

A Consensus Letter
to the HHS Office of Civil Rights and the Centers for Medicare and Medicaid Services
on the Need to Finalize the Proposed Rule to
Expand the Rights of Patients to Access their Test Results

October 18, 2012

The Honorable Kathleen Sebelius
Secretary
United States Department of Health and Human Services

William V. Corr
Deputy Secretary, Department of Health and Human Services

Leon Rodriguez
Director, Office of Civil Rights

Marilyn Tavenner
Administrator, Centers for Medicare and Medicaid Services

Thomas R. Frieden
Director, Centers for Disease Control and Prevention

cc: Todd Park, United States Chief Technology Officer
Farzad Mostashari, National Coordinator for Health Information Technology
Joy Pritts, Chief Privacy Officer, Office of the National Coordinator for Health
Information Technology
Bryan Sivak, Chief Technology Officer, Department of Health and Human Services

*Re: Support for the 2011 Proposed Rulemaking on the CLIA Program and HIPAA Privacy
Rule; Patients' Access to Test Reports, RIN 0938-AQ38*

Dear Secretary Sebelius, Director Rodriguez, Administrator Tavenner, and Director Frieden:

On September 14, 2011, your agencies put forward a proposed rulemaking, RIN 0938-AQ38, which would expand patients' right to access their health records by giving them the right to receive their test results directly from laboratories. **We are writing to voice our whole-hearted support for that proposed rule** and to encourage you to do all in your power to finalize it promptly, so that the current obstacles patients face in gaining access to their test results are removed as soon as possible.

Background. The 2003 HIPAA Privacy Rule gave individuals the crucial right to access their protected health information. The 2009 HITECH Act modernized and broadened patient access rights further by allowing individuals to obtain copies of their records in electronic format. **Unfortunately, however, these access rights have proved illusory when it comes to laboratory test results.** The reason is that the Privacy Rule created an exception¹ from access

¹ 45 CFR § 164.524(a)(iii)(A) (2011).

rights for protected health information maintained by a covered entity subject to the Clinical Laboratory Improvements Amendments of 1988 (CLIA). In addition, regulations issued by the Centers for Medicare and Medicaid Services (CMS) permit test results to be released only to authorized persons and the individual responsible for using the test results. “Authorized persons” is defined as “an individual authorized *under State law* to order tests or receive tests, or both [*emphasis added*].”²

Because only a few states expressly authorize labs to release test results directly to patients, this regulatory framework prevents patients in all but a few states from having direct access to copies of their test results. The combination of the HIPAA Privacy Rule, the CMS CLIA rule, and state laws thus puts test results in a uniquely restricted category compared to other health information, which greatly impairs patients’ ability to see, save, use, and share their own test results.

The Department’s Proposed Rule. Your proposed Rule would break through this regulatory barricade and grant individuals the right to receive their test results directly from laboratories in all 50 states. The proposed Rule would accomplish this by (a) specifying that, upon patient request, laboratories may provide access to completed test results that, using the lab’s authentication process, can be identified as belonging to that patient,³ and (b) removing the exceptions for CLIA-certified and CLIA-exempt labs from the HIPAA right of access to one’s protected health information.⁴

Your proposed Rule explained that, according to the Health Information Technology Policy Committee, many stakeholders, including some laboratories, public health authorities, electronic health record vendors, health policy experts, health information exchanges, and providers, perceive that these CLIA barriers impede patient access to their records and prevent patients from taking a more active role in their personal health care decisions. You also explained that providing direct patient access to lab results would support our national commitments and goals regarding the widespread adoption of EHRs, robust health information exchange, and greater patient engagement in healthcare.

Our position. We fully support the proposed Rule. Our reasons include:

- First and foremost, granting patients direct and timely access to test results will improve clinical care and patient outcomes. Patients can respond faster and more appropriately when they learn their test results quickly. For example, it is not unusual that the appropriate response to a particular lab result is to make an appointment with a relevant specialist or take other actions. But difficulties in reaching the ordering doctor may unnecessarily delay appropriate next steps, as well as create unnecessary stress during the “phone tag” period.
- Even worse, some patients are being harmed by *never* learning of their lab results. Approximately 7% of clinically significant test results – tests that would have a potential impact on clinical care – are *never* reported to patients, potentially delaying

² 42 CFR § 493.2 (2011).

³ 42 CFR § 493.1291 (2011).

⁴ 45 CFR § 164.524 (2011).

or preventing important treatment decisions and causing harm.⁵ Giving patients direct access to their results would help reduce the number of test results lost entirely.

- We do not think that patients' direct receipt of their own lab results will cause them to suffer undue emotional harm, particularly since a provider can communicate promptly to provide context and interpretation. Some health systems have, in fact, found the opposite to be true; Kaiser Permanente has shown that delivering lab results online directly to patients in a timely fashion improves provider/patient relationships.⁶ In fact, even the availability of clinical notes written by one's physician has been recently shown to have minimal negative effects and significant positive outcomes. The results from three different health systems showed that patients accessed notes frequently, a large majority reported clinically relevant benefits and minimal concerns, and doctors reported a negligible increase in workload. No doctors elected to stop sharing their notes with patients and 99% of patients wanted the practice to continue.⁷
- A common reason for requesting one's lab results is often, somewhat ironically, so that they can be handed directly to a specialist or a new provider, especially when the circumstances are urgent. *Patients can only deliver what they possess.* If patients routinely access and save their lab results, they'll be available quickly in emergencies. As stated recently by Lygeia Ricciardi, acting director of the Office of the National Coordinator's Office of Consumer eHealth, "We want people to think about being empowered with information before that crisis hits."⁸
- The clinical consequences of timely, direct access to one's health information are significant. Todd Park, the federal Chief Technology Officer, recently explained, "When patients have timely access to their records, they can spot errors and omissions, which improves treatment outcomes and helps them avoid unnecessary procedures. Getting access to your own data isn't an abstract thing. It can literally make the difference between life and death."⁹
- The proposed Rule would help save money for our overburdened health care system. When patients cannot easily obtain and save copies of lab results and procedures, and thus cannot quickly share them with other providers, expensive tests and procedures often must be unnecessarily repeated.

⁵ Casalino LP, Dunham D, Chin MH, et al. Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results. *Arch Intern Med.* 2009;169(12):1123-1129.

⁶ Silvestre, A, Sue, V, and Allen, J, *Electronic Health Records: If You Build It, Will They Come? The Kaiser Permanente Model Of Online Health Care*, Health Affairs, March/April 2009 28:2334-344; doi:10.1377/hlthaff.2

⁷ Delbanco, Tom MD, *Inviting Patients to Read Their Doctors' Notes: A Quasi-experimental Study and a Look Ahead*, Annals of Internal Medicine, Oct. 2, 2012, <http://annals.org/article.aspx?articleid=1363511>.

⁸ Sarasohn-Kahn, Jane, *Health IT Promotion Goes Direct-to-Consumer*, iHealthBeat, Sept. 11, 2012, <http://www.ihealthbeat.org/perspectives/2012/health-it-promotion-goes-directtoconsumer.aspx>.

⁹ Burns, Ed, *ONC looks to make Blue Button public, boost patient engagement*, SearchHealthIT.com, Sept. 12, 2012, <http://searchhealthit.techtarget.com/news/2240163116/ONC-looks-to-make-Blue-Button-public-boost-patient-engagement>

- Currently, an exciting development we are seeing in the technology space today is the plethora of consumer-engaging, patient-empowering apps that provide actionable information consumers can use to improve their health. Much of this tech activity has been spurred by our national investment in HIT and EHRs. However, the success of many of these creative solutions hinges on patients having meaningful, practical access to their health data. Keeping crucial lab results excluded from the information patients can access not only hurts them directly, but also will hurt them indirectly by impeding the development of useful tools that could enable them to manage their health more effectively.
- Finally, as your proposed Rule pointed out, allowing direct access to lab results is entirely consistent with our national emphasis on the importance of patients being more engaged in managing their health. This priority, which has been consistently pursued through HITECH, Meaningful Use incentives, Medicare improvements, veterans' health programs, and other national initiatives, is crucial. Your proposed Rule would fill a gaping hole in patients' ability to access, appropriately respond to, save, and share their health information.

Thank you for issuing this proposed Rule and for considering our comments. We urge you to finalize it quickly. Further delays will not only continue to frustrate and harm patients but also are inimical to our national commitment to patient engagement and a more efficient and effective health system.

Please let us know if we can be of assistance as you move forward.

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