Secretary Sebelius spotlights new efforts to empower patients to increase secure access to their health information

New Office of Civil Rights Director joins HHS from Department of Justice

HHS Secretary Kathleen Sebelius today proposed new rules that would expand the rights of patients to access their health information through the use of health information technology (IT). Specifically, the new rules would empower patients and allow them to gain access to test results reports directly from labs. They would ensure that labs covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provide such information, upon request, directly to patients or their personal representatives. The announcement came at the kick-off of the first-ever HHS Consumer Health IT Summit, which brought consumers, providers, and the public and private sectors together to discuss how best to empower consumers to be partners in their health and care through health IT.

"When it comes to health care, information is power. When patients have their lab results, they are more likely to ask the right questions, make better decisions and receive better care," said Secretary Sebelius. "This Summit offers a unique opportunity for the public and private sectors alike to share strategies to improve consumer access to their health information, while safeguarding the privacy and security of their data."

The Notice of Proposed Rulemaking (NPRM), jointly drafted by the Centers for Medicare & Medicaid Services, the HHS Office for Civil Rights (OCR), and the Centers for Disease Control and Prevention, proposes to amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations and HIPAA privacy regulations to strengthen patients' rights to access their own laboratory test result reports.

Secretary Sebelius also announced the appointment of Leon Rodriguez as the new Director of the Office for Civil Rights. Rodriguez brings his Department of Justice experience to HHS and will be dedicated to ensuring consumers' health information is kept private and secure.

"Consumers need to know that private and secure access to their health information is a given," stated OCR Director Rodriguez. "The privacy and security of health data will be a top priority for OCR during my tenure."

Secretary Sebelius also unveiled today an innovative voluntary Personal Health Record (PHR) Model Privacy Notice, which creates an easy-to-read, standardized template allowing consumers to compare and make informed decisions based on their privacy and security policies and data practices about PHR products. The new template is similar to the Nutrition Facts Labels in that it presents certain complex information in a simple way to improve transparency and consumer understanding about data practices. By making this Model Privacy Notice available, PHR companies can help build greater trust in PHRs.

Today's Summit included more than 25 health care stakeholder organizations, representing consumers, large and small practice providers as well as insurers and health IT industry leaders, that

have pledged to empower consumers by making it easier for them to get secure access to their health information to engage more fully in their health.

"As technology improves more aspects of our daily lives, it makes sense to marry cutting-edge technology with our medical and personal health records so that we can improve both the quality and efficiency of the care that people receive," said National Coordinator for Health Information Technology, Farzad Mostashari, M.D., Sc.M. "We are encouraging everyone to visit our website at www.HealthIT.gov to read our newly released Strategic Plan that sets forth our comprehensive plans for consumer empowerment for the next five years."

The Summit highlighted vital benefits of electronic health records and health IT, including:

- *Health IT empowers patients*. For example, people at risk for heart attacks may use mobile health applications to manage their weight, diet, and medication adherence.
- *Health IT can facilitate lasting quality improvements*, which can lead to greater efficiency and cost savings in the long-term.
- *Health IT is driving innovation* in all parts of consumers' lives – from new interactive applications to devices like digital pedometers and other devices that capture important health information from everyday experiences.
- *Health IT helps coordinate better care*, and can be a powerful tool if you or a loved one is managing a serious medical condition.
- *Health IT has robust security* and all users, from patients to caregivers to doctors, can easily and safely access and share health information electronically.
- *Health IT may help diagnose health problems sooner*, avoid medical errors and provide safer care which can result in lower costs.

"We are at a critical moment in time when we can either choose to innovate, or lag behind in care," said Dr. Mostashari. "A commitment by health care stakeholders to support health IT and provide greater consumer access to their health information is the first step toward a healthier future."

In the coming year, ONC will work with health care stakeholders to further consumer access to information and empower consumers to become active participants in their health. The new website, www.HealthIT.gov creates dedicated consumer-oriented information that describes the benefits of health IT, provides consumer health education materials and will be a valuable resource for learning about new advances in health IT.

For more information about the proposed amendments to the CLIA and HIPAA Privacy regulations, please visit https://www.cms.gov/apps/media/fact_sheets.asp.

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HHS proposes broad patient rights to access clinical laboratory test result reports

Overview: As part of an ongoing effort across the Department of Health and Human Services (HHS) to empower patients to be informed partners with their health care providers in making health care decisions, HHS today proposed rules that would give patients (and their authorized representatives) direct access to their own laboratory test result reports.

The proposed rule is being jointly issued by three agencies within HHS - the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC), which are responsible for laboratory regulation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and the Office for Civil Rights (OCR), which is responsible for administering the Privacy Rule that was issued under the Health Insurance Portability and Accountability Act of 1986 (HIPAA). The proposed rules are also consistent with a proposed regulation under the HITECH Act that would bolster patients' rights to access their information stored in electronic health records and that would help ease the transition to nationwide adoption of electronic health records.

Background: The proposed rules address the interplay between the CLIA rules, state laws governing direct disclosure to patients of their laboratory test results, and the Federal Privacy Rule, which currently defers to CLIA's disclosure provisions and which preempts contrary State laws on privacy and disclosure of personal health information. Under existing CLIA regulations, a laboratory may release patient test results directly to the patient only if (1) the ordering provider expressly authorizes the laboratory to do so at the time the test is ordered, or (2) state law expressly allows for it.

The current Privacy Rule generally requires certain health care providers such as most clinical laboratories to give individuals access to their health information on request. However, the Privacy Rule's access requirements, deferring to the CLIA rules, include an exception for direct access by patients to their laboratory test result reports. Thus in 26 states without laws authorizing direct disclosure of test results to patients and 13 states that expressly prohibit it, patients do not have access to their complete medical information.

Provisions of the Proposed Rule: The proposed rule would amend the CLIA regulations to allow laboratories to give a patient his/her individual test result reports on request. At the same time, the proposed rule would eliminate the Privacy Rule's exception for an individual's access to laboratory test result reports. The amended Privacy Rule would, in turn, preempt contrary state laws governing a patient's direct access to lab result reports.

The proposed rule can be downloaded from the *Federal Register* Inspection Desk at www.ofr.gov/inspection.aspx. Comments will be accepted for 60 days, and a final rule, responding to comments will be published later this year.

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