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Congress of the United States

U.S. House of Representatives

Committee on Small Business

2361 Rayburn House Office Building
Washington, DC 20515-6315

June 12, 2012

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201
Via Facsimile: 202.690.7450

Re: Institute of Medicine's Health Information Technology Report

Dear Secretary Sebelius:

The House Small Business Committee, on which I serve, is required by the Rules of the House to study and investigate the problems of all types of small businesses. This jurisdiction extends to matters concerning small businesses and health care. I chair the Committee's Subcommittee on Healthcare and Technology.

On November 8, 2011, the Institute of Medicine (IOM) issued a report (report) calling for greater public and private oversight of health information technology ("health IT").[1] In its report, IOM said evidence in the medical literature about the impact of health IT on patient safety is mixed, and little published evidence has been found to quantify the magnitude of the risk.[2] In fact, the report noted, the increasing use of health IT creates an "urgent need" for the development of a research agenda for the technology.[3]

For a number of reasons, improvements in patient safety have been slow.[4] Gail Warden, president emeritus of the Henry Ford Health System and chair of the committee that wrote the report,

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[1] INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES, HEALTH IT AND PATIENT SAFETY: BUILDING SAFER SYSTEMS FOR BETTER CARE (2011) [hereinafter IOM Report] *available at* http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building Safer-Systems-for-Better-Care.aspx.

[2] *Id.* at 3.

[3] *Id.* at 6.

[4] Jennifer S. Myers, M.D. and Richard P. Shannon, M.D., *Chasing High Performance: Best Business Practices for Using Health Information Technology to Advance Patient Safety*, AM. J. OF MANAGED CARE 1 (2012), *available at* http://www.ncbi.nlm.nih.gov/pubmed/22554037. *See also* J.L. Schnipper, C. Hamann, C. Ndumele, *Effect of Electronic Medication and Reconciliation Application and Process Redesign on Potential Adverse Drug Events: A Cluster Randomized Study*, ARCH. INTERN. MED. 771 (2009).

said, "safer systems require efforts to be made by all stakeholders" and "the public sector must also be part of the solution."[5]

On June 2, 2011, the Small Business Subcommittee on Healthcare and Technology held a hearing on the barriers to health IT that are encountered by physicians and other health professionals in small and solo practices.[6] At the hearing, physicians expressed strong concerns about the cost to purchase and maintain health IT systems, as well as the staff training and downtime necessary to implement such a system.[7] Additional federal requirements that physicians adopt health IT and demonstrate its "meaningful use" are being implemented, as well as Medicare reimbursement penalties for those practices that fail to do so.[8] There is anecdotal evidence that some small and solo practice physicians may be giving up their practices or affiliating with larger practices and/or hospitals, in part because of health IT requirements.[9] At the same time, we continue to hear media reports of patient safety risks, some of which have allegedly resulted in serious patient injuries and even deaths.

The IOM report recommended that the Secretary of Health and Human Services (HHS) issue a plan within 12 months to minimize patient safety risks associated with health IT and report annually on the progress being made. The report further recommended that the plan should include a schedule for working with the private sector to assess the impact of health IT on patient safety, and recommended several other steps to help improve the safety of health IT.

Because I agree with the report that oversight, as well as transparency and accountability, are important to ensure patient safety as physicians adopt health IT, I am writing to request the following:

1. A copy of the Secretary's plan to minimize patient safety risks, and the associated schedule for working with the private sector, as recommended by the report. If such a plan and schedule have not yet been issued, please so indicate and note when they may be expected to be completed and provided.

2. The number, type, description, location and origin of any and all health IT-related errors involving medication dosing, failure to detect fatal illnesses and treatment delays due to human-computer interactions, loss of data or other events that have resulted in patient risks, injuries

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[5] IOM Report at x.

[6] *Not What the Doctor Ordered: Health IT Barriers for Small Medical Practices: Hearing Before the House Small Business Subcommittee on Healthcare and Technology,* 112th Congress (2011) [hereinafter Subcommittee hearing].

[7] Subcommittee hearing (statements of Sasha Kramer, M.D., and Denise Lea Elliott, D.P.M.) *available at* http://smbiz.house.gov/UploadedFiles/Kramer_Testimony.pdf and http://smbiz.house.gov/UploadedFiles/Elliot_Testimony.pdf.

[8] *See, e.g.*, Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314 (July 28, 2010) (codified at 42 C.F.R. pts. 412, 413, 422 and 495) *available at* http://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf; and Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2, 77 Fed. Reg. 13,698 (March 7, 2011) (codified at 42 C.F.R. pts. 412, 413 and 495) *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-03-07/pdf/2012-4443.pdf.

[9] AMERICAN ACADEMY OF FAMILY PHYSICIANS, THE FAMILY PHYSICIAN'S PRACTICE AFFILIATION GUIDE 2, 10 (2010); *see also* AMERICAN MEDICAL ASSOCIATION, AMED NEWS, EMR COURTSHIP: HOSPITALS WOOING DOCTORS TO STAY AFLOAT (AUGUST 23, 2010); and SMALL PRACTICES: ADAPTING TO SURVIVE (JUNE 27, 2011).

and deaths which have been reported to HHS and/or the Office of the National Coordinator for Health IT (ONC), and the causes of such adverse events, errors, failures and/or losses, if known.

3. The status of the development of a mechanism for health IT vendors and users to report health IT-related deaths, injuries and unsafe conditions, as recommended by the report, and a copy of the description or analyses of such a mechanism.

4. A copy of a list of the members of a health IT safety council funded by HHS to evaluate criteria and develop methods for assessing and monitoring safety and measuring the impact of health IT on safety, as recommended by the report, and a list of all of the council's meetings, agenda and/or reports.

5. A copy of the quality management principles and risk management processes for the design and implementation of health IT products as recommended by the report that have been developed by HHS, CMS, FDA and/or ONC.

6. Any internal HHS or FDA reports, analyses, investigations, memoranda or other documents outlining the authority, capability and advisability of FDA or another federal agency to regulate electronic health records and/or other health IT devices.

I would appreciate your providing these materials within 30 days of the date of this letter.

I share your commitment to our nation's health care system. Because health IT has the promise to improve health care delivery for patients, physicians and other medical professionals, I remain eager to work with you to ensure that health IT is safe, effective and affordable.

Sincerely,

Renee L. Ellmers
Chairwoman