

## 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*

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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.



### **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 ISO 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

















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.







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.



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.



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:











**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 004010X094A1 for 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 HCIdesa 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 HCIdesa 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 HCIdesa 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.





