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November 11, 2011

The Honorable Kathleen Sebelius  
Secretary  
U.S. Department of Health and Human Services  
Washington, DC 20201

Donald M. Berwick, MD, MPP  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Baltimore, MD 21244

Thomas R. Frieden, MD, MPH  
Director  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
Atlanta, GA 30329

Leon Rodriguez  
Director  
Office of Civil Rights  
U.S. Department of Health and Human Services  
Washington, DC 20201

Dear Secretary Sebelius, Administrator Berwick, and Directors Frieden and Rodriguez:

HIMSS appreciates this opportunity to comment on the [proposed NPRM on CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports](#) published in the *Federal Register* [CMS-2319-P] by the Department of Health and Human Services (HHS) on September 14, 2011 regarding proposed changes in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA).

HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 50 years ago, HIMSS and its related organizations have offices in Chicago, Washington, DC, Brussels, Singapore, Leipzig, and other locations across the United States. HIMSS represents more than 40,000 individual members, of which two-thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 500 corporate members and more than 150 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote

information and management systems contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

The NPRM specifically requests comments around the following:

- The ability of laboratories to provide electronic copies of protected health information in machine readable formats;
- The potential impact of this rule on Certificate of Waiver and Certificate of PPM laboratories;
- The burdens associated with providing formats as requested by individuals, machine readable or otherwise;
- More information is requested on the number of laboratories that are not HIPAA-covered entities and the estimated amount of patient requests that a laboratory might receive; and
- More information is requested from laboratories that do provide direct access to how they provide this (i.e. web, fax, hard copies and fees).

In reviewing the government's questions and request for public comment, several key areas emerged as considerations for the government to take into account when considering the impacts of this proposed rule on laboratories. These include:

- Potential laboratory workflow process and cost impacts, particularly given the varying degrees of change required by laboratories that actively receive or transmit data electronically, and those that have not started;
- Patient identification and authentication requirements; and
- Alignment between the emerging HIPAA requirements for labs and the ones proposed in this rule.

### **Laboratory Process and Cost Impacts**

The NPRM provides an analysis of the estimated costs to laboratories for implementing direct patient reports, including the impacts on each state according to existing state law pertaining to the release of information directly to patients versus to providers. The NPRM also proposes to allow labs to levy fees for supplying patients with certain forms of electronic media—i.e., CD or portable memory devices. The proposed rule requested clarification on the analyses it provided, as well as clarity on costs it derived, and those that may be unknown for anticipated cost impacts. HIMSS suggests that costs for the healthcare system need to be considered, particularly in the following areas:

- 1) **Laboratory Readiness and Customer Service:** Customer service functions and associated training requirements that are not currently handled by the laboratories may be necessary, despite the fact that patient interaction may be better handled by the patient's care team.
- 2) **Laboratory Fees:** The NPRM permits laboratories to impose fees on patients who request certain forms of electronic media. However, this presumes that laboratories have the capacity to fulfill those requests. Given the wide array of transferrable electronic

media, patient portals, and personal health records that exist, fulfilling such requests has the potential to be a time-intensive and costly endeavor.

- 3) **Appropriate Staffing:** In addition to customer service staff, laboratories may need to employ personnel with a health information management (HIM) background. These professionals possess an understanding of the requirements for information release, proper authorization, verification, accounting for disclosures, and pertinent federal and state law.
- 4) **Laboratory Interface Capabilities:** There are significant development cost and time cost components associated with the release of information, as well as the development of necessary interfaces between the laboratory and other systems, and the elements associated to each. Changes within laboratory systems interface can alter the designated record set, which affects other systems.

For example, labs with electronic transmittal capabilities can receive electronic orders from a hospital's EHR system and also send information to other EHR systems – often with interfaces connecting the systems. When new fields are added to laboratory systems that address the transactions outlined in the NPRM, both the EHRs and the interface will have to build these new fields and accommodate the passage of this new data. Added work on the interface can entail a significant expense, increasing the cost impact on laboratories. Finally, the release of information involving third parties can impact cost and workforce requirements.

### **Patient Identification and Authentication**

Critical to the release of information to a patient is verification of that patient/user as the individual she claims to be. The individual must also be authorized to receive the information. Therefore, it is reasonable and necessary for steps to be taken to ensure release only to the patient or authorized representative. HIMSS supports efforts to achieve uniformity among the States and federal government on patient identification and authentication, and information protection. The NPRM does not appear to clarify what level of assurance is required for patient identification. HIMSS requests that the government provide guidance to assist laboratories in deciding the appropriate assurance levels, as defined in NIST Special Publications 800-63, to effectively counter identified risks.

In an effort to address a cumulative solution to patient identity integrity, HIMSS has joined with nine other organizations to establish the Coalition for an Informed Patient Identity Integrity Solution. The coalition is focused on advancing the issue of a consistent patient-data matching strategy to realize the full benefits of health information technology. Legislative language in ongoing Labor HHS Appropriations states that HHS cannot... “promulgate or adopt any final standard,” until HHS reports to Congress on how any proposed solution will protect patient privacy and security. HIMSS recommends that HHS should begin an informed study to examine the necessity, advantages, and cost/benefit of implementing a consistent patient-data matching strategy. Such a study could result in the necessary collective solution.

## Alignment of Federal Requirements

Finally, HIMSS urges the government to align federal privacy rules between the emerging HIPAA requirements for labs and those proposed in this rule. The emerging requirements for labs to electronically provide information, as mandated by the HITECH Act, will come into effect after the NPRM's effective date. This may mean additional impacts on laboratories that must first meet requirements under these proposed rule changes, and then must change to meet the HITECH-required changes to HIPAA, as well as changes expected in Meaningful Use Stage 2. Additionally, HIMSS requests that guidelines for release be aligned throughout HHS. Release guidelines should be consistent for time, type, and media use. HIMSS members support consistent guidelines across providers (and HIEs) including labs to ultimately achieve EHR adoption goals set forth by the Secretary.

HIMSS appreciates the opportunity to provide comments to the government on this issue as we continue our commitment to improving patient care through the use of information technology. We look forward to continued dialogue and communication as we work toward a connected and robust health care delivery system. If you have any additional questions please contact [Thomas M. Leary](#), Senior Director, Federal Affairs, 703.562.8814 or [Stephanie Jamison](#), Director, Government Services, 804.922.3066.

Sincerely,



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President/CEO  
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