



David C. Harlow

Chair, Public Policy Committee

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SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201
Attn: CMS-2319-P

Re: Medicare, Medicaid, and CLIA Programs; Patient Access to Laboratory Test Reports (CMS-2319-P)

To whom it may concern:

*On behalf of the Society for Participatory Medicine, I am writing to offer our **support** for the proposed revisions to the HIPAA and CLIA regulations that would provide patient access to lab results directly from laboratories upon request, bringing patient access to lab results in line with access to other health records under HIPAA.*

*The Society for Participatory Medicine has individual and institutional members nationwide comprising patients, non-professional caregivers, and clinicians. It was founded to study and promote participatory medicine, which is centered around networked patients shifting from being mere passengers to responsible drivers of their health, and providers who encourage and value them as full partners. For further background on the Society and its tenets, we invite you to peruse the Society's website (<http://participatorymedicine.org>), its online journal, *The Journal of Participatory Medicine* (<http://jopm.org>) and its blog, *e-patients.net* (<http://e-patients.net>).*

*In our view, patient access should not be delayed until after test results are provided to clinicians. According to a paper published in the *Archives of Internal Medicine* (see *Arch Intern Med – Abstract: Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results*, June 22, 2009, Casalino et al. 169 (12): 1123 -<http://bit.ly/pY2wDv>), a review of over 5000 patient*

records at 23 primary care clinics found that physician practices failed to inform patients of abnormal test results about 7% of the time. Thus, it is unreasonable to require patients to wait; instead, patients should be permitted to have access to their own records, including lab results, and to inquire of their clinicians should they have questions about the test results. If clinicians are concerned about patients' abilities to understand the results, then they should arrange for explanations to be included with each test result.

There is opposition to the proposed rule by some providers, who express a concern that a patient who receives lab results directly may well (a) misintepret a value that is "normal" for the population at large but that might not be "normal" for her and/or (b) fail to communicate with the clinician who ordered the test. In our fee-for-service world, some cynics may say that some clinicians are being inappropriately incentivized to seek another billable patient encounter for discussion of results. In the future of bundled, episodic, prospective payment systems, this would not be a concern. In fact, since we will be asking the entire health care system to be doing more with less as a result of the nation's fiscal and political environments, frictionless sharing of information should be welcomed by providers. Providers will continue to receive lab results, and will continue to be expected to discuss them with their patients.

Patient-centeredness and patient engagement, key elements of the health reform law, cannot be achieved unless patients are seen as partners in their own care by clinicians. Patients cannot be effective partners in their own care without full access to their medical records, including all lab results. Through historical accident, some lab test results are already accessible to patients under HIPAA, while others are not. The proposed regulations would eliminate this discrepancy, and should be finalized as soon as possible. Since some lab results are already accessible to patients under applicable state and federal laws and regulations, the logistics of enabling access have already been tackled, and may be extended to this new group of lab results without undue delay.

Thank you for your consideration.

Sincerely,



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