News Release

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Health IT workgroup to discuss patient safety, innovation, and regulatory efficiency

Members of a n ew workgroup that will focus on identifying key considerations to improve patient safety and promote innovation in health information technology (Health IT), including mobile medical applications, have been selected by the U.S. Department of Health and Human Services (HHS) and Federal Communications Commission (FCC). The workgroup will report to the Health IT Policy Commitee which advises the Office of the National Coordinator for Health IT (ONC).

The workgroup will hold its first meeting April 29, 2013. The workgroup' s membership includes agency officials and experts representing patients, consumers, health care providers, startup companies, and health plans or other third-party payers. The workgroup also includes venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders.

"Patients already benefit from innovative information technology tools such as electronic health records that allow their providers to improve coordination and delivery of care," HHS Secretary Kathleen Sebelius said. "This workgroup will help the Health IT Policy Committee consider new ways to navigate this rapidly growing industry while promoting innovation and protecting patient safety."

"New technologies can revolutionize health care, helping to improve patient outcomes, while expanding access, creating convenience and lowering health care costs for millions of Americans," said FCC Chairman Julius Genachowski. "We anticipate that this talented group of leaders from their respective fields of discipline will help to bring fresh ideas to the table with an eye towards ensuring patient safety."

The Food and Drug Administration Safety and Innovation Act (FDASIA) directed the HHS Secretary, acting through the Commissioner of the U.S. Food and Drug Administration (FDA), and in consultation with ONC and the Chairman of the FCC, to develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT, including medical mobile applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. The FDA, FCC, and the HHS Office of the National Coordinator for Health IT (ONC) will review and consider the recommendations provided by the Health IT Policy Committee, based on input from the workgroup, as the three agencies write the report.

The workgroup meetings will provide opportunities for the public to comment. Documents discussed by the workgroup will be available, as available, at http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/fdasia.

The FDASIA Workgroup members include the following people:

- David Bates, Brigham and Women's Hospital, Chair
- Patricia Brennan, University of Wisconsin-Madison
- Geoff Clapp, Better
- Todd Cooper, Breakthrough Solutions Foundry Inc.
- Meghan Dierks, Harvard Medical Faculty, Division of Clinical Informatics
- Esther Dyson, EDventure Holdings
- Richard Eaton, Medical Imaging & Technology Alliance
- Anura Fernando, Underwriters Laboratories
- Lauren Fifield, Practice Fusion Inc.
- Michael Flis, Roche Diagnostics
- Elisabeth George, Philips Healthcare
- Julian Goldman, Massachusetts General Hospital/ Partners Healthcare
- T. Drew Hickerson, Happtique Inc.

- Jeffrey Jacques, Aetna
- Robert Jarrin, Qualcomm Incorporated
- Mo Kaushal, Aberdare Ventures/National Venture Capital Association
- Keith Larsen, Intermountain Health
- Mary Anne Leach, Children's Hospital Colorado
- Meg Marshall, Cerner Corporation
- Mary Mastenbrook, Consumer
- Jackie McCarthy, CTIA - The Wireless Association
- Anna McCollister-Slipp, Galileo Analytics
- Jonathan Potter, Application Developers Alliance
- Jared Quoyeser, Intel Corporation
- Martin Sepulveda, IBM
- Joseph Smith, West Health
- Michael Swiernik, MobileHealthRx Inc.
- Paul Tang, Palo Alto Medical Foundation
- Bradley Thompson, Epstein Becker Green P.C.

Three Federal representatives, one from ONC, FDA, and FCC, will serve as Ex Officio/non-voting members of the workgroup and will provide subject matter expertise regarding the authority and current policies implemented by each agency.

- Jodi Daniel, ONC
- Bakul Patel, FDA
- Matthew Quinn, FCC

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