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John E. Niederhuber, MD
Director
National Cancer Institute

Governor Bob Wise
President
Alliance for Excellent Education

September 13, 2010

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: HITECH Privacy and Security Rule Modifications
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW.
Washington, DC 20201

Re: Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act ("HITECH")

RIN: 0991-AB57

Dear Secretary Sebelius:

C-Change would like to thank you and the Department of Health and Human Services ("HHS" or the "Department") for the opportunity to comment on the proposed modifications to the HIPAA Privacy Rules under the HITECH Act, published in the *Federal Register* on June 14, 2010.

C-Change is a 501(c)3 organization of leaders from more than 145 public, private, and not-for-profit organizations with the shared mission of eliminating cancer as a major public health problem at the earliest possible time by leveraging the expertise and resources of its members. We envision a future where cancer is prevented, detected early and cured or managed successfully as a chronic illness. Our organization convenes multi-sector leaders in the cancer community to address issues that we cannot affect alone. Improving privacy protection and reducing impediments to the research process remains one of our strategic priorities.

The pages that follow are a copy of the comments that we submitted earlier today to the Office of Civil Rights. In short, we believe the proposed modifications appear to be a very modest attempt to remove burdens to the research process with highly debatable impact. Furthermore, they serve as a strong reminder that our Nation needs a more comprehensive approach to research privacy as recommended in the Institute of Medicine report, [Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research](#), if it is to benefit at all from the potential health advances that may be possible under HITECH.

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Realizing the promise of cancer research and the specific benefits of exciting new initiatives such as comparative effectiveness research will greatly benefit people at risk for and living with cancer. These benefits will not be realized or will be severely delayed if the framework guiding research in this Nation is not addressed adequately. We remain willing to constructively participate in any process that HHS pursues to further improve privacy protection and reduce research impediments by offering the expertise of our membership, including researchers, clinicians, and patient advocates.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Kean", with a long horizontal flourish extending to the right.

Tom Kean, MPH
Executive Director

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C-Change would like to thank the Department of Health and Human Services (“HHS” or the “Department”) for the opportunity to comment on the proposed modifications to the HIPAA Privacy Rules under the HITECH Act, published in the *Federal Register* on June 14, 2010.¹

C-Change is one of the nation’s leading organizations dedicated to addressing the major issues and challenges associated with the extraordinary human and economic burden that cancer inflicts on the Nation. Our members are cancer leaders from more than 145 organizations that cut across the public, private and not-for-profit sectors. We are committed to leveraging the leadership and expertise of all sectors of society to eliminate cancer as a major public health problem. Among our major initiatives, we emphatically support the need for a strong national, multi-sector, biomedical research enterprise to be the “engine” of change leading to improved cancer patient outcomes and remain strongly committed to protecting and enhancing the privacy of individuals and families confronting cancer.

C-Change has been very supportive of the Institute of Medicine and the thorough analysis and recommendations that it developed to help our Nation better ensure that both the privacy of research participants is protected and patients and families throughout our nation have access to improved health and health care through the very best research.² Of critical importance, is the fact that, as the IOM Committee summarized in its executive summary:

¹ 75 Fed. Reg. 40,868 (July 14, 2010).

² Institute of Medicine, *Beyond The HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*. The National Academies Press (2009), hereinafter “IOM Report.”

“The committee’s conclusion is that the HIPAA Privacy Rule does not protect privacy as well as it should, and that, as currently implemented, the HIPAA Privacy Rule impedes important health research. The committee found that the Privacy Rule (1) is not uniformly applicable to all health research, (2) overstates the ability of informed consent to protect privacy rather than incorporating comprehensive privacy protections, (3) conflicts with other federal regulations governing health research, (4) is interpreted differently across institutions, and (5) creates barriers to research and leads to biased research samples, which generate invalid conclusions.”³

These are very serious problems for the Nation’s patients and their families and unnecessary burdens to the research process. They do not further patient protection and ultimately may prolong harm as a result of further delaying or making undiscoverable the life-saving prevention and cures that can only be realized through research.

We are pleased that HHS has taken note of this important body of work by citing it favorably in the preamble to the HITECH modifications of the HIPAA privacy regulations. We very much hope that with respect to research privacy, the Department of Health and Human Services shares our commitment to the IOM committee’s three overarching goals:

“(1) improve the privacy and data security of health information;

“(2) improve the effectiveness of health research; and

“(3) improve the application of privacy protections for health research.”⁴

We appreciate that it is not appropriate for the Department to take up the broader recommendations of the IOM Report in this rulemaking by the Office for Civil Rights under the HITECH Act. However, we think that the fundamental conclusion of the IOM committee, that “as currently implemented, the HIPAA Privacy Rule impedes important health research,”⁵ is critically important to what the Department is trying to achieve at this juncture. Given the seriousness of the IOM’s conclusion for the health and health care of the American people, we hope that, at a minimum, the Department in this rulemaking does not increase the impediments to health research. With this in mind, we wish to comment on two aspects of the proposed changes to the HIPAA regulations: (1) various changes to the HIPAA authorization for research, including the request for comment on a possible new authorization for future research, and (2) Provisions implementing the HITECH “Sale of PHI” prohibition that, in the form proposed, add significantly to the burden that the HIPAA regulations impose on research without adding to the protection of privacy of research participants.

Research Authorizations

The Department is appropriately reconsidering two critical problems: the prohibition on compound authorizations in the research context and the confusion about authorizations for future research with data maintained in research repositories and databases. Both of these issues are identified in the IOM Report as impediments to important research that do nothing to enhance the privacy of the research participants. We agree that, until the relevant agencies within HHS are able to create a more comprehensive approach to research and privacy recommended by the IOM report, **it would be helpful to make it possible for institutional review boards (IRBs) to more readily deal with the various elements of informed consent that are impacted by the HIPAA requirements, and to permit individuals to give consent for PHI to be used for future research.**

³ IOM Report, at p. 2.

⁴ IOM Report, at p. 2.

⁵ IOM Report, at p. 2.

We note that in examining these issues, the IOM Committee saw the problem HIPAA creates as rooted in the fact that there is not a single coherent regulatory approach in which privacy is seen together with the other rights of and risks to the research participant. In contrast, the HIPAA authorization has the same mandatory elements for research as in authorizations permitting marketing, sale of records, life insurance underwriting, employer access, or disclosure for any other purpose; it is a document that is designed to serve a regulatory regime that is entirely independent of the regulatory regime that governs health research. It is designed to be a warning about the potential risks to or loss of certain rights. The theoretical framework created under HIPAA to accommodate the research context is a cacophony of concepts and constructs – “research related to treatment,” “research unrelated to treatment,” “treatment conditioned on authorization,” “corollary research activity” – and a host of others that make little or no sense to patients, doctors, researchers, or those who are charged with regulating or overseeing research. As a result of these constructs, **the regulation mandates certain statements and warnings that may be perfectly intelligible as a legal warning to someone who is waiving civil rights, but are intrusive anomalies in the context of the clinical trial in which research participants and their families already are trying to consider and balance risks to life and health that arise from the course of disease as well as treatment and research procedures.** The goal underlying both the federal Common Rule that regulates research risk and its informed consent process is to require researchers to minimize and mitigate all risks, and risks to privacy should be addressed as a coherent part of the informed consent overseen by the IRB. **But the HIPAA authorization statements seem designed more to scare patients than to inform them, and thus are counter to the philosophy and ethics of informed consent that is the foundation for clinical trial participation.** As a result, the IOM found that authorization statements serve as an impediment to research by causing research participants to be confused and unreasonably fearful about the long term legal risks to their families of a patient’s own decision to participate in a clinical trial. Thus, it is disappointing that, as the Department states in the preamble, “the proposed modifications do not alter the core elements or required statements integral to a valid Authorization.”⁶

Thus, while we applaud the Department for proposing to permit compound research authorizations where an authorization for specific research is combined with an authorization for PHI to be included in a research database or repository, we are apprehensive that, when added to all of the other mandatory HIPAA language, the various qualifiers regarding which elements of a given authorization may be conditioned on treatment and which may not, will prove to be yet another set of details that will be complex and confusing to research participants, families and IRBs trying to ensure that HIPAA authorizations, like all written materials provided to research participants, meet the ethical and legal requirements under the Common Rule. This set of modifications appears to be a very modest attempt to remove research burdens with highly debatable impact. Furthermore, the proposed modifications serve as a strong reminder that the Nation needs the more comprehensive approach to research privacy recommended by the IOM Committee if it is to benefit fully from the potential health advances that may be possible under HITECH.

Likewise, pending the development of a more comprehensive approach to privacy in research, **we support the proposal discussed in the preamble in which individuals would be permitted the choice to make an informed decision to allow their PHI to be available for future unspecified**

⁶ 75 Fed. Reg. at 40,893. As noted in the Preamble, the criteria that the regulation has established for waiver of mandatory elements of the HIPAA authorization by an IRB have proved to be too controversial and confusing to be useful in bringing clarity to the multisite clinical trial approval procedures.

research. We are confident that institutions and IRBs, can figure out appropriate ways finding the right balance between the public interest in the privacy of individuals' medical information with the public interest in the sophisticated analysis of suitably protected information to improve health and health care delivery. We note that the precedent established through data use agreements to safeguard information in the research context is an important building block for this effort. **We urge the Department to modify the final rule to permit authorizations for future unspecified research that are reviewed and approved by an Institutional Review Board as meeting the requirements for informed consent under the federal Common Rule.**

Sale of PHI

The HITECH Act added new provisions specifically addressing the sale of PHI or electronic health records.⁷ Our understanding of the HIPAA regulations prior to the passage of this Act is that sale of PHI already was prohibited by the HIPAA regulations if it did not involve specific authorization of the individual. As provided under the regulation at 45 CFR:

“ § 164.502 Uses and disclosures of protected health information: general rules.

(a) Standard. A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.”

Nothing in any subpart of part 164 or subpart C of part 160 prior to the enactment of HITECH authorized any covered entity to sell PHI or electronic health records and it seems obvious that a sale of PHI would be a prohibited disclosure. Thus, we think the best interpretation of the statutory language is that it was intended to require HIPAA authorizations in those situations where there is a sale of electronic health records or PHI, as defined under the HITECH Act, to require the authorization to explicitly disclose the fact of the remuneration associated with such a sale.

However, as the proposed regulation is drafted, this is not its primary result. Instead, the proposed regulation, on its face, turns every disclosure authorized under the HIPAA regulation where there is direct or indirect remuneration between the authorized recipient and a covered entity into a *de facto* “sale of PHI” since there is no statutory or regulatory definition of this term. Once so reconceived by the proposed regulation, the new authorization element – and the requirement of an authorization -- is added to every lawful disclosure unless the situation fits into one of the statutory exemptions the HITECH Act articulated for the “sale of PHI” provision. To the extent that this is a permissible interpretation of the statutory language, we think that it is an unintended consequence for the reasons outlined below. **We urge HHS not to pursue this interpretation because of the extremely untoward additional burdens it imposes on otherwise lawful research disclosures and uses of PHI.**

We see evidence that HHS is aware of the implications of such an overly broad interpretation in its discussion of the need to add to the list of exceptions established by the HITECH Act the new provision at 45 CFR 164.508(a) (4)(ii)(H), which says that the new language relating to remuneration for the sale of PHI is not required for disclosures “Permitted by and in accordance with the applicable requirements of this subpart, where the only remuneration received by the covered entity is a reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law.” As HHS observes in the preamble:

⁷ 45 USC 17935(d) “PROHIBITION ON SALE OF ELECTRONIC HEALTH RECORDS OR PROTECTED HEALTH INFORMATION.”

“We have included this proposed exception as necessary and appropriate to ensure that the proposed authorization requirement does not deter covered entities from disclosing protected health information for permissible purposes under subpart E just because they routinely receive payment equal to the cost of preparing, producing, or transmitting the protected health information. We emphasize that this exception would not apply if a covered entity received remuneration above the actual cost incurred to prepare, produce, or transmit the protected health information for the permitted purpose, unless such fee is expressly permitted by other law.”⁸

But the focus on the cost of data preparation and not the other legitimate fees that may be incident to lawful disclosures has caused the regulation to turn the statutory provision on its head. In effect, instead of adding a new element to the individual’s authorization where there is indeed a sale of PHI, HHS has created rules for a new marketplace for selling PHI. As one prominent academician has stated in an article discussing this provision, “The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 allows such sales [of PHI] but limits pricing to a cost-based fee for data preparation and transmission.” Professor Evans’ article continues to elaborate the parameters of the new regime that HHS is launching under this statutory provision:

“This article explains why supplying data to researchers is set to become a profitable line of business for entities that hold large stores of health data in electronic form. Health information systems are a form of infrastructure, and Congress’s cost-based fee for data preparation and transmission echoes pricing schemes traditionally used in other infrastructure industries such as railroads, electric power transmission, and telecommunications. Cost-based fees for infrastructure services, of constitutional necessity, must allow recovery of operating and capital costs including a return on invested capital - in other words, a profit margin.”⁹

We are concerned about the public utility and related regulatory feasibility of HHS creating a new infrastructure to regulate the new data market that it is creating through its interpretation of this provision of the HITECH Act. The proposed regulation does not suggest that HHS, through OCR, is setting up the necessary administrative apparatus to provide the cost regulation determinations as discussed in Professor Evans’ analysis.

If implemented as proposed, we are concerned that this provision will cause additional, perhaps catastrophic, burdens on research. To wit: as we understand the proposed regulation as drafted, pursuant to proposed 45 CFR 164.508(a) (4)(ii)(H), every HIPAA authorization that is part of a clinical trial will now have to include the mandatory language regarding a sale of PHI. As drafted, because the remuneration for research services could be “indirect” remuneration for disclosure of PHI under the research authorization and informed consent, the proposed regulation would require IRBs to ensure that the sale of PHI disclaimer be included in all informed consents in addition to all of the other mandatory HIPAA statements. This is precisely the kind of extraneous, confusing and off-putting mandatory language that the IOM Committee found to be a needless burden on research.

⁸ 45 CFR at 40,892.

⁹ Evans, Barbara J., *Waiving Your Privacy Goodbye: Privacy Waivers and the HITECH Act’s Regulated Price for Sale of Health Data to Researchers* (August 23, 2010). Univ. of Houston Public Law and Legal Theory Working Paper No. 2010-A-22. Available at SSRN: <http://ssrn.com/abstract=1660582>

In effect, the proposed regulation is *increasing* the research burden by the approach that it has taken to the Sale of PHI under the HITECH Act.

Because of the approach taken in the proposed regulation, the same new impediment under 45 CFR 164.508(a) (4)(ii) is added to every instance in which an IRB would make a waiver of informed consent and/or authorization. It also is added as a finding necessary to any Data Use Agreement. **In effect, every IRB waiver of authorization or consent now has to make a finding that any direct or indirect remuneration between the data recipient and covered entity does not exceed the cost of data preparation and transmission. IRBs are not equipped to make such a finding.** This would be yet another ambiguous element where the multiple IRBs involved in a multi-site research project might well disagree. Moreover, absent guidance from HHS that payment of an IRB fee for review of a protocol is part of the cost of preparation of data, as argued by Professor Evans in the paper cited above, the new criteria HHS has established for waiver of authorization could not be met where the researcher pays the IRB fees, pays for the cost of storage and maintenance of tissue samples that may include code numbers making them PHI, or where data in a clinical data repository likewise include codes, dates or other indicia that make them PHI under the regulation. This would indeed be a significant new HIPAA impediment to research.

In virtually all bona fide research, there is collaboration between clinician investigators and third party researchers and sponsors. Federal and state fraud and abuse laws already regulate the payments that are permissible or prohibited in these circumstances. Moreover, under federal regulations, entities with an assurance of compliance with the Common Rule have established programs for overseeing the potential for conflicts of interest that might arise from investigators compensation or investment arrangements research sponsors. For HHS to add a cost inquiry to the IRB's waiver criteria make applicable under the HIPAA regulation as it has in its approach here, will likely eliminate use of the waiver by many institutions. **This, as IOM and HHS are aware, would result in a catastrophic loss of the ability to engage in health care systems and public health research, as all research where there is any non-government funding for the research activities now require an authorization of each patient to provide the HHS-required notice that waivers are a the sale of PHI.**

Finally, we note that under the request for comments, if the sale of PHI provision is implemented as proposed for consideration with respect to the public health reporting under HIPAA, it would be an additional finding for the provider to make before any public health report. Because FDA and other agencies are trying to build new systems to better detect adverse events, **if HHS were to go forward to impose such a cost requirement as a prerequisite for legally reporting adverse events or provider participation in registries for Food and Drug Administration-required Risk Evaluation and Mitigation Strategies (REMS) or other surveillance programs, it could well undermine these efforts to make new medicines available promptly.** Our patients need access to innovative medicines and sound ways of evaluating risks and benefits. Congress has provided for this through the FDA regulations implementing REMS. It would be further damaging for HHS to undermine these systems by creating confusion and concern about the permissibility of public health reporting where third parties may provide funding for data systems that might be considered to be "indirect" remuneration for making the otherwise lawful and necessary public health report.

Recommendation for an alternative approach to the Sale of PHI

We are concerned that even inadvertently co-opting the underlying principles of the Common Rule for waiver of consent by adding a cost regime may work well for those who would create a

commercial market buying and selling health information, but it would be paralyzing for bona fide public health, health services, and clinical research. A “sale of PHI,” without any defining regulation to the contrary, could be understood as a situation in which the purchaser is under no obligation to protect the privacy of the data subjects. This, as the IOM Report makes clear, is antithetical to the purposes of health research in this country and it is contrary to the Common Rule protections by which research institutions and entities are bound. The researchers that our patients depend on, whether academics, clinicians, or employees of entities that develop new medical innovations, are committed to the privacy of their research participants, and are grateful to them for their willing participation. **We urge HHS to abandon the proposed approach that seems to have created this new commercial market and instead to implement the new HITECH requirements more explicitly protecting patients from the risks of unknowingly authorizing the sale of PHI in a manner that is more analogous to the general way it has implemented the additional authorization requirements required when the authorization is for PHI to be used for marketing.** We think this is more consistent with the concerns Congress may have had that electronic health records made possible by HITECH might well pose an increased attractiveness to those wishing to sell PHI.

We think that the better approach to interpreting the HITECH statutory language is to establish a definition of “sale of PHI or electronic health records” which includes the exceptions outlined in the statute. While not altogether simple for covered entities to implement, it is an approach to implementing the statutory language that would enable the compliance burden under the new HITECH requirement to be borne by the covered entity separately from the burdens directly imposed by the HIPAA regulation on the covered entity’s IRBs. More importantly, such an approach may help prevent the waiver of authorization for research from being co-opted by commercial interests that may not be concerned with health care research. It is critical, as the IOM report argues, that needless additional burdens and findings that are not integral to the research risks not be imposed on IRBs whether in the waiver context or in approving the language of informed consents and HIPAA authorizations.

We would propose the following alternative to that proposed by HHS at new section 164.508(a)(4). This proposal basically transforms the language HHS inserted as one of the mandatory elements of a HIPAA authorization at (a)(4) of the proposed rule into a definition of “sale of PHI” codified at 164.501, along with a separate a new requirement for authorizations where there is a “sale of PHI” as defined by the regulation.

Add the following new proposed definition of Sale of PHI to the definitions section in 45 CFR § 164.501:

Sale of Protected Health Information: (1) Except as provided in paragraph (2) of this definition, sale of protected health information means a disclosure of protected health information where the disclosure made is in exchange for direct or indirect remuneration from or on behalf of the recipient of the protected health information to the covered entity disclosing the information.

(2) Notwithstanding remuneration which may appear to be indirect remuneration incident to an otherwise permissible disclosure, “sale of protected health information” does not include a disclosure of protected health information:

(A) For public health purposes pursuant to § 164.512(b) or § 164.514(e);

(B) For research purposes pursuant to § 164.512(i) or § 164.514(e), where the only remuneration received by the covered entity is a reasonable cost-based fee to cover the cost to prepare and transmit the protected health information for such purposes;

(C) For treatment and payment purposes pursuant to § 164.506(a);

(D) For the sale, transfer, merger, or consolidation of all or part of the covered entity and for related due diligence as described in paragraph (6)(iv) of the definition of health care operations and pursuant to § 164.506(a);

(E) To or by a business associate for activities that the business associate undertakes on behalf of a covered entity pursuant to §§ 164.502(e) and 164.504(e), and the only remuneration provided is by the covered entity to the business associate for the performance of such activities;

(F) To an individual, when requested under § 164.524 or § 164.528; and

(G) Required by law as permitted under § 164.512(a).

Under an approach using this definition, HHS then does not need the general cost-based exception it created as (H), because otherwise lawful disclosures would not be excluded from the definition of “sale of PHI” if the remuneration from or on behalf of the recipient was “in exchange for the PHI.” In our view, **HHS should clarify that fee for service arrangements, such as compensation for managing clinical trial participation, analyzing data, payment for the costs associated with operating tissue banks and repositories, and the fees associated with IRB review should not be regarded as remuneration in exchange for PHI.** These are bona fide costs of research whose payment does not pose additional risk to the privacy of research participants. The modifications to the HIPAA regulation under HITECH should not be implemented in a way that undermines the research infrastructure.

Once the definition is established, the authorization requirement could then be set forth in § 164.508(a)(4):

Authorization required: Sale of protected health information. (i) A covered entity must obtain authorization in compliance with 45 CFR 164.508 for any sale of protected health information as defined in 45 CFR 164.501. (ii) Such an authorization must state that the disclosure will result in remuneration to the covered entity.

Thank you for the opportunity to comment on these proposed modifications of the HIPAA regulation, and for your efforts to ensure that the privacy of research participants is protected without imposing additional impediments and burdens on the conduct of research that are not helpful for protecting privacy in research settings.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Kean", with a long horizontal flourish extending to the right.

Tom Kean, MPH
Executive Director