Consumer Partnership for eHealth

November 14, 2011

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
Attention: CMS–2319–P
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports

Dear Secretary Sebelius:

The undersigned consumer organizations are members of the Consumer Partnership for eHealth (CPeH). The CPeH is a coalition of consumer, patient and labor organizations working on both the national and local levels that, since 2005, has advocated for patient-centered policies related to health IT. We are dedicated to changing the way health care is organized, financed and delivered by using information more effectively.

We appreciate the opportunity to voice our strong support for the Proposed Rule "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports."[1] The current HIPAA Privacy Rule grants individuals the right of access to their personal health information, yet exceptions limit one's ability to obtain laboratory results directly upon request. CPeH applauds the NPRM's proposal to remove the Privacy Rule individual access exception for Clinical Laboratory Improvement Amendments (CLIA)-covered entities, and to clarify that federal regulation will pre-empt contrary state law and thus fill a void in state law regarding direct patient access to lab results.

The NPRM brings an appropriate alignment of regulations to support patients' access to their health data, an essential component of health reform and solid step toward meeting the goals of the National Quality Strategy. Further, it signals the Department's broader commitment to promoting individual access to and use of health information, which we encourage and applaud.

Patient Engagement

The proposed amendments would further the ability of patients to become true partners in their health care decisions, promote the transparency our health care system needs, and ultimately help us use our health care dollars more wisely. By allowing patients to have

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[1] 76 Fed. Reg. 56712-56724 (September 14, 2011).

direct access to their laboratory test results if and when they want such access, the NPRM would allow for greater individual choice and engagement in managing their own health. This empowerment is essential to improve the quality, safety and efficiency of our health care system, as it adds an additional, highly-invested, member to the care team: the patient him or herself.

Upon receipt of their results, if individuals decide they want additional information from or consultation with their physician, they may pursue it. The NPRM in no way compels direct access, nor does it eliminate the traditional avenue for receipt of labs through one's doctor. This proposed rule simply provides an additional path for the transmission of information to patients, thereby giving them the option and opportunity to be more active and engaged partners in their own health and care if they so choose.

Potential for Quality and Safety Improvement

The NPRM also has the potential to increase health care quality and safety, as well as promote efficiency. In the current care environment doctors – especially primary care physicians – can be overworked and often understaffed. When the only avenue for patients to obtain their lab results is for a lab to send them to a physician's office, which then must interpret the results and set up a call or appointment with a patient, it can unfortunately be that results get delayed or worse. In fact, recent studies cite that between seven and 20 percent of lab results do not make it to the patient.[2]

In the event that results are lost entirely, repeat tests are likely to be required. Reducing the potential for delays, errors and duplicate tests will drive improved care quality, lessen the potential for negative health consequences of a lost or delayed result, and increase efficiency of the system more broadly. Direct access to health information further allows patients, as well as their caregivers, to become partners in all aspects of these improvements.

Accompanying Education and Context

In response to the Department's request for comments regarding best practices in the direct provision of patients' laboratory results, we note that although we firmly believe patients should have the legal right to direct access to *all* of their health information, *ideally* lab results would include accompanying metadata, as is already available, to attach linguistically- and culturally-appropriate, patient-specific educational materials – available in common languages other than English, if the patient wishes – to help interpret and explain the results to patients. These materials should be neutral explanatory materials, limited to the tests and test results themselves, and should not include, for example, marketing materials. This metadata could also be used for patients to link, easily and electronically, to emerging consumer-based applications, as well as communities of support. We urge HHS to explore these ideas and their implementation further.

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[2] *See, e.g.*, Casalino, L. et al, "Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results," *Archives of Internal Medicine* (June 2009), *available at:* http://archinte.ama-assn.org/cgi/content/full/169/12/1123; Gandhi, T. et al, "Missed and Delayed Diagnoses in the Ambulatory Setting:A Study of Closed Malpractice Claims," *Annals of Internal Medicine* (Oct. 2006).

Absence of this information, however, is no reason to deny individuals their fundamental right to their own health data, and we are deeply uncomfortable with what can feel like a paternalistic notion that all patients are or will be unable to understand their health data without physician explanation. Furthermore, although patients would no longer have to go to health care providers to receive their test results, this does not mean providers are cut out of the conversation. Ordering providers will themselves continue to receive their own copies of test results and should retain responsibility for reporting and explaining them, and for providing context to their patients.

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We applaud HHS' commitment to expand and promote patients' access to their own health information, thereby furthering patients' engagement in their care decisions. We appreciate the opportunity to comment and look forward to the Final Rule.

Sincerely,

AARP
American Association on Health and Disability
American Hospice Foundation
Caring from a Distance
Center for Democracy and Technology
Center for Medical Consumers
Childbirth Connection
Consumer Consortium Advancing Person-Centered Living
Consumers Union
Healthwise
Mothers Against Medical Error
National Consumers League
National Family Caregivers Association
National Health Law Program
National Partnership for Women & Families
The Children's Partnership