Appendix C
Past Recommendations

Recommendations from Past Reports

On Healthcare, Information Technology, Patient Safety, Privacy, National Security, Computerized Medical Records, Standards, and Interoperability

Compiled May 17, 2005

Table of Contents

Recommendations from Past Reports

From ***Records, Computers and the Rights of Citizens: Report of the Secretary's Advisory Committee on Automated Personal Data Systems*** (July 1973)

RECOMMENDATIONS

Under current law, a person's privacy is poorly protected against arbitrary or abusive record-keeping practices. For this reason, as well as because of the need to establish standards of record-keeping practice appropriate to the computer age, the report recommends the enactment of a Federal "Code of Fair Information Practice" for all automated personal data systems. The Code rests on five basic principles that would be given legal effect as "safeguard requirements" for automated personal data systems.

- There must be no personal data record-keeping systems whose very existence is secret.
- There must be a way for an individual to find out what information about him is in a record and how it is used.
- There must be a way for an individual to prevent information about him that was obtained for one purpose from being used or made available for other purposes without his consent.
- There must be a way for an individual to correct or amend a record of identifiable information about him.
- Any organization creating, maintaining, using, or disseminating records of identifiable personal data must assure the reliability of the data for their intended use and must take precautions to prevent misuse of the data.

We recommend the enactment of legislation establishing a Code of Fair Information practice for all automated personal data systems.

- The Code should define "fair information practice" as adherence to specified safeguard requirements.
- The Code should prohibit violation of any safeguard requirement as an "unfair information practice."
- The Code should provide that an unfair information practice be subject to both civil and criminal penalties.
- The Code should provide for injunctions to prevent violation of any safeguard requirement.
- The Code should give individuals the right to bring suits for unfair information practices to recover actual, liquidated, and punitive damages, in individual or class actions. It should also provide for recovery of reasonable attorneys' fees and other costs of litigation incurred by individuals who bring successful suits.

Pending the enactment of a code of fair information practice, we recommend that all Federal agencies (i) apply the safeguard requirements, by administrative action, to all Federal systems, and (ii) assure, through formal rule making, that the safeguard requirements are applied to all other systems within reach of the Federal government's authority. Pending the enactment of a code of fair information practice, we urge that State and local governments, the institutions within reach of their authority, and all private organizations adopt the safeguard requirements by whatever means are appropriate.

Existing laws or regulations affording individuals greater protection than the safeguard requirements should be retained, and those providing less protection should be amended to meet the basic standards set by the safeguards. In particular, we recommend:

- That the Freedom of Information Act be amended to require an agency to obtain the consent of an individual before disclosing in personally identifiable form exempted category data about him, unless the disclosure is within the purposes of the system as specifically required by statute.
- That pending such amendment of the Act, all Federal agencies provide for obtaining the consent of individuals before disclosing individually identifiable exempted-category data about them under the Freedom of Information Act.
- That the Fair Credit Reporting Act be amended to provide for actual, personal inspection by an individual of his record along with the opportunity to copy its contents, or to have copies made; and that the exceptions from disclosure to the individual now authorized by the Fair Credit Reporting Act for medical information and sources of investigative information be omitted.

In light of our inquiry into the statistical-reporting and research uses of personal data in administrative record-keeping systems, we recommend that steps be taken to assure that all such uses are carried out in accordance with five principles:

First, when personal data are collected for administrative purposes, individuals should under no circumstances be coerced into providing additional personal data that are to be used exclusively for statistical reporting and research. When application forms or other means of collecting personal data for an administrative data system are designed, the mandatory or voluntary character of an individual's responses should be made clear.

Second, personal data used for making determinations about an individual's character, qualifications, rights, benefits, or opportunities, and personal data collected and used for statistical reporting and research, should be processed and stored separately.

Third, the amount of supplementary statistical-reporting and research data collected and stored in personally identifiable form should be kept to a minimum.

Fourth, proposals to use administrative records for statistical reporting and research should be subjected to careful scrutiny by persons of strong statistical and research competence.

Fifth, any published findings or reports that result from secondary statistical-reporting and research uses of administrative personal data systems should meet the highest standards of error measurement and documentation.

In addition, we recommend that all personal data in such systems be protected by statute from compulsory disclosure in identifiable form. Federal legislation protecting against compulsory disclosure should include the following features:

- The data to be protected should be limited to those *used exclusively for statistical reporting or research*. Thus, the protection would apply to statistical-reporting and research data derived from administrative records, and kept apart from them, but not to the administrative records themselves.
- The protection should be limited to data *identifiable with, or traceable to, specific individuals*. When data are released in statistical form, reasonable precautions to protect against "statistical disclosure" should be considered to fulfill the obligation not to disclose data that can be traced to specific individuals.
- The protection should be specific enough to qualify for non-disclosure under the Freedom of Information Act exemption for matters "specifically exempted from disclosure by statute." 5 U.S.C. 552(b)(3).

- The protection should be available for data in the custody of all statistical-reporting and research systems, whether supported by Federal funds or not.
- Either the data custodian or the individual about whom data are sought by legal process should be able to invoke the protection, but only the individual should be able to waive it.
- The Federal law should be controlling; no State statute should be taken to interfere with the protection it provides.

Use of the Social Security Number

We take the position that a standard universal identifier (SUI) should not be established in the United States now or in the foreseeable future. By our definition, the Social Security Number (SSN) cannot fully qualify as an SUI; it only approximates one. However, there is an increasing tendency for the Social Security number to be used as if it were an SUI. There are pressures on the Social Security Administration to do things that make the SSN more nearly an SUI.

We believe that any action that would tend to make the SSN more nearly an SUI should be taken only if, after careful deliberation, it appears justifiable and any attendant risks can be avoided. We recommend against the adoption of any nationwide, standard, personal identification format, with or without the SSN, that would enhance the likelihood of arbitrary or uncontrolled linkage of records about people, particularly between government and government-supported automated personal data systems.

We believe that until safeguards against abuse of automated personal data systems have become effective, constraints should be imposed on use of the Social Security number. After that the question of SSN use might properly be reopened.

As a general framework for action on the Social Security number, we recommend that Federal policy with respect to use of the SSN be governed by the following principles:

First, uses of the SSN should be limited to those necessary for carrying out requirements imposed by the Federal government.

Second, Federal agencies and departments should not require or promote use of the SSN except to the extent that they have a specific legislative mandate from the Congress to do so.

Third, the Congress should be sparing in mandating use of the SSN, and should do so only after full and careful consideration preceded by well advertised hearings that elicit substantial public participation. Such consideration should weigh carefully the pros and cons of any proposed use, and should pay particular attention to whether effective safeguards have been applied to automated personal data systems that would be affected by the proposed use of the SSN. (Ideally, Congress should review all present Federal requirements for use of the SSN and determine whether these existing requirements should be continued, repealed, or modified.)

Fourth, when the SSN is used in instances that do not conform to the three foregoing principles, no individual should be coerced into providing his SSN, nor should his SSN be used without his consent.

Fifth, an individual should be fully and fairly informed of his rights and responsibilities relative to uses of the SSN, including the right to disclose his SSN whenever he deems it in his interest to do so.

In accordance with these principles, we recommend specific, preemptive Federal legislation providing:

(1) That an individual has a legal right to refuse to disclose his SSN to any person or organization that does not have specific authority provided by Federal statute to request it;

(2) That an individual has the right to redress if his lawful refusal to disclose his SSN results in the denial of a benefit, or the threat of denial of a benefit; and that, should an individual under threat of loss of benefits supply his SSN under protest to an unauthorized requestor, he shall not be considered to have forfeited his right to redress; and

(3) That any oral or written request made to an individual for his SSN must be accompanied by a clear statement indicating whether or not compliance with the request is required by Federal statute, and, if so, citing the specific legal requirement.

In addition, we recommend

(4) That the Social Security Administration undertake a positive program of issuing SSNs to ninth-grade students in schools, provided (a) that no school system be induced to cooperate in such a program contrary to its preference; and (b) that any person shall have the right to refuse to be issued an SSN in connection with such a program, and such right of refusal shall be available both to the student and to his parents or guardians.

From ***Medical Records: Problems of Confidentiality and Privacy*** (February, 1978)

RECOMMENDATIONS

- The individual's right to control, use, and access his health care records, while obtaining requisite services and benefits, requires further consideration.

From ***Health Data in the Information Age: Use, Disclosure, and Privacy*** (1994)

RECOMMENDATION 2.1 ACCURACY AND COMPLETENESS

To address these issues, the committee recommends that health database organizations take responsibility for assuring data quality on an ongoing basis and, in particular, take affirmative steps to ensure: (1) the completeness and accuracy of the data in the databases for which they are responsible and (2) the validity of data for analytic purposes for which they are used.

Part 2 of this recommendation applies to analyses that Health Database Organizations (HDOs) conduct. They cannot, of course, police the validity of data when used by others for purposes over which the HDOs have no a priori control.

RECOMMENDATION 2.2 COMPUTER-BASED PATIENT RECORD

Accordingly, the committee recommends that health database organizations support and contribute to regional and national efforts to create computer-based patient records.

RECOMMENDATION 3.1 CONDUCTING PROVIDER-SPECIFIC EVALUATIONS

The committee recommends that health database organizations produce and make publicly available appropriate and timely summaries, analyses, and multivariate analyses of all or pertinent parts of their databases. More specifically, the committee recommends that health database organizations regularly produce and publish results of provider-specific evaluations of costs, quality, and effectiveness of care.

RECOMMENDATION 3.2 DESCRIBING ANALYTIC METHODS

The committee recommends that a health database organization report the following for any analysis it releases publicly:

- general methods for ensuring completeness and accuracy of their data;
- a description of the contents and the completeness of all data files and of the variables in each file used in the analyses;
- information documenting any study of the accuracy of variables used in the analyses.

RECOMMENDATION 3.3 MINIMIZING POTENTIAL HARM

The committee recommends that, to enhance the fairness and minimize the risk of unintended harm from the publication of evaluative studies that identify individual providers, each HDO should adhere to two principles as a standard procedure prior to publication: (1) to make available to and upon request supply to institutions, practitioners, or providers identified in an analysis all data required to perform an independent analysis, and to do so with reasonable time for such analysis prior to public release of the HDO results; and (2) to accompany publication of its own analyses with notice of the existence and availability of responsible challenges to, alternate analyses of, or explanation of the findings.

RECOMMENDATION 3.4 ADVOCACY OF DATA RELEASE: PROMOTING WIDE APPLICATIONS OF HEALTH-RELATED DATA

To foster the presumed benefits of widespread applications of HDO data, the committee recommends that health database organizations should release non-person-identifiable data upon request to other entities once those data are in analyzable form. This policy should include release to any organization that meets the following criteria:

- it has a public mission statement indicating that promoting public health or the release of information to the public is a major goal;
- it enforces explicit policies regarding protection of the confidentiality and integrity of data;
- it agrees not to publish, redisclose, or transfer the raw data to any other individual or organization; and
- it agrees to disclose analyses in a public forum or publication.

The committee also recommends, as a related matter, that health database organizations make public their own policies governing the release of data.

RECOMMENDATION 4.1 PREEMPTIVE LEGISLATION

The committee recommends that the U.S. Congress move to enact preemptive legislation that will:

- establish a uniform requirement for the assurance of confidentiality and protection of privacy rights for person-identifiable health data and specify a Code of Fair Health Information Practices that ensures a proper balance among required disclosures, use of data, and patient privacy;
- impose penalties for violations of the act, including civil damages, equitable remedies, and attorney's fees where appropriate;
- provide for enforcement by the government and permit private aggrieved parties to sue;
- establish that compliance with the act's requirements would be a defense to legal actions based on charges of improper disclosure; and

- exempt health database organizations from public health reporting laws and compulsory process with respect to person-identifiable health data except for compulsory process initiated by record subjects.

RECOMMENDATION 4.2 DATA PROTECTION UNITS

The committee recommends that health database organizations establish a responsible administrative unit or board to promulgate and implement information policies concerning the acquisition and dissemination of information and establish whatever administrative mechanism is required to implement these policies. Such an administrative unit or board should:

- promulgate and implement policies concerning data protection and analyses based on such data;
- develop and implement policies that protect the confidentiality of all person-identifiable information, consistent with other policies of the organization and relevant state and federal law;
- develop and disseminate educational materials for the general public that will describe in understandable terms the analyses and their interpretation of the rights and responsibilities of individuals and the protections accorded their data by the organization;
- develop and implement security practices in the manual and automated data processing and storage systems of the organization; and
- develop and implement a comprehensive employee training program that includes instruction concerning the protection of person-identifiable data.

RECOMMENDATION 4.3 RELEASE OF PERSON-IDENTIFIED DATA

The committee recognizes that there must be release of patient-identified data related to the processing of health insurance claims. The committee recommends, however, that a health database organization *not* release person-identifiable information in any other circumstances *except* the following:

- to other HDOs whose missions are compatible with and whose confidentiality and security protections are at least as stringent as their own;
- to individuals for information about themselves;
- to parents for information about a minor child except when such release is prohibited by law;
- to legal representatives of incompetent patients for information about the patient;
- to researchers with approval from their institution's properly constituted Institutional Review Board;
- to licensed practitioners with a need to know when treating patients in life-threatening situations who are unable to consent at the time care is rendered; and
- to licensed practitioners when treating patients in all other (non-life-threatening) situations, *but only with the informed consent of the patient*.

Otherwise, the committee recommends that health database organizations not authorize access to, or release of, information on individuals with or without informed consent.

RECOMMENDATION 4.4 RESTRICTING EMPLOYER ACCESS

The committee recommends that employers not be permitted to require receipt of an individual's data from a health database organization as a condition of employment or for the receipt of benefits.

The committee recommends that an HDO report the following for any analysis it releases publicly:

- general methods for ensuring completeness and accuracy of data;
- a description of the contents and the completeness of all data files and of the variables in each file used in the analyses;
- information documenting any study of the accuracy of variables used in the analyses (Recommendation 3.2).

THE FOLLOWING IS THE SAME AS RECOMMENDATION 4.1

The committee recommends that the U.S. Congress move to enact preemptive legislation that will:

- establish a uniform requirement for the assurance of confidentiality and protection of privacy rights for person-identifiable health data and specify a Code of Fair Health Information Practices that ensures a proper balance among required disclosures, use of data, and patient privacy;
- impose penalties for violations of the act, including civil damages, equitable remedies, and attorney's fees where appropriate;
- provide for enforcement by the government and permit private aggrieved parties to sue;
- establish that compliance with the act's requirements would be a defense to legal actions based on charges of improper disclosure; and
- exempt health database organizations from public health reporting laws and compulsory process with respect to person-identifiable health data except for compulsory process initiated by record subjects (Recommendation 4.1).

From ***Standards for Medical Identifiers, Codes, and Messages Needed to Create an Efficient Computer-stored Medical Record*** (1994)

RECOMMENDATIONS

1. The American Medical Informatics Association (AMIA) recommends the use of the SSN as the patient identifier at the present time. In addition, we recommend the addition of a self-check digit to the SSN to reduce errors of identification whenever the number is hand-entered by an operator. Other options for patient identifiers should be explored for the long haul.
2. We suggest that the Health Care Financing Administration (HCFA) consider using alphanumeric codes (to reduce the number of key strokes needed to enter the identifier to a practical number), and that the Universal Physician Identifier Number (UPIN) be expanded to include all health care providers for the purpose of provider identification.
3. For the next five years, all private and government care agencies should use published health care informatics message standards as a starting point for all new applications involving applicable internal and external health care information transmissions. Different published standards would apply to different kinds of communications, depending upon the subject matter and kind of communication as described below.

4. AMIA recommends that HL7 be used for within-institution transmission of orders, clinical observations, and clinical data (including test results); admission, transfer, and discharge records; and charge and billing information.

5. ASTM E1238 should be used for most interchanges of clinical data between institutions. HL7, which is a practical superset of ASTM E1238, is an alternative when tighter linkages are desired.

6. ACR-NEMA should be used for the transmission of radiologic images and for message transmissions within PACS.

7. AMIA recommends the use of ASTM E1394 for communication of information from laboratory instruments to computer systems.

8. AMIA suggests that the NCPDP be used for communication of prescription billing information and eligibility information between the community pharmacies and third-party payers.

9. AMIA suggests the use of ASC X12's standards for billing and remittance transactions between a health care provider and a third-party payer.

10. AMIA recommends its (ASTM E1460, or "Arden Syntax") use for the transmission of medical logic modules.

11. AMIA recommends its (ASTM E1467) use for the transmission of such EEG and EMG signals.

12. ANSI Z39.50 is a draft standard for transmitting requests for bibliographic information to bibliographic retrieval systems. AMIA recommends that it be considered for all such communications.

13. AMIA recommends that during the initial five years of standards development, the federal government invest in efforts to integrate and extend these standards to all health care messages. Furthermore, we suggest that the federal government build public-domain translators between the current message systems to permit future integration of systems. The translators should be submitted as ANSI and/or IS0 standards, and would be based on the object modeling framework being developed by the joint working group created by the HISPP Message Standards Developers Subcommittee (MSDS) and coordinated by IEEE MEDIX for modeling.

14. With advice from AHCPR and CPRI, and in coordination with ANSI HISPP and the message standards developers, they should have the formal responsibility for developing these standards.

15. Codes are needed to address (at least, the following) subject domains:

    - Drugs (e.g., penicillin V)
    - Diagnoses (e.g., pneumonia, heart failure)
    - Symptoms and findings (e.g., fatigue, swollen ankle)
    - Anatomic sites (e.g., right lower lobe of lung)
    - Microbes and etiologic agents (e.g., E. coli)
    - Clinical observations (e.g., blood pressure, oral intake, physical examination of heart)
    - Patient outcome variables and functional status (e.g., SF-36, Hamilton depression score, Inter-Study TYPE variables)
    - Medical devices (e.g., hip implant, tongue blades)
    - Units of measure

- Diagnostic study results (e.g., blood glucose, chest, x-ray, cardiac MUGA)
- Procedures (e.g., triple bypass surgery, endoscopy, skin care)

From ***For the Record: Protecting Electronic Health Information*** (1997)

RECOMMENDATIONS

1. All organizations that handle patient-identifiable health care information—regardless of size—should adopt the set of technical and organizations policies, practices, and procedures described below to protect such information.

2. Government and the health care industry should take action to create the infrastructure necessary to support the privacy and security of electronic health information.

2.1 The Secretary of Health and Human Services should establish a standing health information subcommittee within the National Committee on Vital and Health Statistics to develop and update privacy and security standards for all users of health information. Membership should be drawn from existing organizations that represent the broad spectrum of users and subjects of health information.

2.2 Congress should provide initial funding for the establishment of an organization for the health-care industry to promote greater sharing of information about security threats, incidents, and solutions throughout the industry.

3. The federal government should work with industry to promote and encourage an informed public debate to determine an appropriate balance between the privacy concerns of patients and the information needs of various users of health information.

3.1 Organizations that collect, analyze, or disseminate health information should adopt a set of fair information practices similar to those contained in the federal Privacy Act of 1974.

3.2 The Department of Health and Human Services should work with state and local governments, health care researchers, and the health care industry to establish a program to promote consumer awareness of health privacy issues and the value of health information for patient care, administration, and research. It should also conduct studies that will develop a series of recommendations for improving the level of consumer awareness of health data flows.

3.3 Professional societies and industry groups (i.e., the American Hospital Association, American Medical Informatics Association, American Health Management Association, College of Health Information Management Executives, Healthcare Information and Management Systems Society, Computer-based Patient Records Institute, and American Medical Association, etc.) should continue to expand their leadership roles in educating members about privacy and security issues in their conference discussions and publications.

3.4 The Department of Health and Human Services should conduct studies to determine the extent to which—and the conditions under which—users of health information need data containing patient identities.

3.5 The Department of Health and Human Services should work with the US Office of Consumer Affairs to determine appropriate ways to provide consumers with a visible, centralized point of contact regarding privacy issues (a privacy ombudsman).

4. Any effort to develop a universal patient identifier should weigh the presumed advantages of such an identifier against potential privacy concerns. Any method used to identify patients and to link patient records in a health care environment should be evaluated against the privacy criteria listed below.

    1. The method should be accompanied by an explicit policy framework that defines the nature and character of linkages that violate patient privacy and specifies legal or other sanctions for creating such linkages. That framework should derive from the national debate advocated in Recommendation 3.

    2. It should facilitate the identification of parties that link records so that those who make improper linkages can be held responsible for their creation.

    3. It should be unidirectional to the degree that is technically feasible: it should facilitate the appropriate linking of health records given information about the patient or provided by the patient (such as the patient's identifier), but prevent a patient's identity from being easily deduced from a set of linked health records or from the identifier itself.

5. The federal government should take steps to improve information security technologies for health care applications.

5.1 To facilitate the exchange of technical knowledge on information security and the transfer of information security technology, the Department of Health and Human Services should establish formal liaisons with relevant government and industry working groups.

5.2 The Department of Health and Human Services should support research in those areas listed below that are of particular importance to the health care industry, but that might not otherwise be pursued.

- Methods of identifying and linking patient records.
- Anonymous care and pseudonyms.
- Audit tools.
- Tools for rights enforcement and management.

5.3 The Department of Health and Human Services should fund experimental testbeds that explore different approaches to access control that hold promise for being inexpensive and easy to incorporate into existing operations and that allow access during emergency situations.

From ***The Computer-Based Patient Record: An Essential Technology for Health Care*** (1991, 1997)

SUMMARY OF THE RECOMMENDATIONS OF THE INSTITUTE OF MEDICINE COMMITTEE ON IMPROVING THE PATIENT RECORD

The committee recommends the following:

1. Health care professionals and organizations should adopt the computer-based patient record (CPR) as the standard for medical and all other records related to patient care.

2. To accomplish Recommendation No. 1, the public and private sectors should join in establishing a Computer-based Patient Record Institute (CPRI) to promote and facilitate development, implementation, and dissemination of the CPR.

3. Both the public and private sectors should expand support for the CPR and CPR system implementation through research, development, and demonstration projects. Specifically, the committee recommends that Congress authorize and appropriate funds to implement the research and development agenda outlined herein. The committee further recommends that private foundations and vendors fund programs that support and facilitate this research and development agenda.

4. The CPRI should promulgate uniform national standards for data and security to facilitate implementation of the CPR and its secondary databases.

5. The CPRI should review federal and state laws and regulations for the purpose of proposing and promulgating model legislation and regulations to facilitate the implementation and dissemination of the CPR and its secondary databases and to streamline the CPR and CPR systems.

6. The costs of CPR systems should be shared by those who benefit from the value of the CPR. Specifically, the full costs of implementing and operating CPRs and CPR systems should be factored into reimbursement levels or payment schedules of both public and private sector third-party payers. In addition, users of secondary databases should support the costs of creating such databases.

7. Health care professional schools and organizations should enhance educational programs for students and practitioners in the use of computers, CPRs, and CPR systems for patient care, education, and research.

From ***To Err Is Human: Building a Safer Health System*** (2000)

RECOMMENDATIONS

4.1 Congress should create a Center for Patient Safety within the Agency for Healthcare Research and Quality. This center should

- 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; and
- Develop knowledge and understanding of errors in health care 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.

5.1 A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should

- Designate the National Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;
- Require all health care organizations to report standardized information on a defined list of adverse events;
- Provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and

- Designate the Center for Patient Safety to:

    1) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and

    2) receive and analyze aggregate reports from states to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).

5.2 The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should

- Describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
- Convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
- Periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and
- Fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

6.1 Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

7.1 Performance standards and expectations for health care organizations should focus greater attention on patient safety.

- 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.

7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety.

- Health professional licensing bodies should

    1) implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and

    2) work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.

- Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should

    1) develop a curriculum on patient safety and encourage its adoption into training and certification requirements;

    2) disseminate information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and web sites on a regular basis;

3) recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies and drugs;

4) work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and

5) collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.

7.3 The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and post-marketing processes through the following actions:

- Develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;
- Require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names; and
- Work with physicians, pharmacists, consumers, and others to establish appropriate responses to protect the safety of patients.

8.1 Healthcare 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. Patient safety programs should

- Provide strong, clear and visible attention to safety;
- Implement non-punitive systems for reporting and analyzing errors within their organizations;
- Incorporate well-understood safety principles, such as standardizing and simplifying equipment, supplies, and processes; and
- Establish interdisciplinary team training programs for providers that incorporate proven methods of team training, such as simulation.

8.2 Healthcare organizations should implement proven medication safety practices.

From ***Networking Health: Prescriptions for the Internet*** (2000)

RECOMMENDATIONS

1.1 The health community should ensure that technical capabilities suitable for health and biomedical applications are incorporated into the testbed network being deployed under the Next Generation Internet initiative and eventually into the Internet.

1.2 To ensure that the Internet evolves in ways supportive of health needs over the long term, the health community should work with the networking community to develop improved network technologies that are of particular importance to health applications of the Internet.

- More readily scalable techniques to guarantee bandwidth on demand.
- Stronger forms of authentication.
- Symmetric or dynamically reconfigurable broadband technologies for the last mile.
- Hardened quality-of-service guarantees.
- Disaster operations.

1.3 The National Library of Medicine should forge stronger links between the health and networking research communities to ensure that the needs of the health community are better addressed in network research, development, and deployment.

1.4 The National Institutes of Health and its component agencies should fund information technology research that will develop the complementary technologies that are needed if the health community is to take advantage of the improved networking technologies that can be expected in the future.

2.1 The Department of Health and Human Services should fund pilot projects and larger demonstration programs to develop and demonstrate interoperable, scalable Internet applications for linking multiple health organizations.

2.2 Federal agencies such as the Department of Veterans Affairs, the Department of Defense, the Health Care Financing Administration, the National Institutes of Health, and the Indian Health Service should serve as role models and testbeds for the health industry by deploying Internet-based applications for their own purposes.

2.3 Health organizations in industry and academia should continue to work with the Department of Health and Human Services to evaluate various health applications of the Internet in order to improve understanding of their effects, the business models that might support them, and impediments to their expansion.

2.4 Public and private health organizations should experiment with networks based on Internet protocols and should incorporate the Internet into their future plans for new networked applications and into their overall strategic planning.

3.1 Professional associations with expertise in health issues and information technology should work with health care organizations to develop and promulgate guidelines for safe, effective use of the Internet in clinical settings.

3.2 Government, industry, and academia should work together with professional associations with experience in health and information technology to educate the broader health care communities about the ways the Internet can benefit them.

3.3 The Department of Health and Human Services should commission a study of the health information technology workforce to determine whether the supply of such workers balances the demand for them, to identify the kinds of training and education that workers at different levels will need, and to develop recommendations for ensuring an adequate supply of people with training at the intersections of information technology and health.

4.1 The Department of Health and Human Services should more aggressively address the broad set of policy issues that influence the development, deployment, and adoption of Internet-based applications in the health sector.

From ***the National Committee on Vital and Health Statistics (NCVHS) Report to the Secretary on Uniform Standards for Patient Medical Record Information*** (2000)

RECOMMENDATIONS

This Report reflects the belief that significant quality and cost benefits can be achieved in healthcare if clinically specific data are captured once at the point of care and that all other legitimate data needs are derived from those data. The standards for patient medical record information that will result from the recommendations in this Report will be consistent and compatible with the HIPAA financial and administrative transaction standards, including the upcoming claims attachment standards.

In consideration of broad industry testimony on these key issues, the NCVHS recommends that the Secretary of HHS:

1. Adopt the Guiding Principles for Selecting PMRI Standards as the criteria to select uniform data standards for patient medical record information (PMRI). These Guiding Principles are based on those published in the notice of proposed rulemaking for selecting financial and administrative transaction standards, which have been modified by adding characteristics and attributes that specifically address interoperability, data comparability, and data quality.

2. Consider acceptance of forthcoming NCVHS recommendations for specific PMRI standards. The first set of these recommendations will be delivered to the secretary eighteen months following submission of this Report and will include suggested implementation timeframes that consider industry readiness for adoption. For each recommendation for PMRI standards, NCVHS encourages the Secretary to provide an open process to give the public an opportunity to comment on the PMRI standards proposals before final rules are adopted.

3. Provide immediate funding to accelerate the development and promote early adoption of PMRI standards. This should take the form of support for:

   a. government membership and participation in standards development organizations

   b. broader participation of expert representation in standards development

   c. enhancement, distribution, and maintenance of clinical terminologies that have the potential to be PMRI standards through:

      (1) government-wide licensure or comparable arrangements so these terminologies are available for use at little or no cost.

      (2) augmentation of the national Library of Medicine's Unified Medical Language System (UMLS) to embody enhanced mapping of medical vocabularies and classifications.

      (3) development and testing of quality measures and clinical practice guidelines, such as published in the Agency for Healthcare Research and Quality (AHRQ) clearinghouses, and patient safety measures for their compatibility with existing and developing healthcare terminologies.

      (4) development and testing in multi-agency projects, such as GCPR (Government Computer-based Patient Record) framework project.

   d. coordination of data elements among all standards selected for adoption under HIPAA through the development and maintenance of an open meta-data registry and working conferences to harmonize message format and vocabulary standards.

e. improvement of drug data capture and use by:

(1) requiring the Food and Drug Administration (FDA) to make publicly available its National Drug Codes (NDC) database registry information.

(2) requiring the FDA to develop a drug classification system based on active ingredients so that all drugs that fall into a given category can be identified by the name of that category.

(3) encouraging the FDA to participate in private sector development and ongoing maintenance of a reference terminology for drugs and biologics that promotes the ability to share clinically specific information.

f. early adoption of PMRI standards within government programs to provide broadened feedback to the standards development community.

4. For each standard recommended by NCVHS, commit funding for development of a uniform implementation guide, development of conformance testing procedures, and ongoing government licensure of, or comparable arrangements for, healthcare terminology standards.

5. Support demonstration of the benefits and measurement of the costs of using uniform data standards for PMRI that provide for interoperability, data comparability, and data quality.

6. Support increases in funding for research, demonstration, and evaluation studies on clinical data capture systems and other healthcare informatics issues.

7. Accelerate development and implementation of a national health information infrastructure. HHS should work in collaboration with other federal components, state governments, and the private sector on demonstration and evaluation projects and test beds.

8. Promote United States' interest in international health data standards development through HHS participation in international healthcare informatics standards development organizations and, in cooperation with the Secretary of the Department of Commerce, through monitoring the activity of U.S. healthcare information system vendors abroad.

9. Promote the equitable distribution of the costs for using PMRI standards among all major beneficiaries of PMRI. This may take the form of incentives for submission of data using the PMRI standards that can support [[text out]]

10. Encourage enabling legislation for use and exchange of electronic PMRI, including:

a. comprehensive federal privacy and confidentiality legislation. This would ensure that all health information in any medium, used for any purpose, and disclosed to any entity receives equal privacy protection under law.

b. uniform recognition by all states of electronic health record keeping; and national standards for PMRI retention and electronic authentication (digital signatures).

From ***Crossing the Quality Chasm: A New Health System for the 21st Century*** (2001)

RECOMMENDATIONS

1. All health care organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States.

2. All healthcare organizations, professional groups, and private and public purchasers should pursue six major aims; specifically, health care should be safe, effective, patient-centered, timely, efficient, and equitable.

3. Congress should continue to authorize and appropriate funds for, and the Department of Health and Human Services should move forward expeditiously with the establishment of monitoring and tracking processes for use in evaluating the progress of the health system in pursuit of the above-cited aims of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. The Secretary of the Department of Health and Human Services should report annually to Congress and the President on the quality of care provided to the American people.

4. Private and public purchasers, healthcare organizations, clinicians, and patients should work together to redesign healthcare processes in accordance with the following rules:

    - *Care based on continuous healing relationships*. Patients should receive care whenever they need it and in many forms, not just face-to-face visits. This rule implies that the health-care system should be responsive at all times (24 hours a day, every day) and that access to care should be provided over the Internet, by television, and by other means in addition to face-to-face visits.

    - *Customization based on patient needs and values*. The system of care should be designed to meet the most common types of needs, but have the capability to respond to individual patient choices and preferences.

    - *The patient as the source of control*. Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them. The health system should be able to accommodate differences in patient preferences and encourage shared decision-making.

    - *Shared knowledge and the free flow of information*. Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.

    - *Evidence-based decision making*. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.

    - *Safety as a system property*. Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.

    - *The need for transparency*. The health care system should make information available to patients and their families that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice, or choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.

    - *Anticipation of needs*. The health system should anticipate patient needs, rather than simply reacting to events.

    - *Continuous decrease in waste*. The health system should not waste resources or patient time.

    - *Cooperation among clinicians*. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

5. The Agency for Health Care Research and Quality should identify not fewer than 15 priority conditions, taking into account frequency of occurrence, health burden, and resource use.

In collaboration with the National Quality Forum, the agency should convene stakeholders, including purchasers, consumers, healthcare organizations, professional groups, and others, to develop strategies, goals, and action plans for achieving substantial improvements in quality in the next 5 years for each of the priority conditions.

6. Congress should establish a Healthcare Quality Innovation Fund to support projects targeted at (1) achieving the six aims of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity; and/or (2) producing substantial improvements in quality for the priority conditions. The fund's resources should be invested in projects that will produce a public-domain portfolio of programs, tools, and technologies of widespread applicability.

7. The Agency for Healthcare Research and Quality and private foundations should convene a series of workshops involving representatives from health care and other industries and the research community to identify, adapt, and implement state-of-the-art approaches to addressing the following challenges:

    - Redesign of care processes based on best practices.
    - Use of information technologies to improve access to clinical information and support clinical decision making.
    - Knowledge and skills management.
    - Development of effective terms.
    - Coordination of care across patient conditions, services, and settings over time.
    - Incorporation of performance and outcome measurements for improvement and accountability.

8. The Secretary of the Department of Health and Human Services should be given the responsibility and necessary resources to establish and maintain a comprehensive program aimed at making scientific evidence more useful and accessible to clinicians and patients. In developing this program, the Secretary should work with federal agencies and in collaboration with professional and health care associations, the academic and research communities, and the National Quality Forum and other organizations involved in quality measurement and accountability.

9. Congress, the executive branch, leaders of health care organizations, public and private purchasers, and health informatics associations and vendors should make a renewed national commitment to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical educations. This commitment should lead to the elimination of most handwritten clinical data by the end of the decade.

10. Private and public purchasers should examine their current payment methods to remove barriers that currently impede quality improvement, and to build in stronger incentives for quality enhancement.

11. The Healthcare Financing Administration and the Agency for Healthcare Research and Quality, with input from private payers, healthcare organizations, and clinicians, should develop a research agenda to identify, pilot test, and evaluate various options for better aligning current payment methods with quality improvement goals.

12. A multidisciplinary summit of leaders within the health professions should be held to discuss and develop strategies for (1) restructuring clinical education to be consistent with the principles of the 21st-century health system throughout the continuum of undergraduate, graduate, and continuing education for medical, nursing, and other professional training programs; and

(2) assessing the implications of these changes for provider credentialing programs, funding, and sponsorship of education programs for health professionals.

13. The Agency for Healthcare Research and Quality should fund research to evaluate how the current regulatory and legal systems (1) facilitate or inhibit the changes needed for the 21st-century health care delivery system, and (2) can be modified to support health care professionals and organizations that seek to accomplish the six aims set forth in Chapter 2.

From the ***Final Report National Health Information Infrastructure (NHII)—Information for Health: A Strategy for Building the National Health Information Infrastructure*** (2001)

RECOMMENDATIONS FOR THE NATIONAL HEALTH INFORMATION INFRASTRUCTURE (NHII)

Federal Government

1. The Secretary of Health and Human Services should create a senior position to provide strategic national leadership for the development of the NHII and set the agenda for NHII investments, policymaking, and integration with ongoing health and healthcare activities inside and outside of Government.

2. Other HHS agencies/offices with missions and activities in NHII-related areas should designate an office or individual to participate in NHII strategic planning and ensure coordination within the agency/office and with the central NHII office.

3. Congress should provide new or expanded funding for programs that support the personal health, healthcare provider, and population health dimensions individually and jointly, with special attention to areas for which the Federal Government has a leading or exclusive role and areas already mandated by HIPAA. Examples of funding include support for

    - Development of State and local population health information capacities.
    - Professional training programs for the Federal, State, and local public health work force, and for the private healthcare work force, in information technology skills.
    - Technology centers that bring together interdisciplinary teams to explore issues related to the NHII, with an emphasis on activities that link the three dimensions.
    - Healthcare providers for investments in interoperable linked systems that support health related information flows across plans and providers.
    - Federal information technology research and development activities to stimulate research in health and healthcare applications.
    - Pilot projects that integrate data from the healthcare provider and personal health dimensions into the population health dimension at the State and local levels.

    Congress should supplement HIPAA to address standards issues related to the NHII. A "Health Information Portability and Continuity Act" should provide for the portability of health information across information systems, plans, and providers to ensure continuity of care; promote the adoption of clinical data standards; and promote consumer/patient control of personal health information.

    Congress should pass national laws and identify regulatory responsibilities for overarching issues that apply to the NHII, such as the confidentiality of personal health information, the security of health information systems, reimbursement for clinically necessary and effective electronically delivered health services, and consumer protection for misuses and abuses of health information.

4. Federal health data agencies should collaborate with State and local government agencies and standards organizations to develop common data reporting formats and standardized methods of transmission of all pertinent health data. These activities should build upon CDC NEDSS, the Health Care Service (837) Data Reporting Guide and upon efforts to develop public health data conceptual models, extending these beyond communicable diseases. This effort also should be coordinated with the United States Health Information Knowledgebase or metadata registry operated by the ANSI Healthcare Informatics Standards Board.

Other Stakeholders

Although the Committee was told that the Federal Government should assume leadership, it also heard that the Federal Government cannot build the NHII alone. Its ability to lead and coordinate rests on the assumption that many other stakeholders in the public and private sectors will play key roles within their own areas and will work together.

State and Local Government

1. Each State should establish a mechanism to provide strategic leadership and coordination of activities related to the NHII. This mechanism, which may be a new office, preferably located in the Office of the Governor, Office of the State Health Officer, or other combined health and human services agency, should have broad oversight of the integration of NHII components into the public health and healthcare programs in their States. The functions of the leadership would be to solicit input from all relevant stakeholders, including consumers, about the development and uses of the NHII and to oversee personal health information privacy issues and activities.

2. State and local data agencies should collaborate with Federal agencies and standards organizations to develop common data reporting formats and standardized methods of transmission for all pertinent health data.

3. State and local health agencies should invest in the collection and analysis of population health data to permit real-time, small-area analysis of acute public health problems and to understand health issues related to new or rapidly growing populations and health disparities, and they should combine health data sources for population analysis.

Healthcare Providers

1. Each healthcare professional and provider membership and trade organization should establish a mechanism to provide strategic leadership on issues related to NHII development and implementation. The functions of the leadership would include representing the membership or trade organization in meetings convened by HHS and collaborative activities with other stakeholders, promoting internal review of organizational practices and systems for consistency with the NHII and developing timetables for needed revisions and enhancements, and overseeing personal health information privacy issues and activities.

2. Healthcare provider organizations. Each individual healthcare provider organization should establish a mechanism to provide strategic leadership and coordination on issues related to NHII development and implementation. The leadership would be responsible for overseeing personal health information privacy and security issues and activities and ensuring that stakeholders from the personal health and population health dimensions can provide appropriate input into plans and decisions. The leadership should identify representatives with diverse backgrounds to participate actively in the work of standards development organizations.

Healthcare Plans and Purchasers

1. Each healthcare plan and purchaser should establish a mechanism to provide strategic leadership and coordination on issues related to NHII development and implementation. These responsibilities could be assigned to the Chief Information Officers of their organizations. A designated

individual should represent the organization in meetings convened by HHS and collaborative activities with other stakeholders and oversee personal health information issues and activities.

2. Healthcare plans and purchasers should examine their practices and systems for consistency with the NHII and set timetables for needed revisions and enhancements. They should ensure that stakeholders from the personal health and population health dimensions provide appropriate input into NHII plans and decisions.

3. Healthcare plans and purchasers should identify representatives with diverse backgrounds to participate actively in the work of standards development organizations.

Standards Development Organizations

1. Standards development organizations should develop new or modified standards as requirements become known.

2. Standards development organizations should ensure participation by consumer representatives.

3. Standards development organizations should identify mechanisms to accelerate the standards development process and improve the coordination of standards development across standard setting bodies and consistent with the direction of the NHII.

4. Standards development organizations should promote cooperation with standards being developed internationally for population health, patient care, or data-security purposes.

Information Technology Industry

1. Information technology organizations and trade groups should designate internal representatives to provide strategic leadership and coordination on issues related to NHII development and implementation. Representatives should participate in meetings convened by HHS and collaborative activities with other stakeholders.

2. The information technology industry should develop and promote cost-effective healthcare software and technologies that comply with national standards so that they can support the appropriate sharing of electronic information for healthcare providers, consumers/patients, and public health agencies and the improved delivery of clinical and public health services.

Consumer and Patient Advocacy Groups

1. Consumer and patient advocacy groups should promote policies that encourage the use of electronic technologies in healthcare organizations and by healthcare providers to improve the quality of services, to decrease rates of adverse effects, and to increase access to on-line/wireless health information and services for consumers, patients, and clients. They should advocate for privacy protections for consumers, patients, and clients when they exchange health information electronically and for equal access to technology and information by all population groups.

2. Consumer and patient advocacy groups should participate in NHII-related committees organized by national and State agencies, and by health plan and provider organizations, and in standards development efforts.

3. Consumer and patient advocacy groups should collaborate with healthcare provider organizations, health plans and purchasers, and public health organizations to promote and facilitate the use of information technologies by healthcare providers, health plans, and public health entities.

Community Organizations

1. Community organizations should help identify community health data needs.

2. Community organizations should identify necessary partnerships to exchange health data. They also should identify and help reduce barriers to community level collection and exchange of health data.

3. Community organizations should develop local laypersons' capacities to collect and apply health data to individual and community health improvements.

4. Community organizations should develop programs that address the "digital divide" and promote equal access to technology and information by all population groups.

Academic and Research Organizations

1. Academic and research organizations should develop research proposals that integrate health information infrastructure and applications with other types of information infrastructure development (e.g., NGI and Internet2).

2. Academic and research organizations should develop collaborations with service providers, standards development organizations, and their communities to take innovations from research to implementation.

From ***Fostering Rapid Advances in Health Care: Learning from System Demonstrations*** (2002)

RECOMMENDATIONS

In response to a request from the Secretary of the Department of Health and Human Services, the Institute of Medicine convened a committee to identify possible demonstration projects that might be implemented in 2003, with the hope of yielding models for broader health system reform within a few years. The committee is recommending a substantial portfolio of demonstration projects: 10-12 chronic care demonstrations, a primary care demonstration with 40 participating sites, 8-10 information and communications technology infrastructure demonstrations, 3-5 state health insurance coverage demonstrations, and 4-5 state liability demonstrations. As a set the demonstrations address key aspects of the healthcare delivery system and the financing and legal environment in which healthcare is provided. The launching of a carefully crafted set of demonstrations is viewed as a way to initiate a "building block" approach to health system change.

These demonstrations should lead to a health care system in which patients' experiences would be very different from today's norm. For a typical patient with one or more chronic conditions requiring ongoing management, as well as preventive and acute care needs, the system should provide a continuous relationship with a personal clinician who functions with the support of a multidisciplinary team. Patients should be able to access care over the Internet, by telephone, and by other means in addition to face-to-face visits. There should be few concerns about safety, but in the event that a patient is harmed, the clinician should inform the patient immediately, apologize, and take action to mitigate the consequences. Care should not vary illogically from clinician to clinician or place to place. Each patient should receive the best that science has to offer, whether for ongoing treatment of a chronic condition or care for an acute episode. This does not imply one-size-fits-all care. Patients will have different preferences (e.g., watchful waiting versus surgical intervention for prostate cancer), differing needs for education and support, and differing constraints (e.g., a need for home care with family support versus short-term rehabilitative care).

For many people, chronic disease could have been avoided or delayed had educational and other supportive interventions been provided to assist them in modifying health behaviors. These demonstration projects would involve the following components:

- Coordinating structure—During the first year, the grant recipient would be responsible for establishing a broad-based coordinating structure with participation from all stakeholders.

- Chronic care management programs—Each demonstration site would establish chronic care

management programs that would provide evidence-based treatment of chronic diseases, services to detect and minimize the consequences of common geriatric syndromes, services to meet the preventive and acute care needs of the enrolled chronically ill population, and extended outreach and coordination with social and environmental services.

- Information and communications technology—A major component of these demonstrations should be the expanded use of Information and Communications Technology (ICT) to improve care for the chronically ill.
- Benefits, Co-payments, Provider Payments, and Accountability—Demonstration sites should be given the flexibility under Medicare and other insurance programs to innovate in such areas as benefits coverage, beneficiary co-payments, provider payments, and accountability.
- Learning collaboratives and community-wide educational efforts—Each demonstration site, with assistance from the National Library of Medicine and the Agency for Healthcare Research and Quality (AHRQ), should engage in efforts to assist clinicians and patients in gaining access to scientific knowledge, practice guidelines, certified protocols, identified best practices, and decision support tools.

The 21st-century healthcare system should deliver far greater value than is currently the case. Patients have a right to demand—and healthcare leaders have an obligation to act now to ensure that they receive—care that is safe, effective, patient-centered, timely, efficient, and equitable. The committee believes the proposed demonstration projects would represent a substantial step in that direction.

From ***The Future of the Public's Health in the 21st Century*** (2002)

RECOMMENDATIONS

1. The Secretary of the Department of Health and Human Services (DHHS), in consultation with states, should appoint a national commission to develop a framework and recommendations for state public health law reform. In particular, the national commission would review all existing public health law as well as the Turning Point Model State Public Health Act and the Model State Emergency Health Powers Act; provide guidance and technical assistance to help states reform their laws to meet modern scientific and legal standards; and help foster greater consistency within and among states, especially in their approach to different health threats.
2. All federal, state, and local governmental public health agencies should develop strategies to ensure that public health workers who are involved in the provision of essential public health services demonstrate mastery of the core public health competencies appropriate to their jobs. The Council on Linkages between Academia and Public Health Practice should also encourage the competency development of public health professionals working in public health system roles in for-profit and nongovernmental entities.
3. Congress should designate funds for the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) to periodically assess the preparedness of the public health workforce, to document the training necessary to meet basic competency expectations, and to advise on the funding necessary to provide such training.
4. Leadership training, support, and development should be a high priority for governmental public health agencies and other organizations in the public health system and for schools of public health that supply the public health infrastructure with its professionals and leaders.

5. A formal national dialogue should be initiated to address the issue of public health workforce credentialing. The Secretary of DHHS should appoint a national commission on public health workforce credentialing to lead this dialogue. The commission should be charged to determine if a credentialing system would further the goal of creating a competent workforce and, if applicable, the manner and time frame for implementation by governmental public health agencies at all levels. The dialogue should include representatives from federal, state, and local public health agencies, academia, and public health professional organizations who can represent and discuss the various perspectives on the workforce credentialing debate.

6. All partners within the public health system should place special emphasis on communication as a critical core competency of public health practice. Governmental public health agencies at all levels should use existing and emerging tools (including information technologies) for effective management of public health information and for internal and external communication. To be effective, such communication must be culturally appropriate and suitable to the literacy levels of the individuals in the communities they serve.

7. The Secretary of DHHS should provide leadership to facilitate the development and implementation of the National Health Information Infrastructure (NHII). Implementation of NHII should take into account, where possible, the findings and recommendations of the National Committee on Vital and Health Statistics (NCVHS) working group on NHII. Congress should consider options for funding the development and deployment of NHII (e.g., in support of clinical care, health information for the public, and public health practice and research) through payment changes, tax credits, subsidized loans, or grants.

8. DHHS should be accountable for assessing the state of the nation's governmental public health infrastructure and its capacity to provide the essential public health services to every community and for reporting that assessment annually to Congress and the nation. The assessment should include a thorough evaluation of federal, state, and local funding for the nation's governmental public health infrastructure and should be conducted in collaboration with state and local officials. The assessment should identify strengths and gaps and serve as the basis for plans to develop a funding and technical assistance plan to assure sustainability. The public availability of these reports will enable state and local public health agencies to use them for continual self-assessment and evaluation.

9. DHHS should evaluate the status of the nation's public health laboratory system, including an assessment of the impact of recent increased funding. The evaluation should identify remaining gaps, and funding should be allocated to close them. Working with the states, DHHS should agree on a base funding level that will maintain the enhanced laboratory system and allow the rapid deployment of newly developed technologies.

10. DHHS should develop a comprehensive investment plan for a strong national governmental public health infrastructure with a timetable, clear performance measures, and regular progress reports to the public. State and local governments should also provide adequate, consistent, and sustainable funding for the governmental public health infrastructure.

11. The federal government and states should renew efforts to experiment with clustering or consolidation of categorical grants for the purpose of increasing local flexibility to address priority health concerns and enhance the efficient use of limited resources.

12. The Secretary of DHHS should appoint a national commission to consider if an accreditation system would be useful for improving and building state and local public health agency capacities. If such a system is deemed useful, the commission should make recommendations on how it would be governed and develop mechanisms (e.g., incentives) to gain state and local government participation in the accreditation effort. Membership on this commission should include representatives from CDC, the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, and nongovernmental organizations.

13. CDC, in collaboration with the Council on Linkages between Academia and Public Health Practice and other public health system partners, should develop a research agenda and estimate the funding needed to build the evidence base that will guide policy making for public health practice.

14. The Secretary of DHHS should review the regulatory authorities of DHHS agencies with health-related responsibilities to reduce overlap and inconsistencies, ensure that the department's management structure is best suited to coordinate among agencies within DHHS with health-related responsibilities, and, to the extent possible, simplify relationships with state and local governmental public health agencies. Similar efforts should be made to improve coordination with other federal cabinet agencies performing important public health services, such as the Department of Agriculture and the Environmental Protection Agency.

15. Congress should mandate the establishment of a National Public Health Council. This National Public Health Council would bring together the Secretary of DHHS and state health commissioners at least annually to

    1. Provide a forum for communication and collaboration on action to achieve national health goals as articulated in *Healthy People 2010*;

    2. Advise the Secretary of DHHS on public health issues;

    3. Advise the Secretary of DHHS on financing and regulations that affect governmental public health capacity at the state and local levels;

    4. Provide a forum for overseeing the development of an incentive-based federal–state-funded system to sustain a governmental public health infrastructure that can assure the availability of essential public health services to every American community and can monitor progress toward this goal (e.g., through report cards);

    5. Review and evaluate the domestic policies of other cabinet agencies for their impact on national health outcomes (e.g., through health impact reports) and on the reduction and elimination of health disparities; and

    6. Submit an annual report on their deliberations and recommendations to Congress.

The Council should be chaired by the Secretary of DHHS and co-chaired by a state health director on a rotating basis. An appropriately resourced secretariat should be established in the Office of the Secretary to ensure that the Council has access to the information and expertise of all DHHS agencies during its deliberations.

Community

16. Local governmental public health agencies should support community-led efforts to inventory resources, assess needs, formulate collaborative responses, and evaluate outcomes for community health improvement and the elimination of health disparities. Governmental public health agencies should provide community organizations and coalitions with technical assistance and support in identifying and securing resources as needed and at all phases of the process.

17. Governmental and private-sector funders of community health initiatives should plan their investments with a focus on long-lasting change. Such a focus would include realistic time lines, an emphasis on ongoing community engagement and leadership, and a final goal of institutionalizing effective project components in the local community or public health system as appropriate.

Health Care Delivery System

18. Adequate population health cannot be achieved without making comprehensive and affordable health care available to every person residing in the United States. It is the responsibility of the federal government to lead a national effort to examine the options available to achieve stable health care coverage of individuals and families and to assure the implementation of plans to achieve that result.

19. All public and privately funded insurance plans should include age-appropriate preventive services as recommended by the U.S. Preventive Services Task Force and provide evidence-based coverage of oral health, mental health, and substance abuse treatment services.

20. Bold, large-scale demonstrations should be funded by the federal government and other major investors in health care to test radical new approaches to increase the efficiency and effectiveness of health care financing and delivery systems. The experiments should effectively link delivery systems with other components of the public health system and focus on improving population health while eliminating disparities. The demonstrations should be supported by adequate resources to enable innovative ideas to be fairly tested.

Businesses and Employers

21. The federal government should develop programs to assist small employers and employers with low-wage workers to purchase health insurance at reasonable rates.

22. The corporate community and public health agencies should initiate and enhance joint efforts to strengthen health promotion and disease and injury prevention programs for employees and their communities. As an early step, the corporate and governmental public health community should:

    a. Strengthen partnership and collaboration by:

        - developing direct linkages between local public health agencies and business leaders to forge a common language and understanding of employee and community health problems and to participate in setting community health goals and strategies for achieving them; and

        - developing innovative ways for the corporate and governmental public health communities to gather, interpret, and exchange mutually meaningful data and information, such as the translation of health information to support corporate health promotion and health care purchasing activities.

    b. Enhance communication by

        - developing effective employer and community communication and education programs focused on the benefits of and options for health promotion and disease and injury prevention; and

        - using proven marketing and social marketing techniques to promote individual behavioral and community change.

    c. Develop the evidence base for workplace and community interventions through greater public, private, and philanthropic investments in research to extend the science and improve the effectiveness of workplace and community interventions to promote health and prevent disease and injury.

    d. Recognize business leadership in employee and community health by elevating the level of recognition given to corporate investment in employee and community health. The Secretaries of DHHS and the Department of Commerce, along with business leaders (e.g., chambers of commerce and business roundtables), should jointly sponsor a Corporate Investment in Health Award. The award would recognize private-sector entities that have demonstrated exemplary civic and social responsibility for improving the health of their workers and the community.

Media

23. An ongoing dialogue should be maintained between medical and public health officials and editors and journalists at the local level and their representative associations nationally. Furthermore, foundations and governmental health agencies should provide opportunities to develop and evaluate educational and training programs that provide journalists with experiences that will

deepen their knowledge of public health subject matter and provide public health workers with a foundation in communication theory, messaging, and application.

24. The television networks, television stations, and cable providers should increase the amount of time they donate to public service announcements (PSAs) as partial fulfillment of the public service requirement in their Federal Communications Commission (FCC) licensing agreements.

25. The FCC should review its regulations for PSA broadcasting on television and radio to ensure a more balanced broadcasting schedule that will reach a greater proportion of the viewing and listening audiences.

26. Public health officials and local and national entertainment media should work together to facilitate the communication of accurate information about disease and about medical and health issues in the entertainment media.

27. Public health and communication researchers should develop an evidence base on media influences on health knowledge and behavior, as well as on the promotion of healthy public policy.

Academia

28. Academic institutions should increase integrated interdisciplinary learning opportunities for students in public health and other related health science professions. Such efforts should include not only multidisciplinary education but also interdisciplinary education and appropriate incentives for faculty to undertake such activities.

29. Congress should increase funding for Health Resources and Services Administration (HRSA) programs that provide financial support for students enrolled in public health degree programs through mechanisms such as training grants, loan repayments, and service obligation grants. Funding should also be provided to strengthen the Public Health Training Center program to effectively meet the educational needs of the existing public health workforce and to facilitate public health worker access to the centers. Support for leadership training of state and local health department directors and local community leaders should continue through funding of the National and Regional Public Health Leadership Institutes and distance-learning materials developed by HRSA and the Centers for Disease Control and Prevention (CDC).

30. Federal funders of research and academic institutions should recognize and reward faculty scholarship related to public health practice research.

31. The committee recommends that Congress provide funds for CDC to enhance its investigator-initiated program for prevention research while maintaining a strong Centers, Institutes, and Offices (CIO)-generated research program. CDC should take steps that include:

    - expanding the external peer review mechanism for review of investigator-initiated research;
    - allowing research to be conducted over the more generous time lines often required by prevention research; and
    - establishing a central mechanism for coordination of investigator-initiated proposal submissions.

32. CDC should authorize an analysis of the funding levels necessary for effective Prevention Research Center functioning, taking into account the levels authorized by P.L. 98–551 as well as the amount of prevention research occurring in other institutions and organizations.

33. NIH should increase the portion of its budget allocated to population- and community-based prevention research that:

- addresses population-level health problems;
- involves a definable population and operates at the level of the whole person;
- evaluates the application and impacts of new discoveries on the actual health of the population; and
- focuses on the behavioral and environmental (social, economic, cultural, physical) factors associated with primary and secondary prevention of disease and disability in populations.
- furthermore, the committee recommends that the Director of NIH report annually to the Secretary of DHHS on the scope of population- and community-based prevention research activities undertaken by the NIH centers and institutes.

34. Academic institutions should develop criteria for recognizing and rewarding faculty scholarship related to service activities that strengthen public health practice.

From ***Information Technology for Counterterrorism: Immediate Actions and Future Possibilities*** (2003)

Short-Term Recommendation 1: The nation should develop a program that focuses on the communications and computing needs of emergency responders. Such a program would have two essential components:

- Ensuring that authoritative, current-knowledge expertise and support regarding IT are available to emergency-response agencies prior to and during emergencies, including terrorist attacks.
- Upgrading the capabilities of the command, control, communications, and intelligence (C3I) systems of emergency-response agencies through the use of existing technologies. Such upgrades might include transitioning from analog to digital systems and deploying a separate emergency-response communications network in the aftermath of a disaster.

Short-Term Recommendation 2: The nation should promote the use of best practices in information and network security in all relevant public agencies and private organizations.

- *For IT users on the operational level*: Ensure that adequate information-security tools are available. Conduct frequent, unannounced red-team penetration testing of deployed systems. Promptly fix problems and vulnerabilities that are known. Mandate the use of strong authentication mechanisms. Use defense-in-depth in addition to perimeter defense.
- *For IT vendors*: Develop tools to monitor systems automatically for consistency with defined secure configurations. Provide well-engineered schemes for user authentication based on hardware tokens. Conduct more rigorous testing of software and systems for security flaws.
- *For the federal government*: Position critical federal information systems as models for good security practices. Remedy the failure of the market to account adequately for information security so that appropriate market pro-security mechanisms develop.

From ***Patient Safety: Achieving a New Standard for Care*** (2004)

RECOMMENDATIONS

Recommendation 1. Americans expect and deserve safe care. Improved information and data systems are needed to support efforts to make patient safety a standard of care in hospitals, in doctors' offices, in nursing homes, and in every other health care setting. All health care organizations should establish comprehensive patient safety systems that:

- Provide immediate access to complete patient information and decision support tools (e.g., alerts, reminders) for clinicians and their patients.
- Capture information on patient safety—including both adverse events and near misses—as a by-product of care, and use this information to design even safer care delivery systems.

Recommendation 2. A national health information infrastructure—a foundation of systems, technology, applications, standards, and policies—is required to make patient safety a standard of care.

- The federal government should facilitate deployment of the national health information infrastructure through the provision of targeted financial support and the ongoing promulgation and maintenance of standards for data that support patient safety.
- Health care providers should invest in electronic health record systems that possess the key capabilities necessary to provide safe and effective care and to enable the continuous redesign of care processes to improve patient safety.

Recommendation 3. Congress should provide clear direction, enabling authority, and financial support for the establishment of national standards for data that support patient safety. Various government agencies will need to assume major new responsibilities, and additional support will be required. Specifically:

- The Department of Health and Human Services (DHHS) should be given the lead role in establishing and maintaining a public–private partnership for the promulgation of standards for data that support patient safety.
- The Consolidated Health Informatics (CHI) initiative, in collaboration with the National Committee on Vital and Health Statistics (NCVHS), should identify data standards appropriate for national adoption and gaps in existing standards that need to be addressed. The membership of NCVHS should continue to be broad and diverse, with adequate representation of all stakeholders, including consumers, state governments, professional groups, and standards-setting bodies.
- The Agency for Healthcare Research and Quality (AHRQ) in collaboration with the National Library of Medicine and others should

  (1) provide administrative and technical support for the CHI and NCVHS efforts; (2) ensure the development of implementation guides, certification procedures, and conformance testing for all data standards; (3) provide financial support and oversight for developmental activities to fill gaps in data standards; and (4) coordinate activities and maintain a clearinghouse of information in support of national data standards and their implementation to improve patient safety.
- The National Library of Medicine should be designated as the responsible entity for distributing all national clinical terminologies that relate to patient safety and for ensuring the quality of terminology mappings.

Recommendation 4. The lack of comprehensive standards for data to support patient safety impedes private-sector investment in information technology and other efforts to improve patient safety. The federal government should accelerate the adoption of standards for such data by pursuing the following efforts:

- *Clinical data interchange standards.* The federal government should set an aggressive agenda for the establishment of standards for the interchange of clinical data to support patient safety. Federal financial support should be provided to accomplish this agenda.
    - After ample time for provider compliance, federal government health care programs should incorporate into their contractual and regulatory requirements standards already approved by the secretaries of DHHS, the Veterans Administration, and the Department of Defense (i.e., the HL7 version 2.x series for clinical data messaging, DICOM for medical imaging, IEEE 1073 for medical devices, LOINC for laboratory test results, and NCPDP Script for prescription data).
    - AHRQ should provide support for (1) accelerated completion (within 2 years) of HL7 version 3.0; (2) specifications for the HL7 Clinical Document Architecture and implementation guides; and (3) analysis of alternative methods for addressing the need to support patient safety by instituting a unique health identifier for individuals, such as implementation of a voluntary unique health identifier program.
- *Clinical terminologies.* The federal government should move expeditiously to identify a core set of well-integrated, nonredundant clinical terminologies for clinical care, quality improvement, and patient safety reporting. Revisions, extensions, and additions to the codes should be compatible with, yet go beyond, the federal government's initiative to integrate all federal reporting systems.
    - AHRQ should undertake a study of the core terminologies, supplemental terminologies, and standards mandated by the Health Insurance Portability and Accountability Act to identify areas of overlap and gaps in the terminologies to address patient safety requirements. The study should begin by convening domain experts to develop a process for ensuring comprehensive coverage of the terminologies for the 20 IOM priority areas.
    - The National Library of Medicine should provide support for the accelerated completion of RxNORM for clinical drugs. The National Library of Medicine also should develop high-quality mappings among the core terminologies and supplemental terminologies identified by the CHI and NCVHS.
- *Knowledge representation.* The federal government should provide support for the accelerated development of knowledge representation standards to facilitate effective use of decision support in clinical information systems.
    - The National Library of Medicine should provide support for the development of standards for evidence-based knowledge representation.
    - AHRQ, in collaboration with the National Institutes of Health, the Food and Drug Administration, and other agencies, should provide support for the development of a generic guideline representation model for use in representing clinical guidelines in a computer-executable format that can be employed in decision support tools.

Recommendation 5. All healthcare settings should establish comprehensive patient safety programs operated by trained personnel within a culture of safety. These programs should encompass (1) case finding—identifying system failures, (2) analysis—understanding the factors that contribute to system failures, and (3) system redesign—making improvements in care processes to prevent errors in the future. Patient safety programs should invite the participation of patients and their families and be responsive to their inquiries.

Recommendation 6. The federal government should pursue a robust applied research agenda on patient safety, focused on enhancing knowledge, developing tools, and disseminating results to maximize the impact of patient safety systems. AHRQ should play a lead role in coordinating this research agenda among federal agencies (e.g., the National Library of Medicine) and the private sector. The research agenda should include the following:

- Knowledge generation
    - High-risk patients—Identify patients at risk for medication errors, nosocomial infections, falls, and other high-risk events.
    - Near-miss incidents—Test the causal continuum assumption (that near misses and adverse events are causally related), develop and test a recovery taxonomy, and extend the current individual human error/recovery models to team-based errors and recoveries.
    - Hazard analysis—Assess the validity and efficiency of integrating retrospective techniques (e.g., incident analysis) with prospective techniques.
    - High-yield activities—Study the cost/benefit of various approaches to patient safety, including analysis of reporting systems for near misses and adverse events.
    - Patient roles—Study the role of patients in the prevention, early detection, and mitigation of harm due to errors.
- Tool development
    - Early detection capabilities—Develop and evaluate various methods for employing data-driven triggers to detect adverse drug events, nosocomial infections, and other high-risk events (e.g., patient falls, decubitus ulcers, complications of blood product transfusions).
    - Prevention capabilities—Develop and evaluate point-of-care decision support to prevent errors of omission or commission.
    - Data mining techniques—Identify and develop data mining techniques to enhance learning from regional and national patient safety databases. Apply natural language processing techniques to facilitate the extraction of patient safety–related concepts from text documents and incident reports.
- Dissemination—Deploy knowledge and tools to clinicians and patients.

Recommendation 7. AHRQ should develop an event taxonomy and common report format for submission of data to the national patient safety database. Specifically:

- The event taxonomy should address near misses and adverse events, cover errors of both omission and commission, allow for the designation of primary and secondary event types for cases in which more than one factor precipitated the adverse event, and be incorporated into SNOMED CT.
- The standardized report format should include the following:
    - A standardized minimum set of data elements.
    - Data necessary to calculate a risk assessment index for determining prospectively the probability of an event and its severity.
    - A free-text narrative of the event.
    - Data necessary to support use of the Eindhoven Classification Model—Medical Version for classifying root causes, including expansions for (1) recovery factors associated with near-miss events, (2) corrective actions taken to recover from adverse events, and (3) patient outcome/functional status as a result of those corrective actions.

- A free-text section for lessons learned as a result of the event.
- Clinical documentation of the patient context.

- The taxonomy and report format should be used by the federal reporting system integration project in the areas for basic domain, event type, risk assessment, and causal analysis but should provide for more extensive support for patient safety research and analysis (Department of Health and Human Services, 2002c).

From ***Letter to HHS Secretary Tommy G. Thompson from John R. Lumpkin, Chairman, National Committee on Vital and Health Statistics: First Set of Recommendations on E-Prescribing Standards*** (2004)

RECOMMENDED ACTIONS:

Recommended Action 1.1: HHS should ensure that e-prescribing standards are not only appropriate for Medicare Part D but also for all types of prescribers, dispensers, and public and private sector payers.

Recommended Action 1.2: HHS should ensure that e-prescribing standards are compatible with those adopted as HIPAA and CHI standards, and with those recommended in November 2003 by NCVHS for clinical data terminologies.

Recommended Action 2.1: HHS should work with the industry in its rulemaking process to determine how best to afford flexibility in keeping standards in pace with the industry, including standards for HIPAA and e-prescribing. For example, HHS might consider recognizing new versions of standards, without a separate regulation, if they are backward compatible.

Recommended Action 3.1: HHS should recognize as a foundation standard the most current version of NCDPDP SCRIPT for new prescriptions, prescription renewals, cancellations, and changes between prescribers and dispensers. The National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard would include its present code sets and various mailbox and acknowledgement functions, as applicable.

Recommended Action 3.2: HHS should include the fill status notification function of the NCPDP SCRIPT Standard in the 2006 pilot tests. These pilot tests should assess the business value and clinical utility of the fill status notification function, as well as evaluate privacy issues and possible mitigation strategies.

Recommended Action 4.1: HHS should financially support the acceleration of coordination activities between Health Level 7 (HL7) and NCPDP for electronic medication ordering and prescribing. HHS should also support ongoing maintenance of the HL7 and NCPDP SCRIPT coordination.

Recommended Action 4.2: HHS should recognize the exchange of new prescriptions, renewals, cancellations, changes, and fill status notification within the same enterprise [[delete bracketed number?]][10] as outside the scope of MMA e-prescribing standard specifications.

Recommended Action 4.3: HHS should require that any prescriber that uses an HL7 message within an enterprise convert it to NCPDP SCRIPT if the message is being transmitted to a dispenser outside of the enterprise. HHS also should require that any retail pharmacy within an enterprise be able to receive prescription transmittals via NCPDP SCRIPT from outside the enterprise.

Recommended Action 5.1: HHS should actively participate in and support the rapid development of an NCPDP standard for formulary and benefit information file transfer, using the RxHub protocol as a basis.

Recommended Action 5.2: NCVHS will closely monitor the progress of NCPDP's developing a standard for a formulary and benefit information file transfer protocol, and provide advice to the Secretary in time for adoption as a foundation standard and/or readiness for the 2006 pilot tests.

Recommended Action 6.1: HHS should recognize the ASC X12N 270/271 Health Care Eligibility Inquiry and Response Standard Version 004010X092A1 as a foundation standard for conducting eligibility inquiries from prescribers to payers/PBMs.

Recommended Action 6.2: HHS should support NCPDP's efforts to create a guidance document to map the pharmacy information on the Medicare Part D Pharmacy ID Card to the appropriate fields on the ASC X12N 270/271 in further support of its use in e-prescribing.

Recommended Action 6.3: HHS should work with ASC X12 to determine if there are any requirements under MMA with respect to how situational data elements are used in the ASC X12N 270/271, especially concerning the quality of information needed for real-time drug benefits. Use of these situational data elements could be addressed in trading partner agreements. Specifications of use of situational data elements, as well as proper usage of the functional acknowledgments, should be included in the 2006 pilot tests.

Recommended Action 6.4: HHS should ensure that the functionality of the ASC X12N 270/271, as adopted under HIPAA, keeps pace with requirements for e-prescribing and that new versions to the Standard be pilot tested.

Recommended Action 7.1: HHS should support ASC X12 in their efforts to incorporate functionality for real-time prior authorization messages for drugs in the ASC X12N 278 Health Care Services Review Standard Version 004010X094A1for use between the prescriber and payer/PBM.

Recommended Action 7.2: HHS should support standards development organizations and other industry participants in developing prior authorization work flow scenarios to contribute to the design of the 2006 pilot tests.

Recommended Action 7.3: HHS should evaluate the economic and quality of care impacts of automating prior authorization communications between dispensers and prescribers and between payers and prescribers in its 2006 pilot tests.

Recommended Action 7.4: HHS should ensure that the functionality of the ASC X12N 278, as adopted under HIPAA, keeps pace with requirements for e-prescribing and that new versions to the Standard be pilot tested.

Recommended Action 8.1: HHS should actively participate in and support rapid development of an NCPDP standard for a medication history message for communication from a payer/PBM to a prescriber, using the RxHub protocol as a basis.

Recommended Action 8.2: NCVHS will closely monitor the progress of NCPDP's developing a standard medication history message for communication from a payer/PBM to a prescriber, and provide advice to the Secretary in time for adoption as a foundation standard and/or readiness for the 2006 pilot tests.

Recommended Action 9.1: HHS should include in the 2006 pilot tests the RxNorm terminology in the NCPDP SCRIPT Standard for new prescriptions, renewals, and changes. RxNorm is being included in the 2006 pilot tests to determine how well the RxNorm clinical drug, strength, and dosage information can be translated from the prescriber's system into an NDC at the dispenser's system that represents the prescriber's intent. This translation will require the participation of intermediary drug knowledge base vendors until the RxNorm is fully mapped.

Recommended Action 9.2: HHS should accelerate the promulgation of the Food & Drug Administration's (FDA) Drug Listing rule and hence the ability to support the correlation of National Drug Code (NDC) with RxNorm (e.g., for passing daily updates of the SPL to NLM for inclusion in the DailyMed). Timely rulemaking is critical to sustain the daily use of RxNorm beyond the 2006 pilot tests.

Recommended Action 9.3: HHS should ensure that, if the Medicare Part D Model Guidelines and NDF-RT differ, an accurate mapping exists so they both can be used successfully.

Recommended Action 10.1: HHS should support NCPDP, HL7, and others (especially including the prescriber community) in addressing SIG components in their standards. This should include preserving the ability to incorporate free text whenever necessary (e.g., for complex dosing instructions, and to address special cultural sensitivities, language, and literacy requirements).

Recommended Action 10.2: HHS should include in the 2006 pilot tests the structured and codified SIGs as developed through standards development organization efforts.

Recommended Action 11.1: HHS should ensure that the NPI, when it becomes available, is incorporated as the primary identifier for dispensers in the NCPDP SCRIPT and other e-prescribing standards.

Recommended Action 11.2: HHS should accelerate the enumeration of all dispensers to support transition to the NPI for e-prescribing.

Recommended Action 11.3: HHS should permit the industry to use the NCPDP Provider Identifier Number in the event that the NPS cannot enumerate dispensers in time for Medicare Part D implementation.

Recommended Action 11.4: HHS should evaluate how mass enumeration of dispensers for the NPI can occur using the NCPDP Provider Identifier Number database.

Recommended Action 11.5: HHS, when requiring the NPI as the primary identifier for dispensers, should protect the ability to maintain linkages to the NCPDP Provider Identifier Number database for current claims processing purposes.

Recommended Action 12.1: HHS should ensure that the NPI, when it becomes available, is incorporated as the primary identifier for prescribers in the NCPDP SCRIPT and other e-prescribing standards. It should be noted that the NPI must be at the individual prescriber level, because a prescription cannot be written at a group level.

Recommended Action 12.2: HHS should accelerate the enumeration of all prescribers to support transition to the NPI for e-prescribing.

Recommended Action 12.3: HHS should permit the industry to use the NCPDP HCIdea in the event that the NPS cannot enumerate prescribers in time for Medicare Part D implementation.

Recommended Action 12.4: HHS should work with the industry to identify issues and possible solutions that deal with all elements of the prescriber location and include those solutions in the 2006 pilot tests.

Recommended Action 12.5: HHS should evaluate how mass enumeration of prescribers for the NPI can occur using the NCPDP HCIdea database.

Recommended Action 12.6: HHS, when requiring the NPI as the primary identifier for prescribers, should protect the ability to maintain linkages to the NCPDP HCIdea database for e-prescribing routing functions.

Recommended Action 13:1: HHS should support the efforts of standards development organizations to incorporate in the foundation standards as many as possible of the additional functions required for MMA, as identified in these recommendations.

Recommended Action 13.2: HHS should include foundation standards with as many as possible of the additional functions required for MMA in the 2006 pilot tests.

Recommended Action 13.3: HHS should immediately begin to work with the vendors to ensure readiness for the pilot tests on January 1, 2006.

Recommended Action 13.4: HHS should identify and widely publicize specific goals, objectives, timelines, and metrics to guide the design and assessment and increase industry awareness of the 2006 pilot tests. HHS should include metrics that address economic, quality of care, patient safety, and patient and prescriber satisfaction factors.

Recommended Action 13.5: After the pilot tests, HHS should develop and widely disseminate information concerning any economic and quality of care benefits of e-prescribing, provide comprehensive education on implementation strategies, describe how e-prescribing can be implemented consistent with the privacy protections under HIPAA, and address other elements that contribute to successful and widespread prescriber adoption and patient acceptance.

Recommended Action 14.1: HHS should financially support standards coordination activities to ensure a seamless e-prescribing process across provider domains (e.g., physician office, hospital, long term care), dispensers, and payers/PBMs.

Recommended Action 14.2: HHS should encourage standards development organizations to adopt a change management process that permits versions to maintain interoperability.

Recommended Action 15.1: HHS should ensure that regulations define the parameters of safe harbor, ensure preservation of provider/patient choice, and require that e-prescribing messages received through e-prescribing applications be free from commercial bias.

Recommended Action 16.1: HHS should support standards development organizations in their development of conformance tests for the e-prescribing standards and their implementation guides.

Recommended Action 16.2: HHS should require that e-prescribing system vendors validate the conformance of their e-prescribing messages.

Recommended Action 16.3: The HHS Office of the National Coordinator for Health Information Technology should investigate how e-prescribing applications might best be certified.

From: ***Letter to HHS Secretary Mike Leavitt from Simon P. Cohn, Chairman, National Committee on Vital and Health Statistics: Second Set of Recommendations on E-Prescribing Standards*** (2005)

Recommended Action 1.1: HHS, Drug Enforcement Administration (DEA), and state boards of pharmacy should recognize the current e-prescribing network practices that are in compliance with HIPAA security and authentication requirements as a basis for securing electronic prescriptions. These security practices are discussed in the background and illustrated in Appendix A. In addition, these practices are applied in conjunction with the dispensers' responsibility to use their professional judgment in determining the validity of prescriptions. Different requirements may be needed for transmission of electronic prescriptions that do not go through such networks.

Recommended Action 1.2: HHS and Department of Justice (DOJ) should work together to reconcile different agency mission requirements in a manner that will address DEA needs for adequate security of prescriptions for all controlled substances, without seriously impairing the growth of e-prescribing in support of patient safety as mandated by MMA.

Recommended Action 2.1: HHS should evaluate emerging technologies such as biometrics, digital signature, and PKI for higher assurance authentication, message integrity, and non-repudiation in a research agenda for e-prescribing and all other aspects of health information technology.

Recommendations Relative to Progress on NCVHS Recommendations from the September 2, 2004 Letter:

Recommended Action 3.1: NCVHS will continue to monitor the progress of the development of the NCPDP Formulary and Benefit Coverage Message Standard and will report any further recommendations to HHS based upon this progress.

Recommended Action 4.1: NCVHS will continue to monitor the progress of the development of the NCPDP Medication History Message Standards and will report any further recommendations to HHS based upon this progress.

Recommended Action 5.1: HHS should include the fill status notification function of the NCPDP SCRIPT Standard in the 2006 pilot tests, consistent with NCVHS recommendations of September 2, 2004.

Recommended Action 6.1: HHS should include evaluation of structured and codified SIGs in the 2006 pilot tests, consistent with NCVHS recommendations of September 2, 2004.

Recommended Action 7.1: HHS should include evaluation of RxNorm in the e-prescribing pilots. The pilots should evaluate the use of RxNorm codes as the primary identifiers of orderable drugs in prescription messages. This would assess how well the RxNorm codes capture the intent of the prescriber and whether a dispenser can accurately fill the prescription based on the Rxnorm code. RxNorm should also be evaluated for use where a proprietary code is used for the orderable drug and the RxNorm code is included in the message to provide interoperability with other proprietary coding systems from drug knowledge bases.

Recommended Action 7.2: HHS should take immediate steps to accelerate the promulgation and implementation of FDA's Drug Listing Rule in order to make the inclusion of RxNorm in the 2006 pilot tests as comprehensive as possible. Delayed promulgation may jeopardize the success of the 2006 pilot tests. This is also necessary to achieve the patient safety objectives of MMA.

Recommended Action 8.1: HHS should support the standards development organizations (NCPDP, HL7, and ASC X12) in their efforts to incorporate functionality for real-time prior authorization messages for medications in the ASC X12N 278 Health Care Services Review Standard and ASC X12N 275 Claims Attachment Standard.

Recommended Action 8.2: HHS should include the evaluation of the interaction of standards related to the flow of prior authorization in the 2006 e-prescribing pilot tests.

Recommended Action 9.1: HHS should recognize the exchange of prescription messages within the same enterprise as outside the scope of MMA e-prescribing standard specifications.

Recommended Action 9.2: HHS should require that any prescriber that uses an HL7 message within an enterprise convert it to NCPDP SCRIPT if the message is being transmitted to a dispenser outside of the enterprise. HHS also should require that any retail pharmacy within an enterprise be able to receive prescription transmittals via NCPDP SCRIPT from outside the enterprise.

Recommended Action 9.3: HHS should financially support the acceleration of coordination activities between HL7 and NCPDP for electronic medication ordering and prescribing. HHS should also support ongoing maintenance of the HL7 and NCPDP SCRIPT coordination.

Recommended Action 10.1: HHS should identify and evaluate any privacy issues (within the context of the HIPAA Privacy Rule and health records laws) that arise during the 2006 pilot tests of e-prescribing. Special attention should be placed on issues regarding individuals' rights to request restrictions on access to their prescription records.

Recommended Action 10.2: HHS should use experience gained from the e-prescribing pilot tests to develop appropriate actions for handling privacy issues.

From ***Quality Through Collaboration: The Future of Rural Health*** (2005)

RECOMMENDATIONS

1. Congress should provide appropriate direction and financial resources to assist rural providers in converting to electronic health records over the next 5 years. Working collaboratively with the Office of the National Coordinator for Health Information Technology:
    - The Indian Health Service should develop a strategy for transitioning all of its provider sites (including those operated by tribal governments under the Self-Determination Act) from paper to electronic health records.
    - The Health Resources and Services Administration should develop a strategy for transitioning community health centers, rural health clinics, critical access hospitals, and other rural providers from paper to electronic health records.
    - The Centers for Medicare and Medicaid Services and the state governments should consider providing financial rewards to providers participating in Medicare or Medicaid programs that invest in electronic health records. These two large public insurance programs should work together to re-examine their benefit and payment programs to ensure appropriate coverage of telehealth and other health services delivered electronically.
2. The Agency for Healthcare Research and Quality's Health Information Technology Program should be expanded. Adequate resources should be provided to allow the agency to sponsor developmental programs for information and communications technology in five rural areas. Communities should be selected from across the range of rural environments, including frontier areas. The 5-year developmental programs should commence in fiscal year 2006 and result in the establishment of state-of-the-art information and communications technology infrastructure that is accessible to all providers and all consumers in those communities.
3. The National Library of Medicine, in collaboration with the Office of the National Coordinator for Health Information Technology and the Agency for Healthcare Research and Quality, should establish regional information and communications technology/telehealth resource centers that are interconnected with the National Network of Libraries of Medicine. These resource centers should provide a full spectrum of services, including the following:
    - Information resources for health professionals and consumers, including access to on-line information sources and technical assistance with on-line applications, such as distance monitoring.
    - Lifelong educational programs for health care professionals.
    - An on-call resource center to assist communities in resolving technical, organizational, clinical, financial, and legal questions related to information and communications technology.

Summary of Nationwide Health Information Network (NHIN) Request for Information (RFI) Responses (2005)

RECOMMENDATIONS

Drawn from the respondents' unique perspectives, the comments offered a wide range of thoughtful suggestions. Among the many opinions expressed, the following concepts emerged from the majority of RFI respondents:

- A NHIN should be a decentralized architecture built using the Internet linked by uniform communications and a software framework of open standards and policies.
- A NHIN should reflect the interests of all stakeholders and be a joint public/private effort.
- A governance entity composed of public and private stakeholders should oversee the determination of standards and policies.
- A NHIN should be patient-centric with sufficient safeguards to protect the privacy of personal health information.
- Incentives will be needed to accelerate deployment and adoption of a NHIN.
- Existing technologies, federal leadership, prototype regional exchange efforts, and certification of EHRs will be the critical enablers of a NHIN.
- Key challenges will be the need for additional and better-refined standards; addressing privacy concerns; paying for the development and operation of, and access to the NHIN; accurately matching patients; and addressing discordant inter- and intra-state laws regarding health information exchange.

Health Information Technology (HIT) Leadership Panel Final Report (2005)

RECOMMENDATIONS

The HIT Leadership Panel identified three key imperatives for HIT:

1. Widespread adoption of interoperable HIT should be a top priority for the U.S. health care system.
2. The federal government should use its leverage as the nation's largest health care payer and provider to drive adoption of HIT.
3. Private sector purchasers and health care organizations can and should collaborate alongside the federal government to drive adoption of HIT.

Rather than attempting to implement HIT all at once through a "big bang," implementation should occur through a well-planned sequence of steps and incentives to promote widespread HIT adoption.

Both carrots (i.e., incentives) and, when necessary, sticks (i.e., mandates, other requirements) should be used to promote the widespread adoption of HIT.

The HIT Leadership Panel also suggested that mechanisms be created to incentivize or otherwise assist providers to install HIT and reengineer health care processes to take full advantage of its potential benefits.

The national HIT vision must be communicated clearly and directly to enlist consumer support for the widespread adoption of HIT, including the necessary investment to achieve this vision. This vision should convey how the American consumer has the most to gain from adoption of HIT, including more safe and effective health care in a more efficient, personalized, and secure system.

The federal government and other HIT proponents must specifically address the protections to privacy and confidentiality afforded by the Health Insurance Portability and Accountability Act (HIPAA) and continue to promote and enforce related standards and safeguards accordingly.

The federal government should monitor progress and impact of widespread HIT adoption to ensure that no population group is left out or disadvantaged by this transition in HIT.