June 3, 2008

Honorable John Dingell
Chairman
Honorable Joe Barton
Ranking Member
House Committee on Energy and Commerce
2125 Rayburn Building
Washington, DC 20515

Dear Chairman Dingell and Ranking Member Barton:

The American Medical Informatics Association (AMIA) and the American Health Information Management Association (AHIMA) thank you for providing us the opportunity to comment on your recently posted health information technology draft legislation. AHIMA and AMIA congratulate you and your staff on this effort and believe that you have developed a very positive and helpful legislative draft.

As requested by your staff, AMIA and AHIMA are providing you with specific and detailed comments. Representing more than 57,000 professionals who are on the front lines of implementing electronic health records, deploying health information technology, and managing health information, we hope that you find our comments helpful to the further evolution of your proposal. If you have any comments, questions or wish to meet, please do not hesitate to contact AMIA Legislative Representative Doug Peddicord at doug.peddicord@whaonline.org or 202-543-7460, or AHIMA's Director of Government Relations Don Asmonga at don.asmonga@ahima.org or 202-659-9440.

Our comments follow:

Title I

Sec. 101

Sec. 3001 (b) Purpose

Add: (10) Promotes and insures an adequate and effective health information technology, management and informatics workforce that will enable the efficient and

effective use of electronic health record systems and the electronic exchange of health information.

Sec. 3001 (c)(2) HIT Policy Coordination

As a goal of the HIT Policy Coordination, we recommend the addition of language to insure the uniform use of approved standards.

On page 9, line 13 after "efforts" add: ", the uniform use of approved standards and…"

Sec. 3001 (c)(3) Resource Requirements

One of the most critical resources for the effective implementation and use of electronic health record systems and a nationwide health information network is the workforce who will be implementing and using the system. In this section, we recommend adding a workforce component to the language.

On page 13, line 7 after "investment" add: ", the current and future workforce necessary to insure the effective implementation and use…"

Sec. 3002 (c)(G) Membership and Sec. 3003 (c)(vi) Membership

The subject matter that is under discussion is health information technology and the storage, management and exchange of electronic health information. Of the members of the HIT Policy Committee and the HIT Standards Committee appointed by the Comptroller General of the United States, there is not a designated expert in the accumulation, analysis, storage, management and exchange of health information. This expertise is critical in describing and understanding the regulatory, legal, and processes necessary for the use, disclosure and exchange of health information regardless of its form or medium.

To insure these important areas are expertly represented, we recommend the addition of a health informatics and a health information management expert in this content area.

Sec. 3002 (c)(6) Membership and Sec. 3003 (c)(5) Membership (Outside Involvement)

The description of the HIT Policy Committee fails to recognize another Congressionally mandated group, the National Committee of Vital and Health Statistics. This committee has existed for almost 60 years and in the last ten years has also been given the oversight of the Health Insurance Portability and Accountability Act of 1996 requirements for administrative simplification. The role of this committee will overlay that of the HIT Policy Committee and perhaps this group's roles need to be considered since they will be addressing the same data use and some of the same standards.

In reviewing these sections, we discovered that there is no formal recognition of the standards work that is already on-going. First, we believe it is important to therefore recognize the standards development organizations (SDO) and their work.

Second, we suggest that the role of the existing Health Information Technology Standard Panel (HITSP) be recognized and identified. HITSP's role is to harmonize standards, a process that normally would occur after the standards had been finalized by the SDOs and tested according to other parts of this section. Without such harmonization there can be tested but competing standards. While the sustainability of HITSP, to date, has been in question, this vital role, usually supported by the government in other nations, has proven very positive to ensure standard interoperability and improve acceptance of standards by the healthcare industry. HITSP is also representative of all sectors of the healthcare industry and as such can provide good industry oversight to the testing and other activities prescribed to NIST

Third, we suggest, as noted above, that the role of the Certification Commission for Health Information Technology (CCHIT) also be recognized. Once standards are tested and recommended, and harmonization has occurred, the products that should carry the standard to make functionality available to the user need to be certified. This successful process is helping to promote the adoption and implementation of standards therefore leading to interoperability and the capability of health information exchange.

In addition to recognizing these groups, some formal or ad hoc relationship should occur between the Standards Committee and these groups.

Besides the groups just mentioned, there are a number of other functions that need to be recognized by both the Policy and Standards committees. First, AHIMA and AMIA have addressed in our paper "Healthcare Terminologies and Classifications: An Action Agenda for the United States", the need for a public/private body to coordinate the terminologies and classifications that are carried in the various clinical standards being considered. Most industrial countries have such a body and HR 2406 has recommended funding to determine just how such a group should function in the US. We recommended that this bill carry this same provision and perhaps establish a place holder for such a group. (See our comments on NIST below.)

A second function under discussion by the federal government and the healthcare industry is data stewardship - the coordination and facilitation of data sets used for quality reporting, patient safety, research and other uses beyond that of clinical care. The Agency for Healthcare Research and Quality (AHRQ) sought input for such a function and AHIMA has submitted a paper on this subject, but AHRQ has yet to make a recommendation.

Sec. 3002 (e) Publication and Sec. 3003 (e) Publication

In addition to publishing and posting the recommendations of the HIT Policy Committee and the HIT Standards Committee, we believe it is important to also publish public

announcements for solicitation of new candidates to these committees and how nominations can be submitted for appointment. Language should be added to each section that states:

" of all policy recommendations, terms of each individual member, and the timelines and process for submitting individual nominations…"

Sec. 3003 (b)(3) Schedule

This section is inconsistent with other similar sections in the draft bill by only requiring the Secretary to publish the schedule in the Federal Register. To insure consistency, we recommend adding the "website" to this section.

Sec. 121 Grant, loan, and demonstration programs

Sec. 3011

In this section there are requirements relating to the matching of grant dollars. AMIA and AHIMA suggest that Congress consider waiving any matching requirement in the areas of highest need. This should especially be done in situations where technology users or education programs exist in communities that may be considered underserved or rural. We are concerned that where the need might be the greatest, potential grantees may not be able to raise the necessary matching funds.

Sec. 3012

In adding Sec. 3012 to the Public Health Service Act the draft bill creates a "demonstration program to integrate information technology into clinical education". As experts in issues relating to training individuals in healthcare and related settings in the appropriate use of health information technologies to improve care, reduce costs, and ensure the confidentiality and security of health information, AMIA and AHIMA applaud this provision. We would suggest that the description of the demonstration program be amended to read, a "demonstration program to integrate information and communications technology into clinical education" because this better captures the 'communications' that may occur between computers, patients, caregivers, information managers, and the like. Also, we note that the current language may be too narrow in stipulating health professions and nursing schools and schools with a graduate medical education program, since much training in health information management and research is also provided by colleges and universities at the graduate and undergraduate level, as well as by community colleges and associate-degree granting schools that may not meet the definition of health professions school, as well as non-profit professional organizations like AMIA and AHIMA that provide training for healthcare professionals already engaged in healthcare but in need of training to keep up with advances in HIT. In further explicating the demonstration program proposed in this section, we would recommend to you a review of the language of the "10,000 Trained by 2010 Act" (HR 1467).

Title II

AMIA and AHIMA are very supportive of the integration of the National Institute for Standards and Technology for testing and research and development programs pertaining to health information technology initiatives. An important element contained in Congressman Gordon's HR 2406, the "Healthcare Information Technology Enterprise Integration Act," was the need for harmonization of standards including classifications and terminologies. We believe that it is important that this critical issue should be addressed in any HIT proposal that is considered by Congress. Therefore, in Title II, we recommend the addition of a new section:

Sec. 203 "Strategic Plan for Healthcare Technologies and Classifications."

(a) In General—The Director of the National Institutes of Standards and Technology, in consultation with the Director of the National Science Foundation, not later than 90 days after the date of the enactment of this Act, shall establish a task force whose membership includes representatives of other Federal agencies and industry groups (such as the American Medical Informatics Association, American Health Information management Association, and the Health Information Management Systems Society) to develop a strategic plan including recommendations for—

a. The development, adoption, and maintenance of terminologies and classifications;

b. Gaining commitment of terminology and classification stakeholders (such as developers, end users, and other service and technology suppliers) to principles and guidelines for open and transparent processes to enable cost-effective interoperability and complete and accurate information;

c. The design of a centralized authority or governance model, including principles for its operation and funding scenarios;

d. United States participation in international health terminology standards development organizations; and

e. Any other issues identified by the task force.

(b) Task Force Report—The task force shall report its finding and recommendations to the (appropriate House/Senate Committees) not

later than 18 months after the date of the enactment of this Act. The task force shall terminate after transmitting such report.

(c) Federal Advisory Committee Act—The task force established under this section shall not be subject to the Federal Advisory Committee Act.

(d) Authorization of appropriations—There are authorized to be appropriated such sums as may be necessary to the Director of NIST to carry out this section.

Title III

Sec. 301 and Sec. 311 Application of Security Provisions and Penalties to Business Associates and **Application of Penalties to Business Associates of Covered Entities for Violations of Privacy Contract Requirements**:

AHIMA and AMIA have long advocated the principle that "protections should follow health information" and so we support the extension of the HIPAA Security Rule and the application of Privacy Rule penalties to the Business Associates (BAs) of Covered Entities (CEs). We do note that such an extension is likely to significantly complicate the negotiation and renegotiation of current and future contractual agreements between hundreds of thousands of CEs and BAs and would suggest that the final bill include a reasonable phase-in period (for instance, of 1 year) before the provisions of Sec. 301 and Sec. 311 take effect.

Sec. 301 and Sec. 315 Breach Notification

As responsible stewards of health information, AMIA and AHIMA support the inclusion of breach notification requirements that apply to CEs and BAs. In regard to these requirements, we would raise five issues that deserve further consideration as drafting of your legislation continues.

1. The bill's current language (at Sec 301) requires (unless there is insufficient contact information to do so) first-class mail reporting of breaches to affected individuals; we would suggest that electronic notification via e-mail should also be permitted, if the affected individual has indicated a preference for such communications beforehand.

2. The bill's current language (Sec 301(e)(2)) calls for notice to the media if the protected health information of more than 500 residents of a State has been breached. We support the principle of notice to the media as a means of alerting the public to a potential breach of health information. However, in the draft such notice must take place in addition to first-class mail reporting – because of the enormous costs that may be involved in such written notice if a large number of individuals may be affected, we suggest that you consider the use of notice to the media *instead of* written

notification if the protected health information of some threshold number (for example, 25,000 individuals) may have been compromised. Again, such an example illustrates that electronic notification via e-mail should also be permitted in addition to notice to the media if the affected individual has indicated a preference for such communications beforehand.

3. In the temporary breach notification requirements imposed on vendors of personal health records (PHRs) at Sec 315, we note that two exemptions from reporting are outlined. The first is if the vendor makes a "reasonable determination" that the breach would not create a "reasonable risk of substantial harm, embarrassment, inconvenience, or unfairness to the individual". The second exemption from reporting allows the presumption that reasonable risk of harm will not have occurred if the individually identifiable health information has been encrypted. AMIA and AHIMA strongly support both of these exemptions and we suggest that similar language be added to Sec 301 in order to clarify that exemptions to reporting based on determination of "reasonable risk" and the presumption of "no reasonable risk" if identifiable health information has been encrypted applies not only to PHR vendors but to CEs as well.

4. Even as we express support for the inclusion of breach reporting requirements applicable to CEs and BAs, we should note that creating new processes for breach reporting will engender significant new costs for affected CEs and BAs, whether or not they ever actually incur a breach. Again, AHIMA and AMIA would suggest that it would be useful to include in Title III an additional study by the GAO of such costs and of the impact of breach reporting on public confidence.

5. Perhaps most importantly, AMIA and AHIMA believe that the breach reporting requirements of Federal legislation must preempt the myriad State laws that have been enacted in this area. Unlike, the use of the broad concepts of the HIPAA Security and Privacy Rules as a 'floor' for protecting the security and confidentiality of health information, the efficacy of breach reporting requirements turns on specifics, such as timelines for reporting, (whether 10 or 15 or 30 days, for example). In an era when the delivery of health care is rarely limited by geographic area, the breach reporting requirements outlined in your bill will become one of (potentially) 51 sets of requirements that will, at best, impose costs on CEs, BAs and PHR vendors while, in general, providing uncertain value to individuals.

Sec. 312 (b) Disclosures Required to be Limited

In an apparent attempt to be more protective of privacy than the current 'minimum necessary' standard, this section requires that disclosures by CEs utilize "limited data

sets" when possible, including in relation to disclosures for payment and health care operations activities. As you know, the "limited data set" was created to facilitate health outcome and other population research activities, and we question whether the removal of all direct identifiers called for in its definition is practicable for many payment or health care op activities – for instance, a payer cannot ascertain the correctness of a claim without the individual's name nor can a hospital execute infection control assessments without direct identifiers. Further, within most covered entities the generation of 'limited data sets' would create a second set of records for most patients and impose extraordinary costs. Absent compelling evidence that the use and disclosure of personal health information for treatment, payment and health care operations has caused harm to the confidentiality and security of health information – which has not been asserted by any reliable source – AMIA and AHIMA are reluctant to alter the existing HIPAA framework relating to the minimum necessary standard.

Sec. 312 (c) Accounting of Certain Disclosures

We note with interest the requirement stipulated in this section that CEs that utilize an electronic health record (EHR) be required to furnish to the individual upon request an audit trail of disclosures for treatment, payment and health care operations. While some existing EHR systems have such audit capabilities in place, other systems would need to be retrofitted. Especially in light of the extraordinarily rare occurrence of audit trail requests by individuals today, we question whether the imposition of additional new costs occasioned by this requirement will be of value. Further, we have some concern that this particular requirement could actually incentivize some CEs, (perhaps especially small and rural providers) to remain in paper record systems. AHIMA surveys over recent years have shown limited requests for such audits.

Sec. 314 Study on Application of Privacy and Security Requirements to Vendors of Personal Health Records

By comparison to even 10 years ago, when most protected health information (PHI) was held by organizations that were defined as covered entities within the HIPAA framework, today there is a plethora of other entities that are acquiring, maintaining, using, and disclosing PHI. AHIMA and AMIA applaud the study relating to PHR vendors called for in this section. We would suggest that the study include not only the identification of security, privacy and notice requirements that should apply to such vendors, but also to the '3rd party applications' that will 'sit on top of' the health information databases maintained by PHR vendors. That is, while it will be useful to examine security, privacy and notice requirements that should apply to PHR vendors, consumers will not be well-served if such requirements do not apply to the 3rd parties that individuals may 'authorize' to access a personal health record.

The members of our two associations are truly on the front lines of implementing electronic health records and health information technology. AHIMA is the premier association of over 53,000 health information management (HIM) professionals whose members are dedicated to the effective management of the personal health information

needed to deliver quality healthcare to the public. Founded 80 years ago to improve the quality of medical records, AHIMA is committed to advancing the health information management profession in an increasingly electronic and global environment through leadership in advocacy, education, certification, and lifelong learning. For additional information, you can visit www.ahima.org.

With over 4,000 physicians, nurses and other informaticians, AMIA is the premier organization in the United States dedicated to the development and application of medical informatics in the support of patient care, teaching, research and healthcare administration. AMIA links developers and users of health information technology, creating an environment that fosters advances that revolutionize healthcare. To learn more, you can visit www.amia.org.

Thank you again for providing us the opportunity to work with you on this much needed legislation.

Sincerely

Don E. Detmer, MD, MA, FACMI
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AMIA

Linda L. Kloss, RHIA, CAE, FHIMA
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AHIMA

cc: Rep. Frank Pallone, Health Subcommittee Chairman
Rep. Nathan Deal, Health Subcommittee Ranking Member