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January 28, 2009

The Honorable Harry Reid
Senate Majority Leader
S-221 United States Capitol
Washington, DC 20510

The Honorable Mitch McConnell
Senate Minority Leader
S-230 United States Capitol
Washington, DC 20510

Dear Senators Reid and McConnell:

On behalf of DMAA: The Care Continuum Alliance, I applaud your leadership in congressional efforts to effectively promote and incentivize broad adoption of health information technology (HIT). DMAA views as critical the efficient and effective management of aggregated health information and the dissemination of that information as appropriate with strict adherence to patient privacy in support of population health improvement and targeted improvements in health care quality for patients with multiple chronic illnesses.

DMAA continues to support the inclusion of provisions in the American Recovery and Reinvestment Act of 2009 that would promote the adoption of HIT as an investment in national infrastructure and build on the development of interoperability standards that encourage the portability of electronic health information and assist in the widespread achievement of health quality benchmarks. Still, as DMAA represents more than 200 corporate and individual stakeholders -- including wellness, disease and care management organizations, pharmaceutical manufacturers and benefits managers, health information technology innovators, biotechnology innovators, employers, physicians, nurses and other health care professionals, and researchers and academicians -- we remain gravely concerned that privacy and security provisions accompanying HIT promotion initiatives will slow or inhibit access to essential health information that supports, and even determines, the provision of medical care and services to individuals with debilitating and chronic illnesses.

DMAA supports efforts to protect the integrity of personal health information (PHI) in concert with the protection of the availability of information for treatment, payment, chronic care coordination, and care management. This process must involve patients, caregivers, providers, and payers. DMAA, with other health provider representatives, looks forward to working with you and other congressional health care leaders to modify HIT privacy and security provisions, such as those approved by the Senate Appropriations Committee and reported out with economic stimulus legislation by the House Committees on Ways & Means and Energy & Commerce, respectively. While

DMAA recognizes careful updates to the HIPAA Privacy Rule can strengthen the protection of consumer privacy, some of the House bill's provisions could have deleterious effects on health care delivery and efficacious patient care:

- **Business Associates (Sec. 4401, 4402, 4404, 4411 per Title IV in House Ways & Means and Energy and Commerce Committee proposed legislation)**

The Health Information Technology for Economic and Clinical Health (HITECH) Act has a profound impact on business associates and imposes significant compliance burdens that do not exist under the current HIPAA Privacy Rule or Security Standards.

The Act requires business associates to comply in the same manner as covered entities, which dramatically increases the business associate compliance burden. For example, a business associate would be required to conduct a security risk analysis and develop comprehensive written policies and procedures to reflect compliance with HIPAA Security Standards.

A new notification provision would require business associates to notify covered entities of breaches of "unsecured protected health information." The provision requires business associates to identify each individual whose unsecured personal health information (PHI) has been or is reasonably believed to have been involved in the breach. "Unsecured Protected Health Information" is defined as PHI that is not secured in accordance with guidance issued by the Secretary. A breach will be considered "discovered" when a business associate knows or should have known about it, or when it is discovered by an employee, or agent of the business associate or covered entity. Comprehensive written policies will be critical for business associates to ensure compliance with this notice requirement. While the HITECH Act provides some clarification regarding compliance obligations for business associates, the bill would impose significant compliance obligations. Existing business associate agreements will require updating to reflect these new obligations and new forms will require time to be developed.

- **Marketing (Sec. 4406)**

While language in this section of the HITECH Act retains existing Privacy Rule exceptions from the definition of marketing, the section prohibits a covered entity or business associate from making such communications without patient authorization, if the covered entity or business associate has received direct or indirect payment in exchange for the communication. In practice, this has the potential to impose patient authorization requirements (a significant administrative burden) in connection with many non-marketing communications. Patients, burdened with new authorization requirements, may opt to forego potentially valuable communications related to proactive health care (refill reminders, vaccination notifications, adherence information, and prescription benefits) to avoid this burden.

- **Accounting of Disclosures (Sec. 4405(c))**

The HITECH Act significantly changes accounting requirements for covered entities that maintain personal health information (PHI) in an electronic health record (EHR). Under HIPAA, covered entities are not required to account for disclosures of treatment, payment or health care operations. These exceptions will not apply to disclosures through an EHR under the HITECH Act, significantly increasing the accounting burden for certain covered entities. Further, the bill's language makes it likely that covered entities would also have to account for all electronic disclosures of PHI made by business associates with EHRs. Even an electronic accounting obligation of three years preceding the date of a patient's request could prompt disclosures of tremendous amounts of information of questionable value to the patient. Further, the imposition of this requirement could negate the positive steps taken in the stimulus vehicle to promote the adoption of EHRs and encourage medical innovation and research.

- **Disclosure of Treatment, Payment, or Health Care Operations (Sec. 4405(d))**

Language in the HITECH Act ultimately may realize a narrowing of the health care operations definition. The health care operations provisions of HIPAA were originally drafted to facilitate health care administration and ensure timely access to quality care for patients. Any increase in the administrative burden could impact negatively these goals.

- **Prohibition on Sale (Sec. 4405)**

With certain exceptions, the HITECH Act prohibits the sale or exchange of PHI for direct or indirect remuneration without a patient's authorization. This provision, like the Act's proposed changes to current marketing provisions, could hinder otherwise permissible uses and disclosures of PHI through the imposition of an authorization requirement. We remain concerned that use of "remuneration" language -- rather than "monetary compensation" -- increases the number and variety of information exchanges that could be impacted.

- **Creating authority for state attorneys general to enforce HIPAA Privacy Rule (Sec. 4410(e))**

Health care providers support strongly efforts to improve enforcement of the existing Rule, and many steps taken by HHS' Office of Civil Rights in recent years successfully have encouraged compliance . The Department of Justice and the OCR maintain considerable authority to realize civil and criminal enforcement of HIPAA. Providing additional incentives for states to seek monetary damages or injunctive relief should be reconsidered. State attorneys general currently possess the authority and tools to enforce state laws protecting PHI and DMAA would encourage additional OCR outreach to state attorneys general to speed the investigation of suspected HIPAA violations.

These proposals are well-intentioned, but DMAA feels strongly that balanced approaches to preserve patient privacy and security could serve as an opportunity to encourage healthcare transparency; to support healthcare reform and advancement as a collaborative process including patients, providers, and payers; and to allow health care professionals to meet efficient and economical standards that require patient

advisement of health risks and privacy risks when faced with certain information access decisions.

Again, we thank you for recognizing the challenge to safeguard the personal health information of all individuals while advancing initiatives to interconnect health care professionals, inform clinicians, engage patients, and provide access to health information technology components that improve population health. We look forward to supporting passage of a straightforward economic recovery package that provides for the ongoing discussion of complex medical and health privacy issues with you further during the 111th Congress.

Sincerely,

A handwritten signature in black ink, appearing to read "Tracey Moorhead". The signature is written in a cursive, flowing style.

Tracey Moorhead
President & CEO

cc: Members, Senate Committee on Health, Education, Labor and Pensions