administration

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

RURAL HEALTH

ent budget proposal for FY 2001

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

Est. Cost \$1.0 M

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

Est. Cost \$1.0 M

roposed initiative:

ish new Rural Clinicians' Care Councils as an incremental expansion to the Office of
Health Policy's Outreach and Network Development Program. The proposed program
provide grants to develop and evaluate the effectiveness of ten local organizations of rural
ans, rural hospitals and health care agencies called "Rural Clinicians' Care Councils",
ls). These Councils will coordinate the care of patients with complex medical problems,
te referrals of these patients among the multiple agencies involved in their care; and detect,
analyze and prevent recurrence of prescribing errors and other patient management errors.
Councils develop, their clinician membership and patient enrollment will expand to
; other health providers and patients of their local communities. Their first priority will be
age the care of local patients to raise quality and prevent iatrogenic injury and death. As
ecome secure in their ability to manage care to increase quality, the Councils will be able to
t with Managed Care Organizations (MCOs) to manage the local care of their subscribers.

Est. Cost \$5.0 M

Health Resources and Services Administration

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

Center for Quality/Office of the Administrator

proposed initiative for FY 2001:

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

Est. Cost \$3 M



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

DIRECTOR

JAN 3 2000

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

Mr. Lew

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

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

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

Sincerely,

Janice R. Lachance
Director

Enclosure

00W

REDUCING MEDICAL ERRORS

OPM'S CENTER FOR BENEFITS DESIGN AND DELIVERY

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

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

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

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

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

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

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

Date: February 10, 2000

Note to: John Eisenberg, Director, Agency for HealthCare Research and Quality

From: Jeff Kang, Director, Office of Clinical Standards and Quality

RE: HCFA Action Items for the response to IOM Medical Errors Report

John, we have reviewed the Executive Summary of the QuIC response to the IOM Report (sent by you on 2/6, 11 a.m.) and found that 2 of 3 HCFA action items were not included in the list of Action Items from QuIC Report. These should be included. In addition, we are providing wording which includes projected time frames. Finally, this language has been cleared by our General Counsel.

1. Since the PRO program currently has appropriate peer review protections of data collection efforts that assist the health care industry in learning about and reducing medical errors, within 6 months, HCFA, with a PRO, intends to develop a pilot of a "confidential", penalty-free learning system with several hospitals on a voluntary basis.
2. By the end of the year, HCFA intends to publish requirements that hospitals, which participate in the Medicare program, have ongoing error reduction efforts (which would affect all their patients). In order to comply with such a requirement, hospitals are likely to institute automated pharmacy order entry systems, etc..."

The third HCFA action item related to the pilot on reporting "never" events is included as the 1st bullet under Reporting Systems. However, we have modified the language, as follows:

The QuIC will ask the Quality Forum to unambiguously define, within 12 months, a set of egregious errors that are preventable and should never occur. These never events will serve as the basis for a HCFA-sponsored mandatory reporting demonstration project with a State that already has an existing mandatory reporting requirement. The purpose of the demonstration is to examine how information can be collected, and whether such information is of use to the public, purchasers, and policymakers. HCFA, in partnership with the State, will publish the hospital rates for these events without patient identifiers. HCFA, its QuIC partners and the State will evaluate the demonstration.

Also, HCFA Action Item 2 above is absent from the QuIC Actions to Support Reporting for Learning and Accountability. Please include the following to reflect this HCFA activity:

By the end of the year, HCFA intends to publish requirements that hospitals, which participate in the Medicare program, have ongoing error reduction efforts.

We will be sending you some additional comments today. Thanks for your attention to this.

FAX

UNITED STATES SENATOR • CONNECTICUT

Joseph I. Lieberman



Fax to:

Devara

Date

Fax#

456-7431

Pages

From:

Message:

Figure 5
Occurrence Criteria for Surgery—Operating and Recovery Room

Swedish Covenant Hospital
Surgery, Operating and Recovery Room
Quality-of-Care Indicators

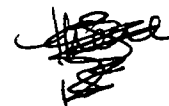
Please circle the number corresponding to the appropriate quality-of-care indicator, imprint patient plate, and forward to the Quality Assurance Department.

Name of Procedure

Date

1. Patient complaint.
 2. Any of the following incomplete upon patient arrival in OR:
a. history and physical b. consultation c. chest x-ray d. EKG (over 40) e. lab and pregnancy test (under age 45)
 3. No written consent or improper consent for procedure performed.
 4. Surgical procedure done for which surgeon does not have privileges.
 5. Cancellation of surgery.
 - *6. Wrong patient operated on.
 - *7. Wrong procedure performed.
 8. Unplanned removal of organ or body part not covered in consent.
 - *9. Patient burn resulting from equipment.
 10. Instrument breakage or unplanned disconnection of equipment which has potential for patient injury.
 11. Incorrect needle, sponge, or instrument count or omission of count.
 12. Break in sterile technique.
 - *13. Foreign object or material found.
 - *14. Patient operated on for repair of laceration, perforation, tear, or puncture of an organ subsequent to performance of an invasive procedure.
 - *15. Return to OR for repair or removal of organ or body part damaged in surgery.
 16. Discrepancy between pre- and postoperative diagnosis.
 17. No tissue removed in any of the following cases:
a. Exploratory laparotomy
b. Indirect hernia repair
c. Laminectomy
 18. Respiratory or cardiac arrest.
 19. Acute MI during or following surgery.
 - *20. Death OR_____ RR_____
 21. Any other untoward patient reaction in OR/RR
- *Please complete an occurrence report on these items and forward to the hospital Risk Manager.

LEVEL 1 - 1 OF 1 STORY

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December 26, 1999, Sunday, Late Edition - Final

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LENGTH: 1745 words

845 

HEADLINE: AMBITIOUS EFFORT TO CUT MISTAKES IN U.S. HOSPITALS

BYLINE: By PETER T. KILBORN

BODY:

Spurred by an Institute of Medicine report last month, big employers, health care organizations, state regulators and the federal government are stepping up pressure to revamp a health care system that calls itself the best in the world, yet hides and ignores mistakes that kill tens of thousands of patients a year.



Largely in response to the report, eight executives of some of the nation's biggest companies, including General Motors and General Electric, disclosed this week that they had formed an organization they call The Leapfrog Group to encourage all employers to make safe medicine a top priority of the health insurance they provide their workers and to steer workers to hospitals that make the fewest mistakes.



For the first time, too, the Joint Commission on Accreditation of Health Care Organizations, the independent group in Chicago that accredits most of the nation's hospitals, will begin making unannounced, random inspections in January. For years, the commission has been accused of such close ties to the industry that its inspections were little more than formalities that hospitals could prepare for.

Upon release of the report, "To Err Is Human: Building a Better Health System," the American Hospital Association and the Institute for Safe Medication Practices, a nonprofit research group, announced a project to reduce the incidence of errors arising from medication.

The government has responded with the same urgency. President Clinton seized upon the report to order federal health agencies to reduce the number of errors by 50 percent in five years. Three United States senators said they would schedule hearings into medical errors early next year, and many state regulators say they will step up efforts to detect and fix error-prone practices.

Taken together, the reactions to the report by the Institute of Medicine, a part of the National Academy of Sciences, the nation's top scientific advisory group, represent the most ambitious effort ever to confront mistakes in the nation's hospitals.

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The New York Times, December 26, 1999

"This is definitely the future," said Dr. Howard Koh, the public health commissioner for Massachusetts. "It's a paradigm shift. We view this as a new way of looking at adverse outcomes."

Instead of "singling out practitioners to blame," Dr. Koh said the industry can develop safer ways to deliver care. As an example of the kind of systematic planning that could help, he said intravenous solutions could be mixed in the pharmacy by pharmacists, rather than be left to nurses on the hospital floor.

Specifically, the report suggested that medical errors kill 44,000 to 98,000 people a year. Though these numbers were previously known in the world of health care, the report has had a galvanizing effect, because of the academy's prestige, and because of the professional expertise and nonpartisan credibility of its authors, including prominent physicians, hospital officials and executives of health maintenance organizations.

The report called for sweeping changes in the health care system, including mandatory disclosure of serious mistakes leading to death or injury, voluntary disclosure of less serious mistakes and the five-year, 50-percent error reduction goal that the president promptly endorsed.

It urged Congress to create a National Center for Patient Safety to collect the reports and identify the flaws in the system -- such as an emergency room doctor who falls asleep on the job after working 48 hours straight -- that, the institute says, lead to most errors.

Regulators typically inspect hospitals no more than once a year and doctors' offices hardly ever. The institute, in effect, urges continuous scrutiny and reporting of flaws in patient care by everyone on the staff of a health care facility.

With its emphasis on gathering information and using it to develop better processes, said Dr. John R. Lumpkin, director of the Illinois Department of Public Health, "We're talking about a traumatic transformation about how health care is delivered."

But for all the momentum, patient advocates and some regulators warn that for most hospitals and physicians a culture of defensiveness and secretiveness is dug in deep, and will be difficult to change. They pointed out that for years some states, like New York, California, Colorado, Massachusetts and Florida, have mandated hospital disclosure of serious mistakes and worked with health care providers to identify the missteps leading to them. But little reduction in the incidence of mistakes has resulted.

They also say that some doctors have their own wall of silence, not unlike that of police officers, and are reluctant to report colleagues who make mistakes.

"You don't tell on each other," said Anna Polk, director of the Agency for Health Care Administration in Florida. Ms. Polk oversees one of the nation's oldest and most comprehensive systems to report and prevent errors, yet one that she said the culture obstructs.

"There's a strong back current that keeps people from being entirely honest," Ms. Polk said. "It's a very old culture. It's a very longstanding culture. And



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it's a very powerful culture." A physician who discloses another physician's mistake, she said, faces "almost certain retribution, like losing referrals. We've seen that over and over."

Others said the report does not go far enough in making demands on the health care industry. "The report is a very good start," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, a patient advocacy group. But in not insisting on more autopsies, he said, the authors overlooked a vital source of information about medical errors.

About 5 percent of patients who die in hospitals receive autopsies, compared with more than 40 percent 30 years ago, so the doctor who signs a death certificate can attribute the death to causes other than his or his colleague's mistake.

Even if the disclosure rules described in the report become a reality, they will be tough to enforce. Since early this year, for example, the State of Colorado has been listing unusual "occurrences" in hospitals without naming names or assigning blame, on the Web page of the Department of Public Health and the Environment. But nearly all of those listings, of 44 pages of 300- and 400-word detailed accounts, involve patient and staff behavior, like altercations and sexual abuse.

The State of New York, which has some of the toughest reporting requirements, says thousands of problems, many of them errors, have occurred since the current system was adopted in April last year.

Among them, state records disclose 410 unexpected deaths since then, 33 cases of surgery performed on the wrong patient, 138 instances of leaving foreign objects behind in patients' bodies after surgery, 25 cases of patients who were wrongly administered radioactive material, 2,093 unintended procedure-related injuries requiring repairs and more than 10,000 cases of unplanned reoperations, or returns to operating rooms because something went awry.

For their part, physicians say they are too often blamed for problems that are really systemic.

"We're talking about all American society," said Dr. Dennis S. O'Leary, president of the commission that accredits hospitals and other health care institutions. "We have a blame and punishment society. When something goes wrong, we want a hanging. That's not a climate that favors voluntary reporting of anything."

Dr. Nancy W. Dickey, a Texas physician and recent president of the American Medical Association, said doctors endorse much of the report and that through its National Patient Safety Foundation, the association encourages the kind of system analysis that the institute urged rather than looking for culprits.

"But we have concerns about reporting mechanisms," Dr. Dickey said, "and would want to see nonpunitive and confidentiality measures" included in any new system. Still, she said, the reporting should be voluntary. "We are opposed to mandatory reporting," she said.

In that respect, the association stands apart from nearly all the other medical institutions that have responded to the the institute's report. The

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American Hospital Association, often an A.M.A. ally in opposing tighter government regulation, supports mandatory disclosure of serious mistakes.

"There's no question in our mind that there needs to be a better reporting system, a national reporting system," said Richard Wade, senior vice president of the hospital association. "We have questions about how it would work and about liability. But there probably needs to be mandatory reporting of serious events."

Beyond the efforts of regulators, big business may have tremendous influence on whether or not the academy's suggestions are followed.

For a couple of years, health care executives of several major companies and representatives of big California and Minnesota employers have been meeting to explore ways of exploiting their clout as buyers of health services to improve service.

Since the release of the Institute of Medicine's report, the Business Roundtable, the organization of the chief executives of the most of the nation's 100 biggest companies, has allocated funds for the group to open an office and hire staff.

The leader of the Leapfrog Group, Bruce Bradley, director of managed care plans at General Motors, said the goal is writing "a common agenda to drive quality improvement."

Dr. Mary Jane England, director of the Washington Business Group on Health, an association of large company health program executives, said, "Employers do not want their employees maimed."

"They want them at work," she said. "They have learned how to use engineering to improve processes to hold down costs and improve quality. It's a systems issue. It's not new. We just haven't put it in place in the medical community." Steve Wetzell, a member of the Leapfrog Group and executive director of the Buyers Health Care Action Group, which coordinates employee insurance coverage for big Minnesota companies, said abundant analysis shows that hospitals that perform the same surgical procedures thousands of times make fewer mistakes than those who rarely perform the procedure.

So to encourage safer medicine, he said, businesses would give workers incentives to use the more experienced hospitals. "From an employer's perspective," Mr. Wetzell said, "this is a no-brainer. It saves money and employees get better faster."

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National Association of Protection & Advocacy Systems

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December 20, 1999

The Honorable Togo D. West, Jr.
Secretary of Veterans Affairs
810 Vermont Ave.
Washington, D.C. 20420

**Re: NAPAS Comments In Regard to the *New York Times* Article (12/19/99) Entitled
"Report Details Medical Errors in Veterans Hospitals" Written by Robert Pear.**

Dear Secretary West,

NAPAS is a national, nonprofit membership organization made up of federally-funded Protection and Advocacy (P&A) Programs and the Client Assistance Program (CAP). These programs, which are conducted in each state and territory, protect the rights of individuals with disabilities and advocate on behalf of such individuals to ensure that they have access to needed services and supports, including employment services and Social Security benefits. NAPAS and its member programs are committed to ensuring the self-determination, independence, empowerment, integration, and inclusion of children and adults with disabilities into all aspects of American society. **NAPAS has two programs in which it could potentially provide protection and advocacy services for patients in veterans hospitals to improve the quality of health care service delivery and decrease the incidence of abuse and neglect-PAIMI and PAIR.**

P&As have the authority to advocate on behalf of people with mental illness who live in institutions through the federally mandated program **entitled Protection and Advocacy for Individuals with Mental Illness (PAIMI)** that is administered by the Substance Abuse and Mental Health Services Administration's Center for Mental Health Services (CMHS). Under PAIMI, P&As provide services for people with a significant mental illness or emotional impairment, as determined by a mental health professional, who are inpatients or residents of a facility rendering care or treatment (including persons in the process of being transported to such facilities). This mandate covers a very broad range of public and private facilities, including general and psychiatric hospitals, nursing homes, board and care homes, community housing, juvenile detention facilities, homeless shelters, and jails and prisons. In fiscal year 1998, P&As provided direct services for almost 16,000 individual clients with mental disabilities through the PAIMI Program. In addition, PAIMI staff provided information and referrals services to approximately 52,000 people, and education, training and outreach services to hundreds of thousands more people.

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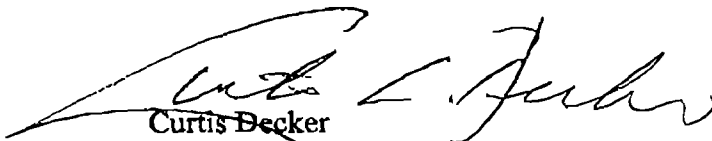
The Protection and Advocacy of Individual Rights Program (PAIR) was created (under the Rehabilitation Act) to provide a safety net for individuals with disabilities who are being subjected to abuse, neglect, and other violations of their rights, but who do not meet the narrow eligibility requirements for the other federally-funded protection and advocacy (P&A) programs. The PAIR Program represents a vitally important component of the P&A System's comprehensive effort to advocate for the rights of all persons with disabilities. P&As under the PAIR Program have a mandate to pursue legal, administrative, and other appropriate remedies or approaches to ensure the protection of, and advocacy for, the rights of eligible individuals.

The Department's report of 3,000 documented medical mistakes and mishaps (3,000 in less than two years), 277 cases of suicide, and 476 attempted suicides indicate a pressing need to increase monitoring and patient advocacy so that patients will be protected from medical incidences that could jeopardize their safety and quality of life.

The major policy piece that is missing in the protection of veteran patients is an external, independent, legally based system of monitoring and patient advocacy. The existing P&A system is an ideal model for such a system and has been exercising this authority in state medical facilities for many years.

I am available to discuss with you the potential of the P&A system and its possible application to veterans facilities to improve the quality of health care and increase the quality of life for our veterans.

Sincerely,



Curtis Decker
Executive Director

Cc: Chris Jennings, Deputy Assistant to the President for Health Policy
Gene Sperling, Chairman, National Economic Council
Jonathan Young, Associate Director, Office of Public Liaison

OFFICE OF THE COMMISSIONER
Food and Drug Administration

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

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

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

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

FDA Initiatives to Improve Patient Safety in the FY 2001 Budget

page 2

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

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

proposes to act on the IOM recommendations and to engage in several other activities beyond what the IOM recommended to promote safer health care. While some of the recommendations of the IOM can be addressed individually by specific agencies, such as those proposed for the AHRQ and FDA, the majority of the proposed actions require joint effort. Collaboration – federal agencies working together through the QuIC, and with states and the private sector organizations – can more rapidly and more effectively improve patient safety. 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.

The QuIC believes that the mandatory and voluntary reporting systems for learning and accountability proposed in this report are important and complementary. A table depicting the QuIC's actions to develop or enhance reporting systems for learning and accountability, as well as the reporting issues that require further testing is included at the end of this Executive Summary. In addition, the QuIC proposes actions in response to the President's directive that it identify other ways in which the nation can advance patient safety.

The QuIC's key proposals for Federal actions on the IOM recommendations to create leadership, implement public accountability, develop a robust knowledge base about medical errors, and change the culture in health care organizations are summarized below. They are enumerated in the summary list of action items at the end of this Executive Summary. More detailed information on these actions is contained in Chapters 2, 3 and 4.

Public Accountability Through Reporting

The QuIC agrees with the IOM's statement of the need for public accountability on health care safety, and supports the need for mandatory reporting. The public wants and deserves the safest health care system possible, and it should receive information documenting how providers and institutions are working to achieve that level. Patients also need to know whether providers and institutions are successful in meeting this goal, and when and where they have fallen short. True public accountability only exists through the development of reporting systems that collect data that are useful for those making health care decisions and present the information in a manner that is readily understandable.

The QuIC agencies are eager to provide this level of accountability, but recognize that our current knowledge about collecting and reporting information on medical errors is inadequate. Better systems for obtaining information about errors are needed, and current techniques need improvement for identifying factors which predispose an organization to errors. More experience is needed to know which information decision makers will find relevant and valid, as well as about what format will make the information readily understandable and usable by the public.

The QuIC believes that the nation should rapidly develop, implement, and test reporting systems that meet the public's need to have information about the safety of the health care system. This report describes several ways that such a reporting system can enhance public accountability, while at the same time Federal agencies can contribute to the information and methods that health care institutions and professionals need to know to improve the care that they provide. Several mechanisms for reporting are already in place and can be improved; others will be begun as part of this initiative; and still others will be developed as the nation learns more about how these systems can be designed and implemented to be most effective.

Several states are engaged in efforts to provide public accountability through data collection and reporting. Those efforts are bolstered by HCFA's Conditions of Participation (CoP), which require that hospitals comply with reporting requirements and other state laws. Mandatory reporting systems also exist at the Federal level. For example, manufacturers are required to report promptly to FDA information on unexpected adverse drug reactions provided by consumers and health care providers.

As a first step in meeting the IOM's recommendations for accountability and reporting, the QuIC proposes to evaluate existing Federal and State reporting systems, as well as those operated by accrediting and other oversight organizations. This evaluation will inform efforts to ensure that these systems -- and those that will be developed in the future -- are effective by providing an understanding of what makes these systems successful and how information can best be used by the intended recipients. AHRQ will lead the QuIC evaluation effort and share the results with states and other organizations, such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) to enable them to initiate or improve reporting systems for their citizens. The QuIC agencies will work with the Congress to enhance mandatory reporting on patient safety and public accountability based on the results of this evaluation.

In addition to supporting the improvement, diffusion, and enhancement of existing reporting systems, the QuIC proposes to take immediate action to provide the public with information on the most egregious errors. This is consistent with the IOM's recommendation that a mandatory reporting system be developed for the most serious medical errors. The QuIC will ask the private-sector Quality Forum (the National Forum for Health Care Quality Measurement and Reporting) to define specific types of errors that should never be allowed to occur (e.g. wrong limb amputation) and develop, within a period of twelve months, a set of measures to collect institution-level data on such errors. In identifying the data to be collected, the QuIC will ask the Quality Forum to assure that the confidentiality of patients will be protected. HCFA will initiate a state-based collaborative demonstration reporting project using these measures to examine how data can be collected, the best means to provide information to the public, purchasers, and policymakers, and what other information should be made available to the public.

The QuIC agencies propose several additional mechanisms for collecting and providing

useful information on patient safety. HCFA will require hospitals participating in the Medicare and Medicaid programs to have ongoing error reduction efforts. OPM will place similar requirements on the health plans with which it contracts, and report whether the plans have reliable safety on its website. FDA-based systems will report to the public on the safety of drugs, devices, and biological products such as blood. In addition, AHRQ will develop national information on errors, based on Federal and state data that cannot be traced to individual patients, to include in the National Quality Report that it is developing with DHHS partners.

The QuIC will also ask the Quality Forum to develop a list of patient safety measures that health care institutions should undertake. The QuIC believes that health care institutions should make available to the public information about whether they have adopted those patient safety measures that have been shown to reduce errors based on evidence about their effectiveness.

Learning from Errors

While systems for accountability will encourage actions to improve safety, they do not always contain sufficient information to inform providers about what they can do to prevent future errors or their harmful impact. To that end, the IOM recommended the creation of systems that collect "information for learning" about the root causes of errors and which evaluate the effectiveness of technologies and methods intended to prevent them. Experience in other industries suggests these systems for learning must build on the collection of extensive information on errors, regardless of their severity, and include a mechanism to provide analysis and information back to the people most likely to be involved in an error.

Currently, valuable reporting systems for learning about medical errors exist at the Federal level. The QuIC proposes to integrate these with other medical error collection efforts to develop a substantial national repository of aggregated information for analysis and learning by health care providers and policymakers. The QuIC agrees with the Institute of Medicine that these programs need to offer confidentiality to retain the privacy of individual patients and the anonymity of clinicians and institutions reporting their errors and near misses. Experience in other industries, such as aviation, demonstrates that this anonymity encourages reporting.

Federal agencies participating in the QuIC will undertake the following initiatives to promote learning and improving from experience with medical errors:

- Lead Efforts to Improve Safety. Several actions are proposed in this document that will provide Federal leadership to improve patient safety. The Agency for Healthcare Research and Quality will create a center for patient safety to fulfill the responsibilities outlined in the IOM report. The AHRQ center, which will be called the Center for Quality Improvement and Patient Safety (CQIPS), will lead efforts to

Executive Summary and Actions (DPC revision)

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 reporting 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 report back to him with a strategy to reduce medical errors and improve patient safety. This report responds to the President's request and recommends an action plan to implement Administration initiatives designed to help prevent mistakes in the nation's health care delivery system. **[This executive summary does not reflect the directive which asked us to look for ways other than that in the IOM report. We should add material from the 3rd and 4th chapters]**

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:

- Create a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety;
- Implement new efforts to 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.

Clinton-Gore Commitment to Improving Patient Safety

The Federal government has become a leader in promoting health care quality and 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 **[This probably overstates the role of the commission in focusing on patient safety. It was one of the Commission's conclusions but it was not a 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.” **[did he state that at the formation of the QuIC or as part of the directive. The reader will surmise the QuIC has done nothing to date and is just now taking on an issue with errors. We need to put this work into the broader quality context so the other pieces aren’t seen as wholly separate.]**

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”, 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 more generally related to health care quality, including over and under-use of services.

The Departments of Defense (DOD) and the Veterans Affairs (VA), serving 3.5 million patients **nationwide [the VA serves 3.5 million but the DoD serves around 8.5 million others. These numbers need to be checked with the VA and DoD.]**, have begun to implement computerized physician order entry systems, which have proven effective in reducing medical errors such as drug interactions. In addition, the Veterans Administration has implemented a computerized medical record in X percent of their 172 hospitals nationwide, making it possible to significantly reduce errors and correctly measure risks 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 begun to use barcode technology to reduce errors in the use of medications.

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. *[insert sentence on CDC reporting results]* FDA receives approximately 100,000 reports per year of adverse events associated with medical devices and over 250,000 reports of adverse events associated with pharmaceuticals. FDA estimates that over one-third of the adverse events associated with medical devices and ____ of the adverse events associated with pharmaceuticals are preventable. The Department of Labor’s Pension and Welfare Benefit Administration (PWBA) has advised employers and plan decision makers to include quality among factors they consider in selecting health plans for employees.

While these agencies 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.

A National Epidemic

It is clear that the rate of error in the health care field is 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 as many as 98,000 Americans. 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, much of it funded by the 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 (Leape, 1994). If the performance levels found in the ICU were applied to the airline or banking industries, it would be the equivalent of 840 unsafe airplane landings per day and 320,000 checks being deducted from the wrong account per hour (Dean, 1996). 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 in only 96.3 percent of the time – an alarmingly high prevalence of adverse events (Gawande, 1999).

Many of these adverse events are associated with the use of pharmaceuticals, and are potentially preventable. The IOM estimates that the number of lives lost to preventable medication errors are estimated to account for over 7,000 deaths annually – more than the number of Americans injured at the workplace. In addition, medication related errors are estimated to increase hospital costs by \$4,700 per admission – 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).

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. In particular, it describes efforts to develop mandatory and voluntary reporting systems for the public to use in judging health care safety and making choices about their care. Information from both will enrich the base of knowledge that health care professionals can use to learn how to prevent errors.

The QuIC fully supports 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 create a Center for Patient Safety within the Agency for Healthcare Research and Quality 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, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

QulC Response. The Administration endorses the IOM recommendation and is pleased that the President has included \$20 million in the FY 2001 budget to create a new Center for Quality Improvement and Patient Safety at the Agency for Healthcare Research and Quality. **We need to leave the sentences noting how we are integrating patient safety into the broad quality agenda.]** The Center will work with private sector entities, including the Quality Forum, to develop national goals for patient safety; issue an annual report on the state of patient safety nationally **We need to note the dovetail with the National Quality Report];** promote the translation of research findings into improved practices and policies; and educate consumers 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 data **[We can make analyses and summaries available not the raw data. We need to have time to explore what the right thing to do is as opposed to committing to this now.]** available to the public in a manner that protects privacy.

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. **We are really losing something with only breaking this down into mandatory versus voluntary and losing the importance of the learning vs. accountability of the framework I think we are setting ourselves up to look as though we did not carefully think through the issue. Even as a purely political document, we may lose support from those who will otherwise support us, including every expert in this field and many of those who have already testified. We need more balance and we need more re voluntary reporting]**

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 states choose not to implement the mandatory reporting system, HHS should serve as the responsible entity.

Voluntary Reporting Systems. The IOM report rejects the establishment of a national voluntary reporting system and 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 can identify potential precursors to error and prevent 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 **after we demonstrate how they can be most useful in the states where they currently exist**, and that these systems should have both mandatory and voluntary components. Well designed reporting systems serve two important functions -- to hold health systems accountable for delivering high quality health care and to provide important information to researchers and health systems decision-makers that will improve patient safety.

Mandatory Reporting Systems. The Administration 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. We agree with the IOM that the scope of events targeted by mandatory reporting systems should be limited to serious and preventable adverse events associated with death or significant patient harm. By limiting this required reporting system to the most profound challenges in the health care delivery system, this approach will most effectively target these problems. It will also minimize the cost to health care organizations of operating the oversight system and ensure the availability of resources to appropriately follow up on and analyze reported events[**This implies that the organizations will take the lead on analysis and reporting. There is little evidence that that will happen, and it the opportunity for broader learning. Every expert in this field will say that it provides a huge incentive for under-reporting, and they will strongly criticize the QuIC report on these grounds..**]. The QuIC believes that information collected through a mandatory reporting system should be aggregated by health system and made public [**This language may be a bit strong for the Federal providers. The DoD may want to review this carefully given some of their statements at earlier meetings.**]. However, there should be no identification of patients or individual health care professionals.

We agree with the IOM that patients should have access to any and all information [**What does any and all mean? Does that mean that the charts, details of the analysis, etc will all be publicly reported? This will certainly prove unpopular from both the providers' and accreditors' views. We will lose a lot of support from them, and an open statemntert about "any and all" information being available will be practically very difficult. It may generate privacy concerns as well. In addition, we don't know anything about the value of such reporting. It seems like the look before we leap (evaluate before we implement) tone of our**

discussions in the QuIC have been abandoned here. Testimony in the Senate and House hearings by expert suggests they would roundly criticize this language.]leading up to and including the occurrence of a preventable error that caused death or serious injury. 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 to extend these peer review protections to this information. Moreover, the QuIC believes that these mandatory reporting systems should not be used as a tool for punitive action by state and local authorities but rather as should be used as a mechanism for highlighting errors that can and should be prevented in the future.

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, 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 [or individual incompetence. This language is a good addition.]**.

The IOM has a set of specific recommendations for the structure of a nationwide mandatory reporting system. The QuIC believes that, at this time, there is not sufficient evidence to determine whether establishing Federal requirements for reporting or encouraging the development and implementation of state-based mandatory reporting systems would be most effective. Therefore, in order to demonstrate the importance of implementing mandatory reporting systems and to create an environment in which there is more widespread support for their use, the Administration will take the following actions:

- *Implementing a mandatory reporting system in the over 300 hospitals operated by the Department of Defense [would this be publicly reported? If that is the case it will need to be reviewed by DoD. It is quite different from what DoD has been saying].* Beginning this spring, the Department of Defense will invest \$X million begin to implement a mandatory reporting system in its 300 hospitals **[need to check the numbers with DoD, it is much closer to 150 worldwide]** serving approximately 8 million patients. This mandatory reporting system, which will be modeled on the system in operation at the Department of Veterans Affairs, will be fully implemented in ____ and will collect information on adverse events, medication errors, and other patient safety issues. This data will be used to design corrective action **[DoD providers will read this as punitive action unless the focus on systems is reinforced here.]** to ensure patient safety.
- *Expand mandatory reporting requirements for blood banks nationwide.* By the end of the year, the Food and Drug Administration (FDA) will improve the safety of transfusions by requiring all X blood banks and establishments dealing with blood products to report errors and accidents, such as mistyping blood and distributing contaminated blood products. Failure to report these incidents will result in _____.
- *Identify a set of patient safety measurements critical to the identification and prevention of medical errors.* The QuIC will ask the Quality Forum to identify patient safety measures that should be adopted by all hospitals within six months and encourage their widespread use. Developing standardized measures lays the foundation for a uniform system of data collection and facilitates the development of these systems.

- *Identifying issues related to the implementation of mandatory reporting systems.* Using the Quality Forum's recommendations for patient safety standards, the Health Care Financing Administration (HCFA) will develop a pilot project to implement mandatory reporting systems in up to X hospitals participating in the Medicare program. **Committing to a certain number of hospitals may force HCFA to implement the pilot in a state which may be suboptimal.].** This pilot project will help identify issues related to the implementation of mandatory reporting systems and better inform states and health systems developing these systems.
- *Determine the most effective way to present information on the incidence of medical errors to the public.* HCFA will work with the Quality Forum and states with mandatory reporting systems to establish a pilot project to determine how data on medical errors can be presented – and the impact of providing such information – to the general public and local policy officials **[This is more appropriate for AHRQ to take it on.in thatr it goes beyond Medicare and is, in essence, a research project].** Since informing the public about the safety of their health care systems is a critical component of mandatory reporting systems, this pilot project will inform action on this issue.
- *Examine existing mandatory reporting systems.* The QuIC 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. The QuIC will monitor the number of states with mandatory reporting systems over the next three years. If all states have not implemented mandatory reporting systems within that time, the QuIC will develop recommendations to the President that would assure that all health care institutions are reporting serious preventable adverse events within the next 12 months **[This was beyond the scope of our discussions to date and will need to be reviewed by others to assure buy0in from QuIC agencies. It also may violate the instructions from OMB not to make commitments that will require out year funds.].**

Although currently the QuIC believes that moving towards a mandatory reporting system is the appropriate course of action, it is important to note that if research conducted by AHRQ and other agencies indicates that the implementation of these systems does not significantly enhance patient safety, these results will be included in the QuIC's final recommendations on this issue at the end of the three year period.

Voluntary Reporting Systems. The QuIC agrees with the IOM that voluntary reporting systems are a critical component of a national strategy to reduce errors. The information from voluntary reporting systems is usually gathered by an independent entity **[are they referring to the ASRS model? I think the original language was clearer in this section.]** in order to identify patterns of error that apply to all health care systems. This information, which would include data on so-called “near-misses” that do not have immediate impact on patients, would be used to educate

providers and alter systems of care to prevent harming patients. In order to encourage the development of voluntary reporting systems, the Administration will:

- *Implement a voluntary reporting system nationwide for Veterans Administration hospitals.* By the end of the year, the VA will implement a voluntary reporting system for both adverse events and “near misses” 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. **[timeline will require VA clearance]**
- *Examine existing voluntary systems.* The QuIC 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 make recommendations about which entity or entities would be best to collect, analyze, and disseminate information on frequently occurring errors and the best interventions to prevent them.

[the balance and complementary relationship between mandatory and voluntary reporting is lost in this version. It seems like voluntary reporting is far less important than mandatory here and the experience from other industries and wisdom of our funded researchers in this field (Berwick and Leape especially) states that the mandatory is for the exception and the voluntary could provide the greatest value. Again, we will satisfy those anxious to see mandatory reporting, but we will lose credibility – and political support – from those who are advocates of emphasizing the learning aspects of patient safety]

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:

- *Requiring the X hospitals in the Medicare program to implement patient safety programs.* By the end of the year, HCFA will publish regulations requiring all X hospitals participating in the Medicare program to have ongoing error reduction programs that emphasize reducing medication errors **Have ASPE and HCFA signed onto this, given the DHHS reluctance to go beyond where we are with the COP?** In order to comply with this requirement, hospitals are likely to implement automated pharmacy order entry systems and include automatic safeguards built into the treatment process against harmful drug interactions and other adverse side effects **[this was discussed in one of our conference calls with the White House and HCFA felt strongly that we should not commit to specifics. We discussed the use of the word “likely” and that was still felt to be unacceptable at this juncture. Has HCFA changed its opinion?]**
- *Requiring the over 300 health plans in the Federal Employees Health Benefits Program to implement patient safety programs.* In their annual call letter to be issued in the spring of

2000, 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.

- *Educating private sector employers and employees about the importance of patient safety.* 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. **[We may want to insert language noting that the majority of care is beneficial and that errors are the rule. I am afraid this could be viewed as “scare the public” campaign unless that is stated up front.]**

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 are state-based programs. However, the QuIC will provide technical assistance to any state or professional agencies seeking to ensure a basic level of knowledge for health care providers on patient safety issues or promote model patient safety programs that include evidence based best patient safety practices to provider organizations. **This is reasonable but the QuIC will have to discuss how this can be done.]**

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, is pleased that the President has committed \$33 million, an increase of 39 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 interaction problems and other dosage errors related to medications.

- *Providing patient safety information to the public.* Within a year, FDA will provide access to databases linked to health care systems and other sources of adverse event and marketing data, and link these to existing registries of product users.

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 action.

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 172 hospitals serving 3.5 million patients nationwide. This year, the VA will invest \$X million to increase the requirement for patient safety training for staff from 20 to 25 hours a year and place “patient safety checklists” in operating rooms in every hospital nationwide.

The Department of Defense. Beginning this fall, the Department of Defense will begin the implementation of a computerized medical record, including an automated entry order system for pharmaceuticals, that will be phased to all DOD facilities over three years **[most DoD facilities have had this for a few years and a savvy reporter will catch on here.]** DOD will also pilot a new patient safety program in 10 hospitals that includes a special focus on improving the quality of care in “high hazard areas”, including labor and delivery rooms, emergency rooms, operating rooms, and intensive care units **This is likely the IHI process (breakthrough series that the QuIC is organizing) ...]**

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

QuIC Response. The QuIC endorses this recommendation. This year, the Veterans Administration will invest \$X million to complete the implementation of an automated order entry system in all of its hospitals and a barcoding system for the distribution of medications. A 1999 evaluation of this system indicates that it has reduced medication errors by 70 percent since its implementation. By the end of October 2000, the Department of Defense will invest \$X million to implement an integrated pharmacy system that enables clinical screening for drug interactions at military and private pharmacies serving DOD beneficiaries nationwide. 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

automated pharmacy order entry systems **[This is a very big price tag sentence. Are we ready to push the providers on thisIt may be the right thing to do, but it has insufficient evidence to be mandated, and will likely generate anger from the hospital community.]**

Conclusion

The bold actions called for by the IOM report require a collaborative response among Federal agencies and between government and the private sector. 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, such as those proposed for AHRQ, FDA, DOD, and VA, the majority of the proposed actions require joint effort. Collaboration – federal agencies working together through the QuIC, and with states and the private sector organizations – can more rapidly and more effectively improve patient safety. 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.

Need sections on private sector work and actions beyond the IOM recommendations. We also should add back the language we had in an earlier version about working with Congress to restore some balance to the approach here. Currently this reads like a very heavy handed approach from the administration.]

FEDERAL RESPONSE TO THE INSTITUTE OF MEDICINE'S RECOMMENDATIONS	
IOM Recommendation	Federal Action
4.1 Creation of a Center for Patient Safety at AHRQ	HHS will invest \$20 million to establish the Center for Quality Improvement and Patient Safety in FY 2001.
5.1 Establishment of a nationwide mandatory reporting system that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm.	The QuIC supports [with resources?] the development of a 50 state system to collect standardized information on adverse events. If the majority of states have not implemented mandatory reporting systems within three years, the QuIC will develop recommendations to assure that all health care institutions are reporting serious preventable adverse events within the next 12 months. [This needs to be discussed with the QuIC] DOD will implement a mandatory reporting system in its over 300 hospitals serving 8 million patients. [This needs DoD clearance, especially if it is to be public] FDA will expand its mandatory reporting system for medical errors related to blood products to include all blood banks nationwide.
5.2 Encourage the development of voluntary reporting efforts	The VA is implementing a voluntary reporting system for both adverse events and "near misses" nationwide. [We had a lot more on voluntary reporting and the balance between the two in this table is indicative of the thrust of this rewritten document.]
6.1 Congress should pass legislation to extend peer review protections to data collected to improve patient safety and quality	The QuIC is supportive of this legislation and believes it should apply to both mandatory and voluntary reporting systems. However, it must include provisions to ensure that new protections do not undermine current mechanisms to address criminal activity or negligence.
7.1 Performance standards and expectations for health care organizations should focus greater attention on patient safety	HCFA will require hospitals in the Medicare program to have error reduction programs. OPM will require FEHBP plans to use error reduction techniques.
7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety	The QuIC endorses this recommendation and will provide technical assistance to state or professional agencies seeking to undertake these activities.
7.3 FDA should increase attention to the safe use of drugs in both pre and post marketing processes	FDA will invest \$13 million to develop: new standards to help prevent medical errors caused by proprietary drug names that sound similar or packaging that looks similar; new label standards that highlight common drug interactions and dose errors.
8.1 Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility	DOD will invest \$X million in a patient safety program that includes a computerized medical record and pilot a new patient safety program that focuses on improving the quality of care in "high hazard areas".
8.2 Health care organizations should implement proven medication safety practices	VA will invest \$X million to fully implement their computerized order entry system. DOD will invest \$X million to begin the implementation of a similar

	system. In order to comply with the new proposed requirement that hospitals in Medicare must have error reduction programs, hospitals are likely to implement automated pharmacy order entry systems.
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