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September 13, 2010

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building
Room 509-F
200 Independence Avenue, SW
Washington, DC 20201

Attn: RIN 0991-AB57

Dear Secretary Sebelius:

DMAA: The Care Continuum Alliance respectfully submits these comments in response to the Notice of Proposed Rulemaking (NPRM) for Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health (HITECH) Act issued in the *Federal Register* on July 14, 2010.

DMAA: The Care Continuum Alliance members provide an array of services along the entire continuum of care, including wellness, disease management and complex case management. DMAA: The Care Continuum Alliance members include wellness, disease management and population health management organizations, health plans, physician groups, hospitals, labor unions, employer organizations, pharmaceutical manufacturers, pharmacy benefit managers, health information technology innovators and device manufacturers, academicians and others. These diverse organizations share the vision of aligning all stakeholders to improve the health of populations. Our members seek to improve health care quality and contain health care costs at a population level by providing targeted interventions and services to individuals who are well, at-risk for or managing one or more chronic conditions.

DMAA: The Care Continuum Alliance supports efforts to guard the integrity of protected health information (PHI) in concert with the protection of the availability of information for treatment, payment, chronic care coordination, and care management. We appreciate the opportunity to assist the Department in the development of these regulations.

We agree with the Department that privacy and security of PHI are essential components of promoting the increased adoption of health information technology and

electronic health records (EHRs). Provisions in both HITECH and the Affordable Care Act (ACA) are designed to dramatically change the way in which health care is delivered and financed – changes in HIPAA are appropriate to address the changing environment.

With that said, DMAA: The Care Continuum Alliance has the following concerns with the NPRM as drafted:

Minimum Necessary

Section 164.502(b)(1) of the HIPAA Privacy Rule requires covered entities to limit uses, disclosures and requests for PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Currently, covered entities have discretion to determine the minimum amount of PHI necessary for each of a countless variety of transactions involving PHI. Section 13405(b)(1)(A) of HITECH eliminates some of this discretion and attempts to define the “minimum necessary” standard. Under HITECH, a covered entity will only be in compliance with the minimum necessary standard if it limits uses, disclosures and requests for PHI to the “limited data set” as defined under HIPAA, or if needed, the minimum amount of information beyond a limited data set. HITECH also requires the Secretary to issue further guidance regarding the minimum necessary standard.

We have serious concerns about the imposition of a rigid and somewhat arbitrary list of data points on an infinite universe of health care transactions - even if covered entities have the option of using additional data points as necessary. We strongly urge that the final rule be clarified to emphasize a covered entity’s discretion to determine the minimum amount of PHI that is necessary in any given circumstance, as permitted under HITECH. The limited data set or any other standard could simply be identified as a safe harbor for compliance purposes, but not a requirement. We caution against any standard that would have unintended consequences of restricting the appropriate flow of information necessary for health care service delivery or support.

Marketing

The proposed regulation makes distinction between communications for health care operations and treatment. Further, the NPRM requires notice to patients in addition to notification to patients of the right to “opt-out” of subsidized treatment communications. We recognize that Congress has mandated restrictions on subsidized health care operations communications and appreciate the inappropriate uses of PHI that Congress is trying to prevent.

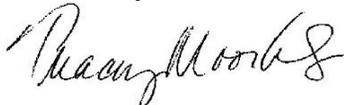
Under HITECH and the proposed regulation, a covered entity’s receipt of payment in exchange for making certain communications that would otherwise constitute health care operations transforms those communications into marketing. However, we believe it is important to point out that many legitimate and important patient outreach efforts rely on the health care operations exception to the marketing rule.

DMAA: The Care Continuum Alliance members work closely with their clients to ensure that patients receive a range of important health care operations and treatment communications including but not limited to prevention, health promotion and wellness programs as well as communications specifically targeting patients with certain conditions. Some of these communications are very difficult to distinguish between health care operation and treatment and in fact, a majority of which are intended to support and enhance treatment. Restricting these communications seems inconsistent with increasing patient engagement and promoting prevention and wellness, key goals of HITECH and ACA.

We are also concerned with the notice and opt-out requirements for pure treatment-related communications. We echo comments on this issue made by the Confidentiality Coalition regarding Congressional intent in carving out treatment communications and point out that if patients were able to restrict treatment communications it could actually hinder a provider's ability to effectively provide care. We believe information is "meaningful" when it results in the intended behavior change or experience of those individuals. Not all communication is successful in achieving necessary behavior change or compliance with standards of care and multiple communication messages may be required in order to increase member engagement. Opt-out provisions reduce the likelihood that the majority of people in need of treatment communications will actually achieve improved health. Care coordination, care management, innovative delivery models and EHRs efforts could also be hindered - another potential unintended consequence and inconsistent with provisions and initiatives in HITECH and ACA.

We appreciate the opportunity to offer these comments and look forward to working with the Department as the rule gets implemented.

Sincerely,

A handwritten signature in black ink, appearing to read "Tracey Moorhead". The signature is fluid and cursive, with the first name "Tracey" and last name "Moorhead" clearly distinguishable.

Tracey Moorhead
President and CEO