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HEALTH INFORMATION TECHNOLOGIES: HOW INNOVATION BENEFITS PATIENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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HEALTH INFORMATION TECHNOLOGIES: HOW INNOVATION BENEFITS PATIENTS

WEDNESDAY, MARCH 20, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123 of the Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Present: Representatives Pitts, Burgess, Hall, Shimkus, Blackburn, Gingrey, Lance, Guthrie, Griffith, Bilirakis, Ellmers, Pallone, Green, Barrow, Christensen, Sarbanes, and Waxman (ex officio).

Staff present: Clay Alspach, Chief Counsel, Health; Matt Bravo, Professional Staff Member; Debbee Hancock, Press Secretary; Sydne Harwick, Staff Assistant; Sean Hayes, Counsel, Oversight and Investigations; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Legislative Clerk; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and the Economy; Heidi Stirrup, Health Policy Coordinator; Alli Corr, Democratic Policy Analyst; Eric Flamm, FDA Detailee; Amy Hall, Democratic Senior Professional Staff Member; Elizabeth Letter, Democratic Assistant Press Secretary; Karen Nelson, Democratic Deputy Committee Staff Director for Health; Rachel Sher, Democratic Senior Counsel; and Matt Siegler, Democratic Counsel.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. The subcommittee will come to order. The chair will recognize himself for an opening statement.

Today's hearing is part of a series of Energy and Commerce subcommittee hearings this week that focus on health, technology and innovation.

In the last few years, health information technologies, including mobile medical applications, electronic health records, personal health records, computerized health care provider order entry systems, and clinical decision support, have transformed the provision of health care in this country. Electronic health records hold great promise for the delivery of care given and the quality of care received in this country. They have also been identified as key components of future payment reforms such as those envisioned for medical providers under the SGR.

There are now mobile medical apps for wireless thermometers, apps that calculate body mass index, apps that track the number of miles a runner has jogged and those that can wirelessly transmit data to wearable insulin pumps. These apps can range from the complex, like mobile cardiac outpatient telemetry that uses wireless sensors, to those that allow users to count calories.

To give you a sense of the scope of their importance, it has been estimated that 500 million people will be using medical apps by the year 2015. Therefore, it goes without saying that these technologies hold great potential for patients and providers. However, with the proliferation of these technologies have come concerns about how their use may negatively impact patients. Some have argued that federal oversight of these health information technologies is important to safeguard patients from malfunctioning technology.

In response to these concerns, the Office of the National Coordinator in December of 2012 put out a proposal for a risk-based regulatory scheme for electronic health records that sought to address the needs of Americans both as consumers and patients. The Food and Drug Administration has also put forward a proposal, in the form of draft guidance issued in July 2011, indicating its intent to regulate certain apps as medical devices under section 201(h) of the Federal Food, Drug and Cosmetic Act.

While FDA's attention to the needs of patients is commendable, its action requires very close scrutiny. This subcommittee has examined in the past the negative impacts that FDA regulation, with its uncertainty, high costs, and long approval times, has had on the medical device industry. If we allow the same to happen in this space, such negative impacts could cripple a still evolving and promising industry, where the average developer is small and the cost of these apps is relatively inexpensive.

Some have also raised concern that the FDA may further expand the definition of "medical device" in the future to include other technologies, such as smartphones or tablets, and thus the medical device tax passed in the Patient Protection and Affordable Care Act could apply to them.

Therefore, this hearing is an appropriate place to examine the extent to which the FDA and other federal agencies should be involved in regulation of health information technologies and what such a regulatory framework might look like.

With these thoughts in mind, I want to thank our witnesses for being here today and look forward to their testimony.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

Today's hearing is part of a series of Energy and Commerce subcommittee hearings this week that focus on health, technology and innovation.

In the last few years, health information technologies, including mobile medical applications (apps), electronic health records, personal health records, computerized health care provider order entry systems, and clinical decision support, have transformed the provision of health care in this country.

Electronic Health Records hold great promise for the delivery of care given and quality of care received in this country. They have also been identified as key components of future payment reforms such as those envisioned for medical providers under the SGR.

There are now mobile medical apps for wireless thermometers; apps that calculate body mass index; apps that track the number of miles a runner has jogged and

those that can wirelessly transmit data to wearable insulin pumps. These apps can range from the complex, like mobile cardiac outpatient telemetry (MCOT) that uses wireless sensors, to those that allow users to count calories. To give you a sense of the scope of their importance, it has been estimated that 500 million people will be using medical apps by 2015.

Therefore, it goes without saying that these technologies hold great potential for patients and providers. However, with the proliferation of these technologies have come concerns about how their use may negatively impact patients. Some have argued that federal oversight of these health information technologies is important to safeguard patients from malfunctioning technology.

In response to these concerns, the Office of the National Coordinator in December 2012 put out a proposal for a risk-based regulatory scheme for electronic health records that sought to address the needs of Americans both as consumers and patients.

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Therefore, this hearing is an appropriate place to examine the extent to which the FDA—and other federal agencies—should be involved in regulation health information technologies and what such a regulatory framework might look like.

With these thoughts in mind, I want to thank our witnesses for being here today and look forward to their testimony.

Mr. PITTS. And no one is seeking recognition. I will close my statement and recognize the ranking member of the Subcommittee on Health, Mr. Pallone, for 5 minutes for his opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE JR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you. Thank you, Chairman Pitts.

Today is an important examination of the ways in which health information technologies can benefit patients, doctors, and the health care system as a whole. HIT is an absolutely essential underpinning to the future of delivery and payment reform.

The notion that if we can improve the coordination of care, patient safety, disease management, and prevention efforts, we can save money for the entire system. It is not baseless. In fact, it has the utmost merit. Modernizing our health care system and moving into an electronic era is part of a national conversation that is occurring, and politicians of both political parties, providers, and patients all agree that HIT holds tremendous promise for improving the performance of our healthcare system in a way that will increase access, enhance quality, and indeed lower costs.

That is why as chairman of this subcommittee, I worked alongside many of my colleagues, Democrat and Republican alike, and we passed the Health Information Technology for Economic and Clinical Health Act, otherwise known as HITECH or the HITECH Act. Together, we recognized with that bill that there was a need

for the Federal Government to commit to expanding the use of information technology in the health care sector, and that its widespread adoption would have significant long-term benefits. This critical law contained unprecedented funding to promote the adoption of health information technology among hospitals, doctors, and health care providers through initiatives by the Office of the National Coordinator of HHS and through Medicare and Medicaid incentives. This historic investment has begun to help modernize our Nation's use of technology to truly ensure a high-performing 21st century health system, and in building an infrastructure of fundamental change.

The truth is that we have made great progress so far, and there are even more opportunities that will be realized in the future through the implementation of this law. As a result of these programs, electronic health records, EHRs, and meaningful use of those records has increased dramatically in recent years, and we will hear today from some of the witnesses how it is working to make life better for patients and serving as a catalyst for innovation.

Now I am afraid that my Republican friends are going to spend this day making up false stories about how the Affordable Care Act and FDA regulation is stifling innovation—how our smartphones are going to be taxed and Apple's manufacturing plants will be inspected, but I have to say this is nonsense. The reality is the future of mobile health is very bright. In fact, there is an effort underway by the Federal Government to open up large sets of data to be used by developers to create these mobile applications, and many of these apps are designed to assist both individuals and health care providers in managing health care decisions and delivery. One industry analyst estimates that the total revenues of the mobile medical app market will grow to $26 billion by 2017, and because of the HITECH Act, this open data will be able to be networked and shared with providers to improve patient health and lower costs.

But I believe, and I think all of our witnesses today will agree with me, that if a technology developer is going to make health-based claims, then there must be a role for FDA to ensure it is safe and effective, and I hope that is what comes out of today's hearing is a better understanding of how the successful adoption of health information technology will have a transformative effect on the quality of health care in the United States, as well as the economy of health care.

So I thank you all, thank the chairman, and I would yield back the balance of my time.

Mr. PITTS. Chair thanks the gentleman, and now recognizes the vice chair of the subcommittee, Dr. Burgess, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for the recognition. I am grateful to the chairman for holding this hearing, grateful to our panel for presenting to us today.

The title of the hearing is fitting. As somebody who worked in health care, I recognize the benefit that innovation brings to pa-

tients. From the newest means to detect and diagnose conditions, to the cures and diseases that once were thought untreatable, innovation has led the way to bettering the lives of patients.

Health care innovation doesn't always lower costs, but it always holds the potential to improve the quality of life and therefore is a goal worth pursuing in and of itself.

The tools that future doctors will have at their disposal will be unparalleled in the history of medicine for their ability to alleviate human suffering and improve lives, but we need to get the tools in their hands. From custom biologics to nanotechnology to the promises of the human genome, we are on the cusp of a medical revolution. The President, in an Executive order, ordered federal agencies to review and remove outdated regulations. I absolutely agree with Mr. President, but the proof really remains to be seen.

The biggest impediment to innovation is the uncertainty of regulation. If the Federal Government thinks about regulating something, that almost always means it is planning to over-regulate. There is the difficultly, because the lifeblood of innovation, venture capital, will be drained away from the cures that might have been.

As a doctor, first do no harm. I don't want to do anything that will harm a patient. But while the FDA struggles with their core requirements that they propose to venture into new areas like mobile apps and research only products and health information technology, it really does require a soft touch. Instead of talking to stakeholders, including members of Congress, where updates may be needed from time to time, and significant proposed regulatory changes could stop innovation in their tracks, we are just not seeing it happen. Companies will build it, doctors will use it, patients will benefit if we could just get out of the way and ensure responsible regulation in a timely fashion.

The reason I care about this so much is because not just today, this is about the future. This is about the men and women that will follow after us in the practice of medicine. These are about the ideas that somebody hasn't even had yet. The lack of a reliable and consistent regulatory process signals an inability to handle the events for technology in the future.

Mr. Chairman, this hearing is timely. It is in conjunction with other hearings being done in other subcommittees and the full committee. Technology had a hearing yesterday. We will have a hearing in Oversight and Investigations tomorrow. But it is part of a process.

I would like now to yield the balance of the time available to the gentlelady from Tennessee, the vice chair of the full committee.

Mrs. BLACKBURN. I thank the gentleman for yielding, and welcome to each of you. We are delighted that you are here.

As Dr. Burgess said, we had a Telecom Subcommittee hearing yesterday, and looked at the impediments to innovation. It was fantastic to have a group of innovators sitting at your table and talking to us about the problems that they are seeing.

Now, one of my colleagues said that he feared we would spend our time making up stories about how HHS and FDA kind of get in the way, but we don't have to make them up. All we have to do is read the testimony from yesterday.

One of the things that came through regularly in their words was that the uncertainty that is there from the FDA, this big gray area in the center, that you don't know if you are going to be regulated as a medical device. If you don't know how far that arm of government is going to reach and how massive the overreach will be, or will it be contained and will there be some certainty?

Now, I don't think it is up to the FDA to provide that certainty. I think it is up to Congress to decide what FDA's role should be. We are seeking your thoughts and the panel yesterday and tomorrow to make certain that we approach this in the appropriate manner. What we want to be certain that we do is allow the environment for innovation to take place. As Dr. Burgess said, these are tools that today's doctors and future doctors are going to be able to use. I think 15 percent of apps are used by providers. That is something that will yield to cost savings. At the same time, patients are able to have a more active participation in their health care, from managing diseases and chronic conditions, by having access to an app that goes with them everywhere they go.

So we look forward to hearing from you to setting the right path forward, and we thank you for your time.

I yield back.

Mr. PITTS. Chair thanks the gentlelady, and now recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman.

Today is our second day of hearings on this subject. This is the week that this committee decided that in three of its subcommittees, we would hold hearings to scare people that they won't be able to develop what we want to see developed, innovative ways to communicate in the health space. The Energy and Commerce Committee has a history of bipartisan accomplishments, and even in this area, and that is one of the reasons, to me, why the partisan hyperbole we have heard from some on this topic is so disappointing.

Yesterday, the Telecommunications Subcommittee examined mobile medical applications and the FDA regulation of medical devices. Both sides of the aisle agree we must promote innovation in the dynamic mobile medical applications market. Both sides agree that it is essential for the FDA to ensure the safety and effectiveness of potentially dangerous medical devices, even if they are also connected to a mobile platform. But we spent far too much of yesterday's hearing debating an imaginary tax on smartphones, because in the Affordable Care Act, there is a tax on medical devices. So you have got two things to worry about. If you innovate, FDA might look at it and regulate it, and two, if it is a medical device, it may be taxed. Oh, you shouldn't sleep anymore at might worrying about these problems Republicans are dreaming up.

So they said FDA is going to regulate these iPhones, the same way it regulates heart valves. Well, that is a political talking point and it is just not real. I hope today we can focus on this commit-

tee's real bipartisan accomplishments in health information technology.

In the 111th Congress, the Congress before the last one, our committee passed what was called the Health Information Technology for Economic and Clinical Health Act as part of the Recovery Act. They called this the HITECH—that is the way we do it, so we got a new acronym. This law resulted in an explosion of electronic health records and other advanced health information technology—exactly what we wanted to see. Physicians, hospitals, pharmacies, health care providers across the country are building an infrastructure network as important to our Nation's future as the interstate highway system. It is just like the construction of the interstates. Building this infrastructure is challenging. Hundreds of thousands of physicians, tens of thousands of hospitals, clinics, pharmacies are going to connect to this network and HHS is—made a lot of progress by engaging a wide variety of stakeholders and driving coordination without mandating a "one size fits all" solution. So we are trying to develop the ability technologically to communicate, and it is an ambitious goal. A seamlessly connected health information infrastructure protects privacy while demanding the highest quality, most efficient care. We haven't reached that goal yet, but I believe we are on track to get there.

So given our enormous progress, it would be rash and unwise to turn back now. This is worth doing. Similar to the health IT, our approach to mobile health applications has to strike the correct balance between innovation and patient safety. Well, we had a hearing yesterday where we made it clear that FDA wouldn't take mobile apps and regulate mobile apps, even if they had information on general health and wellness, and even if it functioned as electronic health record system. I think it is wise. We shouldn't regulate this in any way as a medical device. But if you had something on your iPhone that purports to help diagnose skin cancer or congenital heart defects, well, you got to have some appropriate regulatory scrutiny. You get a lot of false positives, you get false negatives, people are being confident in these devices, and we better know whether you can be confident in these devices, if they are going to tell you that a mole, don't worry about it, it is not cancerous, when, in fact, it could be melanoma.

We don't believe in this country that buyer should beware. Well, my colleagues in Congress should act. Congress has acted, and in fact, when we had the Medical Devices User Fee Act in the last Congress, we specifically rejected in that bill a moratorium on FDA's use of its authority over medical devices that happened to be implemented as mobile applications.

My last point is even if it is regulated as a medical device, it is not going to be charged with a tax. That tax only goes to certain kinds of devices. So don't be scared. Look at the law, look at the reality, and don't listen to the political rhetoric which this week has been orchestrated very carefully by my Republican colleagues.

Yield back the balance of my time.

Mr. PITTS. Chair thanks the gentleman.

That concludes our opening statements. We have one panel today. I would like to thank our distinguished panel of experts for providing testimony today, and I will introduce them at this time.

First, Dr. Joseph Smith, Chief Medical and Chief Science Officer, West Health Institute; secondly, Ms. Christine Bechtel, Vice President, National Partnership for Women and Families; third, Mr. Jim Bialick, Professor of Public Policy, Georgetown Public Policy Institute; fourth, Dr. Jacqueline Mitus, Senior Vice President, Clinical Development and Strategy, McKesson Health Solutions; and finally, Dr. David Classen, Chief Medical Information Officer, Pascal Metrics, Associate Professor of Medicine and Consultant in Infectious Diseases, University of Utah School of Medicine.

Thank you all for coming this morning. You will each be given 5 minutes to summarize your testimony. Your written testimony will be entered into the record.

Dr. Smith, we will start with you. You are recognized for 5 minutes for your opening summary.

STATEMENTS OF JOSEPH M. SMITH, M.D., Ph.D., CHIEF MEDICAL AND CHIEF SCIENCE OFFICER, WEST HEALTH INSTITUTE; CHRISTINE BECHTEL, VICE PRESIDENT, NATIONAL PARTNERSHIP FOR WOMEN AND FAMILIES; JIM BIALICK, EXECUTIVE DIRECTOR, NEWBORN COALITION; JACQUELINE MITUS, M.D., SENIOR VICE PRESIDENT, CLINICAL DEVELOPMENT AND STRATEGY, MCKESSON HEALTH SOLUTIONS; AND DAVID CLASSEN, M.D., CHIEF MEDICAL INFORMATION OFFICER, PASCAL METRICS, AND ASSOCIATE PROFESSOR OF MEDICINE AND CONSULTANT IN INFECTIOUS DISEASES, UNIVERSITY OF UTAH SCHOOL OF MEDICINE

STATEMENT OF JOSEPH M. SMITH

Dr. SMITH. Chairman Pitts, Ranking Member Pallone, and members of the subcommittee, thank you for the opportunity to testify today. I am Dr. Joseph Smith, Chief Medical and Science Officer for the West Health Institute, a nonpartisan, nonprofit, applied medical research organization dedicated to lowering the cost of health care for public good by research and development of innovative, patient-centered solutions.

Our Nation's health care system is in dire need of dramatic change as we lead the world in health care spending, lag many of our peer nations in critical health outcomes, and face into a growing aging population a tsunami of chronic disease, with a relative shortage of physicians, it is difficult to overstate our challenges, but suffice it to say that our health care delivery system is exceeding both our Nation's budget and our provider's bin without yet meeting our patient's needs.

We see an enormous opportunity to use information technology, device innovation, mobile and wireless technology, and smart and learning systems to both transform health care delivery and create empowered, informed consumers of health care. Health care must be allowed and encouraged to rapidly evolve using the same innovations that have already revolutionized banking, education, retail, computing, photography, and communication. We must take proactive steps to assure that those technologies that have enabled a revolution of decentralization, democratization, automation, and personalization, and other aspects of our lives and our economy have the same beneficial impact on health care.

To enable this transformation, three elements appear required. One, streamlined, predictable, transparent, risk-based regulation that fosters innovation and investment for the benefit of patients, as well as our ailing health care system; two, a proactive regulatory and reimbursement stance on true functional interoperability, not only EHR interoperability, but specifically, medical device interoperability to create an integrated, fully coordinated web of patient-centered health care technology; and three, reimbursement policy that aligns stakeholder incentives and drives adoption of appropriate technology to improve safety, efficiency, and cost of care.

At this point in time, when health care is truly a "burning platform," we need to stimulate innovation and experimentation. This requires a clear, consistent, and timely approach to regulation. Outside of health care, we have witnessed a revolution in information, communication, and device technology driven by innovation and investment, all encouraged by a predictable regulatory posture. Within health care, however, we have yet to fully exploit the potent intersection of these technologies.

With respect to medical apps, while we have witnessed an explosion of innovation in the health and wellness applications, we have seen relatively little activity in the critically important, but more heavily regulated, areas of remote monitoring, diagnosis and treatment of those chronic diseases that burden patients, and make up the lion's share of our health care spending. And for medical apps and clinical decision support, it is an open question of whether the existing medical device regulatory framework can be sufficiently modified to provide the applicability, clarity, predictability, and timeliness required.

The FDA's draft guidance on mobile medical apps offered some improved clarity, but still described significant areas of regulatory discretion, and now after lengthy delay without becoming finalized has left an industry in limbo.

Going forward, considering the frequency with which both general app user interfaces and medical treatment guidelines used in clinical decisions support algorithms that are routinely updated, the prospect of having all such changes subject to the complex regulatory process for medical device revision seems more than daunting. Whatever the process, we must drive regulation at the pace of innovation, and not vice-versa.

The second priority is to use regulatory and reimbursement policy to encourage true functional interoperability of information systems, and medical devices. Health care needs to exploit a truly connected and coordinated med app technology that can be seen as originating at the patient with those surrounding or even implanted medical devices with seamless sharing of relevant information among all such devices and the background EHR. The current lack of such true functional interoperability results in safety hazards and inefficiencies that we do not tolerate in other less critical areas, and it creates additional barriers for new innovative entrants.

Standards-based interoperability allows the information required for commerce and banking and communication and education to move at the speed of innovation, and yet, when it comes to our

health care, information is stuck in multiple non-communicating silos as lifesaving devices are forced to work independently, despite being inches apart, all in service of the same critically ill patient.

Today we released a study illustrating that true functional medical device interoperability not only brings improvements in patient safety and efficiency, but may also result in savings of more than $30 billion annually. Established labeling for medical device interoperability and inclusion of such stage three meaningful use could encourage adoption of such functional interoperability for patient benefit and health care savings.

The third priority area is regulation of reimbursement policy that promotes aligned incentives. Reimbursement systems that disproportionately reward hospital-based procedures over office-based procedures, or face-to-face encounters over remote encounters need to give way to reimbursement based on outcome, not location, and value, not volume. Only in this way will we unleash the power of information communication and medical device technology.

In closing, the West Health Institute believes that streamlined, predictable, transparent, risk-based regulation, a proactive regulatory and reimbursement stance on medical device interoperability, and realistic and actual policy to align stakeholder incentives can help to unleash a needed and long overdue transformation of our health care delivery system to allow it to sustainably address the needs of today's patients and meet tomorrow's challenges.

Thank you very much.

[The prepared statement of Dr. Smith follows:]

Testimony of Joseph M. Smith, MD, PhD
Chief Medical and Science Officer, West Health Institute
Subcommittee on Health, Committee on Energy and Commerce,
U.S. House of Representatives
"Health Information Technologies: How Innovation Benefits Patients"
March 20, 2013

SUMMARY OF KEY POINTS:

- The West Health Institute (WHI) sees an enormous opportunity to use information technology and device innovation to transform health care delivery and create empowered, informed consumers of health care.

- We believe the three key enablers of this needed transformation are:

  1. **Predictable, transparent risk-based regulation that fosters innovation and investment**. Unclear, unpredictable, and/or heavy-handed regulation can have a chilling effect on the intersection of mobile technology, medical information, and clinical decision support. Stimulating innovation and experimentation requires a clear and consistent approach for when regulation enters the process and how far-reaching it should be. Our current regulatory environment favors large incumbents with domain expertise and financial resources necessary to navigate the ambiguity, complexity and, often, modified guidelines that unpredictably "move the goal posts." Clear, predictable, and appropriate risk-based regulation can unleash the disruptive innovation required to transform health care to a sustainable enterprise.

  2. **A proactive regulatory and reimbursement stance to achieve true functional interoperability**. A WHI analysis shows that true medical device interoperability could improve the delivery of quality patient care and result in more than $30 billion a year in savings. True system-wide functional interoperability exceeds the relatively narrow issue of electronic health records and specifically includes functional interoperability between medical devices to create seamless information exchange around the patient. In the absence of such interoperability information is confined in multiple non-communicating silos as lifesaving devices just inches away from one another are forced to work independently.

  3. **Reimbursement policy that aligns stakeholder incentives and drives adoption of appropriate technology**. The Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations were intended to protect consumers, but are sometimes applied as a reason not to share patient data. Patient care suffers when providers experience delays in receiving needed information. We must ensure that policies enable data sharing. In addition, systems that disproportionately reward face-to-face encounters over remote encounters must give way to reimbursement based on outcome and value - not process, location, and volume. Enabling technologies and disruptive care delivery models exist, however, until incentives are aligned, they will not be broadly embraced.

Testimony of Joseph M. Smith, MD, PhD

Before the
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives

Hearing on:

"Health Information Technologies: How Innovation Benefits Patients"

March 20, 2013

Chairman Pitts, Ranking Member Pallone and members of the Subcommittee, thank you for the opportunity to testify about the important topic of health information technology (IT). My name is Joseph Smith, and I am the Chief Medical and Science Officer of the West Health Institute, a non-partisan, non-profit, applied medical research organization. In addition to my current role, I have spent the last 28 years at the intersection of medicine and innovative technology, practicing and teaching medicine and clinical cardiac electrophysiology in academic and private practice settings, as well as designing and developing novel medical device technology.

Our nation's health care system is in dire need of dramatic change. The subtitle of the Institute of Medicine's (IOM) recent publication on U.S. health says it all: "Shorter Lives, Poorer Health."[1] The report illustrates that Americans are living sicker and dying quicker than citizens of peer nations that spend far less for higher quality outcomes. The economics are unsustainable. As we approach spending nearly 20

[1] Institute of Medicine of the National Academies, *U.S. Health in International Perspective: Shorter Lives, Poorer Health* (January 9, 2013). Available: http://www.iom.edu/Reports/2013/US-Health-in-International-Perspective-Shorter-Lives-Poorer-Health.aspx.

percent of our gross domestic product [GDP][2] and our family budgets[3] on health care, we risk foreclosing on the American Dream, hindering our international competitiveness, and potentially compromising our national security. The logistical challenges of extending our current model of care delivery to an aging population, with a growing shortage of physicians, only make the need for change more clear. Further evidence of the enormity of this challenge was provided in the recent IOM report as it described that the time required for a family physician to deliver guideline-based care to one-day's patient panel requires an impossible 21.7 hours.[4] Our health care delivery system is clearly exceeding our nation's budget and our providers' bandwidth.

Faced with this crisis of cost and the unsustainability of our health care delivery system, the Gary and Mary West Foundation started the West Health Institute in 2009. The West Health Institute is an applied medical research organization dedicated to lowering the cost of health care by driving patient-centered solutions that make quality health care more affordable, more accessible, and more efficient.

We see an enormous opportunity to use information technology, device innovation, and smart/learning systems to transform health care delivery and create empowered, informed consumers of health care. Health care must be allowed and encouraged to rapidly evolve using the same innovations that have already revolutionized other industries. Banking, education, retail, computing, photography, and communication have all been transformed in our lifetimes, lowering their complexity and cost while improving efficiency and ease of use. Health care has avoided this modernization, persisting in a model of delivery that to our grandparents is as recognizable as it is complex and unaffordable. We must take

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[2] Centers for Medicare & Medicaid Services, *National Health Expenditure Data 2010-2011*. Available: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html
[3] Commonwealth Fund, *2003 and 2010 Medical Expenditure Panel Survey -- Insurance*
[4] *Id. Page S-5*

proactive steps to assure that the disruptive forces of decentralization, democratization, automation, and personalization - that have beneficially revolutionized other aspects of our lives and our economy - have the same beneficial impact on health care.

This is about much more than electronic health records (EHRs). The conversation needs to be elevated to one of enabling the vision and promise of medical information and device technology to create integrated, interoperable learning systems to dramatically improve outcomes, lower costs, and create a higher-value health care system. Importantly, the technological elements required to realize this transformation in health care delivery are close at hand, but our regulatory and reimbursement systems frustrate the innovation, development, and adoption required to realize the full vision.

We believe three key enablers of the needed transformation are:

- Streamlined, predictable, transparent, risk-based regulation that fosters innovation and investment for the benefit of patients, as well as our ailing health care system;

- A proactive regulatory and reimbursement stance on true functional interoperability, not just the semantic interoperability of our electronic health records, but also medical device interoperability -- to take full advantage of the medical technology that we have to create an integrated, coordinated health care system; and

- Reimbursement policy that aligns stakeholder incentives and drives adoption of appropriate technology to improve the safety, efficiency, and cost of health care delivery.

The first priority addresses the essential need for innovation and the chilling effect that unclear, unpredictable, or heavy-handed regulation can and does have in this critically important intersection of mobile technology, medical information, and clinical decision support. At this point in time, when health care is a true "burning platform," we need to stimulate innovation and experimentation. To do so, we need a clear and consistent approach for when regulation enters the process, as well as how far-reaching it should be. Outside of health care, we have witnessed a revolution in information and communication technology driven by innovation and investment, and a similar dramatic increase in the capability and economy of ubiquitous (non-medical) electronic devices, all encouraged by a predictable regulatory posture. Within health care, however, we have yet to fully exploit the potent intersection of these technologies. Even with respect to 'medical apps,' the overwhelming majority of offerings are health and wellness applications, , and the bulk of the available 97,000 mobile health apps are dedicated to medical providers as opposed to consumers or patients. Unfortunately, there is relatively little activity in the critically important - but more heavily regulated - areas of remote monitoring, diagnosis, and treatment of those chronic diseases that burden patients and make up the lion's share of our health care spending.

Tele-dermatology represents an interesting case study. The lightly regulated smart phone with its integrated camera can be readily used to photograph a suspicious mole and transmit a picture to a dermatologist, and there is no additional regulatory burden encountered by its use. Yet, when this becomes packaged as a specific, user-friendly, documented, and downloadable app from the app store, purpose-built for use in tele-dermatology, it requires FDA approval. By 2017, more than 3.4 billion people will have smartphones or tablets with access to mobile applications: we must encourage innovation from all corners for use in solving our most pressing and burdensome health care needs.

We need to recognize that our current regulatory environment favors the large incumbents that already have the domain expertise and financial resources to navigate the ambiguity, complexity and, quite often, modified guidelines that unpredictably "move the goal posts." If we are to have any hope of democratizing and decentralizing health care, we need to encourage the disruptive innovation required to transform it to a sustainable enterprise. We need to "free" the innovation cycle with predictable and transparent risk-based regulation so that the full benefits of these emerging and rapidly evolving technologies can be realized. Specifically for medical apps and clinical decision support, it is an open question whether the existing medical device regulatory framework can be modified to provide sufficient applicability, clarity, and predictability, or whether we need to consider an alternative, less burdensome framework to spur innovation. The FDA's draft guidance on mobile medical apps offered some improved clarity, but still described significant areas of "regulatory discretion," and now after lengthy delay without becoming finalized, has left an industry in limbo. And going forward, considering the frequency with which both apps and medical treatment guidelines used in clinical decision support algorithms are routinely updated, the prospect of having all such changes subject to the complex regulatory process for medical device revision seems more than daunting. As we address this, we must learn to move regulation at the pace of innovation and not vice-versa.

The second priority is to use regulatory and reimbursement policy to encourage true functional interoperability of information systems and medical devices. We view interoperability as the ability of medical devices and health care systems to seamlessly communicate and exchange information to improve the delivery of care. This connected and coordinated net can be seen as originating at the patient and surrounding or even implanted medical devices, with seamless sharing of relevant information among all such devices and the background EHR. The current lack of such true, functional interoperability results in safety hazards and inefficiencies that we do not tolerate in

other, less critical settings and it creates additional barriers for new, innovative entrants. One need only consider the democratizing influence of the Internet communication protocols and the resulting deluge of innovation to understand the full impact of interoperability. And today, while all of our Internet-enabled devices freely and instantaneously share e-mail and information, the medical devices that surround our most acutely ill patients most often function completely blinded of the critically important information being collected by other such devices only inches away. Standards-based interoperability allows e-mail to work seamlessly across different servers, cars to fill-up their gas tanks at different filling stations, phone calls to be completed between different head-sets, and yet, when it comes to our health care, information is stuck in multiple non-communicating silos as lifesaving devices are forced to work independently. We can do better.

An analysis (attached) conducted by the West Health Institute, which was released to the public today, shows that the delivery of quality patient care could be enhanced and made dramatically more affordable by medical device interoperability. Our analysis suggests that true functional medical device interoperability improves patient care, increases efficiency, and results in more than $30 billion a year in health care savings.

To realize these benefits, providers, payers, medical device manufacturers, and the government will need to collaborate to promote the development, testing, certification, labeling, and adoption of seamlessly interoperable devices. Industry trends are already driving providers and payers to converge and share risk through care coordination, clinical integration, and improved population health management. Stakeholder collaboration will provide a strong platform for accelerating adoption of medical device interoperability and realizing its associated benefits.

The third priority area is policy that promotes aligned incentives. We are starting to see the unintended consequences of well-meaning policy. For example, the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations were intended to protect consumers, but are complicated and sometimes mistakenly applied as a reason not to share patient data. Fear of HIPAA violations results in onerous requirements for sharing. Patient care suffers when providers experience delays in receiving needed information. We must ensure that policies enable requisite data sharing across traditional and emerging participants in the health care ecosystem. The financial services industry has developed secure approaches to privacy and security that, while imperfect, provide sufficient protection to enable a revolution in banking and retail services. Health care should learn from this example and allow the Internet, which changes everything, to change health care.

Reimbursement systems that disproportionately reward hospital-based procedures over office-based procedures, or face-to-face encounters over remote encounters, need to give way to reimbursement based on outcome, not process, and value, not volume. Only in this way will we unleash the power of information, communication, and medical device technology. Enabling technologies and disruptive care delivery models exist; however, until incentives are aligned, they will not be broadly embraced. Telemedicine is one such example where the technology allows remote care, but reimbursement mechanisms frustrate full and best use as practitioners are often not paid for the care they can provide remotely, providing perverse incentives for unneeded patient travel and excessive costs of care.

In closing, the West Health Institute believes the following are imperatives in order to reach our nation's health IT goals and create a model of health care delivery in service of the patient:

- Streamlined, predictable, transparent, risk-based regulation;
- A proactive regulatory and reimbursement stance on medical device interoperability; and
- Realistic and actionable policy to align stakeholder incentives.

Thank you for your time. This is an important conversation and, on behalf of the West Health Institute, we look forward to advancing these imperatives for patients and our health care system. I am happy to answer any questions.

Selected references for the value of telemedicine, telehealth and remote monitoring:

- As early as 1997, Kaiser Permanente's Tele-Home Health Research Project demonstrated that the use of Remote Monitoring could provide a 33-50 percent decrease in the cost of care delivery and increased patient satisfaction.[1]

- A 2009 report produced by the Center for Technology and Aging identified that remote patient monitoring is among seven technologies with great potential to improve care of chronic conditions, reduce healthcare costs and maximize the independence of older adults[2]

- Research performed by the New England Healthcare Institute (2009) demonstrates that remote patient monitoring has the potential to prevent between 460,000 and 627,000 heart failure-related hospital readmissions each year. Based on this reduction in hospitalization, NEHI estimates an **annual national cost savings of up to $6.4 billion dollars**[3]

- Centura's Health at home has demonstrated the ability of telehealth to significantly reduce readmission rates for home care– based Medicare beneficiaries to 6 percent.[4]

- Building on its success with telehealth, Centrua Health at home (CHAH) recently completed a oneyear program to further decrease 30-day rehospitalization rates and increase quality of life among older adults by expanding its telehealth services. The project was funded by the Center for Technology and Aging as one of five grant projects in the Remote Patient Monitoring Diffusion Grants program. CHAH integrated two independent, successful home health service programs, a clinical call center staffed by registered nurses (RNs) and a remote patient monitoring (RPM) program. The year-long program reduced the frequency of 30-day rehospitalizations and home RN visits, while improving quality of life, self-management, and education among patients.[4]

- Remote physiological monitoring was implemented in the Veterans Health Administration (VHA) as part of a larger coordinated care program. The VHA sought to improve the quality of care and reduce overall spending by delivering the right care to the right patient at the right time, especially for patients with chronic conditions who are at high risk for hospitalization. VHA nurses used a Web-based application to review monitored patients' data. This coordinated care has resulted in decreased outpatient visits, lower hospital admissions, and fewer prescription medications.[5] In addition,

    - Emergency room visits decreased 40%.
    - Hospital admissions dropped 63%.
    - Patients experienced a 60% reduction in bed days.
    - Nursing home admissions decreased 63%.
    - Patients reported a 95% satisfaction rate with the program.

  An update to this experience provided by its Director, Dr. Adam Darkins on March 15, 2013 includes

    - In FY2012, VA specific Telehealth Applications (Clinical Video Telehealth, Home Telehealth and Store and Forward Telehealth (SFT) provided care from 150 VA Medical Centers (VAMCs) and 750 Community Based Outpatient Clinics (CBOCs) to 497,342 patients; This amounted to 1,429,424 telehealth episodes of care. Forty-nine percent (49%) of these patients lived in rural areas, and may

otherwise have had limited access to VA healthcare; The number of Veterans receiving care via VA's telehealth services is growing approximately 29% annually

- In FY2012, of the 119,535 Veterans enrolled for home telehealth services in VA, 42,699 patients were supported by HT to live independently in their own homes, patients who otherwise would have needed long-term institutional care. The current census (point prevalence) of home telehealth receiving care on March 14th 2013 is 77,461.

- Since FY2003, VA has delivered over 800,000 patient telemental health encounters from 146 VA facilities to 531 VA community based outpatient clinics (CBOCs), an 18-fold increase in consultations over these years.
    - In FY2012, VA delivered over 217,000 telemental health consultations to over 76,000 patients, this activity took place between 146 VAMCs and 531 CBOCs.
    - In FY2010, VA established a National Telemental Health Center. In FY2012, this center provided 1,251 video encounters to 427 unique patients at 24 sites that were in 13 states.
    - The scope of VA's telemental health services includes all mental health conditions with a focus on post-traumatic stress disorder, depression, compensation and pension exams, bipolar disorder, behavioral pain and evidence-based psychotherapy.
    - In FY2012, chronic disease management provided via home telehealth devices supported 7,100 patients with chronic mental health conditions to live independently in their homes, so far in FY2013 VA has conducted over 3,632 video consultations with 912 Veterans directly into their homes.

For further reading:

Remote Patient Management: Technology-Enabled Innovation And Evolving Business Models For Chronic Disease Care[6]
Source: Health Affairs
Date: 2/2009

Remote patient management (RPM) is a transformative technology that improves chronic care management while reducing net spending for chronic disease. Broadly deployed within the Veterans Health Administration and in many small trials elsewhere, RPM has been shown to support patient self-management, shift responsibilities to non-clinical providers, and reduce the use of emergency department and hospital services. Because transformative technologies offer major opportunities to advance national goals of improved quality and efficiency in health care, it is important to understand their evolution, the experiences of early adopters, and the business models that may support their deployment.

Remote patient management technologies are attracting new interest from organizations at risk for the consequences of poorly managed chronic disease care.

THE MOST PRESSING TASK OF HEALTH CARE is to make care effective and affordable; this is particularly important in the case of chronic disease. In this paper we examine current and emerging business models in health care that use new technologies for the remote management of chronic care, and early evidence that these technologies may enable new levels of efficiency and patient self-management.

Systematic Review of Home Telemonitoring for Chronic Diseases: The Evidence Base[7]
Source: JAMIA
Date: 2007

Highly cited review article by Pare et al.

Public Policy Implications for Using Remote Monitoring Technology to Treat Diabetes[5]
Source: Journal of Diabetes Science & Technology
Date: 5/2007

Key abstract:
Since the late 1990s, numerous studies have addressed the efficacy of remotely monitoring patients with the major chronic diseases and tested the feasibility of employing the Internet as a new communications tool in the physician/patient relationship. Vitally important questions have been asked and answered successfully by careful, thoughtful, and thorough investigators. Studies consistently reveal that when used to help monitor glucose levels, RPM lowers A1C levels, improves overall outcomes, and saves everyone time and money.[4-15]

An independent analysis of remotely monitored and nonmonitored patients[16] found that remote monitoring reduced hospitalization and emergency care visits and improved patients' functional status. For diabetes care, the average improvement/stabilization rate in activities of daily living for patients using remote monitoring was 77.2% vs 70.4% for those patients not using remote monitoring. The New England Healthcare Institute[17] studied RPM in cardiac patients and found that RPM delivers value over standard care methods by reducing patient rehospitalization rates by 32%, resulting in a total reduction of 132 patient days per 100 patients, producing a net cost savings of 25% and yielding savings of $1861 per patient over a 6-month postdischarge period.

Home Monitoring for Heart Failure Management[8]
Source:NIH
Date: 1/10/2012

Key abstract:
Two recent meta-analyses have suggested that telemonitoring in ambulatory HF patients can improve mortality by 17 to 47% during six to twelve months of follow-up and reduce hospitalizations by 7 to 48% (22,24).

The difficulty in managing HF is manifest not only by a high rate of HF hospitalizations, currently estimated at approximately 1 million annually in the United States (US) (3), but also by a 30-day readmission rate of 27%, the highest among all medical conditions necessitating hospitalization (4). Acute in-hospital care is responsible for up to 70% of the annual cost of HF in the US and other developed countries (5). Given the aging population and growing economic burden, improved management of the HF patient at home and prevention of hospital admissions have become national priorities. Rehospitalization rates for HF are now the target of publicly reported performance measures, national improvement initiatives, and government incentives (6)

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The Value of Medical Device Interoperability

Improving patient care with more than $30 billion in annual health care savings

West Health Institute

March 2013

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About West Health Institute

The West Health Institute is an independent, non-profit 501(c)(3) medical research organization whose mission is to lower health care costs by developing innovative patient-centered solutions that deliver the right care at the right place at the right time. This is accomplished by conducting innovative medical research, educating key stakeholders and advocating on behalf of patients. Solely funded by pioneering philanthropists Gary and Mary West, the Institute is part of West Health, an initiative combining four separate organizations – the West Health Institute, the West Health Policy Center, the West Health Investment Fund, and the West Health Incubator. The Institute is located in San Diego, California, the global center for health care innovation. For more information, find us at westhealth.org and follow us @westhealth.

Acknowledgements

The Medical Device Interoperability Coordinating Council (MDICC) is an open forum to allow collaboration between stakeholders that are actively engaged in aspects of promoting or creating interoperable medical device systems. The MDICC formed in March 2012 to advance wide adoption of medical devices that seamlessly interoperate with other medical devices and information systems with the goal of enabling improved patient care. This analysis was prompted, in part, by MDICC's efforts, which validated the need to better quantify the value of medical device interoperability. Several individuals within MDICC deserve thanks for their contributions to this work.

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Abstract

Unsustainable and ever-escalating U.S. health care costs, an estimated $700 billion in wasteful spending and the emerging centricity of medical information and its seamless availability in the search for solutions prompt investigation into the value of creating functional medical device interoperability – the ability for medical devices to exchange information with each other and with patient data repositories such as electronic health records. This report examines areas of waste in health care that can potentially be eliminated through greater medical device interoperability and the adoption of commonly accepted standards for interoperability. Waste reduction through greater medical device interoperability would lead to increased efficiency, improved quality and more affordable care. Commonly adopted standards can accelerate the move towards greater medical device interoperability and potentially reduce the cost of achieving interoperability. With all of the caveats associated with estimating the value of a process improvement not yet deployed, our combined top-down and bottom-up modeling suggests that annual savings in excess of $30 billion may be liberated by widespread adoption of functional interoperability for medical devices. To realize the benefits, providers, payers, medical device manufacturers and the government will need to collaborate and partner to promote the development and adoption of seamlessly interoperable devices. Industry trends are already driving providers and payers to converge and share risk through care coordination, clinical integration and improved population health management. Stakeholder collaboration is expected to provide a strong platform for accelerating adoption of medical device interoperability and realizing its associated benefits.

Introduction

Overview

Health care costs continue to consume an ever increasing proportion of U.S. spending, significantly outpacing the growth of our economy for each of the last four decades, and recently reaching as high as 18 percent of Gross Domestic Product (GDP).[1]

While both the absolute level of spending and its disproportionate growth are unsustainable, evidence indicates that as much as a third of this spending is waste (i.e., does not contribute to quality outcomes). According to recent estimates, more than $700 billion of the $2.4 trillion in health care spending could otherwise be avoided through improvements to the health care system.[1] Waste takes many forms, including inefficiency, unnecessary services and missed prevention opportunities and is believed to be broadly distributed across the spectrum of health care delivery.

This study examines the sources of waste in health care that could be eliminated with medical device interoperability, as well as the waste resulting from a lack of commonly adopted interoperability standards. The report's findings suggest that increased medical device interoperability would reduce waste, lead to improvements in quality and decrease the cost of care. Additionally, comprehensive adoption of interoperability standards has the potential to reduce waste related to developing and implementing interoperability and facilitate increased interoperability.

Health IT, Medical Devices and Interoperability

Despite a nationwide push for adoption of information technology throughout the health care system and the concurrent significant advances in the technologies underlying medical devices, numerous barriers continue to impede the realization of health information technology's potential. A lack of functional medical device interoperability is one of the most significant limitations. *Medical device interoperability* refers to information sharing from one device to another or between devices and Electronic Health Records (EHRs). Functional interoperability would enable clinical medical devices to communicate in a consistent, predictable and reliable way. By allowing for the exchange of data with other medical

Waste: Any activity that does not add value to the health care system.

Functional Medical Device Interoperability: the ability for clinical medical devices to communicate in a consistent, predictable and reliable way, allowing for the exchange of, and interaction with, data from other medical devices and with patient data sources and repositories, such as electronic health records (EHRs), in order to enhance device and system functionality.

devices and with patient data sources and repositories, such as EHRs, medical device interoperability would enhance the function of the systems and devices. Exchange of data between EHRs is commonly designated as Healthcare Information Exchange (HIE) and has been analyzed in great detail elsewhere.[2] The reliable and seamless transfer of information through medical device interoperability can facilitate a number of improvements in efficiency and safety that can be quantified in billions of dollars of savings to the health care system, yet, despite these significant benefits, medical device interoperability is limited today.

The Current State of Medical Device Interoperability and Interoperability Standards

According to a recent report by HIMSS Analytics,[3] while over 90 percent of the hospitals surveyed by HIMSS use six or more types of devices that *could* be integrated with EHRs (such as defibrillators, electrocardiographs, vital signs monitors, ventilators and infusion pumps) only a third of hospitals actually integrate medical devices with EHRs today. Additionally, those that are investing in interoperability integrate fewer than three types of devices on average, a far cry from the six to twelve devices that may be present around an intensive care unit (ICU) bed. This lack of interoperability creates significant sources of waste and risk to patient safety because of incomplete or stale information clinicians must rely on for workflow and decision making.

Part of the reason for limited interoperability is the high cost and complexity of medical device integration, which results from the lack of incentives for medical device and HIT companies to use open interfaces to establish interchangeable interoperability. In contrast to the "plug and play" world of consumer electronics, where consumer demand for simple and seamless functionality has driven convergence on a few common standardized interfaces and platforms, providers have not required a consistent means for achieving interoperability. As a result, there is a wide range of methods used by device vendors today. Some vendors use distinct proprietary and closed communication methods even among their own devices. Additionally, some standards are loosely specified, with a number of options for configuration, meaning that even devices that use similar standards may not be able to communicate without further customization. As a result, facilitating the exchange of data between and among medical devices and EHRs currently requires hospitals to invest significant resources in developing custom interfaces and paying for middleware solutions. The cost of medical device integration has been estimated at as much as $6,500 to $10,000 per bed in one-time costs, plus as much as 15 percent in annual maintenance fees.[4] These investments are a substantial undertaking for hospital systems when compared against already squeezed operating margins of less than three percent on revenue of approximately $700,000 per bed (based on average length and cost of inpatient stays).[5,6]

Within the current system, the medical device industry lacks the imperative to offer interoperability among devices because providers who are integrating bear these costs and do not require medical device companies to follow specific standards. Many providers continue to work without interoperability since the value proposition has not been adequately quantified to drive prioritization of the investments necessary to achieve integration over competing technology or other needs. While middleware software providers and systems integrators have issued white papers illustrating the impact of medical device integration at a hospital level,[7] there have been no studies to date attempting to quantify the value of medical device interoperability in

addressing waste across the health care system as a whole. There has also been no detailed examination of the waste generated by the lack of commonly adopted standards. Given the efficiencies and quality assurance tools medical device interoperability offers, this report provides health care stakeholders a clear and compelling case to invest in medical device interoperability.

This paper examines the benefits of medical device interoperability in terms of the reduction of waste in health care. It also estimates the costs that could potentially be eliminated in a world where medical devices are connected in a standardized manner as computer and communications devices do today.

Methodology

This report limited the scope of its analysis to interoperability between clinical medical devices and patient data repositories such as EHRs and device-to-device interoperability. It included only those clinical devices that are potentially interoperable today, encompassing bedside monitoring devices (e.g., ECGs and physiologic monitors), imaging devices, diagnostic devices, surgical devices and therapeutic devices (e.g., infusion pumps). It focused on acute care (encompassing emergency room and inpatient settings) and did not examine the benefits of interoperability between EHRs in different health care organizations since HIEs constitute a distinct type of interoperability and have been analyzed in detail elsewhere.[2] Finally, while it is appreciated that the lack of functional interoperability among consumer medical devices (e.g. glucometers, weight scales and blood pressure monitors) outside the hospital and between such devices and more central EHRs is a related significant and growing challenge with its own attendant waste, the lack of conformity around the magnitude and growth of this aspect of the issue precluded it being included in this analysis, making the results of this work a more conservative estimate of the overall impact of true, functional interoperability.

This analysis followed a three-stage process:

1. *Identification of relevant sources of health care waste.* Relying on the Lean Six Sigma methodology as a lens to define waste as "all activity that does not add value to the health care system," the perspective of each stakeholder within the ecosystem was examined to identify areas where waste could potentially be addressed and eliminated through interoperability.[8] Interviews with more than 30 stakeholders from across the health care ecosystem (including providers, payers, medical device manufacturers and health IT vendors), along with secondary research, led to identifying ten areas of waste that fell into two categories: those arising from the lack of interoperability and those arising from a lack of commonly adopted standards. Of these, some were determined to be primary sources of waste for which the impact of interoperability could be readily quantified, and others were identified as longer-term savings opportunities that were indirect (i.e., would require several additional enabling factors to address) or were difficult to measure and therefore not specifically quantified in this report. (**Figure 1**)

Figure 1: Areas of Waste Identified

Quantified Areas of Waste	Primary Stakeholders Benefited			
	Providers	*Payers*	*Patients*	*Device Co.*
Due to Lack of Medical Device Interoperability				
1. Adverse events from drug errors, misdiagnosis, and failure to prevent harm	✓	✓	✓	
2. Redundant testing resulting from inaccessible information	✓	✓	✓	
3. Clinician time spent manually entering information	✓			
4. Increased length of stay from delays in information transfer	✓			
Due to Lack of Commonly Adopted Standards for Interoperability				
5. Device testing and development costs				✓
6. Provider costs to integrate devices with EHRs	✓			

Indirect or Difficult to Quantify Areas of Waste	Primary Stakeholders Benefited			
	Providers	*Payers*	*Patients*	*Device Co.*
Due to Lack of Medical Device Interoperability				
7. Limited ability to collect and leverage data analytics to improve clinical decision support	✓	✓	✓	
8. Sub-optimal care driven by limited adoption and efficacy of remote patient monitoring (RPM)		✓	✓	
9. Limited ability for operational maintenance and optimization of utilization/inventory management	✓			
Due to Lack of Commonly Adopted Standards for Interoperability				
10. Limited device choice, innovation, and competition due to switching costs	✓			✓

2. *Definition and quantification of the addressable buckets of waste.* For each segment of waste, a reference market was established to set a maximum value of spending that could be impacted by interoperability. For example, the analysis of savings related to "Time wasted manually entering information" first quantified the total value of nurses' time nation-wide as a maximum, and then identified the portion of that time spent manually documenting information and programming devices.

3. *Definition and quantification of the share of costs addressable by interoperability.* The potential impact of interoperable vs. non-interoperable devices was defined based on available clinical literature. Continuing the example of "Time wasted manually entering information," this analysis looked at the impact of medical device integration on documentation and programming time in published case studies to

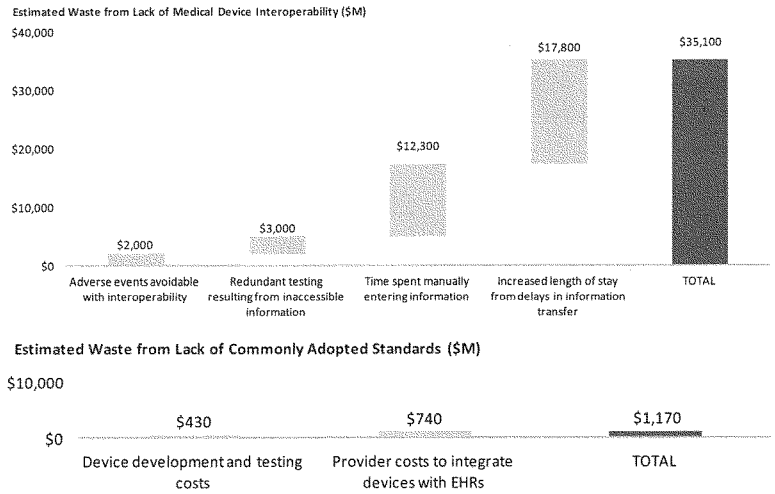
estimate the reduction in waste. Where an exact case study of medical device interoperability was not available, a surrogate analysis was selected based on its relationship to the activities interoperability would address. For example, "Increased length of stay from delays in information transfer," used the impact of another intervention that decreased test turnaround time-point of care testing- to estimate the impact of medical device interoperability on **emergency department** (ED) length of stay.

Summary of Results

The analysis identified an estimated $36 billion in potential annual, addressable waste across segments of health care waste in the U.S. **(Figure 2)**. The bulk of this waste (97percent) relates to the lack of interoperability itself, with the remainder coming from the lack of commonly implemented standards. While a lack of commonly adopted standards for medical device interoperability may result in a small amount of direct savings, it has the ability to facilitate a more rapid adoption of interoperability, which can achieve the benefits described below.

The benefits from interoperability arise from four primary activities: 1) quality improvement through reduction of adverse events due to safety interlocks ($2 billion), 2) reduced cost of care secondary to avoidance of redundant testing ($3 billion), 3) increased clinician productivity secondary to decreased time spent manually entering information ($12 billion) and 4) improvements in patient throughput secondary to shortening length of stay ($18 billion). Benefits from common adoption of standards include reduced costs for medical device development and systems integration within a health system.

Figure 2: Estimated Addressable Waste



Note: Numbers rounded for clarity

For waste due to lack of medical device interoperability, the majority of benefits (93 percent) accrue to providers, followed by payers (6 percent), with initially *de minimis* direct economic benefit to patients. Additionally, device manufacturers and health IT companies are expected to gain little from medical device interoperability **(Figure 3)**. It is important to note that differences in reimbursement policies make it difficult to precisely allocate the magnitude of benefits to each stakeholder; therefore the allocation provided below represents a reasonable estimation and allocation of those benefits. Furthermore, as patients are being asked to bear greater responsibility for the entirety of their medical costs, the savings initially attributed to providers and payors will necessarily decrease overall costs with likely proportional patient savings.

Figure 3: Savings by Stakeholder from Increased Medical Device Interoperability

Area of Waste due to Lack of Medical Device Interoperability	Share of Total ($M)			
	Providers	*Payers*	*Patients*	*Device Vendors*
1. Adverse events avoidable with medical device interoperability	$1,000	$850	$150	
2. Redundant testing resulting from inaccessible information	$1,500	$1,275	$225	
3. Clinician Time Spent Manually Entering Information	$12,300			
4. Increased length of stay from delays in information transfer	$17,800			
Total Savings ($M)	**$32,600**	**$2,125**	**$375**	**$0**
Total Savings (%)	**93%**	**6%**	**1%**	**0%**

Note: Numbers rounded for clarity

For waste related to the lack of commonly adopted standards, the allocation of costs that could be eliminated was based upon interviews of stakeholders, whose views varied significantly, and was therefore a reasonable estimate based upon various expert opinions about how those costs are borne today **(Figure 4)**.

Figure 4: Maximum Potential Savings by Stakeholder due to Lack of Commonly Adopted Standards

Area of Waste due to Lack of Commonly Adopted Standards	Share of Total ($M)			
	Providers	*Payers*	*Patients*	*Device Vendors*
5. Device testing and development costs				$430
6. Provider costs to integrate devices with EHRs	$740			
Total Savings ($M)	**$740**			**$430**
Total Savings (%)	**63%**			**37%**

b Note: Numbers rounded for clarity

Detailed Findings

Note: please see the appendix for detailed calculations for each area of waste.

Lack of Medical Device Interoperability

1. Costs Resulting from Avoidable Adverse Events: *$2 billion*

Medical errors result in as many as three million preventable adverse events each year, driving as much as $17 billion in excess annual medical costs and as many as 98,000 deaths per year.[9,10] Several of the most common causes of medical errors can be substantially addressed by improved medical device interoperability, including drug errors (accounting for 20 percent of adverse events), diagnostic errors (17 percent) and failure to prevent injury (12 percent).[9,10] Errors in technique, accounting for 44 percent, are assumed to be largely unaddressable by improved interoperability.[10]

Figure 5: Case Study: Drug Errors

Current State: A cancer patient's pain is managed with patient-controlled analgesia (PCA) and has a physician order for a relatively low constant infusion rate of analgesia, with an intermittently high rate available when requested by the patient. As the infusion pump is being programmed, these two rates are reversed, resulting in over-sedation and respiratory depression. The patient's monitor demonstrates dropping pulse oximetry, but clinical intervention is delayed until the nurse walks back into room, resulting in anoxic brain injury.

Future State: If the PCA pump were able to communicate with computerized physician order entry, transcription and administrative errors could be avoided. If the physiological monitoring device communicated with the pump, drug administration would automatically be discontinued when physiological parameters move outside a predetermined range.

Drug errors

With and without Medical Device Interoperability

Medication errors can stem from errors in drug ordering by the physician, order transcription by various clinicians, drug dispensing by the pharmacist and drug administration at the point of care (**Figure 5**).

Medical device interoperability will facilitate the push of test results and vital signs readings to clinicians or pharmacists and automate the integration of relevant information to inform ordering decisions, thus avoiding ordering errors stemming from lack of patient information or inadequate monitoring. Interoperability can address transcription and administrative errors by allowing EHRs, physiological monitoring devices and medication administration devices to communicate in a seamless manner. Automation of these activities and functions with medical device interoperability can 1) enable automatic population of drug orders into the devices that administer these drugs, 2) transfer alerts and parameters for drug delivery from an EHR into the device and 3) provide a physiological data feed into the device. Any one of these interventions can reduce drug-related adverse events. For example, the integration of intelligent infusion devices, bar-code-assisted medication administration and electronic medication administration records has been found to reduce errors further than using these systems in a siloed manner, as it enables the automatic population of provider-ordered, pharmacist-validated infusion variables directly into the infusion device, which verifies the dose and

rate against dosing limits defined in the drug library. (Medical device interoperability would not address any pharmacy dispensing errors beyond those that stem from errors in transcription or ordering.)

Calculations

According to a study in *Health Affairs,* adverse drug events result in an estimated $3.8 billion in incremental medical costs annually.[9] Ordering errors account for 39 percent of all drug errors.[11] There are few studies specifically examining the impact of interoperability on ordering errors, but a relevant proxy is the impact of closed-loop e-prescribing, automated dispensing, bar-code and eMAR systems, as such closed-loop systems achieve their benefits by integrating the flow of information among the subsystems which comprise them. A study in *Quality & Safety in Healthcare* found that such a closed-loop system reduced prescribing errors by 47 percent.[12]

Transcription errors account for 12 percent of all drug errors;[11] these errors can be addressed for all types of dosage forms, as interoperability between automated dispensing devices and computerized physician order entry (CPOE) systems can address errors for intravenous and non-intravenous drugs alike. There are few studies on the impact of interoperability between automated dispensing machines and CPOE systems specifically, but the impact of integrating bar-code medication verification with an electronic medication administration system can be used as a proxy, as the latter reduces transcription errors through a similar mechanism: by importing orders electronically from the physician's order entry or pharmacy system. Studies have found that this reduces between 50[13] to 100 percent[11] of transcription errors, so an average value of 75 percent is used.

Administration errors account for 38 percent of all drug errors.[11] Because the mechanism for error reduction is specific to Intravenous (IV) interoperability, the proportion of addressable errors is limited to the 60 percent that are due to intravenously administered medications.[14] A study in the *American Journal of Health-System Pharmacy* found that IV interoperability resulted in a 32 percent reduction in reported monthly errors involving IV administration of heparin,[15] which was used as a proxy for the impact of interoperability on intravenously administered drug errors as a whole, given that the mechanism by which interoperability addresses such errors is not specific to any particular drug.

Based on these assumptions, potential drug error-related savings from medical device interoperability were estimated at more than **$1.3 billion** annually, or 8 percent of the $17 billion total cost of preventable adverse events.

Diagnostic errors

With and without Medical Device Interoperability

Diagnostic errors result from a variety of root causes, such as a failure to account for symptoms, order appropriate tests and consider all relevant diagnoses. Medical device interoperability can reduce such errors by making symptom readings available in real time and pushing test results to a care provider in a timely and clear manner (**Figure 6**).

Figure 6: Case Study: Missed Diagnoses

Current State: A 35 year-old male presents to the Emergency Department with weakness. A nurse notes an abnormal heart rhythm based on bedside monitoring. The printed heart rhythm strip is reviewed by an ER physician, who admits the patient for observation and cardiology consultation. The next day, a cardiologist sees the patient, but the diagnostic rhythm strip in unavailable. Repeated ECGs are non-diagnostic. Additional testing is undertaken to reproduce the arrhythmia, all without effect. The patient is discharged without intervention and returns in 72 hours with worsening symptoms.

Future state: Automated push of information to the EHR would save an electronic version of heart rhythm monitoring results and present it to the cardiologist at the appropriate time, enabling the correct diagnosis and treatment.

Calculations

Joanne Callen and colleagues found that 16.5 percent of missed Emergency Department (ED) diagnoses that harmed patients were due to a breakdown at the step of transmitting test results to the provider.[16] This was applied here as a proxy for the improvement that could be realized by medical device interoperability facilitating the immediate "push" of test results to the EHR so that the care provider has the right information to make appropriate diagnoses.

Based on this assumption, as well as the aforementioned estimates for the costs of preventable adverse events ($16.6 billion) and the percentage due to diagnostic errors (17 percent), it was estimated that interoperability could result in nearly **$466 million** in annual savings related to addressing diagnostic errors, about 3 percent of the total cost of preventable adverse events.

Failure to prevent injury

With and Without Medical Device Interoperability

"Failure to prevent injury" encompasses a variety of potentially preventable conditions. A primary example is ventilator-associated pneumonia; interoperability can reduce its incidence by automating and facilitating the monitoring of physiological parameters and matching the ventilator support needed by individual patients (**Figure 7**). This is particularly important for managing ICU patients with dynamic vital signs and lung capacity in accordance with best practice guidelines. Interoperability supports clinicians in performing frequent "ready-to-wean" assessments, which leads to fewer ventilator days and thus fewer cases of pneumonia.

Postoperative shock can also be addressed by improved interoperability, as integrating continuous vital signs monitoring with alarm systems has been shown to reduce its incidence by allowing earlier intervention in patients whose condition is deteriorating.

Calculations

A study in *Quality & Safety in Health Care* found that the incidence of ventilator-associated pneumonia decreased by 57 percent in response to a bundle of interventions, which included the examination of a number of "trigger tools" to initiate a search for root causes.[17] Based on insights from industry experts who have studied patient safety and device interoperability, interoperability was conservatively assumed to contribute about 25 percent of the value of these interventions. Applying this to the approximately $1.1 billion in health care costs from ventilator-associated pneumonia[18] would result in total potential savings of more than **$163 million**.

Figure 7: Case Study: Failure to Prevent Injury

Current State: A patient is intubated and on a ventilator in the ICU for brain injury. The physician orders a ventilator setting with specific physiological parameters per evidence-based guidelines. Repeat blood gas testing is ordered to maintain these specific parameters. The nurse notifies a respiratory therapist, who draws blood and sends it to the lab. The nurse receives results and calls the physician with findings, which requires a change in the ventilator settings. This cycle occurs four to six times a day based on the patient's dynamic clinical status.

Future State: If blood gas measurements were integrated in real time into ventilator settings to maximize gas exchange, device interoperability could eliminate unnecessary steps and potential delays, minimizing time on a ventilator and thus reducing the duration of hypoxia, the impact of acid-base disturbances and the risk of ventilator-associated pneumonia.

A study in *Anesthesiology* found that continuous pulse-oximetry surveillance reduced "rescue events" (events necessitating the activation of code blue, STAT airway, or HERT teams) by 65 percent.[19] The study indicates that having timely access to information about changes in a patient's clinical status allows providers to intervene and prevent medical injury. A similar rationale can be applied to the prevention of postoperative shock through the increased accessibility of information created by medical device interoperability. Currently, more than $35 million is spent in excess medical costs due to postoperative shock annually.[19] A predictable reduction of 65 percent in postoperative shock cases was implied through improved medical device interoperability, resulting in potential savings of almost **$23 million**.

Together, the impact of interoperability on ventilator-associated pneumonia and postoperative shock totals **$186 million**, or about 1 percent of the total $17 billion cost of preventable adverse events.

In total, with nearly **$1.3 billion in savings related to adverse drug events, $466 million related to diagnostic errors and $186 million related to failure to prevent injury,** the analysis suggests that medical device **interoperability could save more than $2 billion in medical costs across all preventable adverse events**, or more than 11 percent of the $17 billion cost of all preventable adverse events.

Additional Factors to Consider

The estimated $2 billion total savings is a conservative estimate focused only on reportedly preventable adverse events. *Preventable adverse events*, defined as adverse events resulting from medical errors,[20] make up $17 billion in costs. There is reason to believe that some proportion of adverse events typically deemed unpreventable today could be prevented through greater medical device interoperability, as discussed above, such as timely and contextual data display and smart alarms. This could move care past current best practices. (Reliable estimates of the percentage of unpreventable errors that could be addressed by interoperability are not currently available, so they were not included in the estimates for this paper.) Studies also suggest that

adverse events may be susceptible to underreporting. For example, a recent study in *Health Affairs* even found that common methods of adverse event detection miss 90 percent of adverse events, suggesting the incidence could be as much as ten times higher than reported.[21]

While interoperability can further reduce adverse events in the aforementioned ways, it also poses the risk that, in certain instances, an interoperable system could result in magnified systemic errors. For instance, an incorrect drug formulation in a clinically integrated IV system could automatically push to all related infusion pumps hospital-wide, though this would be mitigated by the ability to centrally identify and rapidly respond to and correct such errors. However, this risk is a primary reason any device-to-device interactions or device controls based on information from another system will need to be carefully analyzed to ensure safety and effectiveness.

2. Costs Resulting from Redundant Testing: *$3 billion*

Redundant laboratory and radiology testing account for more than $8 billion in direct health care costs per year, according to a study in *Health Affairs*.[9]

With and without Medical Device Interoperability

Redundant testing stems from numerous factors, including "defensive medicine" driven by lack of trust in tests conducted in other institutions and fear of liability, but it is often simply the result of misplaced, delayed or illegible hard-copy test results (**Figure 8**).

Greater interoperability would allow test results to flow directly into an EHR, eliminating the problem of misplaced or illegible results. Redundant tests due to liability or other hospital policy-related justifications would not be impacted.

Figure 8: Case Study: Redundant Testing

Current State: A 50-year-old has all preadmission testing completed prior to surgery in an associated outpatient center. Results are faxed to the pre-admission testing unit and a copy is given to the patient. The patient loses the paperwork, and the fax never arrives, so the patient must have all labs and ECG repeated on the day of surgery. The ECG is abnormal, without the previous version for comparison. The surgery is delayed and finally cancelled for cardiology evaluation of the abnormality.

Future State: If lab testing devices populated the EHR directly, information would not be lost. This would avoid repeat testing as well as surgical case cancellation by providing the previous ECG for comparison, allowing the provider to evaluate existing versus new abnormalities.

Calculations

According to a study in *Quality & Safety in Healthcare,* errors in reporting results to the physician and charting or filing errors made up an estimated 39 percent of testing process errors.[22] This was used as a proxy for the share of redundant tests, which could potentially be attributed to lost or illegible information (as opposed to hospital policy, potential liability or other reasons). Assuming 95 percent these issues could be resolved with improved medical device interoperability that allows for pushing data to the EHR and potentially to physicians (using picture archiving and communication systems (PACS) as a proxy, as it provides interoperable digital storage and transmission of medical images and is measured as high as 99 percent effective),[23,24] medical device interoperability could create savings of **$3 billion annually, related to avoiding redundant tests from lost information-37 percent of the total costs of redundant testing.**

3. **Costs Resulting from Clinician Time Spent Manually Entering Information:** *$12.4 billion*

Nurse time is a valuable and scarce resource, with nurse salaries accounting for an estimated $173 billion in health care spending per year,[25] and various studies predict a future nursing shortage, resulting from the aging and retiring nurse population and the increasing health care needs of aging baby boomers.[26] Through seamless communication between devices and EHRs, interoperability can reduce the manual verification and documentation activities nurses must currently perform and allow them to use their time more effectively caring for patients.

With and Without Medical Device Interoperability

Studies estimate that about 35 percent of a nurse's shift time is spent on documentation.[27] A significant proportion of this time is spent simply **manually entering vital signs readings** onto paper charts or into EHRs. Interoperability eliminates this time by automatically sending readings from devices to EHRs.

Another source of inefficiency is time spent **manually programming devices** (e.g., infusion pumps), which is a complex, cumbersome process today. Interoperability significantly reduces this time by enabling the automatic population of provider-ordered and pharmacist-validated infusion variables directly into the infusion device.

Calculations

With regards to **manually entering vital signs readings**, studies on the impact of medical device integration find that it eliminates a significant proportion of documentation time. The literature relied on for this analysis suggested a conservative 20 percent reduction in documentation time.[28] When extended across the 1,612,000 registered nurses in U.S. hospitals,[29] paid an average of $106,500 a year,[30,31] this would amount to **more than $12 billion** in annual savings.

Regarding **manual programming of devices**, a study in the *American Journal of Health-System Pharmacy* found that IV interoperability reduced the time to program "smart" infusion pumps by 23 seconds per setup.[15] Extending this over the nearly 750,000 smart pumps estimated to be in use across U.S. hospitals today without EHR integration,[32] assuming two pump setups per day, and the same nurse salary used above, this amounted to **nearly $175 million** in annual savings (see the Appendix for step-by-step calculations).

In total, widespread interoperability could save nurses' time valued at nearly $12.3 billion, or 7 percent of total nurse salaries, representing the cost of over 115,000 nurses.

Studies suggest that the nursing shortage (estimated at 135,000 vacancies in 2008)[33] may have temporarily abated due to the economic downturn, but the shortage is likely to return as the economy recovers and more Americans gain health insurance (with estimates predicting a shortage as high as 500,000 nurses by 2025).[34] Rather than resulting in staff reductions or avoidance of additional hires, these efficiency gains would likely translate into the ability to serve an increasing volume of patients with the current number of nurses, avoiding a future shortage. It could also allow hospitals to increase the amount of nurse time devoted to direct patient care, which has been shown by numerous studies to have a positive impact on patient outcomes and could generate potentially larger savings for the system.[35]

Additional Factors to Consider

The $12.4 billion value calculated above represents a conservative estimate of the clinician time saved through greater interoperability for several reasons. First, the calculations only examined the impact on nurses' time saved, as this was the impact most widely measured in the clinical literature, but Rausch and Judd suggest that greater interoperability could save time for support staff as well.[28] Physicians also waste time collecting information from disparate sources while making rounds. Thus physician time could be saved by consistent and comprehensive presentation of data generated by medical devices. Both physicians and nurses could potentially save additional time from streamlining operating room and other patient safety checklists by automatically populating information from the relevant medical devices. Furthermore, the 20 percent time savings used represents a low estimate of the time savings found in the literature, with several studies finding time savings of 40 percent or more.[36,37] It is worthwhile to note that the gains associated with interoperability's effect on nursing time may differ greatly by region, as nurse wages show significant regional variation. Another conservative limitation to the estimate above is its calculations of device programming time looked only at smart pumps, omitting other programmable devices (e.g., ventilators), though given that most devices do not require nearly the same level of programming, the additional impact of this may be relatively small. These several factors suggest that the actual value created in this category could be two to three times as large as that estimated in this analysis.

4. **Costs Resulting from Increased Length of Stay:** *$17.8 billion*

With and Without Medical Device Interoperability

Delays in receiving test results hinder decision making, unnecessarily extending the length of emergency department visits and inpatient hospital stays. Medical device interoperability, by pushing test results to the clinician, would accelerate decision making, reducing length of stay and providing opportunities for "right-sizing" of departments or avoidance of future staff augmentation.

Calculations

Within the emergency department, the impact on length of stay of reduced test turnaround time due to satellite point-of-care testing was used as a proxy for the impact of greater interoperability, given that interoperability is expected to reduce length of stay through a similar mechanism – increased speed of test results. A study in the *Archives of Pathology and Laboratory Medicine* found that by decreasing test turnaround time by an average of 87 percent, ED point of care testing decreased length of stay by 41 minutes.[38] Extending this across the more than 136 million ED visits per year, each with an average stay of approximately 3.5 hours,[39] would result in a total reduction in length of stay equal to more than 26 million additional ED visits eliminated each year. Valuing each visit at an average cost of $380[40] would yield potential savings of **nearly $9.9 billion** annually, or 19 percent of total ED spending.

Hospitals could realize these savings in a variety of ways, such as reducing or repurposing ED resources. Alternatively, given that nearly 3 percent of attempted visitors currently leave without being seen,[41] hospitals might use the additional capacity to better serve this cohort, potentially resulting in increased throughput and revenue of as much as $1.5 billion, but for the sake of this analysis, the impact was captured as savings.

With regards to *inpatient stays*, the impact of reduced test turnaround time due to combining computerized physician order entry (CPOE) with electronic medication administration records was used as a proxy for the impact of greater interoperability because it looked at the impact of faster test results on length of stay, this time through the integration of clinical systems. A study in the *Journal of the American Medical Informatics Association* found sizeable reductions in radiology procedure completion and lab result reporting times which resulted in a decrease from 3.91 to 3.71 days in severity-adjusted length of stay in one hospital, and no significant impact in the other.[42] Using this as a proxy for the impact of medical device interoperability yields an average impact of 0.1 day reduction in length of stay. Extending across more than 39 million annual inpatient stays,[6] each averaging 4.6 days[6] and $9,200 in cost,[6] yields estimated reduction in inpatient stays worth **$7.9 billion**, or 2 percent of total inpatient spending.

In total, the value of reduced length of stay due to medical device interoperability comes to **$17.8 billion**, or 4 percent of total Emergency Department and Inpatient costs.

Additional Factors to Consider

In addition to reducing length of stay, the timely transfer of information provided by medical device interoperability would improve the quality of care by enhancing clinical decision-making through the presentation of comprehensive, up-to-date information to clinicians. For example, medical device integration at St. John's Medical Center increased its vital sign charting frequency from every 15 minutes to every five minutes, which helped to improve patient outcomes and overall quality of care.[43]

Lack of Commonly Adopted Standards

The preceding section discusses waste in the health care system due to the lack of interoperability - the inability for devices to electronically share data and information with each other and with hospital information systems and to enable clinicians to act upon this information. As discussed in the introduction, the most common solution to addressing these issues today is the development of customized interfaces between devices, as the diverse implementations and limitations of currently adopted standards do not allow "plug-and-play" interoperability. But this lack of commonly adopted standards itself results in further waste, as device manufacturers must incur testing and development costs to facilitate interoperability with a diverse range of systems, and health care providers must, in addition, invest resources to integrate devices with EHRs and other information systems. These costs, in turn, inhibit a move to greater interoperability across the health care system.

5. Device Development and Testing Costs

In interviews conducted with device manufacturers, estimates of the costs of developing and testing devices to facilitate interoperability with EHRs varied by manufacturer, averaging $740,000 per device per EHR.[44] An estimated 235 potentially interoperable devices are approved by the FDA each year,[45] but interviews with manufacturers suggested that, at most, half of the devices released each year involve additional investments to facilitate interoperability. These assumptions result in an estimated $87 million in development and testing costs across the industry to achieve interoperability with each EHR vendor. Using the conservative assumption that device manufacturers seek to achieve interoperability with six other systems on

average (the top six EHR vendors account for 80 percent of market share,[46] making them the most likely candidates for interfacing) yields annual industry-wide testing and development costs of more than $520 million today. While adopting standards will include short-term increases in costs, in the longer term, overall industry testing and development related to interoperability would likely decline relative to the expenses incurred today. If vendors only had to achieve interoperability with one common set of standards, these costs could drop to $87 million, saving approximately **$430 million** in device development and testing costs industry-wide, or nearly 2 percent of total industry research and development (R&D) spending.[47]

6. Provider Integration Costs

It is important to note that a substantial proportion of the costs of interoperability are also passed on to providers, with device companies in some cases supporting interoperability between their device and hospital systems on an as-requested basis. Hospitals spend billions of dollars annually on EHR implementation[48] and hospital development and integration, a portion of which is invested in achieving medical device interoperability.

Starting with one-time integration costs of $10,000 per bed per year,4 and assuming 7 percent of hospitals integrate devices to EHRs per year (based on the percentage of hospitals moving into advanced stages of EHR adoption each year[49]), and 15 percent annual maintenance costs for the 33 percent of hospitals with a level of current interoperability,[3] annual provider investment in interoperability is estimated at $1.1 billion. Assuming that 66 percent of these costs could be reduced with commonly adopted standards, as hospitals go from using three different sets of interfaces (based on the HIMSS Analytics finding[3] that hospitals integrate an average of three types of devices today) to one set of interfaces would yield an estimate of nearly **$740 million** in potential annual savings.

Given the substantial costs of integration, reducing these costs through convergence on common "plug-and-play" standards could greatly accelerate the move to medical device interoperability among providers, much as convergence on the USB standard revolutionized interoperability for computer peripherals and other electronics, with more than six billion USB-enabled products sharing information today.[50]

Who Benefits?

A high-level analysis suggests that the majority of benefits related to increased medical device interoperability and improved adoption of common standards for interoperability may accrue to providers (93 percent), followed by payers (6 percent) and patients (1 percent) (**Figure 9**).

Figure 9: Savings by Stakeholder

Area of Waste due to Lack of Medical Device Interoperability	Share of Total ($M)			
	Providers	*Payers*	*Patients*	*Device Vendors*
1. Adverse events avoidable with medical device interoperability	$1,000	$850	$150	
2. Redundant testing resulting from inaccessible information	$1,500	$1,275	$225	
3. Clinician Time Spent Manually Entering Information	$12,300			
4. Increased length of stay from delays in information transfer	$17,800			
Total Savings ($M)	**$32,600**	**$2,125**	**$375**	**$0**
Total Savings (%)	**93%**	**6%**	**1%**	**0%**

Note: Numbers rounded for clarity

Area of Waste due to Lack of Commonly Adopted Standards	Share of Total ($M)			
	Providers	*Payers*	*Patients*	*Device Vendors*
5. Device testing and development costs				$430
6. Provider costs to integrate devices with EHRs	$740			
Total Savings ($M)	**$740**			**$430**
Total Savings (%)	**63%**			**37%**

Savings from avoidance of adverse events would accrue in part to providers, payers and patients. While payers and patients typically bear the costs of treatment, payers are increasingly penalizing providers for preventable adverse events by limiting or denying reimbursement. The extent to which each stakeholder bears costs and accrues benefits varies by payer and by type of event (e.g. never events), making it difficult to quantify the precise proportion of savings accruing to each stakeholder. To provide a directional estimate, it was assumed that the benefits are split in half with providers gaining roughly $500 million. The remaining $500 million is divided between payers and patients based on the ratio of national health expenditure for each, 85 percent ($425 million) and 15 percent ($75 million) respectively.

As with adverse events, reimbursement for redundant testing varies based on payer contracts, and reimbursement trends are moving to deny payment for tests already performed. For reasons similar to those above, providers have been assumed to bear half the costs of such testing, and therefore capture 50 percent of the savings. The remaining 50 percent was again allocated to payers and patients based on the ratio of national health expenditure for each.

Savings from decreased length of stay are assumed to accrue entirely to providers, who are typically paid a flat fee for visits regardless of length of stay. Likewise, providers bear the full costs of nurse salaries, and therefore capture the entirety of the savings relating to time wasted manually entering information.

Medical device companies accrue all benefits that may result from the reductions in research and development resulting from common adoption of standards for interoperability, and providers accrue the related reductions in capital and development expenditure and maintenance created by avoiding custom integration solutions.

Additional Benefits Not Quantified

Lack of Medical Device Interoperability

The benefits discussed above form the core case for interoperability, representing benefits that could be realized directly. However, there are a number of additional benefits enabled by interoperability which are more difficult to quantify or require additional enabling factors to be realized.

Greater medical device interoperability could enable rapid advances in clinical decision support, as the continuous flow of patient-specific physiologic information (e.g., vital signs) to data repositories would enable advanced data analytics. This combination of real-time patient data can help to achieve clinical workflow improvements not realizable today and result in improved affordability of medical care, the impact of which cannot be quantified prospectively.

Stakeholders would also see benefits of interoperability when using remote patient monitoring systems with the EHRs, which would facilitate viewing of patient-generated data alongside clinically generated data. Remote patient monitoring has been shown to reduce costs and improve outcomes in a number of studies,[51] and by integrating data into providers' workflow, interoperability could encourage provider adoption and further improve efficacy. Additionally, the interoperable transfer of non-clinical device data (e.g., battery status, need for software updates, device location, etc.) would enable the automation of device maintenance currently managed manually, as well as improve inventory and utilization management.

Patients would benefit through reduced premiums and improved care, as well as improved experiences in the system. First, they will spend less time on medical care, as patient time wasted due to redundant tests, extended length of stay and redirects from overcrowded emergency rooms to available hospitals effectively represents foregone wages. Additionally, preventable adverse events result in not only increased medical costs but also increased mortality. While these are significant sources of value, these productivity and mortality benefits are not typically included in the **$700 billion** estimates of waste in the health care system, and therefore have been excluded from this analysis.

Lack of Commonly Adopted Standards

Commonly adopted standards would also create several additional sources of value beyond the savings estimated above. According to interviews with health system engineering experts, the custom interfaces required today pose the risk of a high volume of systematic medical errors if developed incorrectly, and writing and maintaining these interfaces to a high level of reliability is difficult and expensive for device manufacturers, particularly as the supply of qualified labor becomes increasingly scarce. By reducing the need for custom interfaces, commonly adopted standards would lessen these costs and risks.

Furthermore, the costs of proprietary interfacing with a variety of EHRs and other hospital information systems limits innovation among device manufacturers, particularly smaller players, who lack the scale to recover these fixed interoperability costs. As has been seen in other industries with the adoption of USB and wireless communication standards, commonly adopted standards allow small companies to quickly and efficiently create and bring new technologies to market. This not only lowers the barriers to innovation for small device manufactures and start-up companies, but can also be a major influence in fueling the economic growth.

This increase in innovation and competition would, in turn, allow providers to choose from a broader range of devices and potentially result in reduced prices paid for devices and greater innovation in new devices –benefits difficult to quantify, but repeatedly mentioned by provider interviewees. These benefits would be further bolstered by a reduction in switching costs, compared to the current situation where investments in interoperability with a given vendor's devices create substantial barriers to a hospital buying devices from different vendors in the future.

Conclusion

Summary

This study estimates that widespread medical device interoperability can eliminate **$36 billion** of waste in the health care system. Functional interoperability leads to increased efficiency, lower costs and better quality of care through four primary drivers: 1) quality improvement through reduction of adverse events due to safety interlocks ($1.9 billion), 2) reduced cost of care secondary to avoidance of redundant testing ($1.5 billion), 3) increased clinician productivity secondary to decreased time spent manually entering information ($12 billion) and 4) improvements in patient throughput secondary to shortening length of stay ($18 billion).

Impact on Efficiency

The reduction in clinician time spent manually entering information allows providers to improve workflow and optimize staffing models. Physicians and nurses can redirect time saved for value-added activities such as direct bedside care, patient education and care coordination. In addition, providers can allocate time to fulfill the requirements established by value-based purchasing and hospital readmissions reduction programs. With an aging population and expansion of insurance coverage leading to increased demand for services, providers are more prepared to respond to the call to provide better care at a lower cost.

Through timely access to relevant and complete clinical information, medical device interoperability can shorten length of stay and create additional capacity without an increase in cost. Shorter length of stay is attained by improving the quality of care for existing patients. Increased capacity creates an opportunity for providers to right-size their departments, achieve appropriate bed utilization and management metrics and expand access to care for patients not currently being served in the system.

Impact on Costs and Quality

Interoperability drives direct cost savings by decreasing the number of procedures completed through avoidance of redundant testing and adverse events. The "data push" capabilities enabled by functional interoperability will help overcome the latency or inaccuracy of reporting test results that often result in redundant testing today. A reduction in adverse events driven by safety interlocks enabled by interoperability also results in direct savings by removing the cost of care associated with treating patients who experience these events. The distribution of these cost savings will depend on the contracts established between payers, providers and patients.

A system-wide improvement in quality of care is achieved through automation of processes and reduction of the number of opportunities for human error. Adverse events decline as clinical work flow is simplified and the number of steps to diagnose and treat a patient is reduced. Avoiding redundant testing also

improves the patient experience and overall quality of care by reducing the number of procedures a patient must endure and the time the patient spends in the system.

Limitations and Areas for Further Research

This analysis was undertaken to estimate the magnitude of potential health care delivery cost savings resulting from the availability and widespread adoption of true, functional medical device interoperability. As there are few examples of such plug-and-play interoperability, a variety of assumptions and extrapolations from surrogate circumstances were employed, referenced as appropriate to guide the reader. Nonetheless, the nature of this work does not afford absolute precision, but rather an order-of-magnitude estimate. Additionally, the current cost of achieving medical device interoperability and, in turn, the potential savings from common adoption of standards are less certain than the estimates of waste addressed by interoperability itself. There is limited research available on the costs of provider integration and limited consensus from stakeholders on the proportion of device development and testing costs and provider integration costs that would be eliminated with commonly adopted standards. This remains an important area for further research, as the substantial costs of achieving interoperability represent a significant barrier to realizing the efficiency, cost and quality benefits detailed above. Experience in other industries suggests that commonly adopted standards would indeed have the desired impact of accelerating adoption and potentially reducing costs of integration, and this should be further examined as a potential solution for medical device interoperability.

Call to Action

Given the opportunity to improve patient care and reduce health care spending by more than $30 billion per annum, the question that follows is how to drive a shift from the current state with a lack of widespread medical device interoperability to a fully networked health care system where the substantial benefits of interoperability can be realized.

Current Efforts towards Increased Interoperability

A number of organizations are working to further medical device interoperability in the clinical environment by promoting various means of standardization. However, no single effort has reached critical levels of adoption. One approach, developing prescribed profiles to facilitate consistent implementation of communication standards, is being led by Integrating the Healthcare Enterprise (IHE), a broad initiative of health care and health information technology stakeholders. This group creates profiles based on existing standards bodies such as IEEE and HL7. The North American branch of IHE facilitates an annual connect-a-thon to validate profiles and hosts a number of demonstrations through an Interoperability Showcase at the HIMSS national meeting. Other efforts include the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program, which has "been working to accelerate the adoption of medical device interoperability by providing interoperability building blocks (use cases, standards, a neutral lab environment and open research tools) and by changing clinical and market expectations of what can be achieved."[52] Most recently, the Association for the Advancement of Medical Instrumentation (AAMI) announced a partnership with the testing, certification and standards development organization Underwriters Laboratories (UL) to develop a suite of standards on medical device interoperability, aiming "not to supplant existing standards or profiles," but rather "to map them into a framework and address further safety issues where applicable."[53]

In the consumer medical device realm, the Continua Health Alliance is promoting the adoption of common standards for interoperability. Meanwhile, a number of consumer-driven medical device companies are taking a market-wide approach to interoperability through the use of Application Programming Interfaces (APIs), with companies such as Fitbit using APIs to share data between activity sensors, smartphones, computers and applications. The clinical device sector has seen limited application of this type of approach. Additionally, in the clinical medical device realm, purchasing behavior of providers has yet to require this level of "plug-and-play" interoperability now common among consumer electronics. There are several efforts that provide requirements guidance for medical device interoperability. For example, Medical Device "Free Interoperability Requirements for the Enterprise" (MD FIRE)[52] comprises a white paper and sample RFP and contracting language. The IHE Patient Care Device User Handbook also describes how and why to acquire and implement systems and devices for device interaction. However, these efforts and efforts by many individual hospital systems have yet to be utilized on a broad scale. While consumers quickly drive technology to common standards for ease of use and rapid adoption, hospitals have yet to share a common voice related to requirements for medical device interoperability.

Who Will Lead the Way?

Despite the numerous activities promoting standardization for medical device interoperability, no common approach has been adopted widely. The value proposition presented above suggests that it is unlikely medical device and IT companies will proactively move towards standardized "plug-and-play" device interoperability, and that providers may have the most significant burning platform for promoting medical device interoperability as a solution to the efficiency, capacity and cost issues they are currently facing, supported by pressure from payers changing to more value-based payment models.

Device Manufacturers

In order to drive rapid adoption of medical device interoperability, incentives for device companies, who will bear the cost to develop the capability within devices, must be aligned with those of the remaining health care stakeholders, who reap the benefits of increased interoperability and adoption of standards. Discussions with medical device industry leaders highlight the fact that although technology to generally enable interoperability exists, market forces today do not create the aligned incentives to produce devices with consistent modes for interoperability.

As discussed previously, device manufacturers are unlikely to see substantial benefits from either increased interoperability or commonly adopted standards. The latter would likely be viewed as diminishing the competitive advantage of large companies who currently tout integration among their own closed system of devices as a benefit of purchasing their bundled device solutions. Moreover, interviewees expressed concerns that the development and testing costs involved in moving to consistent industry-wide standards would be substantial in the short-term relative to the longer-term gains in development costs avoided through convergence on standards. As a result, device manufacturers may not have strong incentives to organically lead the charge towards common adoption of open, plug-and-play interoperability standards until their customers – health care providers coordinate to provide clear requirements to consistently, perhaps even fully integrated with their procurement processes.

Providers

Providers accrue the vast majority of benefit from medical device interoperability at $33 billion, or 93 percent of the total, primarily due to productivity gains from improved workflow. However, few, if any, providers have achieved functional interoperability, and those that have typically created customized closed systems that are not scalable solutions for the rest of the industry. A 2010 HIMSS Analytics study suggests that more than two-thirds of providers have entirely forgone the investment required to obtain any level of benefits from functional interoperability to date.[3]

Interviews indicated that the benefits of interoperability are not well documented and are currently superseded by other decision-making criteria, such as current regulation and limited budgets for competing

projects. Many providers are currently most concerned with meeting the immediate, Stage 1, requirements for Meaningful Use of EHRs, incentivized by deadlines for funding from the Centers for Medicare and Medicaid Services (CMS). Stage 1 requirements create minimal standards for sharing selected and prescribed information among stakeholders – an important first step, but a far cry from the interoperability requirements needed to realize the benefits detailed above. Based on the recent Stage 2 requirements and proposals for Stage 3, Meaningful Use is missing an opportunity to advance medical device interoperability. Although Meaningful Use requirements can establish important prerequisites for collecting device information, they do not currently drive functional medical device interoperability.

Aside from their current focus on basic Meaningful Use, an additional challenge for providers is that they too could incur an appreciable investment of resources to build the infrastructure and replace legacy medical devices to demonstrate interoperability. However, as identified above, the productivity gains and cost savings created by the improved workflow facilitated by medical device interoperability can create a substantial return on these investments.

To realize these returns, providers need support of technology and device companies to address the workflow integration, as well as financial incentives to prioritize interoperability over other investments. If providers begin to consistently require interoperability as a key component in request for proposals (RFPs) for new equipment, they can steer the device and technology industries to resolve the workflow needs and adopt more standard means for implementation of interoperability. This would require increased coordination and collaboration among the various parties currently focused on developing standards and guidelines for interoperability. Additionally, a continued shift toward capitation models by payers will put pressure on providers to aggressively manage limited resources and create a sense of urgency around investments that can improve productivity, such as medical device interoperability.

Payers and Government

Payers and the government (both in its role as a payer through Medicaid and Medicare and more broadly in its position as a regulator with the responsibility to address market failures) are also poised to influence the speed of medical device interoperability. While the analysis in this paper suggests that payers capture a much smaller proportion of benefits from interoperability than providers, payers will secondarily benefit from the reduced cost of services and improved health outcomes associated with the efficiency gains of providers. Additionally, many of the benefits not quantified in this analysis, such as improved adoption and efficacy from remote patient monitoring and the ability for advanced data analytics would result in reduced costs to payers. A continued shift in the payment system from fee-for-service to capitation or other value-based approaches will accelerate the need for providers to improve workflow to achieve better outcomes with fewer resources.

The federal government is already taking steps to incentivize greater interoperability. Broadening Meaningful Use requirements to incorporate functional medical device interoperability could play a crucial role in driving greater interoperability throughout the health care system; however, it would be about five years before this incentive took effect. Government and private payer reimbursement practices will need to be primary drivers to promote provider implementation of medical device interoperability in order for the system to more rapidly realize the savings estimated in this report, similar to how future payments to

providers will be tied to complying with Meaningful Use, readmission and other emerging performance standards.

The continued convergence of payers and providers will create a strong platform for accelerating medical device interoperability. Accountable Care Organizations (ACOs), for example, could be a driver of medical device interoperability, given their need to achieve cost savings while integrating large and disparate networks across EHRs and HIEs. Although ACO participation is currently low, with only 13 percent of hospitals reporting current participation in an ACO or plans to do so within a year according to the Commonwealth Fund, other models of care coordination and collaboration for improved population health management will drive similar needs for the efficiency and quality improvements that can be provided by medical device interoperability.[54]

Coupling this convergence with the systemic capacity challenges providers already face due to increasing demands on the system from 30 million new consumers entering the health insurance market, a rapidly aging population and predicted clinician shortages, providers are finding themselves on a burning platform that requires them to do more with less. This creates a strong case to redirect investment toward medical device interoperability due to its significant impact on clinician productivity and cost reduction.

Appendix: Detailed Calculations

Blue numbers indicate inputs

Lack of Interoperability

Adverse Events: Drug Errors

		Metric	Value	Notes
1	=	Value of adverse event costs attributable to drug errors ($K)	$3,800,000	[9]
2	X	% of drug errors due to ordering errors	39%	[11]
3	X	% preventable by interoperability	47%	[12]
	=	***[A] Value of reduced ordering-related adverse events ($K)***	***$702,000***	
5				
6		Value of adverse event costs attributable to drug errors ($K)	$3,800,000	[9]
7	x	% of drug errors due to transcription errors	12%	[11]
8	x	% preventable by interoperability	75%	[11] [13]
9	=	***[B] Value of reduced transcription-related adverse events ($K)***	***$342,000***	
10				

Adverse Events: Drug Errors - continued

11		Value of adverse event costs attributable to drug errors ($K)	$3,800,000	Calculated above
12	x	% of drug errors due to administration errors	38%	[11]
13	x	% due to intravenous medications	60%	[14]
14	x	% preventable by integrated infusion pumps	32%	[15]
15	=	***[C] Value of reduced administration-related adverse events ($K)***	***$277,248***	
16		**[A] + [B] + [C] = Total potential drug error-related savings from interoperability ($K)**	**$1,321,248**	

Adverse Events: Diagnostic Errors

		Metric	Value	*Notes*
1		Total cost of preventable adverse events ($K)	$16,600,000	[9]
2	x	% of adverse events due to diagnostic errors	17%	[10]
3	=	Value of adverse event costs attributable to diagnostic errors ($K)	$2,884,050	
4	x	% of diagnostic errors addressable by device interoperability	17%	[16]
5	=	**Potential diagnostic error-related savings from interoperability ($K)**	**$465,630**	

Blue numbers indicate inputs

Adverse Events: Failure to Prevent Injury

Ventilator-Associated Pneumonia

		Metric	Value	*Notes*
1		Total annual cost of ventilator-associated pneumonia ($K)	$1,140,000	Estimates range from $780M to $1.5B; midpoint used. [18]
2	x	Reduction in ventilator-associated pneumonia due to bundle of interventions	57%	Ventilator-assisted pneumonia reduced from 7.5 to 3.2 per 1000 ventilator days. [17]
3	x	% attributable to device interoperability	25%	Based on industry interviews.
4	=	**Potential ventilator-associated pneumonia savings from interoperability ($K)**	**$163,400**	

Postoperative Shock

		Metric	Value	*Notes*
1		Total number of postoperative shock incidents caused by errors annually	748	[9]
2	x	Medical cost per error ($K)	47	Mortality cost per error ($46,584) not included. [9]
3	=	Total medical cost of postoperative shock errors ($K)	$35,230	
4	x	% Reduction due to device interoperability	65%	Continuous pulse ox surveillance reduced "rescue events" from 3.4 to 1.2 per 1000 patient discharges. [19]
5	=	**Potential postoperative shock-related savings from interoperability ($K)**	**$22,796**	

Blue numbers indicate inputs

Redundant Testing

		Metric	Value	Notes
1		Direct costs of redundant tests in U.S. hospitals ($K)	$8,172,000	[9]
2	x	% of duplicative tests due to lost information	39%	14.5% of testing process errors due to charting or filing errors; 24.6% due to failure to report results to physicians. [22]
	x	% avoided due to interoperability	95%	99% number from [23] corroborated by qualitative commentary in [24]. 95% value used to be conservative.
4	=	**Potential costs saved by medical device interoperability ($K)**	**$3,035,489**	

Blue numbers indicate inputs

Wasted Clinician Time: Manually Entering Vital Signs Readings

		Metric	Value	*Notes*
1		% of time spent on documentation	35%	Assumed to be constant for hospitals with and without EHRs (studies find varying effects) [27]
2	x	Average annual salary for nurse	$106,500	$50/hour total compensation for hospital RNs [31], x 2130 hrs worked/year [30]
3	x	Total number of registered nurses (RNs) in U.S. hospitals	1,612,000	2.6M licensed RNs employed in nursing, 62% of those work in hospitals [29]
4	=	Total value of nurse time spent on documentation per year ($K)	$60,602,334	
5	x	% of time saved due to interoperability	20%	[28]
6	=	**Total potential annual savings in nurse salaries ($K)**	**$12,120,467**	

Blue numbers indicate inputs

Wasted Clinician Time: Manually Programming Devices

		Metric	Value	*Notes*
1		Reduction in programming time per smart pump setup (min)	0.4	23 seconds per setup. [5]
2	x	Number of infusion setups per smart pump per year	730	Assumption – 2 readings/day x 365 days/yr
3	=	Hours saved in setups per smart pump per year	5	
4	x	Number of smart pumps in use across U.S.	805,560	5,754 U.S. hospitals [55] x 50% using smart pumps x 280/hospital [3]
	x	% of hospitals not interfacing smart pump with EHR today	93%	[3]
5	=	Hours saved in pump setups across U.S. per year	3,497,806	
6	x	Average hourly salary for nurse	$50	[31]
7	=	**Total potential annual savings in nurse salaries ($K)**	**$174,890**	

Blue numbers indicate inputs

Increased Length of Stay

Emergency Department

		Metric	Value	Notes
1		Total number of ED visits	136,072,000	[39]
2	x	Reduction in ED time (hours)	0.68	[38]
3	=	Maximum hours of ED time gained	92,982,533	
4	/	Average length of ED visit (hours)	3.5	[39]
5	=	Number of ED visits saved	26,266,252	
6	x	Average cost of ED visit	$380	$52B total ED expenses and 136M visits [40]
7	=	**Value of ED visits reduced ($K)**	**$9,883,046**	

Inpatient

		Metric	Value	Notes
1		Total inpatient stays	39,400,000	[6]
2	x	Reduction in length of stay (days)	0.1	[42]
3	=	Total days of inpatient time gained	3,940,000	
4	/	Average length of inpatient stay (days)	4.6	[6]
5	=	Number of inpatient stays saved	856,522	
6	x	Average cost per inpatient stay	$9,000	[6]
7	=	**Value of inpatient stays reduced ($K)**	**$7,880,000**	

Blue numbers indicate inputs

Lack of Commonly Adopted Standards

Device Development and Testing Costs

		Metric	Value	Notes
1		Testing and development costs per EMR interface, per device ($K)	$740	Estimates from vendor interviews ranged from $350K to $1.2M; midpoint used
2	x	# of potentially interoperable devices developed per year, industry-wide	235	Based on FDA 510k approvals data
3	x	% of devices with interoperability-related development	50%	Based on vendor interviews
4	=	Costs per EMR interface (industry-wide) ($K)	$86,827	
5	x	Average # of EMR interfaces required today (per device)	6	[46]
6	=	*[A] Total testing and development costs today ($K)*	*$520,960*	
7		Costs per EMR interface (industry-wide) ($K)	$86,827	From line 4 above
8	x	Average # of EMR interfaces required in future state	1	Based on vendor interviews
9	=	*[B] Total testing and dev. costs in future state ($K)*	$86,827	
10		**[A] – [B] = Savings on testing and dev. costs ($K)**	**$434,133**	

Blue numbers indicate inputs

Provider Integration Costs

		Metric	Value	Notes
1		One-time integration cost to EMR, per bed ($K)	$10	[4]
2	x	Average number of staffed beds nationwide per hospital	164	[55]
3	=	Average integration costs per hospital ($K)	$1,637	
4	x	Number of hospitals nationwide	5,754	[55]
5	x	% with integrated devices (installed base)	33%	[3]
6	x	Annual maintenance as % of one-time integration	15%	Industry standard, based on interviews
7	=	*[A] Annual maintenance costs nationwide ($K)*	$466,288	*Calculated*
8		Average integration costs per hospital ($K)	$1,637	From above
9	x	Number of hospitals nationwide	5,754	From above
10	x	% of hospitals integrating devices to EMR per year	7%	[49]
11	=	*[B] Annual one-time costs nationwide ($K)*	*$649,977*	*Calculated*
12		*[A] + [B] = Estimated total integration spending ($K)*	*$1,116,264*	*Calculated*
13	x	Share reduced by implementation of common standards	66%	Standardized from 3 to 1 interfaces (average number of integrated devices today is 3, according to [3])
14	=	**Total potential savings ($K)**	**$736,734**	

Blue numbers indicate inputs

NOTES

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Mr. PITTS. Chair thanks the gentleman, and now recognizes Ms. Bechtel for 5 minutes for an opening statement.

STATEMENT OF CHRISTINE BECHTEL

Ms. BECHTEL. Good morning. I am Christine Bechtel with the National Partnership for Women and Families. We are a nonprofit, nonpartisan consumer advocacy organization. I also serve on the Federal Health IT Policy Committee.

I am honored to speak today about how the EHR Incentive Program, commonly known as "Meaningful Use", is catalyzing fundamental change in our health care system and advancing innovation.

Almost 3 years ago before this same subcommittee, I shared a story of Susan Crowson, and she is a family caregiver from Maryland, and she cared for her father, Pop. Pop was seeing five different doctors, taking three different prescription drugs, two over-the-counter drugs, and daily vitamins to manage a host of complex conditions, including Alzheimer's Disease, and arrhythmia. Susan diligently tracked all of Pop's medications, tests, lab results, and visits on a spreadsheet to help his doctors avoid medical errors and provide the best care possible in our highly fragmented system.

Today, the Meaningful Use Program is making care better for people like Pop and caregivers like Susan. Providers with certified EHRs now maintain up-to-date electronic lists of patient's health conditions, diagnoses, and medications, and doctors can automatically track for drug interactions and allergies. Pop and Susan can get a summary at every office visit so they know the diagnosis and the plan. If Pop is admitted to the hospital, they can send a summary of his admission to his primary care doctor. These are just some of the early innovations in health IT.

Sadly, many of these advances were not put in place quickly enough to help the Crowson family. Since I last testified, Pop has passed away. But thanks to Meaningful Use, patients and family caregivers like Susan are less likely to face these same struggles. They are now coming to expect health IT, just as technology has revolutionized so many other aspects of our life.

Indeed, the arc of adoption has surpassed our expectations. At the last subcommittee hearing in 2010, we wondered if incentive payments would be effective drivers of EHR adoption. We asked if providers would be able to achieve Meaningful Use. Federal officials then offered a high end estimate of 53 percent of office-based physicians would adopt EHRs by 2015. But as of this February, 2 years before the 2015 projection, CMS reports that 40 percent of eligible professionals have already completed phase one of Meaningful Use, either in Medicare or Medicaid, and more than 70 percent have registered for it. Hospitals have been even more successful. Seventy percent are already Meaningful users, and 85 percent have registered.

But there is much more work to do. To foster continued innovation, we must deploy a wider array of standards through HHS's certification program, which has been essential to breaking down technical barriers to the secure sharing of health information. It is this federal leadership which occurs in collaboration with the private sector that is critical to innovation.

We also need new approaches to payment that moves us beyond fee-for-service and creative business case for care coordination and improved health outcomes. This can only be done by rewarding quality and value over volume. But we simply cannot measure and reward this kind of care without health IT.

Even within these limitations, though, advancements in standardization spurred by the Meaningful Use regulations are catalyzing innovation. So for example, Medicare and the VA implemented a feature called Blue Button that allows individuals to securely view and download their health information online, and this innovation is making a world if difference for people like Beth Schindele, who cares for her father, William Graves. With his permission, Beth went to mymedicare.gov and downloaded his health information when he was in the hospital. The data from Blue Button showed that he had more than 63 providers caring for him over the course of four hospitalizations in the last year and a half, and she told me last week "Having the data in my hands during his hospitalization allowed me to prevent the hospital from erroneously placing him on Coumadin, which is a blood thinning medication, and he had stopped taking that 2 years ago. I am so thankful that I did. Within hours of discharge, he fell and he suffered severe head and arm lacerations that would have been life-threatening had he been on Coumadin, and would have resulted in a readmission within just 5 hours of leaving the hospital." Blue Button is a simple, yet powerful, innovation that will help consumers play a critical role in promoting safer, more affordable, and more coordinated care.

For this kind of innovation to accelerate, the challenge before us is to ensure that every provider in the country has health IT. We must expand the Meaningful Use program to connect other providers like long-term care, behavioral health, and home health. No other program in history has done this much this quickly to advance the adoption of health IT, and I am confident that along with payment reform, it will result in better care at a lower cost. Thank you.

[The prepared statement of Ms. Bechtel follows:]

Good afternoon Mr. Chairman, Ranking Member Pallone and distinguished committee members. I am Christine Bechtel, vice president of the National Partnership for Women & Families, a non-profit, non-partisan consumer advocacy organization. For the last four years, I have also served on the federal Health IT Policy Committee as a consumer representative.

With more than 40 years of experience working to make life better for women and families, the National Partnership promotes access to high quality health care, fairness in the workplace and policies that help women and men meet the dual demands of work and family.

As you know, health care is central to the well-being of women and families – it is a key determinant of their quality of life, their economic security, and their ability to thrive, prosper and participate in our society. In collaboration with the consumer coalitions we lead, which include the Consumer Partnership for eHealth (CPeH) and the Campaign for Better Care, we are working to advance private and secure health information technology (IT) in ways that measurably improve the lives of individuals and their families. Advancing and using health IT is essential to making health care more accessible, affordable and effective for consumers because health IT is a tool that can empower consumers to work in partnership with professional care team members and make informed choices about treatment options. It has enormous potential to improve the quality of clinical care, decrease health disparities, and bolster research and public health.

I am honored to be asked to speak with you today about how the Electronic Health Record (EHR) Incentive Program (commonly known as "Meaningful Use") is not only catalyzing a fundamental change in the health care system, but is serving as a springboard for innovation.

Why Health IT Matters

Almost three years ago in testimony before this subcommittee, I shared the story of Susan Crowson, a family caregiver from Maryland, who cares for her father "Pop". At that time, I described how Pop was seeing five different doctors – each of whom monitored and treated a separate problem – and was taking three prescription drugs, two over-the-counter drugs, occasional antibiotics, and daily vitamins to manage a host of complex health conditions including Alzheimer's disease and heart arrhythmia. Susan was his Coordinator in Chief, diligently tracking all of Pop's medications, tests, labs and doctor visits to help his doctors avoid medical errors and provide the best care possible in a highly fragmented system. It was a recipe for mistakes.

Susan built her own spreadsheet to keep track of it all. She left copies with each doctor Pop saw, but the information never made it into their records. She always asked his doctors to

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share his record with the primary care physician and other specialists, but it was rarely done. When she took her dad for lab tests every two months, she was the one making sure each doctor got the results — or it didn't happen. When Pop's doctors would prescribe a new drug, they would tell Susan to check with Pop's other four doctors about potential drug interactions.

The Meaningful Use program was designed with families like Susan's in mind. Today, the work she did to keep Pop safe from medical errors is getting easier because phase one of the Meaningful Use program:

- Enables providers to maintain up-to-date electronic lists of the health conditions, diagnoses, medications, and medication allergies of patients like Pop. They can automatically:
    - Check for drug-drug interactions and drug-allergy problems; and
    - Send prescriptions electronically to Pop's pharmacy of choice, reducing wait time and eliminating handwriting errors.
- Facilitates communication with patients and other providers, including sharing information that provides a more complete picture of a patient's health.
    - For the Crowsons, this would mean Pop and Susan get a summary of every office visit so they know what was diagnosed and what the plan is.
    - Any of Pop's five doctors can send a summary of his record securely to other members of his care team who are Meaningful Users.
    - If Pop is admitted to an EHR-enabled hospital, they can send a Summary Care Record to his primary care doctor once he's discharged.
- Helps caregivers like Susan easily and conveniently access medical records online and send a secure email to his providers.

I must tell you, sadly, that many of these advances were not put in place quickly enough to help the Crowsons. Since I last testified before this subcommittee, Pop has passed away but Susan's heroic work to keep him safe from medical errors and get him high quality care continued to the end of his life. However, because of Meaningful Use, other family caregivers will not face the same overwhelming struggles. In just two years since Meaningful Use was put in place, the experiences and expectations of patients and families are changing dramatically, and these benefits will accelerate as the incentive program continues.

This, I am convinced, is why EHR adoption must become universal.

How Far We've Come

At the last subcommittee hearing in 2010, we discussed and debated this program's potential. We wondered if incentive payments would be effective drivers of EHR adoption. We asked whether Eligible Professionals (EPs) would be able to achieve Meaningful Use. Centers for Medicare and Medicaid Services officials projected a high-end estimate that 53 percent of ambulatory care providers would adopt EHRs by 2015.

But as of February of this year – two years before the 2015 deadline – CMS data show that more than 70 percent of eligible providers (370,000) have already registered for the program, signaling their intent to complete it. And nearly 40 percent have already successfully completed the first phase of either the Medicare or Medicaid incentive program.

Hospitals have been even more successful. Almost 85 percent of Eligible Hospitals have registered for the program and more than 70 percent are meaningful users today.

These data underscore how the investment Congress made in health IT is helping families like Susan Crowson's and patients like Pop. The incentive payments are accelerating the arc of adoption well beyond what we anticipated, and that means patients and families are beginning to reap the benefits of these reforms. We are coming to *expect* the presence of health IT to optimize our health and health care, just as technology has revolutionized so many other aspects of our lives.

Yet we have a ways to go. We all agree that the health care system must change. Despite the best efforts of deeply caring health professionals, our health care system is simply too expensive in both financial and human terms – for patients and providers alike. While the United States is home to the best doctors, clinicians and treatments in the world, the kind of coordination and communication that patients and families want and need is discouraged by our fee-for-service payment system.

Many of our best ideas to change the way we pay for and deliver care – Accountable Care Organizations, Patient-Centered Medical Homes, bundled payments, and others – absolutely hinge on the availability and seamless exchange of health information to introduce efficiencies and cost savings, and to provide the kind of care that improves patients' health. They require measuring and rewarding value and quality over volume.

But we simply cannot measure health outcomes or efficiency without health IT. We need clinical data from the point of care – not just billing data – to provide a complete picture of a patient's health and to accurately assess and pay only for care that is effective, efficient and equitable.

In other words, health IT is an important engine that can drive improvement and innovation in health care, and the Meaningful Use program is its primary fuel.

An Engine for Innovation

In only its first phase, this program has achieved a tremendous amount. There is certainly work remaining, and I believe this work will bear the fruit of remarkable innovation once two things happen:

- First, when a wider array of standards are deployed through the Department of Health and Human Services' (HHS) Certification program (which stipulates the technical specifications of EHRs qualified for the incentive program) and Meaningful Use requirements for data sharing. More robust standards would foster information sharing across more participants in the system, including with non-Meaningful Use

eligible providers like nursing homes. Standards can also help connect medical devices to EHRs.

- Second, as new approaches to payment and delivery are expanded and begin to create the business case for care coordination and improved health outcomes. This will, in turn, drive the creation of innovative tools that foster information sharing – making the right thing to do the easy thing to do.

We have been slow to develop the battery of standards and services needed to make care coordination across health systems easy and efficient for both providers and patients. While experts have been working for decades to create standards and drive their adoption in the private sector, these well-intentioned efforts have been plagued by a maze of competing standards in some areas, and a complete lack of standards in others.

The Meaningful Use regulations and complementary Certification rules have been essential to cutting through the noise and enabling health information to be more uniformly collected and shared. This kind of federal leadership, which occurs in collaboration with the private sector in open and transparent ways, is critical to fostering innovation.

Already, though, advancements in standardization generated by the Meaningful Use and Certification regulations are catalyzing innovation for providers, patients and families. For example, the proportion of hospitals electronically exchanging clinical summaries with outside hospitals tripled between 2008 and 2012. The Office of the National Coordinator for Health Information Technology (ONC) has also funded several advanced research projects that leverage the standards of EHRs. An example is the SMART platform, which is an open way that individual patients, physicians, small software vendors and others can design innovative health IT applications at a lower cost, using an approach that is not unlike developing an iPad app today.

For consumers, Medicare and the Veterans Administration have implemented a standardized feature called Blue Button that allows beneficiaries and veterans to view and download their own health information online. The information from Medicare is based only on claims data, but beginning in January, the Meaningful Use program will include this capability for all eligible providers and hospitals.

This innovation makes a world of difference for people like Beth Schindele, who cares for her father, William Graves. With his permission, Beth went to MyMedicare.gov and downloaded her father's health information while he was hospitalized. She found an app that could upload and display her father's Blue Button information in understandable and useful ways. She told me just last week:

I cannot even begin to explain how access to my father's data has impacted the coordination of his care and improved his life. The data from Blue Button revealed that he had more than 63 providers caring for him during four hospitalizations in the past 1.5 years. Blue Button showed me his current medications, diagnoses, procedures, providers and preventive services needed as well as hospitalizations. Without access to his data, at the point of care, I would not have been able to coordinate his care, and reconcile his medications with his care team. Having the data in my hands during his hospitalization allowed me to have intelligent conversations with his care team and prevent them from erroneously placing him

on a medication he had stopped taking two years ago – and I am so thankful that I was able to do so.

The hospital had an old record showing he had a diagnosis that required him to take Coumadin, which is a blood thinner. And because I had the [Blue Button] data in my hands, I could show them that he was no longer on that medication, and that truly was instrumental in saving his life. Within hours of his discharge he fell and suffered severe head and arm lacerations that would have been life threatening had he been on Coumadin and would have resulted in a readmission within just five hours of discharge.

Beth's story reminds us that it is absolutely critical that health IT systems enable providers to safely and securely share information, not just with each other but with patients and families –a very meaningful innovation. We cannot rely solely on clinicians to detect errors in such a complex system, no matter how hard-working and dedicated they may be. The Blue Button functionality will help consumers play a crucial role in promoting safer care, which in turn will lower costs. And Blue Button will be part of the Meaningful Use program next year, which will provide clinical data from EHRs.

This innovation would not have happened without the leadership of Medicare, the VA, and the Office of the National Coordinator in collaboration with private sector innovators.

Bolster and Expand Meaningful Use

The challenge before us is how to ensure every provider in the country has health IT that is capable of safely and securely measuring the quality of care, coordinating with other providers, and giving patients and family caregivers the information they need to be active partners in care and in health.

We have made remarkable progress already. We must expand the Meaningful Use program, both by advancing its requirements and standards and by extending incentive payments to other, non-eligible providers, such as long-term care, behavioral care, and home-based care.

We all know that how best to fix our health care system has become one of the most contentious issues of our time. But there is no disagreement that we need a more efficient, effective system that provides higher quality care for our sickest and most complex patients at lower costs, and reduces the burden on family caregivers. We now have a track record that demonstrates that Meaningful Use is a critical piece of the way forward. Thank you for the opportunity to testify here today.

Mr. PITTS. Chair thanks the gentlelady and now recognizes Mr. Bialick for 5 minutes for an opening statement.

STATEMENT OF JIM BIALICK

Mr. BIALICK. Chairman Pitts, Ranking Member Pallone, members of the subcommittee, thank you for the opportunity to testify on this important issue. And thank you, Mr. Pitts, for the promotion, but I am actually the Executive Director of the Newborn Coalition. We are an all volunteer organization that came together to promote the development and use of mobile apps and technology in newborn and infant health.

The catalyst for our beginning was the birth of a baby named Eve, who at 40 hours old was diagnosed with a critical congenital heart defect, the most common birth defect in the U.S. affecting nearly 1 in 100 births. Had it not been for an attentive nurse, Eve would have been discharged with a partially formed heart. While a simple screening tool, pulse oximetry, exists to identify these conditions, there is still no national requirement for routine screening. Her mother, our co-founder, started a crusade to ensure that babies like Eve would never again be sent home without first being screened.

We estimate that since our efforts began, the number of babies screened for heart defects in the U.S. has increased by 4,500 percent. To date, we have aided in the drafting of legislation in 23 States and the enactment of nine laws. The first was in New Jersey, where a baby was identified with a heart defect before a discharge on the very first day of screening, and most recently, in California.

We are very proud of these numbers, but we have learned that it is not enough just to screen, but we also have an obligation to accommodate the lifelong needs of those diagnosed by the screening, and consumer technology, such as mobile apps, play an important role in fulfilling that responsibility.

It is important to remember that of the more than four million babies born in the U.S. every year, the majority aren't born in advanced cardiac surgery centers. They may be sent to several hospitals, be seen by more than a few doctors, be given a number of medications, which in today's less than interoperable health care system means mom and dad will be responsible for managing and reconciling most of this information on the best and worst day of their lives.

After leaving the hospital, babies can be monitored continuously from home using a pulse oximeter. These babies are special because they have heart defects, but they are still just babies and their parents are still exhausted. So what do parents do? They use the same smartphone or tablet that they use to manage all of their other important information. Families and providers have come to rely on mobile apps to allow them to capture readings from remote monitoring devices. This means less time having to focus on being a nurse and more time available to be a parent.

The availability of these technologies has created a revolution in how we interact with our data and engage in our health, but it has also created legitimate safety concerns that must be addressed. However, the FDA draft guidance as written would seemingly at-

tempt to regulate the future of health care technology as a standalone medical device. In my written testimony, I have laid out a model for a risk-based framework that very intentionally delineates between health information management apps and actual medical devices.

Applications and the platforms that support them have the ability to integrate and interoperate with any device that will allow it. Consumer demand for integrated technology solutions will drive the market to a wholly interoperable system that can be accessed at any time, anywhere, and by any device, and we would be foolish to believe that this integration will happen and will not include health information.

Consumer technologies have evolved to leverage the Internet to share data, including with medical devices, functionally eliminating the difference between being on a network and physically linking devices with a cord. As a result, we need to be thinking about the regulation of technology differently. What we need is a new patient-centered risk-based regulatory framework for evaluating health technologies that is flexible enough to regulate what we are using today and adaptive enough to accommodate the technologies that have yet to be conceived.

I know the concept of a new regulatory process is daunting, but an existing framework does not create the certainty that the emerging health care technology marketplace needs to flourish. I cringe when I hear from patient organizations that are dedicating a significant amount of their budget to develop a mobile app, because I know their product may have to go through a process that would cost them more than they can afford, rendering their initial investment worthless. I was disheartened when my wife, who is now 4 months pregnant, asked me which app she should use to track her pregnancy. I told her the one with the fewest, least complex features, because I wanted to make sure that she didn't lose all the data that she would enter throughout the pregnancy in the event the manufacturer depreciated certain functionalities to avoid the FDA. To me, that is not certainty and that is not pro-patient.

This committee has the foresight to hold—has had the foresight to hold this hearing because collectively, you recognize that mobile apps are transforming how patients, families, and providers engage in the delivery of health care. Reform will not be without controversy, but it is far better to address this issue now than to wait for traditional approaches to fail at the expense of patients and families.

Thank you again for this opportunity to testify. I look forward to working with you on this important issue, and I am happy to answer any questions.

[The prepared statement of Mr. Bialick follows:]

Testimony of Jim Bialick
Executive Director, Newborn Coalition
To the Energy and Commerce Committee
Subcommittee on Health
March 20, 2013

Chairman Pitts and Raking Member Pallone, Members of the Subcommittee, thank you for the opportunity to testify on this very important issue. My name is Jim Bialick and I am the Executive Director and co-founder of the Newborn Coalition. The Newborn Coalition is an all-volunteer organization that came together to promote the development and use of technology in newborn and infant health.

Why We Started

The catalyst for our beginning was the birth of a baby named Eve in Minnesota who, at 40 hours old, was diagnosed with a critical congenital heart defect. Congenital heart defects are the most common birth defect in the U.S., affecting nearly 1 in 100 births. While a simple screening tool, pulse oximetry, exists to identify these conditions, there still is no national requirement for routine screening.

Had it not been for an attentive nurse that went the extra mile, Eve would have been sent home missing part of her heart. After Eve's recovery from two open-heart surgeries, her mother – our co-founder– started a crusade to prod law makers, regulators and health plans to adopt technology to advance newborn screening for heart defects. We want to make sure that babies like Eve are never sent home without first being screened.

Screening Newborns for Heart Defects

Our ongoing work includes the nationwide implementation of heart disease screening through the pursuit of state legislation. To date, we have aided in the drafting of legislation in 23 states and the enactment of 9 laws. The first was in New Jersey where a baby with a hypoplastic left heart syndrome was identified before discharge *on the very first day screening was required by law.* The most recent law was enacted in California last year, the state where my wife and I grew up and where our parents want us to return and have newborns of our own.

We estimate that since our efforts began, the number of babies screened for heart defects in the U.S. has increased nearly 4,500%. We are very proud of these numbers because we can be confident that more little Americans will go on to live happy and healthy lives. It also gives us hope that healthy babies remain a bipartisan issue.

Technology Helps Babies, Parents, Health Care

As our efforts progress nationwide, we have learned that screening babies for heart defects is not where our jobs end, but rather where they begin. It is not enough just to screen, but we also have a responsibility to accommodate the short term and long-term follow-up needs of those diagnosed by the screening.

There are often very different clinical paths families of a baby diagnosed with a heart defect may take: sometimes this includes at-home monitoring, follow-up imaging to diagnose the defect, or maybe it means emergency surgery to correct an imperfect heart that is trying to sustain an otherwise healthy little baby.

It is important to remember that of the more than 4 million babies born in the US every year, not all of them are born in advanced cardiac surgery centers. They may have been to several hospitals, been seen by more that a few doctors, and been given a number of medications, which in today's less-than-interoperable healthcare system, means mom and dad will likely be responsible for managing and reconciling most of this information on what is likely the best and worst day of their lives.

So what do parent's do? They rely on what they know and use every day: the same smartphone or tablet that they use to manage all of their other important information. And why not? There are more than 97,000 medical applications available in the iOS app store alone.

Because the clinical journey will be different for every baby, we often hear from our network of parent advocates that they are using one or more mobile apps to stay on top of their baby's health information in order to keep their baby's health at the center of his or her ongoing care.

There are apps available that allow parents to access online services such as personal health records to document procedures their baby has undergone and drugs that their baby has been given. In other cases, newborns will be released from the hospital and monitored using a pulse oximeter from home. These babies are special because they have heart defects but they are still, just babies and their parents, are still exhausted. Many families have come to rely on mobile applications that allow them to capture readings from home monitoring devices so they may easily share them with a provider. This means less time having to focus on being a nurse and more time available to be a parent.

Technology Is Transforming Care and Culture

Be it patients, families, or providers, broad-based demand for information technology in healthcare has fostered a creative and innovative market that is has evolved to address the many needs of a diverse consumer population. With this evolution in engineering has come an equal progression in our culture. We are not only demanding more from our applications and devices, but also that the information we manage be platform agnostic and work on our phones, tablets, and PCs identically.

This demand is coming from patients and families as well as providers. A full 62 percent of providers have begun using tablets to deliver care; that number is up 27 percent from only a year ago. Families are using these tools, why shouldn't providers use the of mHealth apps designed specifically for them? The families that we work with want their devices to connect directly to what their doctor is using so that they can know the instant something changes with their baby's health.

As mobile technologies advance, clinicians and entrepreneurs have developed applications to address increasingly complex healthcare and data management issues. While the availability of these technologies has created a revolution in how we interact with our data and engage in our health, it has also created legitimate safety concerns that must be addressed.

Mobile Apps Are Not Medical Devices

Most medical apps are not medical devices as most understand that term and regulating mobile apps as such does not make sense. Mobile apps are developed and sold in a dynamic marketplace: estimates indicate that the number of smartphone consumers using medical apps will grow to 500 million by 2015.

That's why we were so surprised when the FDA issued a draft guidance to regulate mHealth apps as medical devices in 2011. Even then it seemed like the definition the FDA was using for a "mobile medical app" was outdated. Cloud computing has enabled us to access incredibly innovative and powerful software with the click of a mouse or the tap of a touchscreen. Mobile apps can no longer be considered discreet pieces of software that reside on a specific device; the cloud has allowed us to access a myriad of programs through a single app: our Internet browser.

The traditional process for approving and regulating health technologies is not nimble enough to appropriately scale or keep pace with its unprecedented expansion. While the Food and Drug Administration (FDA) has a legitimate role to play in maintaining patient safety for the highest risk products, it is readily apparent that Congress can and should adopt a more flexible model for products that simply manage information. In addition, sequestration is a political reality that has certainly impacted FDA's in-house expertise available to manage a broad range of products. A concern shared by many is whether FDA possesses the manpower and expertise, as well as whether the regulatory science has been fully developed to take on regulation of the mobile medical app market. Many shared these concerns even before sequestration took effect.

Furthermore, the existing FDA structure for regulating medical devices was conceived in an era where personal computing was in its infancy and adoption of consumer technologies in healthcare was nearly non-existent. The device approval process (510(k)) was implemented when our ability to share data was limited to what we could fit on a 5 ¼ inch floppy disk. Why then, do we believe that the approval process will be flexible enough to accommodate the future of multi-function technology and a software market that we literally cannot imagine? The Institute of Medicine put it best in its 2012 report, Health IT and Patient Safety: Building Safer Systems for Better Care: "The current FDA framework is oriented toward conventional, out-of-the-box, turnkey devices."

Applications, and the platforms that support them, have the ability to integrate and interoperate with any device that will allow it. At a point we must assume that increased connectivity between networks will make mobile device data —and what we consider as more traditional data—indistinguishable. Consumer demand for integrated technology solutions will drive the market to a wholly interoperable system that can be accessed at any time, anywhere, and by any device. We are fooling ourselves if we think this revolution will not include health information.

App developers are concerned—and absent change, should continue to be concerned—that their products will be subject to new or additional regulation by a system designed for products that are not information or health management systems. Congress should be concerned that the creativity and innovation that is helping patients and parents may evaporate under well-intentioned, but ill-conceived regulations.

Towards a New Framework: Patient Safety and Innovation

As a result, we need to be thinking about regulating technology differently. What we need is a new framework for evaluating health technologies that can scale to effectively regulate what we are using today, and anticipate technologies yet to be conceived.

A new framework that accounts for data sharing, innovation and patient safety is important to help ensure patients have access to safe and helpful technologies. Patient safety and innovation are not mutually exclusive; they are complementary concepts in a system that clearly lays out the rules of the road. Congress should reevaluate the current process, including FDA's draft guidance on mobile applications, and pass legislation to promote safety and advance innovation.

The Newborn Coalition believes such a system should include the following principles:

1. *Regulations should evaluate technologies and their functionality as designed.* To promote competition and job creation, manufacturers and end-users (consumers and healthcare providers) need clarity about the rules and requirements of the regulatory process. Regulators and end users need guarantees that a product will function as designed. We believe the approach to regulating health information systems must be scientific and based on testable consensus-based standards.

2. *Regulatory structures should evaluate technology based on risk and according to standards.* Products and their level of regulation should be categorized by risk. Risk is determined by the potential for variability in the health information system's operation or a system's ability to function *ad infinitum*: meaning that it is able to generate a response within an expected range regardless of input. FDA should evaluate the highest risk products. Private certifiers with expertise in software design and testing and contracted to the federal government, should evaluate lower risk products.

3. *Standards should incentivize safer products through market signals.* Software and devices developed in accordance with consensus-based standards are more predictable and therefore safer. We suggest creating a process to standardize the assessment of risk and create incentives for developers to create products that conform to standards.

4. *Products should be evaluated by those with the best expertise and experience.* Regulatory bottlenecks can be addressed by implementing a process similar to the Office of the National Coordinator's (ONC) approach in certifying Electronic Health Record (EHR) systems and EHR modules for use in the Meaningful Use Program through accredited industry certifiers. Congress might authorize private certifiers to affirm mobile apps do what they say they can do. In light of the significant regulatory science demands entailed in certifying an array of technologies, ONC, in its Permanent Certification Program, created a process for Standards Development Organizations (SDOs) and private industry, to accredit certifiers for the program. Such an accreditation process will help ensure credible, unbiased certifiers for mobile apps.

It is important to note, the FDA has an important role to play in this regulatory framework, but

that role should be reevaluated based on what is best for patients, parents, and providers. We must be thinking about how this consolidated information network will interact with medical devices that are currently FDA regulated. If consumer technologies are all sharing data across a common network, including with medical devices, then do all technologies on the network become accessories to those regulated medical devices? Will they need to be regulated themselves?

The old adage rings true: you are only as strong as your weakest link. In the era of connected health, the biggest danger to patient safety is being unable to determine where the weak link is. To combat this threat, we must change our thinking from categorically regulating technologies that *may* be used in health care, to evaluating them based on the risk they have of not functioning as designed.

To move away from regulation by categorization we must focus on how these applications have been engineered. Do they comply with a known standard for a given functionality? Is there a way to test that a technology will function as designed? If the answer to these questions is yes, than the software or device is more predictable and therefore poses lower-risk to the end-user.

I know that the concept of a new regulatory framework designed to encourage innovation in the marketplace is daunting to some, but another question we must ask ourselves is: will using a process that was conceived in a different era that is already overburdened by backlog going to create more certainty or will it raise more questions?

Regulatory Policy Has a Real Impact on Patients

I cringe when I hear from patient organizations that are dedicating a significant amount of their budget to developing a mobile medical app for their community because I know that there is a potential that their product is going to have to go through a process that is going to cost them a great deal of money that they don't have, rendering their initial investment worthless.

I worry when I hear from Medicaid providers that are telling their patients to engage in their health through free apps. If apps are medical devices, are they then subject to the 2.3 percent medical device tax? If so, will those apps continue to be free?

And I was disheartened when my wife, who is now four months pregnant, asked me which mobile medical app she should use to track her pregnancy. My gut reaction was to say: the one with the fewest, least-complex features, because I wanted to make sure that she didn't lose all of the data that she would enter throughout the pregnancy in the event that the app was pulled off of the market if FDA advanced their final regulation. I was also concerned the manufacturer might depreciate certain functionalities related to the app to avoid potential regulation.

This feels like the opposite of certainty to me. It is definitely not pro-patient.

This Committee has had the foresight to hold this hearing because collectively you recognize that mobile apps have the capacity to transform how patients, families, and providers engage in the delivery of health care. Congress has a tremendous opportunity to intervene, here and now

before this vibrant and robust market is thrust into an ill equipped regulatory process. Reform of this magnitude will not be without some controversy and growing pains, but it is far better to address this issue now then to wait for traditional approaches to fail. Inaction is something we simply cannot afford.

Thank you again for this opportunity to testify. I look forward to working with you on this important issue and I am happy to answer any questions.

Mr. PITTS. Chair thanks the gentleman, and now recognizes Dr. Mitus for 5 minutes for an opening statement.

STATEMENT OF JACQUELINE MITUS

Dr. MITUS. Good morning, Mr. Chairman and distinguished members of the subcommittee. My name is Jackie Mitus, and I currently serve as Senior Vice President of Clinical Development and Strategy for McKesson Health Solutions. I appreciate the opportunity to appear before you today.

My background as a practicing hematologist/oncologist at the Brigham and Women's Hospital in Boston, and faculty member of Harvard Medical School, as well as my responsibilities at McKesson, have provided me with a unique perspective on health information technology. I have seen first-hand how critical health IT is to advancing the care and safety of patients.

As the largest health IT company in the world, McKesson has actively engaged in the transformation of health care from a system burdened by paper to one empowered by interoperable electronic solutions.

I would like to make two key points today.

First, health IT is foundational to improving the quality, safety and affordability of healthcare.

Second, to ensure continued innovation and leverage the power of health IT, we need a new regulatory framework that is risk-based and specific to health IT.

Health care in our country is undergoing fundamental changes to make it safer, better, and more efficient. Health IT is the foundation of these efforts. It provides access to current, accurate patient information such as medication history, and it supports the clinician in preventing errors, identifying gaps in care, and suggesting appropriate diagnostic and treatment paths. Health IT does not replace physician judgment, but rather, provides guidance and support. The ultimate responsibility for the care and safety of a patient always rests with the treating clinician.

Today, the FDA has authority to regulate medical devices under amendments to the Food, Drug, and Cosmetic Act adopted in 1976. The definition of a medical device in the Act is broad and can be interpreted to include all health IT, including medical software. The current regulatory approach for medical devices, however, is not well-suited for health IT. For example, does an iPad that reminds a patient to refill a prescription make it a traditional medical device? What about an application that allows a clinician to access a medical journal or review an x-ray online? Should these applications and the iPad each be subject to FDA regulations?

Medical software is fundamentally different from medical devices in two important ways. First, the safety of a medical device is almost entirely dependent upon how it is manufactured. The safety of health IT, on the other hand, hinges upon how it is developed and perhaps more importantly, on how it is implemented. Thus, health IT cannot safely be ensured simply through good manufacturing practice.

Second, medical devices, unlike health IT, are directly involved in the treatment of a patient with little, if any, opportunity for a clinician to intervene. The majority of medical software does not di-

rectly or independently act upon a patient, but rather, provides data and guidance. The ability of a learned intermediary to utilize professional judgment distinguishes this technology from traditional medical devices.

Mr. Chairman, we risk using a law enacted nearly a half century ago to regulate a rapidly changing and dynamic era of technology.

In closing, I would like to highlight the work of the Bipartisan Policy Center, BPC, which last month released a report in response to the FDA Safety and Innovation Act. With the input of nearly 100 organizations, including McKesson, the BPC recommended dividing health IT into three risk categories. The first and highest risk category includes technology linked to or used to operate a medical device. This technology would continue to be regulated as a medical device. The second category includes medical software that merely guides the physician, such as clinical decision support or electronic health records. This group would be subject to rigorous accreditation by an independent third party, or perhaps ONC. Finally, the third category, non-clinical technology, such as billing and scheduling software, would not be subject to regulatory oversight. The BPC approach is flexible, protects patient safety, promotes innovation, and leverages existing quality and safety standards.

In conclusion, health IT is imperative to the successful transformation of health care. It improves the quality of patient safety, enables payment and delivery reform, and promotes efficiency and lower cost. That is why it is so important that we regulate health IT thoughtfully to advance care and support innovation. That is why we need a new risk-based framework such as that proposed by the BPC.

On behalf of McKesson, I thank you for the opportunity to share our thoughts.

[The prepared statement of Dr. Mitus follows:]

STATEMENT OF

A. JACQUELINE MITUS, MD
SENIOR VICE PRESIDENT, CLINICAL DEVELOPMENT AND STRATEGY
MCKESSON HEALTH SOLUTIONS

BEFORE THE
ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH
U.S. HOUSE OF REPRESENTATIVES

HEALTH INFORMATION TECHNOLOGIES: HOW INNOVATION BENEFITS PATIENTS

MARCH 20, 2013

Good morning Chairman Pitts, Ranking Member Pallone and distinguished members of the Subcommittee. My name is Jackie Mitus, and I currently serve as Senior Vice President of Clinical Development and Strategy for McKesson Health Solutions. I appreciate the opportunity to appear before you today.

My background as a practicing hematologist/oncologist at the Brigham and Women's Hospital in Boston, and faculty member of Harvard Medical School, as well as my responsibilities at McKesson, have provided me with a unique perspective on health information technology (IT). I have seen first-hand the value that health IT brings to patient care as well as the overriding importance of protecting patient safety.

I work every day on the development and deployment of health information technology solutions that improve the quality and safety of patient care. I am pleased to share with you McKesson's perspective on the benefits and value of health IT and to discuss the need to establish a new regulatory framework for medical software.

For 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. McKesson is the nation's largest distributor of pharmaceuticals, and we pride ourselves on the efficiencies that we bring to the healthcare system by delivering safe medicines every day to pharmacies, hospitals, physician offices, skilled nursing facilities and government locations, including every Department of Veterans' Affairs facility, across the country.

As the largest health IT company in the world, McKesson has decades of experience serving the health IT needs of the largest and most diverse provider base in the industry, including 50 percent of all health systems, 77 percent of health systems with more than 200 beds, 20 percent of all physician practices and 25 percent of home care agencies, which support more than 50,000 home care visits annually. We process billions of financial healthcare transactions annually among physicians, hospitals, pharmacies, insurers and financial institutions, and provide care and claims management solutions to most of America's health insurance companies. In short, we are actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and advance healthcare efficiency.

Based on this breadth of experience, I would like to make two key points to you and members of the subcommittee.

First, health IT is foundational to improving the quality, safety and affordability of healthcare.

Second, to ensure continued innovation in the development of health IT solutions and leverage the power of those solutions to transform healthcare, we need a new risk-based regulatory framework that is specific to health IT.

Let me touch briefly on each of these points.

Health IT: The Foundation for Change and Improvement

Healthcare in our country is undergoing fundamental changes. Each day, clinicians and others critical to providing healthcare services strive to find safer, better, more efficient and increasingly patient centric ways to deliver care. Health IT is the foundation of these efforts.

First and foremost, health IT underpins our ability to dramatically improve quality and safety. Physicians, nurses, pharmacists, paramedics and all health professionals increasingly rely on health IT systems in virtually all care settings. In order to provide safe, effective care, physicians must have timely access to current, accurate patient information, including medical history, medication lists, laboratory and x-ray results, regardless of location. Automating paper records and enabling electronic connectivity is critical to communicating and coordinating across disparate healthcare systems.

Medical software can also help to inform physicians and other clinicians as they assess and treat patients. New advances in clinical care and other important information from text books and medical journals are made readily available through health IT. Additionally, automated clinical systems can help prevent medication errors, identify gaps in care, and suggest appropriate diagnostic and treatment paths.

It is important to note that health IT does not replace physician judgment. Rather, it provides guidance and support by making patient data more readily available, and by automating clinical recommendations. The ultimate responsibility for patient treatment decisions and clinical care rests with the prescribing physician and his or her experience and expertise, along with other

involved clinicians. I will come back to this in a moment when we talk about the differences between medical devices and health IT.

Beyond improving quality and safety, health IT is also critical to transforming the way we deliver and pay for healthcare: transitioning from a volume system that rewards the number of tests or procedures performed to a value system that measures the quality of patient outcomes.

Through data and analytics, transaction processing and cost transparency, health IT provides efficiency and support for delivery and payment reforms. With the adoption of Electronic Health Records (EHRs) and other health IT solutions by both physicians and hospitals, the market has now reached a tipping point where widespread interoperability could make possible the meaningful exchange of information to lower costs and support outcome-based health initiatives.

Clearly, there is still much work to be done to improve health IT. In particular, the health IT industry is engaged in a new alliance to dramatically improve interoperability so that different health IT systems will be able to communicate with one another seamlessly. Earlier this month, McKesson and four other health IT developers announced their intent to form The CommonWell Health Alliance and their plans for CommonWell to be an independent not-for-profit organization open to all health information technology vendors. The Alliance plans to promote and certify a national infrastructure with common standards and policies, which enable patient matching and linking services, HIPAA-compliant patient consent and access management, and a patient record locator and query service. These capabilities will allow care

providers to more easily track and manage patients across disparate locations and to share critical information in an industry standard way.

This effort and many others are ongoing. In the coming weeks, months and years, the pace of innovation in health IT will only increase, and, with it, the promise of improved care.

A New Risk-Based Regulatory Framework for Health IT

Now let me turn my attention to the need for a new risk-based regulatory framework for health IT. Given that health IT is critical to improving healthcare, and ever mindful of the incredible pace of innovation in technology development, it is imperative that health IT is regulated in a way that improves quality, assures patient safety and fosters innovation.

Today, the Food and Drug Administration (FDA) has the authority to regulate medical devices under amendments to the Food, Drug and Cosmetic Act that were made in 1976. The definition of medical device in the Act is broad and can be interpreted to include all health IT, including medical software.

The current regulatory approach for medical devices is generally not well-suited for health IT for three specific reasons.

First, the drafters of the law defined medical devices based on the technology available at the time. No one could have envisioned the progress we would make in the development and implementation of technology in the almost 40 years since that definition was enacted.

For example, does an iPad application to help track the number of steps walked per day, or a reminder that it's time to refill a prescription, render this apparatus a traditional "medical device"? Should each application upgrade require a regulatory review?

Should the software that allows a physician to search a medical textbook or review x-rays on-line be subject to FDA regulation? That software merely provides access to medical data; it does not interpret or act upon the information that is transmitted.

Should clinical decision support software that simply aggregates existing protocols and standards of care be regulated differently than those same standards that appear in printed form and sit on a shelf in the doctor's office? The information is exactly the same; the only difference is that the paper information is now automated and relayed to the physician in a different, more efficient format.

The second reason for a new framework is that there are fundamental differences between medical devices and health IT. For example, safety of medical devices is almost entirely dependent on how they are manufactured. The FDA oversees the manufacturing, production and quality control processes of medical devices where problems might develop.

Safety of health IT systems, on the other hand, is dependent on how they are designed and developed, and, perhaps more importantly, how they are customized, implemented and used. Safety in health IT, therefore, cannot be ensured simply through good manufacturing practices. Instead, it must be a shared responsibility among those who develop the technology, those who implement it, and ultimately those who use it.

Finally, medical devices, ***unlike health IT***, are directly involved in the treatment of a patient, with little if any opportunity for the clinician to intervene. Heart stents, implantable defibrillators and pacemakers all connect to the heart and function automatically without clinician involvement.

Some forms of health IT are inextricably linked to medical devices, such as the software that interprets fetal heart monitors or automatically doses certain medications. In these cases, regulation of the medical software as a device is probably appropriate. However, the majority of medical software, including clinical decision support and EHRs, does not directly treat the patient, but rather provides data and guidance to the clinician in the assessment or treatment of a patient.

The ability of the physician to utilize professional judgment when interacting with these forms of health IT makes these types of technology fundamentally different from traditional medical devices.

Mr. Chairman, we are using a 40 year old law to regulate rapidly changing and dynamic technology. We are regulating manufacturing instead of use, and we are marginalizing the role of clinicians. Simply put, we must not impede medical advances with medical device regulation that is ill-suited for health IT.

The FDA Safety and Innovation Act that was enacted last summer requires the FDA, the Office of the National Coordinator (ONC) of Health IT and the Federal Communications Commission (FCC) to provide Congress with recommendations on a new risk-based regulatory framework for health IT.

To assist these agencies in better understanding the stakeholder perspective, the Bipartisan Policy Center (BPC) convened nearly 100 organizations and companies throughout the healthcare system over the past five months to develop a set of principles to guide the establishment of a risk-based regulatory framework for health IT. The results of this extraordinary collaborative effort were announced last month.

The BPC recommendations are best reflected in the chart on page 13 of the BPC report that has been submitted with my testimony. This chart represents a new regulatory framework for health IT—one that protects patient safety, is risk-based, promotes innovation, is flexible, leverages existing quality and patient safety-related systems and processes, avoids regulatory duplication, and has the support of experts and stakeholders across every sector of health care.

Most importantly, the BPC recommendations divide health IT into three categories according to the relative risk to patients and the opportunity for clinical intervention.

The first category includes technology linked to or used to operate a medical device; again, technology that directly touches the patient. This technology would continue to be regulated by the FDA as a "medical device".

The second category includes technology that informs the treatment of a patient, such as clinical decision support software or EHRs. This software would be subject to a rigorous process of accreditation by an independent third-party, or perhaps ONC.

Finally, the third category, non-clinical technology such as billing and scheduling software, would not be subject to any regulatory oversight.

This proposed framework recognizes the fundamental difference between traditional medical devices that are directly involved in the treatment of a patient, and medical software that helps *guide* the physician in the diagnosis or treatment of a patient.

Mr. Chairman, health IT is imperative to the successful transformation of healthcare. It improves quality and patient safety, enables payment and delivery reform and promotes efficiency and lower costs. It is an essential building block of everything we are trying to accomplish in healthcare. That is why it is so important that we regulate it thoughtfully. That is why we cannot have a one size fits all approach which stifles innovation and delays advances in medical knowledge and care. That is why we need a new risk-based regulatory framework.

McKesson appreciates the opportunity to share our views on health IT with the members of the Subcommittee, and we look forward to continuing to promote the development and use of this important technology that is so vital to patient care.

I am happy to answer your questions.

Health Program
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An Oversight Framework for Assuring Patient Safety in Health Information Technology

Bipartisan Policy Center Health Innovation Initiative

February 2013

BIPARTISAN POLICY CENTER

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ABOUT BPC

Founded in 2007 by former Senate Majority Leaders Howard Baker, Tom Daschle, Bob Dole, and George Mitchell, Bipartisan Policy Center (BPC) is a non-profit organization that drives principled solutions through rigorous analysis, reasoned negotiation, and respectful dialogue. With projects in multiple issue areas, BPC combines politically balanced policy making with strong, proactive advocacy and outreach.

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This report is the product of the Bipartisan Policy Center's Health Project. The findings and recommendations expressed herein do not necessarily represent the views or opinions of the Bipartisan Policy Center, its founders, or its board of directors.

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Executive Summary

More than ten years ago, the Institute of Medicine (IOM) released two landmark reports that catalyzed efforts to improve patient safety in U.S. health care.[1,2] Both reports highlighted the critical role that health information technology (IT) plays in improving the quality and safety of care. Because greater use of health IT has always had strong bipartisan support, members of Congress and leaders across two administrations have taken significant actions to increase the adoption of IT to improve the quality, safety, and cost-effectiveness of health care.

Building upon numerous legislative proposals with bipartisan support over the last decade, the Health Information Technology and Economic and Clinical Health (HITECH) Act of 2009 brought about new authorities, standards, and investments in health IT. As a result of federal, state, and private-sector action, the number of clinicians, hospitals, and other providers across the United States who have adopted health IT to improve the quality, safety, and efficiency of care has significantly increased.

The widespread adoption of health IT largely stems from recognition of the important role that it plays in improving health care quality and safety. However, there are also instances in which it has the potential to create harm if not effectively developed, implemented, or used. Nonetheless, a recent IOM report indicated that health information systems were involved in less than 1 percent of reported errors in health care settings.[3]

Policies are now being developed by the Department of Health and Human Services (HHS) to use health IT to make health care safer and continuously improve the safety of health IT. HHS released for public comment on December 21, 2012, the *Health IT Patient Safety Action and Surveillance Plan for Public Comment*, which represents the administration's proposed approach for addressing safety in health IT. The Food and Drug Administration (FDA) Safety and Innovation Act of 2012, which was passed by Congress and signed into law in July 2012, calls for the HHS secretary to develop—within 18 months—a proposed strategy and recommendations on risk-based regulatory framework pertaining to health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.[4]

Through a collaborative effort, the Bipartisan Policy Center (BPC) has both conducted research and engaged a wide range of experts and stakeholders to develop a set of principles and recommendations for an oversight framework for assuring patient safety in health IT. The framework protects patient safety, is risk-based, promotes innovation, is flexible, leverages existing quality and patient safety–related systems and processes, avoids regulatory duplication, and has the support of experts and stakeholders across every sector of health care.

Principles for an Oversight Framework for Assuring Patient Safety in Health IT

The following set of principles, which were developed through a collaborative process involving experts and stakeholders across every sector of health care, should guide the federal government's strategy and recommendations for a regulatory framework for health IT.

1. Any oversight framework for safety should recognize and support the important role that health IT plays in improving the quality, safety, and cost-effectiveness of care, as well as the patient's experience of care.
2. Assuring patient safety, along with enabling positive patient outcomes, is a shared responsibility that must involve the entire health care system.
3. Any framework for patient safety in health IT should be risk-based, flexible, and not stifle innovation.
4. Existing safety and quality-related processes, systems, and standards should be leveraged for patient safety in health IT.
5. Reporting of patient safety events related to health IT is essential; a non-punitive environment should be established to encourage reporting, learning, and improvement.

Key Elements of an Oversight Framework for Assuring Patient Safety in Health IT

Assuring patient safety in the development, implementation, and use of health IT requires both national focus and public- and private-sector collaboration and leadership.

Health IT broadly falls into three major categories, each of which reflects increasing levels of risk of potential patient harm: (1) administrative or non-clinical software, (2) clinical software, and (3) medical device software. The primary factors that should be used to determine the level of oversight for any type of software include the level of risk of potential patient harm and, for clinical software, the degree of direct clinical action on patients.

Assuring safety in clinical software in particular is a shared responsibility among developers, implementers, and users across the various stages of the health IT life cycle, which include design and development; implementation and customization; upgrades, maintenance, and operations; and risk identification, mitigation and remediation.

Clinical software includes electronic health records, clinical decision support software, and other software used to inform clinical decision-making. Such software should be subject to a new oversight framework, rather than traditional regulatory approaches applied to medical

devices given its lower risk profile taking into account several factors. These factors include the level of risk of potential patient harm, the degree of direct clinical action on patients, the opportunity for clinician involvement, the nature and pace of its development, and the number of factors beyond the development stage that impact its level of safety in implementation and use. This oversight framework should contain four main elements summarized below.

1. Agreement on and adherence to recognized standards and guidelines for assuring patient safety in the development, implementation, and use of health IT.
2. Support for the implementation of standards and guidelines as well as development and dissemination of best practices through education, training, and technical assistance.
3. Developer, implementer, and user participation in patient safety activities, including reporting, analysis, and response, while leveraging patient safety organizations (PSOs).
4. Creation of a learning environment through the aggregation and analysis of data to identify and monitor trends, mitigate future risk, and facilitate learning and improvement.

HHS's current proposed approach—outlined in *Health IT Patient Safety Action and Surveillance Plan for Public Comment*, which was released on December 21, 2012—reflects many of the key elements outlined above, including development of and adherence to standards and guidelines; reporting and analysis of, and response to patient safety events in a non-punitive environment to support mitigation of risk, as well as learning and improvement; and research and implementation support for users, developers, and implementers.

As HHS develops its proposed strategy and recommendations for a risk-based, regulatory framework for health IT, BPC urges the department to consider the principles and recommendations for an oversight framework for health IT outlined above and within this report.

Introduction

More than ten years ago, the Institute of Medicine (IOM) released two landmark reports that catalyzed efforts to improve patient safety in U.S. health care.[5,6] Both reports highlighted the critical role that health information technology (IT) plays in improving the quality and safety of care. Because greater use of health IT has always had strong bipartisan support, members of Congress and leaders across two administrations have taken significant actions to increase the adoption of IT to improve the quality, safety, and cost-effectiveness of health care.

Today, health care costs constitute 18 percent of our nation's gross domestic product and the quality of care remains uneven. Rapidly emerging delivery system and payment models designed to improve quality, reduce costs, and improve the patient's experience of care require a strong IT foundation to be successful. Several studies have shown that health IT, if effectively designed and implemented, has a positive impact on patient safety, the efficiency and effectiveness of care, and patient and provider satisfaction.[7]

Building upon numerous legislative proposals with bipartisan support, the Health Information Technology and Economic and Clinical Health (HITECH) Act of 2009 brought about new authorities, standards, and investments in health IT. Numerous states and private-sector health plans have also implemented policies that promote the adoption and use of health IT. As a result of these efforts, the percentage of office-based physicians who have adopted a basic electronic health record (EHR) has more than tripled in the last five years, totaling 40 percent in 2012.[8] In 2011, 18 percent of hospitals had a basic EHR system in place, up from 11.5 percent the previous year.[9] Many clinicians, hospitals, and other providers have qualified for funding under the Centers for Medicare and Medicaid Services (CMS) EHR Incentive Programs by demonstrating the meaningful use of EHR technology to improve care. As of December 31, 2012, more than $10.7 billion in payments had been made through these incentive programs to approximately 3,500 hospitals and more than 186,000 eligible professionals.[10]

The widespread adoption of health IT largely stems from recognition of the important role that it plays in improving health care quality and safety. However, there are also instances in which it has the potential to create harm if not effectively developed, implemented, or used. A recent IOM report indicated that health information systems were involved in less than 1 percent of reported errors in health care settings.[11] A recently published advisory notice from the Pennsylvania Patient Safety Authority noted that only 3,900 of 1.7 million reports were found to involve health IT.[12]

Policies are now being developed by the Department of Health and Human Services (HHS) to use health IT to make health care safer and to continuously improve the safety of health

IT. The Office of the National Coordinator for Health IT (ONC) commissioned an IOM study on how government and the private sector can maximize the safety of health IT-assisted care. The report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, was released in November 2011. On December 21, 2012, HHS released *Health IT Patient Safety Action and Surveillance Plan for Public Comment*, which represents the administration's proposed approach for addressing safety in health IT.

The Food and Drug Administration (FDA) Safety and Innovation Act of 2012, which was passed by Congress and signed into law in July 2012, requires the HHS secretary, "acting through the Commissioner of Food and Drugs, and in consultation with the National Coordinator for Health Information Technology and the Chairman of the Federal Communications Commission," to post a report within 18 months that "contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[13]

Through a collaborative effort, the Bipartisan Policy Center (BPC) has both conducted research and engaged a wide range of experts and stakeholders—including clinicians, consumers, employers, health plans, hospitals, quality and patient safety organizations, academic and research institutions, and technology companies—to inform federal policy related to patient safety and health IT. As a result of the review of the literature and more than 40 meetings involving nearly 100 organizations representing diverse interests in health care, BPC has developed a set of principles and recommendations for an oversight framework for assuring patient safety in health IT. The framework protects patient safety, is risk-based, promotes innovation, is flexible, leverages existing quality and patient safety–related systems and processes, avoids regulatory duplication, and has the support of experts and stakeholders across every sector of health care.

Chapter 1: Principles for a Framework for Assuring Safety in Health IT

The following set of principles, developed through a collaborative process involving experts and stakeholders across every sector of health care, should guide the federal government's development of an oversight framework for assuring patient safety in health IT.

1. Any framework for safety should recognize and support the important role that health IT plays in improving the quality, safety, and cost-effectiveness of care, as well as the patient's experience of care.

Research shows that health IT has a positive impact on the quality, safety, and cost-effectiveness of health care.[14] Health IT plays a foundational role in the broadly supported national imperative to improve health and health care for all Americans.

While the widespread adoption of health IT largely stems from recognition of the important role that it plays in improving health care quality and safety, there are also instances in which it can create harm if not effectively developed, implemented, or used.

Because of the significant role that health IT plays in improving the quality, safety, and cost-effectiveness of care, as well as the patient's experience of care, any framework for safety should both recognize and support innovation in and adoption of health IT.

2. Assuring patient safety, along with enabling positive patient outcomes, is a shared responsibility that must involve the entire health care system.

Assuring patient safety in health IT is a shared responsibility among the many stakeholders within the health care ecosystem. As noted in the recent IOM report, safety is part of a larger sociotechnical system that takes into account not just the software, but also how it is used.[15] This larger system includes technology, people, processes, organizations, and the external environment.[16]

The level of safety in health IT depends on how the technology is designed, customized, implemented, used, maintained, and incorporated into clinical workflows. The quality of data, the interoperability of IT systems, and the appropriateness of clinical interventions also have an impact on health IT safety. Additionally, education, training, and proficiency of users can play a critical role. Finally, health IT supports—but does not replace—the judgment of clinicians.

Any oversight framework for safety in health IT should have strong support from and involvement of all stakeholders, including patients.

3. Any framework for patient safety in health IT should be risk-based, flexible, and should not stifle innovation.

The scale and scope of oversight requirements intended to ensure patient safety in health IT should be correlated to the potential risk of harm to patients.

Health care is a continually evolving ecosystem that is now undergoing considerable change. Health IT plays a foundational role for rapidly emerging new models of delivery and payment that promise to improve the quality, safety, and cost-effectiveness of care, such as accountable care arrangements and the patient-centered medical home.

Health IT must evolve to support rapidly emerging changes in the health care system and must continually be upgraded and/or customized to address the ever-changing needs of those who deliver, manage, pay for, and receive care. Innovation is needed to continually drive improvements in the cost, quality, and patient experience of care.

Any framework for safety in health IT must be flexible and promote—not stifle—the innovation needed to drive further improvements in health and health care. Current regulatory frameworks that are oriented toward turnkey devices that change infrequently and are often not customized based on the needs of the user, do not align well with the current and anticipated nature of health IT.

4. Existing safety and quality-related processes, systems, and standards should be leveraged for patient safety in health IT.

Policies, processes, and systems associated with assuring safety in health IT should be aligned with and integrated into well-established patient safety and quality programs, including those that involve accreditation, certification, and reporting.

Quality management and safety principles, processes, and standards, which are well-established and common to other industries, should also be leveraged for assuring patient safety in health IT.

Health IT is an essential component of a comprehensive approach to improving patient outcomes and assuring the quality, safety, and efficiency of health care. Any oversight framework for health IT should align with and leverage existing processes, systems, and standards in health care, and should discourage or prevent duplicative or inconsistent requirements.

5. Reporting of patient safety events related to health IT is essential; a non-punitive environment should be established to encourage reporting, learning, and improvement.

Any framework for patient safety in health IT should be data-driven. It should support and promote reporting, sharing, and analysis of patient safety events in a non-punitive environment that maintains confidentiality and enables learning and improvement.

Reporting of patient safety events by users, developers, implementers, and patients is essential to both gaining an understanding of the nature and magnitude of health IT–related safety events and developing and implementing strategies to address risks. Aggregation and analysis of events and timely feedback to developers, implementers, and users are also crucial, so that necessary changes can be made to address identified issues and to mitigate future risk.

Existing reporting processes and bodies, such as those created by the Patient Safety and Quality Improvement Act, should be leveraged. Reporting efforts should be coordinated. They should take into account existing work flows, and the burden of reporting should be minimized. The use of consistent formats for reporting should be encouraged so that data can be easily aggregated and analyzed to support learning and improvement.

Reporting policies should encourage reporting for learning and improvement. As noted in the recent IOM report, "in other countries and industries, reporting systems differ with respect to their design, but the majority employs reporting that is voluntary, confidential and non-punitive."[17] Lessons learned from such other approaches should be integrated into any oversight framework for health IT.

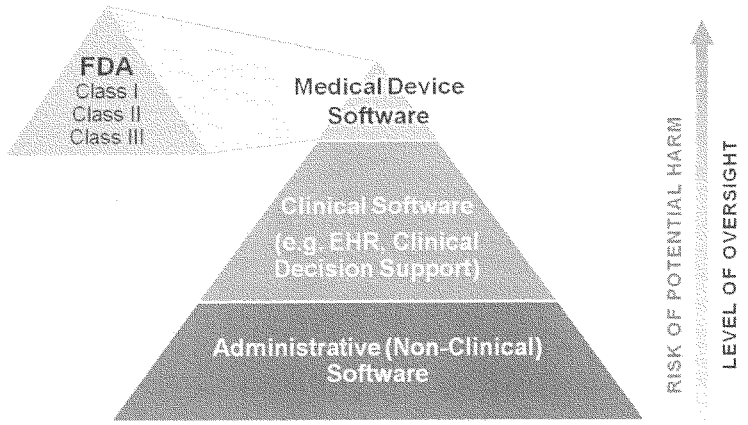
Chapter 2: Key Elements of an Oversight Framework for Assuring Safety in Health IT

Assuring patient safety in health IT is best accomplished through an oversight framework that reflects the principles outlined in this report. The framework should be risk-based and reflect shared responsibility, promote innovation, be flexible to accommodate a rapidly changing health care system, support learning and improvement, and leverage existing safety and quality-related processes, systems, and standards.

A Framework for Oversight Based on Risk

Health IT broadly falls into three primary categories (illustrated in Figure 1 below), each of which reflects increasing levels of risk of potential patient harm: (1) administrative or non-clinical software, (2) clinical software, and (3) medical device software.

Figure 1. A Risk-Based Oversight Framework for Health IT



Administrative software—which supports the administrative and operational aspects of health care but is not used in the direct delivery of care—represents the category with the lowest level of risk of potential patient harm. One example of administrative software is scheduling software, which enables health care providers to schedule appointments with patients. Based on the level of risk of patient harm associated with such software, additional oversight is not warranted.

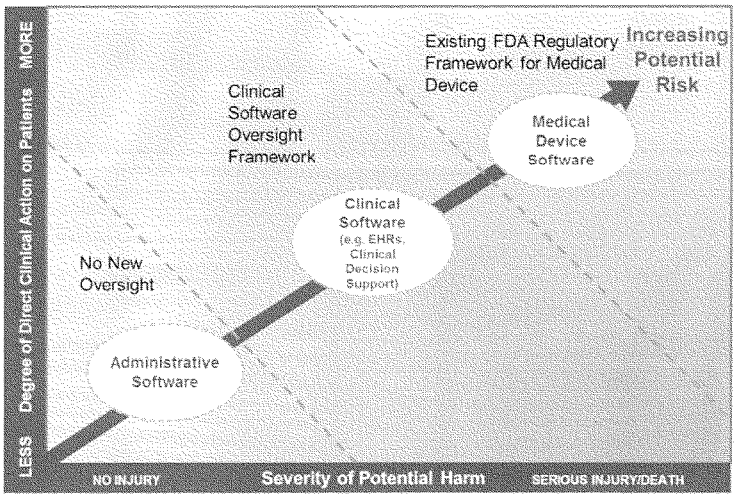
Clinical software informs clinical decision-making and directly supports the delivery of care to patients. Examples include EHRs, computerized physician order entry, and clinical decision support software.

Finally, medical devices, including medical device software, represent a high potential risk of patient harm and in most cases, directly interact with the patient with little or no opportunity for clinical intervention. Examples of traditional medical devices include pacemakers, electrocardiograms, automated external defibrillators, and mammography computer-aided detection systems. Such devices are currently regulated by the FDA as Class I, Class II, or Class III medical devices.

Determining the Level of Oversight

As illustrated in Figure 2, factors used to determine the type of oversight to be applied include: the level of risk of potential patient harm and the degree of direct clinical action on patients.

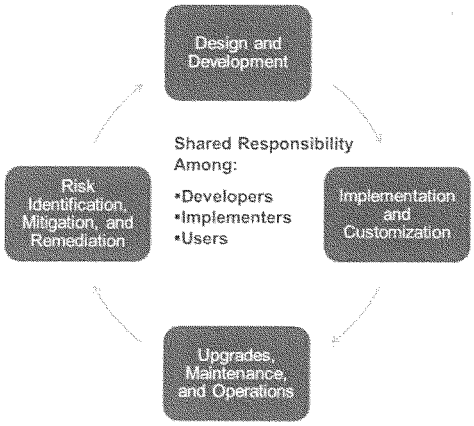
Figure 2. Factors That Determine Level of Oversight



The FDA's current regulatory approach for medical devices is generally not well-suited for health IT. Unlike medical devices, health IT relies not only on how it is designed and developed, but also on how it is customized, implemented, and used. Safety of medical devices is almost entirely dependent on how they are manufactured by developers—which is the focus of medical device regulation. Safety in health IT, however, is a shared responsibility among developers, implementers, and users across the various stages of the health IT life cycle, which include design and development; implementation and customization; upgrades, maintenance, and operations; and risk identification, mitigation, and remediation.

"Developers" are defined as those who develop software for use in health care and can include commercial IT companies, academic institutions, and health care organizations. "Implementers" are defined as those who implement software in the health care setting, and can include the IT and medical informatics departments of provider institutions, consultants, commercial health IT companies, and, in some cases, clinicians and practice management staff. "Users" are defined as those who actually use the software.

Figure 3. Stages of the Health IT Life Cycle



Other factors that impact the level of patient safety in the use of health IT include the quality of data that resides in health IT systems, the level of interoperability and exchange of information across systems, the integration of the software into clinical work flows, and the appropriateness of clinical interventions. Unlike medical devices, health IT is designed to inform—not take the place of—clinical decision-making. Clinical software does not directly interact with patients as medical devices often do. Health IT supports but does not replace

the judgment of clinicians. When using health IT for clinical care, clinicians ultimately retain clinical judgment and discretion.

Another differentiation between medical devices and health IT is that health IT is constantly being upgraded and modified to reflect new evidence and clinical interventions, changing work flows, and new requirements now rapidly emerging from public- and private-sector agencies. Federal and state agencies as well as private-sector payers are increasingly calling upon clinicians, hospitals, and other providers to bolster health IT capabilities to support the implementation of new delivery system and payment reforms, as well as requirements for health IT incentive programs—such as those associated with CMS' Medicare and Medicaid EHR Incentive Programs. Constantly evolving systems, such as health IT, don't lend themselves to discontinuous oversight mechanisms such as those used for medical devices.

Key Elements of the Oversight Framework for Clinical Software

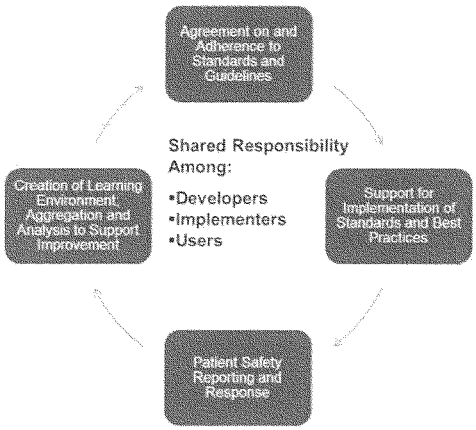
Assuring patient safety in the use of health IT—and in particular, clinical software—requires both national focus and public- and private-sector collaboration and leadership. As noted previously, this is best accomplished through an oversight framework that is not only risk-based and reflects shared responsibility, but also one that promotes innovation, is flexible to accommodate a rapidly changing health care system, supports learning and improvement, and leverages existing safety and quality-related processes, systems, and standards.

As illustrated in Figure 4 below, the oversight framework for the safe use of clinical software should be composed of four main elements:

1. Agreement on and adherence to recognized standards and guidelines for assuring patient safety in the development, implementation, and use of health IT.
2. Support for the implementation of standards and guidelines as well as development and dissemination of best practices through education, training, and technical assistance.
3. Developer, implementer, and user participation in patient safety activities, leveraging PSOs, including reporting, analysis, and response.
4. Creation of a learning environment through the aggregation and analysis of data to identify and monitor trends, mitigate future risk, and facilitate learning and improvement.

Addressing these four elements is a shared responsibility among developers, implementers, and users of clinical software.

Figure 4. Oversight Framework for Patient Safety in Clinical Software



Alignment with HHS-Proposed Health IT Patient Safety Action and Surveillance Plan

The oversight framework for assuring patient safety in health IT outlined in this report aligns with the approach proposed in HHS' *Health IT Patient Safety Action and Surveillance Plan for Public Comment* in several ways, including: the focus on leveraging existing programs and processes, development of and adherence to standards, reporting and response by providers and health IT developers, aggregation and analysis of patient safety events to facilitate improvement, and provision of implementation support through research and development of user tools and best practices related to safety and health IT. As described in more detail below, the oversight framework relies on a process-oriented approach. The HHS plan calls for the use of process standards, but does so within the context of a product-focused EHR certification program.

A more detailed description of each element of the oversight framework for clinical software is provided below, along with recommendations that will speed its implementation.

Chapter 3: Recommendations for an Oversight Framework for Safety in Health IT

1. Agreement on and Communication of a Health IT Safety Oversight Framework That Reflects Shared Principles and Builds upon Key Elements Addressed in This Report

HHS has taken important steps to advance patient safety in health IT–enabled care. First, it commissioned an IOM study on how government and the private sector can maximize the safety of health IT–assisted care. Second, on December 21, 2012, it published *Health IT Patient Safety Action and Surveillance Plan for Public Comment,* which represents the administration's proposed approach to patient safety in health IT. The administration's proposed action plan aligns with many of the principles outlined in this report and signals its intention to manage the oversight of health IT outside of the traditional medical device regulatory regime.

The FDA Safety and Innovation Act of 2012, which was passed by Congress and signed into law in July 2012, calls for the HHS secretary to post—within 18 months—"a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[18]

The possibility of government regulation in health IT has the potential of stifling innovation and much-needed investment in an industry that must significantly expand, evolve, and innovate to support the growing demands of a health care system that is undergoing considerable modernization and transformation to address continuing concerns about rising health care costs and uneven quality.

Imposing a new set of regulations in the midst of a health care environment that is already fiscally challenged and facing many new regulations and requirements brought about by the Affordable Care Act and HITECH, has the potential to overwhelm the system.

At the same time, clinicians, hospitals and other providers, technology companies, and patients are seeking agreement and collaborative action on a set of principles, guidelines, processes, and systems that will support them in both using health IT to improve patient safety and improving the safety of health IT–assisted care.

BPC has both conducted research and engaged a wide range of experts and stakeholders to inform this set of recommendations for an oversight framework for assuring patient safety in health IT.

Recommendation 1.1

As HHS finalizes its patient safety action and surveillance plan and develops its proposed strategy and recommendations for a risk-based, regulatory framework for health IT, we urge the department to consider the principles and recommendations for an oversight framework included in this report.

The oversight framework for patient safety should reflect the following key principles:

1. Recognize and support the important role that health IT plays in improving the quality, safety, and cost-effectiveness of care, as well as the patient's experience of care.
2. Recognize that assuring patient safety, along with positive patient outcomes, is a shared responsibility that must involve the entire health care system.
3. Be risk-based, flexible, and do not stifle innovation.
4. Leverage existing safety and quality-related processes, systems, and standards.
5. Recognize that reporting of patient safety events is essential and that a non-punitive environment should be established to encourage reporting, learning, and improvement.

The oversight framework should enable national focus and public- and private-sector collaboration and leadership. Rather than rely upon existing approaches for the regulation of medical devices, the oversight framework for clinical software should call upon developers, implementers, users, PSOs, and experts, working in collaboration with government, to:

1. Agree upon and promote adherence to—through accreditation, as appropriate--recognized standards and guidelines for assuring patient safety in the development, implementation, and use of health IT.

2. Provide support for the implementation of such standards and guidelines as well as develop and disseminate best practices, through education, training, and technical assistance.
3. Enable developer, implementer, and user participation in patient safety activities, leveraging PSOs, including reporting, analysis, and response.
4. Create a learning environment; aggregate and analyze non-identified patient safety reports to identify and monitor trends, mitigate future risk, and facilitate learning and improvement.

A description of each component of the oversight framework for clinical software and recommendations for the actions needed to support implementation are summarized below.

2. Agreement on and Adherence to Recognized Standards and Guidelines for Assuring Patient Safety

One of the key components of the oversight framework is a process for gaining agreement on process standards and guidelines for assuring patient safety in the development, implementation, and ongoing use of health IT. Developers, implementers, users, and patients, along with patient safety and health IT experts and government, should both inform and play a significant role in the development and continued evolution of such standards and guidelines.

Because assurance of safety in health IT is a shared responsibility that is dependent on how it is developed, implemented, and used, standards and guidelines for assuring patient safety should focus on harmonized processes across the health IT life cycle—as opposed to technical requirements that are limited to specific functionality, such as those that play a predominant role within current EHR certification programs associated with CMS' Medicare and Medicaid EHR Incentive Programs. A process and life cycle approach inherently leads to higher product safety as it enables the delivery of defined and consistent outcomes. As noted in the IOM report on patient safety and health IT, experiences from other industries suggest the best approach to proactively creating highly reliable products is not to certify each individual product but rather, to make sure organizations have adopted quality-management principles and processes in the design and development of products.[19]

Well-established international standards that enable patient safety already exist and are developed under the auspices of the International Organization for Standardization (ISO). Examples of such existing process standards include those that address quality-management systems (ISO 9001), product risk management (ISO 14971), software development (ISO 62304), and usability (ISO 62366). The development of a new ISO standard focused on assuring the safer development, implementation, and operation of health software is currently underway.[20] The complete range of existing standards and

guidelines should be reviewed for applicability to health IT patient safety goals, gaps should be identified and modified, and new standards should be developed as needed. Funding of research in areas where gaps are identified will be needed.

Finally, such standards and guidelines must continually evolve to address changing requirements and the identification of new issues that need focus. Standard and guideline development processes should be tightly linked to and informed by the analysis of aggregated reports from across the health care system, to facilitate learning and improvement.

Independent "voluntary consensus bodies"—defined by OMB Circular A-119 as those that exhibit the attributes of openness, balance of interest, due process, an appeals process, and consensus—are in the best position to facilitate agreement among health care stakeholders on a recognized set of standards and guidelines for patient safety in health IT.[21] Under the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119, the federal government is required to use standards developed by voluntary consensus bodies in its regulatory and procurement activities, unless the use of such standards would be inconsistent with applicable law or otherwise impractical.[22,23]

Recommendation 2.1

Independent, voluntary consensus bodies should engage developers, implementers, users, health IT and safety experts, and consumers to gain ongoing agreement on a set of standards and guidelines for assuring patient safety in the design, development, implementation, and use of health IT.

Recommendation 2.2

Independent voluntary consensus bodies and organizations that represent developers, implementers, users, and patient safety and health IT experts should collaborate on the dissemination of agreed-upon standards and guidelines as well as on the development and delivery of educational programs and implementation support services designed to educate and promote compliance with such standards and guidelines.

Recommendation 2.3

Developers and software implementers that are not a part of provider organizations should demonstrate adherence to recognized and agreed-upon standards and guidelines by undergoing accreditation administered through independent, recognized bodies.

Recommendation 2.4

Existing, independent provider accreditation bodies should be evaluated for their reference and support of recognized standards and guidelines for software implementation and use.

3. Support for Implementation of Standards and Guidelines; Development and Dissemination of Best Practices for Developers, Implementers, and Users

Widespread dissemination of and support for the implementation of standards, guidelines, and best practices for assuring safety in the development, implementation, and use of clinical software is crucial. This can take the form of education, training, and implementation support services offered by organizations with expertise in this area, as well as those who work with software vendors, clinicians, hospitals, and other providers.

Developers, implementers, and users will increasingly need to work together to develop strategies that meet the growing demands of a rapidly changing health care system. More dialogue and collaboration on best practices for assuring safety in the use of health IT is needed among those who develop, implement, and use software in health care. Fear of liability, punitive or regulatory action, and negative press, combined with some lack of trust, all serve as barriers to dialogue among clinicians, hospitals, and technology developers about the actions that can be taken to continually improve patient safety in health IT-enabled care.

Recommendation 3.1

Developers, implementers, users, health IT and patient safety experts, and PSOs should collaborate on the development and dissemination of strategies and best practices for assuring patient safety in the design and development; implementation and customization; upgrade, maintenance, and operations; and risk identification, mitigation, and remediation phases of the health IT life cycle. Such strategies and best practices should align with recognized standards and guidelines. This will require significant investment of resources in research, collaboration, and dissemination.

4. Participation in Patient Safety Activities Including Reporting, Analysis, and Response

Reporting, analysis, and development and execution of corrective actions for individual patient safety events are critical components of an oversight framework for patient safety in health IT.

LEVERAGING EXISTING PATIENT SAFETY-RELATED AUTHORITIES, ORGANIZATIONS, AND PROCESSES

Congress passed the Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act), to encourage health care providers to voluntarily report information on patient safety events and to facilitate the development and adoption of interventions and solutions to improve patient safety.

The Patient Safety Act authorized the creation of patient safety organizations (PSOs). PSOs, which must be certified for listing and evaluated on an ongoing basis by the Agency for Healthcare Research and Quality (AHRQ), serve as patient safety experts and receive data regarding patient safety events that are considered privileged and confidential.[24]

Currently, 88 PSOs are listed on the AHRQ website, representing a range of for-profit and not-for-profit organizations and entities that are components of other organizations, such as hospital associations, medical societies, or health systems.[25]

Rather than establish new authorities or structures for reporting and analysis of patient safety events specific to health IT, PSOs—who are already authorized to serve as patient safety experts and receive data regarding patient safety events that are considered privileged and confidential—should be leveraged to support reporting for patient safety events associated with health IT.

Creating a safety reporting silo that only focuses on health IT would be duplicative, increase unnecessary burden, and also result in the failure to capture many relevant events. Patient safety events associated with health IT are often not identified as such until analysis has been performed by the PSO. Many patient safety problems that have health IT dimensions are characterized by the providers that report them in other ways, such as medication errors, patient identification errors, erroneous laboratory or radiology results, or documentation or communication errors. For example, 43 percent of the device and health IT events in one large PSO database were submitted in a non-health-IT-related category.[26]

Recommendation 4.1

Authorities, structures, and organizations brought about by the Patient Safety and Quality Improvement Act—including patient safety organizations—should be leveraged to support reporting and analysis of health IT–related patient safety events.

ENABLING DEVELOPERS TO PARTICIPATE IN PATIENT SAFETY ACTIVITIES

The Patient Safety Act establishes a culture of safety for providers by providing statutory confidentiality protections for "patient safety work product" (PSWP). Specifically, identifiable patient safety work product is defined, in part, as PSWP that is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product (42 USC 299b-21(2)) .

This provision grew out of the 1999 IOM Report *To Err is Human*, which reported that without protections providers did not share information about errors and thus the errors were repeated. The culture of safety permits providers to participate in activities intended to improve the quality of patient care without fear of liability or harm to professional reputation. Importantly, this provision does not exempt the provider from lawsuits; information in the medical record concerning the underlying facts is not protected under the Patient Safety Act and remains available to plaintiffs, just as it was before the passage of the Act.

PSOs work with clinicians, hospitals, and other providers to analyze and understand the root cause of patient safety events, provide feedback, and develop and disseminate recommendations designed to improve quality and safety. In the case of patient safety events that involve health IT, developers and implementers of software also play a critical role in gaining an understanding of root cause and other contributing factors.

Unless developers have a direct relationship with a PSO, they are not able to participate with the PSO in analyzing, identifying the root causes of, and developing corrective actions for health IT–related patient safety events, because sharing a report with them would break statutory confidentiality protections. Under the Patient Safety Act, developers may have a relationship with a PSO either by becoming a PSO, entering into a joint venture with the PSO, or serving under contract to the PSO, which permits them to participate in patient safety activities

Because health IT safety is a shared responsibility, health IT developers must have the ability to participate with PSOs, clinicians, hospitals, and other providers in patient safety activities to improve the safety and quality of health IT–enabled care without breaking statutory confidentiality protections for providers.

While clinicians, hospitals, and other providers are often in the best position to identify and report patient safety events associated with health IT, there may be situations in which developers or implementers of software are made aware of events associated with use of health IT products through communications with their clients.

Because assuring safety is a shared responsibility, developers should participate in the reporting of patient safety events, just as providers do. Many providers voluntarily report patient safety events to PSOs. In addition, a majority of states have mandatory hospital and other health care provider reporting requirements related to events that cause death or serious harm.[27] The Joint Commission, through its accreditation process, reviews hospitals' activities in response to sentinel events (which are unexpected occurrences involving death or serious injury) and encourages—but does not require—the reporting of such events to Joint Commission's Sentinel Event Database.[28] Like providers, developers can be reluctant to report out of fear of legal liability or harm to reputation.

The current law should be extended to provide confidentiality protections to health IT developers to permit them to report patient safety events, view PSO-protected information, receive and analyze event reports, create and receive quality-improvement

recommendations from the PSO, and work with the providers to develop strategies for improvement.

Like providers, such protections would not exempt developers from lawsuits. Information in the patient's medical record concerning the underlying facts involving any health IT is not protected under the Patient Safety Act and remains available to plaintiffs. Therefore, extending the protections to develop a culture of safety would not limit a developer's potential liability if one of its products directly causes harm to a patient. Additionally, health IT developers and their products must also comply with existing federal or state consumer protection laws, as well as federal and state privacy and security laws and regulations. In summary, expanded protections for developers would not affect laws that are intended to protect patients and consumers.

Recommendation 4.2

Because assuring patient safety in health IT is a shared responsibility, developers—like providers--should report patient safety events to PSOs, as appropriate, with expanded protections and requirements for reporting of events that cause death or serious harm.

Recommendation 4.3

The Agency for Healthcare Research and Quality should explore options for enabling developers to participate in patient safety activities with protections. Such participation would include reporting, review and analysis of patient safety events that are health IT-related, creation and receipt of quality improvement recommendations from the PSO associated with a specific event, and dialogue with the PSO and provider regarding corrective actions that can be taken to mitigate further risk.

REMOVING BARRIERS TO REPORTING AMONG CLINICIANS AND OTHER PROVIDERS

One of the primary barriers to reporting among clinicians, hospitals, and other providers is the burden of reporting and its impact on current work flows. The administration and management of reporting takes considerable time and resources. Reporting efforts should be designed to minimize the burden of reporting. To the extent feasible and possible, reporting should be embedded into current work flows and health IT systems. Another key barrier is the lack of awareness or understanding of the confidentiality protections under the Patient Safety Act. Awareness-building and education programs designed to explain and clarify both the benefits of reporting and the confidentiality protections that are in place can support expanded reporting by clinicians, as well as other providers.

Other barriers to patient safety reporting cited by clinicians include fear of breaching confidentiality provisions of contracts with their health IT vendors and, in some cases, perceived institutional barriers to reporting. Raising awareness among clinicians and other providers by health IT vendors regarding the permissibility of reporting patient safety

events to their PSOs under existing contracts, and further clarifying such language in future contracts, can help to allay such fears among clinicians and other providers. Increasing awareness of the importance of and policies associated with patient safety reporting within institutions can also reduce clinician-perceived barriers to reporting.

Patient safety event reporting, analysis, identification of root cause, and corrective action are critical to improving patient safety in health IT-assisted care. Those who develop, implement, and use health IT should be encouraged to report patient safety events to facilitate learning and improvement and mitigate future risk.

Recommendation 4.4

Organizations representing PSOs, developers, clinicians, hospitals, and other providers should take steps to encourage reporting of patient safety events—including those related to health IT. This can be accomplished by raising awareness of the benefits of reporting and clarifying the confidentiality protections in place to support such reporting. Expanded reporting will further the ability to learn more about the nature and prevalence of risk, enable the development of strategies and best practices to address areas of risk, and facilitate improvement in the quality and safety of health care.

Recommendation 4.5

To address the perceptions of some clinicians that patient safety reporting might breach the confidentiality provisions of contracts with their health IT vendors, developers should raise awareness among their clients that reporting of patient safety events to their PSOs is indeed permissible under their existing contracts. In cases where there is lack of clarity, developers should work to clarify such language in future contracts to help allay fears among those clinicians and other providers who perceive contractual language to be a barrier.

EXPANDING PSO CAPABILITIES ASSOCIATED WITH HEALTH IT–RELATED PATIENT SAFETY EVENTS

While there is a great deal of literature on improving patient safety generally in health care, relatively little is known or has been published about the nature and prevalence of patient safety events associated with health IT development and use.

The development of standards, guidelines, and best practices for traditional PSO activities—such as reporting and analysis of reported events, development of corrective action plans, aggregation and analysis of large data sets, and development of strategies to mitigate future risk for health IT–related patient safety events—is needed. Such development must necessarily occur with significant involvement of developers, implementers, users, and patient safety and health IT experts.

As clinicians, hospitals and other providers, and developers increasingly begin to rely on PSOs for the reporting of patient safety events that are or may be associated with health IT, they will expect that PSOs offering such services will have the expertise and capabilities

associated with this new and emerging field. While baseline knowledge and capabilities should be expected of all PSOs, demonstration and communication of advanced capabilities will help developers, implementers, and users identify PSOs with which they wish to establish a relationship to support reporting of patient safety events associated with health IT. Demonstration of such advanced capability could be accomplished through a PSO-led accreditation program associated with health IT–related patient safety events, with support by developers, implementers, users, and experts in both patient safety and health IT.

Recommendation 4.6

PSOs, developers, implementers, users, and health IT and patient safety experts should collaborate on the development of standards, guidelines, strategies, and best practices for collecting, analyzing, and investigating health IT–related patient safety events; defining corrective action and providing timely feedback; and taking other actions as necessary to mitigate future risk and facilitate learning and improvement.

Recommendation 4.7

PSOs should collaborate with developers, implementers, users, and patient safety and health IT experts on the development and launch of an accreditation program that reflects established standards, guidelines, and best practices and promotes effective implementation of patient safety activities related to health IT. PSOs that wish to specialize in health IT–related patient safety activities should undergo such accreditation.

5. Creation of a Learning Environment for Safety in Health IT

Reporting and responding to individual events is a critical means to enhance safety, but it is not enough. Aggregating and analyzing reports across large populations enables a more rapid identification of underlying patterns and trends as well as emerging risks and the causes of those risks. Aggregation and analysis of patient safety data also supports the development and implementation of interventions to mitigate risk and enable system-wide learning and improvement.

To support PSOs and providers in their efforts to develop and adopt improvements in patient safety, the Patient Safety Act authorized AHRQ to facilitate the development of a network of patient safety databases (NPSD), to which PSOs, health care providers, or others can voluntarily contribute non-identifiable patient safety work product. By facilitating the aggregation and analysis of data nationwide, the NPSD is intended to assist PSOs and providers in their efforts to develop and adopt improvements in patient safety.[29]

Another way in which aggregation, analysis, and improvement activities can take place with the support of confidentiality protections under the Patient Safety Act is through the aggregation and analysis of non-identified patient safety from numerous PSOs into another

PSO that focuses on aggregation and analysis. As patient safety reporting for health IT takes hold, it is likely that a combination of the two scenarios identified above will emerge.

Regardless of the mechanisms used, appropriate governance, policies, protections, and capabilities will need to be established for entities that choose to aggregate large sets of patient safety data to garner trust, assure confidentiality, provide ease of use, minimize burden, and deliver value to participants—all of which will be required to promote significant participation and long-term sustainability.

Recommendation 5.1

Developers, implementers, users, PSOs, patient safety and health IT experts, and consumers should collaborate on the development of key attributes and requirements associated with the aggregation and analysis of non-identified patient safety event data to facilitate learning and to assure patient safety in the use of health IT. Such attributes and requirements will inform PSOs that wish to provide services associated with patient safety in health IT and help them gain the participation and support of developers, implementers, and users who wish to participate in aggregated reporting efforts designed to promote safety in health IT.

ENCOURAGING USE OF STANDARD FORMATS FOR REPORTING AND RESPONSE

The use of standardized formats for reporting will significantly improve the ability for data to be aggregated and analyzed to support system-wide response and improvement.

As noted previously, the Patient Safety Act requires PSOs—to the extent practical and appropriate—to collect patient safety data from providers in a standardized manner. If providers or PSOs choose to submit patient safety data to the NPSD, AHRQ requires that these data be submitted using the AHRQ Common Formats, which are common definitions and reporting formats used to facilitate the collection and reporting of patient safety events. To date, AHRQ has developed Common Formats for two settings of care—acute care hospitals and skilled nursing facilities. Future versions of the Common Formats are being developed for ambulatory settings. AHRQ has also developed Common Formats to support the reporting of patient safety events related to health IT.[30]

Recognizing the importance of using standard formats for the reporting of patient safety events to enable aggregation, analysis, and identification of interventions that mitigate risk and support improvement; developers, implementers, and users who report patient safety events either to a PSO or the NPSD should be encouraged to utilize standardized formats. To the extent feasible and appropriate, the AHRQ Common Formats should be leveraged to support reporting using standardized formats.

Recommendation 5.2

Developers, implementers, users, and PSOs that report patient safety events should utilize standardized formats for such reporting—including those related to health IT.

Recommendation 5.3

Given the increase in adoption of EHRs among clinicians in ambulatory settings and given the critical importance of patient safety reports from such environments—particularly as it relates to health IT, AHRQ should continue and accelerate its efforts to develop Common Formats for ambulatory care.

Recommendation 5.4

To facilitate the aggregation and analysis of patient safety data to support learning and improvement in the area of health IT, PSOs should explore aggregating patient safety events associated with health IT either through reporting to the NPSD or to another PSO that is aggregating such data to support learning and improvement.

Conclusion

Health IT plays a critical role in improving the quality, safety, and cost-effectiveness of care. Continuing to use health IT to make health care safer and assuring the safety of health IT is essential. Through the implementation of the principles and recommendations summarized in this report, the federal government, states, and private-sector leaders across every sector of health care can make significant strides in achieving these dual goals, while continuing to improve how health care is delivered in the United States.

As policy makers consider the development of a regulatory framework for health IT, we urge them to consider the oversight framework outlined in this report, which protects patient safety, is risk-based, promotes innovation, is flexible, leverages existing quality and patient safety–related systems and processes, avoids regulatory duplication, and has the support of experts and stakeholders across every sector of health care.

BPC thanks the many organizations and individuals, listed in the acknowledgements section of this report, who contributed their time and expertise to the development of principles and recommendations included in this report.

Through the BPC Health Innovation Initiative, we plan to continue the dialogue on the principles, policies, and strategies that should be adopted to promote the use of health IT to improve patient safety, while assuring safety in the development, implementation, and use of health IT.

About the Bipartisan Policy Center's Health Innovation Initiative

Founded in 2007 by former Senate Majority Leaders Howard Baker, Tom Daschle, Bob Dole, and George Mitchell, BPC is a nonprofit organization that drives principled solutions through rigorous analysis, reasoned negotiation, and respectful dialogue. With projects in multiple issue areas, BPC combines politically balanced policy making with strong, proactive advocacy and outreach. See www.bipartisanpolicy.org.

In coordination with BPC's Health Project, which is led by Health Project co-leaders and former Senate Majority Leaders Tom Daschle (D-SD) and Bill Frist (R-TN), the Health Innovation Initiative conducts research and collaborates with experts and stakeholders across health care to develop recommendations that promote innovation as well as the use of IT to drive improvements in the cost, quality, and patient experience of care. Key areas of focus include the following:

1. Creating the information foundation for delivery system and payment reforms that promote higher-quality, more cost-effective care.
2. Expanding engagement of consumers in their health and health care to improve outcomes in cost, quality, and patient experience of care.
3. Accelerating the electronic exchange of health information across the multiple settings in which care and services are delivered to support coordinated, accountable, patient-centered care that improves quality and reduces costs.
4. Assuring privacy and security of electronic health information by gaining agreement among stakeholders in health care on a set of principles, policies, and strategies for managing privacy as it relates to both the delivery of care and improvements in population health.
5. Assuring patient safety in health IT, while preserving an environment that fosters the innovation needed for a rapidly changing health care system.
6. Advancing innovation in new areas that will promote better outcomes in quality and cost, including those related to personalized and genomic medicine.

Acknowledgements

BPC would like to thank Janet Marchibroda, director of the BPC Health Innovation Initiative; Katie Golden, BPC health policy analyst; and Ann Gordon, writer and editor, for their contributions to this report.

BPC would also like to thank the following organizations, which contributed their time and expertise to the development of the principles and recommendations included in this report.

Aetna

Alliance for Quality Improvement and Patient Safety

Allscripts

American Academy of Family Physicians

American Academy of Pediatrics

American Cancer Society

American College of Cardiology

American College of Emergency Physicians

American College of Physician Executives

American College of Physicians

American College of Surgeons

American Congress of Obstetricians and Gynecologists

American Medical Group Association

American Medical Informatics Association

American Nurses Association

American Osteopathic Association

American Society of Clinical Oncology

Ascension Health

Association of American Medical Colleges

Association of Clinicians for the Underserved

Association of Medical Directors of Information Systems

athenahealth

AT&T

Baylor Health System

Blue Cross Blue Shield Association

Brookings Institution

CentraStateHealth System

Cerner Corporation

CHIME

Continua Health Alliance

Dell

ECRI Institute

e-MDs

GE Healthcare

Geisinger Health System

Greenway Medical Technologies

HCA Healthcare

Health Fidelity

Healthcare Leadership Council

Health Level Seven

HIMSS

IBM Corporation

Intel Corporation

Intermountain Healthcare

Joint Commission

Kaiser Permanente

McKesson Corporation

Medical Group Management Association

Medtronic

National Association of Children's Hospitals and Related Institutions

National Association of Public Hospitals and Health Systems

National Coalition for Cancer Survivorship

National Medical Association

National Partnership for Women and Families

National Patient Safety Foundation

National Rural Health Association

NewYork Presbyterian Hospitals

NextGen HealthCare

North Shore-LIJ Health System and Hofstra North Shore-LIJ School of Medicine

Philips Healthcare

Poudre Valley Medical Group and Poudre Valley Health System

Practice Fusion

Premier

Qualcomm

Sharp HealthCare

Siemens Healthcare

Summit Health Institute for Research and Education (SHIRE)

Tenet Healthcare Corporation

Tennessee Office of eHealth Initiatives

Texas Office of eHealth Coordination

United Health Group

University of Texas at Houston

Vanderbilt University School of Nursing

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Mr. PITTS. The chair thanks the gentlelady, and now recognizes Dr. Classen for 5 minutes for an opening statement.

STATEMENT OF DAVID CLASSEN

Dr. CLASSEN. Good morning, Chairman Pitts and Ranking Member Pallone, members of the subcommittee. Thank you for the opportunity to testify on this very important issue. I am a practicing infectious disease physician at the University of Utah School of Medicine, and I am the Chief Medical and Informatics Officer at Pascal Metrics, a patient safety organization. I also chair the AHRQ Formats Committee at the National Quality Forum. My background is as an infectious disease physician, medical informaticist and patient safety researcher. As such, I have been on several Institute of Medicine committees that have focused on how to improve patient safety, most recently, the one I will draw my testimony from today, Health IT and Patient Safety: Building Safer Systems for Better Care. One of the focuses of that report was how do we improve the safety of care for our patients most effectively with health IT? How do we do it in a way that doesn't injure our patients or harm them, and how do we do it in a way that does not stifle innovation?

From that report, we looked back through the original To Err is Human report from the Institute of Medicine that suggested that as many as 98,000 lives a year are lost due to medical errors. In our most recent report, we suggest that those estimates of patient safety problems are probably lower than is really the story, based on newer detection problems both in hospitals and in the ambulatory setting of care. So there clearly is a large opportunity for us to use health IT to improve safety of care, both on the inpatient setting in hospitals and on the ambulatory setting.

So one strategy that the Nation has turned to for safer, more effective care is the widespread use of health IT. As we have heard from other panel members, this really is the case over the last several years. We are investing billions of dollars in Meaningful Use to more broadly adopt this health IT. It is clearly playing an ever larger role in the care of patients, and clearly there is evidence that it has improved health care and reduced medical errors.

Continuing to use paper records places patients at unnecessary risk for harm and substantially concerns the ability to reform health care. However, there are concerns about harm that has come from the use of health IT that led to the generation of this IOM report. In this IOM report, health IT and patient safety was defined broadly to include EHRs, patient engagement tools, personal health records, secure patient portals, health information exchanges, and mobile applications.

Practicing clinicians, such as myself, expect health IT to support the delivery of high quality in several ways, including storing comprehensive health data, providing clinical decision support, facilitating communication, and reducing medical errors. It is widely believed that health IT, when designed, implemented, and used appropriately, can be a positive enabler to transform the way care is delivered. Designed and applied inappropriately, health IT can add complexities to the already complex delivery of health care, which can lead to unintended consequences, for example, dosing errors,

failing to detect fatal illnesses, and delaying treatment due to poor human to computer error, actions or loss of data. Merely installing health IT in health care organizations will not result in improved care or safety. Taking together the design, implementation, and use of health IT affects its performance on improving the safety of care.

Safe implementation and safe use of health IT is a complex, dynamic process that requires a shared responsibility among vendors, health care workers, and health care organizations, a partnership, if you will. Many features of software contribute to its safe use, including usability and interoperability, and can also contribute to patient safety problems if we have poor user design, poor work flow, or complex interfaces, which could be a threat to patient safety. The lack of system operability is clearly a major problem in patient safety. We do have some success stories here. Laboratory standards have added—actually facilitated the free flowing of laboratory information. However, we are not there yet and information such as problem lists and medication lists are not currently easily transmitted between health IT systems.

Safety considerations need to be embedded throughout the whole health IT implementation process, including planning, deployment, stabilization, optimization, and transformation. Vendors take primary responsibility for the design and development of technologies ideally with iterative feedback from users. The users assume responsibility for safe implementation at work with vendors throughout the health IT implementation process. This partnership to develop, implement and optimize system is a shared responsibility where vendors and users help each other achieve the safest possible applications of health IT.

It is important to recognize that health IT products generally cannot be installed out of the box. Users often need to ensure that products appropriately match their needs and capabilities in both functionality and complexity of operation. So therefore, in operation health IT can look very different from what it looked like on the shelf.

Ongoing safe use of health IT requires diligent surveillance of evolving needs, gaps, performance issues, and mismatches between user needs and system performance, unsafe conditions, and adverse events. The IOM report believes certain actions are required by both private and public entities to monitor safety in order to protect the public's health, and provided the following recommendations to improve health IT nationwide. In my testimony, I have the recommendations in that report, but in the interest of time, I will leave them in the testimony and conclude my remarks.

Thank you very much.

[The prepared statement of Dr. Classen follows:]

Testimony of David C Classen, MD, MS

Before the
Subcommittee on Health
Committee on Energy and Commerce

U.S. House of Representatives

Hearing on:
"Health Information Technologies: How Innovation Benefits Patients"
March 20, 2013

Chairman Pitts and Ranking Member Pallone, Members of the Subcommittee, thank you for the opportunity to testify on this very important issue.

I am a practicing infectious disease physician at the University of Utah School of Medicine and I am also the Chief Medical Informatics Officer at Pascal Metrics, a federally certified Patient Safety Organization (PSO). I am also Co-Chair of the AHRQ Common Formats Committee at the National Quality Forum.

I am trained as an infectious disease physician and a medical informaticist and also I am a patient safety researcher focused on ways to measure and improve patient safety with health information technology (health IT). Furthermore I have been a member of several Institute of Medicine Committees on patient safety, most recently (2010-11) the one whose report I will touch on today, *Health IT and Patient Safety: Building Safer Systems For Better Care*. Indeed much of my testimony is drawn directly from this IOM report.

More than a decade ago, the Institute of Medicine (IOM) report, *To Err Is Human,* estimated that 44,000-98,000 lives are lost every year due to medical errors in hospitals and led to the widespread recognition that health care is not safe enough, catalyzing a revolution to improve the quality of care. Despite considerable effort, patient safety has not yet improved to the degree hoped for in that IOM report. In the most recent IOM report on *Health IT and Patient Safety*, the estimates of patient safety problems in hospitals are much higher than the original estimates more than

a decade ago, similar studies of ambulatory patient safety issues from the American Medical Association and others cited in this IOM report also suggest that original estimates of safety problems in the outpatient arena may also be low as well.

One strategy the nation has turned to for safer, more effective care is the widespread use of health IT. The U.S. government is investing billions of dollars toward meaningful use of effective health IT so that all Americans can benefit from the use of electronic health records (EHRs). Health IT is playing an ever-larger role in the care of patients, and some components of health IT have significantly improved the quality of health care and reduced medical errors. Continuing to use paper records can place patients at unnecessary risk for harm and substantially constrain the country's ability to reform health care, However, concerns about harm from the use of health IT have emerged.

In this IOM report on *Health IT and Patient Safety*, health IT is defined broadly to include a broad range of products, including EHRs, patient engagement tools (e.g., personal health records [PHRs] and secure patient portals), and health information exchanges (HIEs). Included in this definition of HEALTH IT were mobile applications of any of these tools listed above.

Practicing clinicians such as myself expect health IT to support delivery of high-quality care in several ways, including storing comprehensive health data, providing clinical decision support, facilitating communication, and reducing medical errors.

It is widely believed that health IT, when designed, implemented, and used appropriately, can be a positive enabler to transform the way care is delivered. Designed and applied inappropriately, health IT can add complexity to the already complex delivery of health care, which can lead to unintended adverse consequences, for example dosing errors, failing to detect fatal illnesses, and delaying treatment due to poor human-to-computer interactions or loss of data.

Software-related safety issues are often ascribed narrowly to software coding errors or human errors in using the software. It is rarely that simple. Many problems with health IT relate to usability, implementation, and how software fits with clinical workflow. Focusing on coding or human errors alone often leads to neglect of other important factors (e.g., usability, workflow, interoperability, human factors for example) that may increase the likelihood a patient safety event will occur. Safety is an emergent property of a larger system that takes into account not just the software but also how it is used by clinicians. That larger system – often called a sociotechnical system – includes technology (e.g., software, hardware), people (e.g., clinicians, patients), processes (e.g., workflow), organization (e.g., capacity, decisions about how health IT is applied, incentives), and the external environment (e.g., regulations, public opinion). Adopting a sociotechnical perspective acknowledges that safety emerges from the interaction among these various factors.

Merely installing health IT in health care organizations will not result in improved care or safety. Taken together, the design, implementation, and use of health IT

affects its safety performance. Safe implementation and safe use of health IT is a complex, dynamic process that requires a shared responsibility among vendors, healthcare workers, and health care organizations. Safely functioning health IT should provide easy entry and retrieval of data, have simple and intuitive displays, and allow data to be easily transferred and shared among health professionals.

Many features of software contribute to its safe use, including usability and interoperability. The committee believes poor user-interface design, poor workflow and complex data interfaces are threats to patient safety. The lack of system interoperability is a barrier to improving clinical decisions and patient safety, as it can limit data available for clinical decision-making. Laboratory data have been relatively easy to exchange because good standards exist such as Logical Observation Identifiers Names and Codes (LOINC) and are widely accepted.

However, important information such as problem lists and medication lists are not easily transmitted and understood by the receiving health IT product because existing standards have not been uniformly adopted. Interoperability must extend throughout the continuum of care; standards need to be developed and implemented to support interaction between health IT products that contain disparate data.

Safety considerations need to be embedded throughout the whole health IT implementation process, including the stages of planning and goal setting,

deployment, stabilization, optimization, and transformation. Selecting the right software requires a comprehensive understanding of the data and information needs of the organization and the capabilities of the system. Vendors take primary responsibility for the design and development of technologies, ideally with iterative feedback from users. Users assume responsibility for safe implementation and work with vendors throughout the health IT implementation process. The partnership to develop, implement, and optimize systems is a shared responsibility where vendors and users help each other achieve the safest possible applications of health IT.

It is important to recognize that health IT products generally cannot be installed out of the box. Users often need to ensure that products appropriately match their needs and capabilities— in both functionality and complexity of operation. The process of implementing and supporting software is critical to optimizing value and mitigating patient safety risks. A constant, ongoing commitment to safety—from acquisition to implementation and maintenance—is needed to achieve safer, more effective care. Testing at each of these stages is needed to ensure successful and safe use of health IT.

Ongoing safe use of health IT requires diligent surveillance of evolving needs, gaps, performance issues, and mismatches between user needs and system performance, unsafe conditions, and adverse events. The committee believes certain actions are required by private and public entities to monitor safety in order to protect the public's health and provides the following recommendations to improve health IT safety nationwide—optimizing their use to achieve national health goals, while

reducing the risks of their use resulting in inadvertent harm.

Building on this background, the IOM report on *Health IT and Patient Safety* made a series of recommendations summarized as follows:

Recommendation 1: The Secretary of Health and Human Services (HHS) should publish an action and surveillance plan within 12 months that includes a schedule for working with the private sector to assess the impact of health IT on patient safety and minimizing the risk of its implementation and use.

Recommendation 2: The Secretary of HHS should ensure insofar as possible that health IT vendors support the free exchange of information about health IT experiences and issues and not prohibit sharing of such information, including details (e.g., screenshots) relating to patient safety.

Recommendation 3: The Office of The National Coordinator for Health IT (ONC) should work with the private and public sectors to make comparative user experiences across vendors publicly available.

Recommendation 4: The Secretary of HHS should fund a new Health IT Safety Council to evaluate criteria for assessing and monitoring the safe use of health IT and the use of health IT to enhance safety. This Council should operate within an existing voluntary consensus standards organization.

Recommendation 5: All health IT vendors should be required to publicly register and list their products with ONC, initially beginning with EHRs certified for the meaningful use program.

Recommendation 6: The Secretary of HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.

Recommendation 7: The Secretary of HHS should establish a mechanism for both vendors and users to report health IT–related deaths, serious injuries, or unsafe conditions.

Recommendation 8: The Secretary of HHS should recommend that Congress establish an independent federal entity for investigating patient safety deaths, serious injuries, or potentially unsafe conditions associated with health IT. This entity should also monitor and analyze data and publicly report results of these activities.

Recommendation 9a: The Secretary of HHS should monitor and publicly report on the progress of health IT safety annually beginning in 2012. If progress toward safety and reliability is not sufficient as determined by the Secretary, the Secretary

should direct the FDA to exercise all available authority to regulate EHRs, health information exchanges, and PHRs.

Recommendation 9b: The Secretary should immediately direct the FDA to begin developing the necessary framework for regulation. Such a framework should be in place if and when the Secretary decides the state of health IT safety requires FDA regulation as stipulated in Recommendation 9a above.

Recommendation 10: HHS, in collaboration with other research groups, should support cross-disciplinary research toward the use of health IT as part of a learning health care system. Products of this research should be used to inform the design, testing, and use of health IT. Specific areas of research include
a. User-centered design and human factors applied to health IT;
b. Safe implementation and use of health IT by all users;
c. Sociotechnical systems associated with health IT; and
d. Impact of policy decisions on health IT use in clinical practice.

Thank you and I look forward to answering your questions.

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Mr. PITTS. The chair thanks the gentleman.

Let me ask—start a question. I recognize myself for 5 minutes for this purpose. I will ask each of you this question.

Do you believe that data, Dr. Smith, for the purposes of regulation should be classified as a medical device?

Dr. SMITH. Data, no, sir.

Mr. PITTS. Ms. Bechtel?

Ms. BECHTEL. I have to say this is not my area of expertise.

Mr. PITTS. Mr. Bialick?

Mr. BIALICK. Data, no.

Mr. PITTS. Dr. Mitus?

Dr. MITUS. Data per se, no.

Mr. PITTS. Dr. Classen?

Dr. CLASSEN. Data, no.

Mr. PITTS. Thank you.

Now, Mr. Bialick, do you believe that the newborn patients you are here representing today will be best served by the FDA classifying medical apps as medical devices?

Mr. BIALICK. As the draft guidance is written, no.

Mr. PITTS. Speaking of the FDA draft guidance, many have argued that the FDA is proposing to only regulate apps that are essentially medical devices and does not intend to go any further. And while I may disagree with this presumption, I do think it is very instructive for the purposes of today's hearing. Many years of dealing with the FDA have taught me that it is not what they say they are going to regulate today, but what they could regulate tomorrow.

Are you familiar—I will stay with you, Mr. Bialick—with the term regulatory creep?

Mr. BIALICK. I am.

Mr. PITTS. And what could regulatory creep mean for a combination who seek to innovate in this space and to the patients whose lives may depend upon this innovation for their health and welfare?

Mr. BIALICK. The draft guidance, as it was written, I think refers or relies on terminology like an app that even now is a little bit outdated. The concept of an app is a discreet piece of software on a device. That is really being changed by how the market has embraced cloud technology. The idea that you would have a discreet piece of an app or software that is one little piece, that is different now when an app is also the browser on your smartphone. These technologies are becoming platform agnostic, and so how do we talk about that in reference of, when the draft guidance was written, even the definition of an app has changed during this time, so the idea that we can regulate an app—but these apps are expanding, we need to have clearer lines as to how these things are—where the regulation is going to stop.

Mr. PITTS. OK. Well, let me ask, and each of you can respond. Do you believe the FDA has the expertise to regulate medical app technology, and do you foresee them gaining that expertise in the foreseeable future? Let's just start and go down the line. Dr. Smith?

Dr. SMITH. I think it is, to a point in my testimony, making sure that regulation moves at the speed of innovation. I think it is quite

challenging for the FDA and for many reasons to stay as current as possible on those things which are simply just emerging. And so the simple answer to your question is no. I think the opportunity for external expertise needs to be exploited much more thoroughly than it has been to date.

Mr. PITTS. Mr. Bialick?

Mr. BIALICK. I think that the FDA absolutely has the experience and knowledge in-house to evaluate apps that are actually medical devices. When it talks about just some of these apps that are connecting, sharing information on networks, then no, they don't have the regulatory expertise in-house.

Mr. PITTS. Dr. Mitus?

Dr. MITUS. Concur with my colleagues. Today, the FDA plays a very, very important role in health care. McKesson has many solutions that are regulated by the FDA, whose expertise really is in the regulation of medical devices. Health IT, we believe, it really requires a different paradigm that is not well-suited to the current infrastructure and process under the FDA. It is less about the organization and more around the process.

Mr. PITTS. Dr. Classen?

Dr. CLASSEN. Just citing from the IOM report, the IOM said that if the FDA were to get further involved in the oversight of HIT beyond medical devices, a new framework to do that should be created.

Mr. PITTS. OK. Now Mr. Bialick, can you share any real world examples of patient's lives being changed through the application of new medical technologies?

Mr. BIALICK. Absolutely. I think, from my own experience that I can talk to you with our spread of legislation around congenital heart defect screening, like I said, not everybody is born in a city center so access to some of these remote home monitoring devices is very functional. Not only that, but the telemedicine capacity that we are seeing, especially through some of these devices, is really expanded. Someone said in the hearing yesterday, it is the new house call, and that is absolutely true. We want to keep making sure that these devices are getting to the patients that need them.

Mr. PITTS. My time is expired. Chair recognizes the ranking member for 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to ask some questions of Ms. Bechtel. You testified before this subcommittee in July, 2010, in the early days of the HITECH Act and the Meaningful Use Program, and at that point, the program was just getting off the ground and we heard estimates from CMS that between 21 percent and 53 percent of the eligible providers would adopt EHRs by 2015, and we have come a long way since then. As of February, 2013, 2 years before the 2015 deadline, CMS data shows that more than 70 percent of eligible providers have registered and nearly 40 percent have already successfully completed the first phase of Meaningful Use. The data for hospitals is even more promising. Eighty-five percent of those that are eligible have registered, and more than 70 percent are Meaningful Users today. So Ms. Bechtel, these adoption rates have exceeded expectations, if you would confirm or talk about that, and are we just seeing providers purchase an EHR to check a box or

are we actually seeing real Meaningful Use, and then finally, other than adoption of EHRs, what other signs of progress do you see? I will throw those all into one question.

Ms. BECHTEL. Great. Thank you so much, Congressman.

Yes, I think it is really remarkable that we have made the progress that we have, and it is a testament to the hard work of health care providers and vendors, and the regional extension centers who are helping primary care doctors and critical access hospitals every day to adopt and to implement and really use EHRs in a meaningful way. I think there are some terrific additional signs of progress, like the fact that in 2006 there were almost no e-prescribers, which is really key to eliminating handwriting errors. It creates an enormous amount of efficiency for consumers and their families, and today there are more than a half million. So there is really some amazing work that has been done, and I think number one, it is the key to helping us get to this system we all want through payment reform, and getting there faster, and number two, we have to keep up the pace and we have to keep up the progress. The design of the Meaningful Use Program is such that in the beginning, providers are adopting and they are beginning to implement and use it in some ways like I outlined in my testimony that are very meaningful to patients and families. But as they stay in the program, it is designed to create even more capabilities that benefit patients and families, improve quality, and lower costs, and so future stages will deliver even more societal benefits. I think the key now is just keeping up the pace.

Mr. PALLONE. All right, let me ask you another question about the mobile apps. I am afraid this hearing is really missing the forest for the trees when it comes to the government's role in the growth of mobile apps and health information technology. Far from inhibiting the growth of mobile health applications, the Administration has taken unprecedented steps to open up federal data to app developers and coders, and this public-private collaboration has led to extraordinary growth in the mobile health application space. One example is iTriage, an application created using HHS data that helps consumers locate nearby health care providers. The app has over three million downloads from the iTunes store, far from being slowed down by the Federal Government. If iTriage and scores of other apps have grown and they have grown enormously because of cooperation and openness of the Federal Government. So if you could just tell us about how open government data has contributed to the growth of mobile medical apps, and what that has meant for patients.

Ms. BECHTEL. Yes, I think this is a terrific example of federal leadership that is really driving innovation. Three years ago, HHS launched the Open Health Data Initiative. They created a Web site called healthdata.gov, and if you think about the absolute richness of health data that HHS as an agency has, it is really phenomenal, whether it is FDA or CDC or NIH or even CMS. And so the model for this work was actually NOAA, the National Oceanic and Atmospheric Administration, where once NOAA began to release their weather data publically, we use it in weather forecasts on television, we have it on our smartphones, and so the innovation that occurred is really the model for opening up health data. The Blue

Button functionality that I talked about earlier is a great example. That was one of the first initiatives of the open health data effort, and application developers have taken what is claims data—it is not even the rich clinical data from EHRs yet, but it will be next year. They have taken the claims data and built applications that enable consumers to view their own health information online, but also now, the next step is that they are going to automate it so that I, as a consumer, can decide that I want an automatic feed anytime there is new data, and I can say I would like you to also send it to my primary care doctor. So when we talk about care coordination, which is so essential to consumers, this is a great innovation and they have held more than 20 code-a-thons where application developers and entrepreneurs and different communities have come together to create applications in real time using HHS health data that are really making a difference. U.S. News and World Reports uses it in their health insurance, their best health insurance plans. Health Grade uses it to help consumers pick the best health care providers out there. So there is really no limit to the innovation that I think can occur, because of the collaboration with the Federal Government and entrepreneurial innovators.

Mr. PALLONE. Thank you.

Mr. PITTS. Chair thanks the gentleman and now recognizes the vice chairman, Dr. Burgess, for 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman. Well, it begs the question then, is there going to be an app for the regulatory apps, and I guess that is what we are here to answer today.

Dr. Smith, you brought up an intriguing issue about—when speaking about electronic health records and I guess Meaningful Use and where outcomes, not location actually ought to be considered. I had a physician in the office this morning, a gastroenterologist who said look, I got a problem. I have got an EHR in my office, I use it and it meets all the criteria for Meaningful Use. I go to the ambulatory surgery center. I access the same record online and use it, but because I am in an ambulatory surgery center, it does not count toward Meaningful Use, and in fact, if I spend more than 50.01 percent of my time in the surgery center, which is where I spend my time because I am doing procedures on patients who need them, then suddenly I fall out of the criteria to meet the criteria for Meaningful Use. Is that what you were referring to where you said outcome, not location?

Dr. SMITH. It is in part that. It is also the notion that until we realize that it is all about the outcome and really irrelevant about how we get to that outcome, we will drive rather bizarre behavior, and so when one thinks about telemedicine and the opportunity to——

Mr. BURGESS. He is a gastroenterologist. Bizarre behavior goes with the territory. I am sorry, go ahead.

Dr. SMITH. So I am a cardiologist, and I resemble that remark.

Until we focus entirely on the outcome, we will drive—first incentive will drive instead of taking care of patients at a distance and keeping them on the straight and narrow, we will facilitate the system we have had, which is one of really emergency rescue as opposed to health care.

And so I think with respect to information flow, it has to be seamless. With respect to the burden of chronic disease that we have in this country, the notion that we are best off taking care of folks only when they show up in the emergency room or in the doctor's office is clearly wrong-headed when those patients need the kind of day-to-day iterative care that some of these remote technologies and integrated interoperable systems can provide. And so that is really the point of that comment.

Mr. BURGESS. Now there is a difference between what a lot of us would consider traditional medical advice, and an app. I mean, an intercardiac defibrillator, a traditional medical device, can you sort of delineate the difference there for us?

Dr. SMITH. Oh, absolutely. So, I spent much of my life in either the implementation or even design of implantable defibrillators, and the company I was working for at the time kind of led a charge in making sure that that information that is resonant in those devices could get back to doctors wherever they were when it was most needed, instead of using the patient as a vehicle for bringing that information back to see you in the office. And so there is a huge difference between the one-to-one patient encounter that you can have—and I will point out that you can now have technology mediated encounter versus the information that you can get on the web. I mean, so whether it is an app or whether it is the web, those are really quite different things. And so I think as a physician yourself, you would realize the important differences.

Mr. BURGESS. Well, and the ownership of that data is important as well, and when we talk about an HHS Web site, but that is, at least in theory, the identified data, but you are talking about data that is specific to that patient, specific to that patient encounter.

Dr. SMITH. Absolutely.

Mr. BURGESS. Dr. Mitus, I was fascinated by your testimony. I remember a few years ago in the middle of the chaos of the Haitian earthquake, it was either on CNN or reading a Time magazine article where a doctor who was not an OB doctor was helping take care of a pregnant woman after the earthquake. She had a hypertensive crisis. His reflex action was to reach for an angiotensin converting enzyme inhibitor, but he looked it up on his mobile app and found that that was contraindicated in pregnancy and used something else. I think the story had a happy outcome, but it certainly underscores the power of having that medical information at your fingertips, and you just go into the app store—even as we sat—not that I wasn't paying rapt attention to all of the testimony, but you can download Harrison's Principles of Internal Medicine. You can download the Merck Manual. You can download the Washington Manual, and have that literally at your fingertips in as odd a place as a congressional hearing.

So how does the regulatory environment affect that?

Dr. MITUS. I completely concur that health IT has really revolutionized our ability to provide timely and safe care to patients in ways that that we could never have envisioned even 10 years ago. The power of technology enables us and is very different than a medical device. I believe, though, there is an important distinction, to return to your prior question. A device, in our mind, sits directly connected to a patient and has automation that allows it to inde-

pendently act upon that patient. It is really replacing that human judgment. Whereas a physician who intervenes and accesses medical guidelines, such as a textbook online or receives an alert to potentially prevent a fatal drug interaction is allowed to use their own common sense and judgment, and that is fundamentally different than a device.

Mr. BURGESS. But the FDA looks at it as decision support, so therefore, it is open to regulation. Is that correct?

Dr. MITUS. That is our understanding, and we believe a risk.

Mr. BURGESS. Thank you, Mr. Chairman. I will yield back.

Mr. PITTS. Chair thanks the gentleman and now recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes for questions.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Dr. Mitus, as I understand, you are a hematologist/oncologist. Is that right?

Dr. MITUS. Correct.

Mr. WAXMAN. OK. So let's say you had software that could—claims to diagnose a mole and whether it is melanoma or not. Do you think the FDA ought to regulate that?

Dr. MITUS. That is a very interesting question, and one that I pondered last night after you asked that yesterday. I actually looked up Dr. Mole online to understand, as I was not familiar with that technology. I think that really delineates the challenge that we have before us. What a wonderful piece of technology——

Mr. WAXMAN. Excuse me. I really have a limited time. Do you think it ought to be regulated by the FDA or FDA ought to review it before it is widely used? Yes or no.

Dr. MITUS. I believe that there is risk and there is intelligence in that application, as I understand it, and it is—should be considered a high risk piece of software, and we believe in a risk-based system and it could potentially be regulated by the FDA, much the way mammography software is today.

Mr. WAXMAN. OK. Now you raised a bunch of points in your testimony, and you pose a number of questions. Should an iPad application that helps track the number of steps you walk per day be regulated as a medical device, and FDA says no in their guidance. You asked if it is a reminder time to refill a prescription. FDA's guidance said no, that is not a medical device. You asked a question whether digital versions of a physician's desk reference would be subject to regulation, and FDA says no. Those are not going to be subject to regulation. So I found it puzzling, because FDA addressed them specifically in their draft guidance, a specific list of these examples of what should not be regulated. Is your concern that FDA is going to change its mind and regulate it?

Dr. MITUS. My concern is that there is a spectrum of capabilities that is increasingly delivered through technology, whether on a mobile app or on a desktop, and that gray area as we just described, the ability for a doctor to receive an alert or a warning is not something in my mind that should be regulated as a medical device.

Mr. WAXMAN. Well, I can understand that point of view but you would see the point of view that some things ought to be regulated as a medical device, wouldn't you?

Dr. MITUS. Medical devices certainly should be regulated as medical devices.

Mr. WAXMAN. Well, there is a judgment to be drawn. My colleague said well, that judgment ought to be up to Congress. Do you think Congress should make those distinctions, or should it be the FDA or some government regulatory agency that has some expertise on these kinds of issues? There is a line to be drawn. Who should draw that line?

Dr. MITUS. It is a difficult line to be drawn. I am not—I won't presume to be able to tell you who should draw that line. What we would like to point out——

Mr. WAXMAN. Well, knowing that it is difficult doesn't help. Who should draw the line? There is some that should be regulated as medical devices and some shouldn't. I agreed with your testimony. Those things that are informational based shouldn't be regulated, and FDA agrees with that, but there are some that ought to be diagnosed.

Mr. Bialick, there is a device that remotely monitors infants with congenital heart defects using a pulse oximeter. Pulse oximeters monitor the oxygen saturation of a patient's blood, and especially in the case of newborns with congenital heart defects, they are a critical tool to monitor cardiac health. This is obviously a sensitive and important device. If the device provides the wrong reading or provides faulty information, it can lead to disastrous results. Do you believe that FDA should play a role in ensuring that these types of devices are safe and effective?

Mr. BIALICK. That is why FDA does evaluate pulse oximeters.

Mr. WAXMAN. And you think that is appropriate?

Mr. BIALICK. Pulse oximeters as medical devices, yes. The app that has the potential to connect to a covered device, that is a different story because it is not a traditional medical device. You are talking about medical software at that point. So I would like to talk about drawing the delineation here. That is the delineation I would like to make.

Mr. WAXMAN. Well, the app transmits the information, but the information is based on this pulse oximeter.

Mr. BIALICK. Right, and——

Mr. WAXMAN. And the pulse oximeter ought to be reviewed by the FDA because if it is giving false information, it can have serious consequences, right?

Mr. BIALICK. I agree. Medical devices should be evaluated by the FDA.

Mr. WAXMAN. So say, Dr. Mitus——

Mr. BIALICK. I am sorry.

Mr. WAXMAN. I am switching to Dr. Mitus. If somebody takes a picture of a mole and they say don't worry, you don't have cancer, and they are wrong, that is a serious disaster waiting to happen. We need somebody other than members of Congress to say that ought to be regulated, and the law requires, I think, FDA appropriately to regulate it.

My point to all of you is there is a distinction that has to be made, and the points you raised, Dr. Mitus, were all scary things that just aren't being considered for regulation, and FDA has been very explicit about it. So I am somewhat disappointed that you

would say these things are going to be regulated when FDA says they have no intention of regulating them, and so that is why I asked do you think FDA is going to reverse its stand. Is that what you are worried about?

Mr. PITTS. You may respond.

Mr. WAXMAN. To Dr. Mitus, are you worried the FDA is going to change its mind and suddenly regulate those things?

Dr. MITUS. We are worried that there is a large gray area of medical health IT that could be subject to regulation.

Mr. PITTS. Mr. Bialick, you wanted to say something?

Mr. BIALICK. To your point, Mr. Waxman, you said is this Congress's decision to make this or is this FDA's decision or is this another agency? I would like to say that this is such a big issue and such a dynamic market that no one entity should be making these decisions. There is a clear need for a framework of experts to convene to talk about what is going on at FDA, what is going on at ONC, what is going at FCC, especially as these things consider mobile apps, as well as what Congress's role is in regulating that? So the framework, absolutely Congress has a role. Congress has a role to develop this framework.

Mr. WAXMAN. Well, FDA is required to bring in a group like that and give them guidance, but if you are giving an amorphous group to look at it with nobody having clear responsibility, nothing is going to happen and that is a very dangerous thing if a device can do harm.

My time is expired.

Mr. PITTS. The chair thanks the gentleman and recognizes the gentleman from Illinois, Mr. Shimkus, for 5 minutes.

Mr. SHIMKUS. Thank you, Mr. Chairman. I enjoy following Mr. Waxman, who is obviously very thoughtful. We had part of this debate yesterday in the other hearing, and I think—and I am going to go off script just because Mr. Bialick, on this pulse oximeter—I am not a health care guy but I did read it in your testimony—your point is that that device is a taxed and monitoring. So as I was trying—you are trying to say that data is being formed by the medical device as certified. The transmission of that data to a handheld device is a concern, especially if it gets classified as a Tier III medical device.

Mr. BIALICK. Absolutely.

Mr. SHIMKUS. What happens if it gets classified as a Tier III medical device?

Mr. BIALICK. It would be evaluated as such through the FDA process.

Mr. SHIMKUS. And what else happens to it?

Mr. BIALICK. It gets pulled off the market. It has to go through the entire process. I mean——

Mr. SHIMKUS. And what else happens to it? It gets a big freaking tax on it, a gross tax, not a net tax. So anyway, it is always exciting to be on this committee with my friend from California.

Because we talked about the chips and the shoes, too. Obviously for general fitness, just measuring steps, no, but what if that is a device that has been prescribed?

Mr. BIALICK. Another case.

Mr. SHIMKUS. And my friend, Mr. Pallone, mentioned HHS health and one app. Good for them. How many apps are there? Ninety-seven thousand apps. How are the other 96,999 developed? By the private sector, by individual capital, by people assuming risk. I pulled this up—pull up your page. How many new apps are there to change your app? Notifications, you got to update your app. What happens if this whole process falls into that? So now you have an app, it has had technical problems, maybe it is a Tier II and now you want to update the app. Does that have to go back through the entire process again? These are very, very important—they belittle—the fact that we are having these questions, but the fact that we are having these questions means that we don't have answers.

So what does FDA do when they go to the Institute of Medicine, right, they commission a report, which they did on MDUFA, and they kind of follow that a lot of times. Well, what did the Institute of Medicine just come out on this? Well, one member disagrees with the committee and would immediately regulate health IT as a Class III medical device as outlined in Appendix E. So they are saying all health IT—or this guy, this one respondent says this should be, and there is a fear about that, is there not, because of the things we issued before.

So Mr. Bialick, if FDA regulated health IT as medical devices, would they be subject to the device tax as written in law?

Mr. BIALICK. I default to Congress on that.

Mr. SHIMKUS. I already asked that. The answer is yes. What could this mean for patients, especially for telemedicine and other advancements that are starting to improve the quality and access to care for patients in rural areas, like my district, who are sometimes hours away from the care they need?

Mr. BIALICK. It is a very important question. I think that as telemedicine develops, we are starting to also see a development of our networks of care. So it is not just we go to the one rural doctor that we have access to——

Mr. SHIMKUS. Right.

Mr. BIALICK [continuing]. But rather, we have access to many professionals.

Mr. SHIMKUS. Anybody else want to jump in real quick on this?

Dr. MITUS. I believe it could significantly delay and put at risk the deployment——

Mr. SHIMKUS. Here is what I observed in my district. I have a large rural district. There are 102 counties in the State of Illinois. I represent 33. Where a lot of hospitals are moving to is obviously nurses on site, doctors at computer screens monitoring the real data, and also what they can do is—so the nurse says doc, calls him up, Doc, check this patient X. So they go into the room, the patient is laying there and he will have the nurse open up the eyelid and the camera will zoom in on the eye to make a determination. Now if you follow this debate, now you have got data flowing over in a picture form, i.e., like the mole debate, but it is a camera in essence taking a real time picture. How does that get regulated? And if it, as my colleague from California said, if that should be a Tier III because then do I not have the access to real time picture

of the pupil of a patient, and an immediate doctor intervention, versus calling one from 20 miles away?

My time is expired. I thank you all and I yield back my time.

Mr. PITTS. Chair thanks the gentleman, and now recognizes the gentlelady from Virgin Islands, Dr. Christensen, for 5 minutes for questions.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and thank you to the panelists for being here this morning. I am sorry I missed yesterday's hearing.

But this hearing—this series of hearings is centered on the relationship between innovation and public—and patient safety, and I think the Meaningful Use EHR program is a great example of how government can promote technological innovation that has the potential to significantly improve patient care.

Phase one of the program already enables providers to maintain up-to-date electronic lists of the health conditions, diagnoses, medication, and medication allergies. They can automatically check for drug interactions and drug allergies, as we have heard, and have the ability to send prescriptions electronically to a patient's pharmacy, reducing wait time and eliminating handwriting errors.

Ms. Bechtel, can you give us some information about—some more information about how electronic health records are already helping to improve patient care, and how future phases of Meaningful Use advance our ability to improve that care, and would you add into your answer how it—how HIT—the role it can play in eliminating health disparities?

Ms. BECHTEL. Absolutely. So let me start with health disparities, because I actually think that that is one of the ways that the Meaningful Use Program is making a real difference for patients and families.

In the first stage of Meaningful Use, there were a couple of things that were really important to help disparities. One was collecting better and more granular data about race, ethnicity, language, and gender, because those are categories where we see vulnerable populations and the greatest amount of health disparities, as you know. And so we have now created the ability to collect information like that in a standardized way, and when you do that in a computer system, you can then stratify other information by those data types to identify disparities, and the first step in eliminating them has to be identifying them. We also created a capability for electronic health records to report quality measurement, and which is key to payment later, and so the ability to look at the kind of care that you are providing for different populations that you are serving is really instrumental, and that was not standardized prior to Meaningful Use.

In future stages as well, we are going to see things like a population health dashboard that is going to allow you to look at multiple populations. My hope is that, well into the future we will see things like more advanced intelligence systems that will look for disparities that we didn't even know to look for, for example. So there are some really terrific things.

I think I would say that in terms of what is happening today already right now, the Commonwealth Fund, an independent organization, looked at several different hospitals and they concluded

that health IT adoption has led to faster, more accurate communications, streamlined responses that have improved patient flow. It has reduced duplicative testing and sped up responses to patient inquiries, and that has been really phenomenal.

Yesterday there was a study released by the Quest Collaborative, which Premiere reads, and it is really an indication of what can happen when you blend not just the health IT infrastructure that the Quest hospitals have, but the quality measurement and the public reporting and the payment and all of these things that have bipartisan support, they saved 92,000 lives and $9.1 billion over 4½ years.

Mrs. CHRISTENSEN. Let me try to get another question in. You sat on the Federal HIT Policy Committee and you reported that 70 percent, I think, of physicians are utilizing HIT, but have you seen the adoption in minority practices, practices in rural and poor communities, and if so, if not, is that a concern and is the committee doing anything to address that?

Ms. BECHTEL. Yes, and I think that is also a great question for federal officials tomorrow as well. But yes, we are. So 40 percent of rural primary care providers are working with regional extension centers and are therefore more likely to achieve Meaningful Use, so that is really good news. In terms of providers serving vulnerable populations, many of them will receive payments under the Medicaid program, and every State has, in fact, designed and has begun to implement their programs, and that is really the first step to make sure.

So I think there is very good news, but it is something we must continue to monitor.

Mrs. CHRISTENSEN. OK, thank you. I guess I will yield back the balance of my time. I don't——

Mr. PITTS. Chair thanks the gentlelady and now recognizes the gentleman from Texas, Mr. Hall, 5 minutes for questions.

Mr. HALL. Mr. Chairman, I would like to use part of my time thanking you for bringing this up. It is something I am very, very interested in. I would ask Mr. Bialick, I guess—I hope I pronounced it right. I don't believe anyone has got around to the newborns. If they have, I will wait and write—and ask for written testimony.

But if not, Mr. Bialick, a lot of us remember the sleepless nights and exhausting routines that go along with a newborn at home, and if we are blessed with a child without medical problems, we have sleepless nights also but not like others. Can you share with the committee the additional challenges and/or stresses of medical problems and how technology can be utilized to make their lives better, or—let me shorten it. How do you envision mobile medical technology devices being used to improve care for newborns, and if these technologies are subject to a lengthy bureaucratic approval process, how will that impact patients and families? Because if they apply or register when their newborns are newly born, they won't be newborns when they get around to them.

Mr. BIALICK. Sure. Thank you for that question. Babies with congenital heart defects are super users of the health care system. They are not only going to be using imaging services very early, they are going to need, in critical cases, either immediate interven-

tion, maybe surgically, and then follow-up care with additional imaging throughout their lives.

Now, it happens to be that, like I said, not all babies are born in advance cardiac care centers. They are not all born in coordinated care environments. Half of births in many States are Medicaid births as well, so care can often be fragmented. Right now, the way the health care system has developed, really to stay at the center of your care, you have to be the one that is coordinating it yourself, and mobile apps have allowed us to do that. We are able to hold in our hand the electronic record now, because of something like the Meaningful Use Program of Medicaid providers and maybe several different hospitals, several different specialists. And that not only is comforting to know that you have access to this information, but it is also very valuable because sometimes when you go back into a care situation, it is for a very critical reason, and having this information will help you and your provider and your care team get to answers much faster.

Mr. HALL. I thank you for that. I was a father to three boys, three sons, and I was amazed because they were so intelligent. They could count. If they didn't count four eyes, they wouldn't go back to sleep.

Thank you. I yield back my time.

Mr. PITTS. Chair thanks the gentleman, and now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman. I appreciate that very much.

I have gotten a sense from some of the questions that somehow this is a partisan thing, and I don't think it is, and so I am taking a step back. I am not sure really where that is coming from, but I think it is very interesting as a lawyer and I am learning all this medical stuff, and I thank you all for educating me. But it seems to me that the real question is, and what everybody seems to have agreed on is that we as Congress need to make sure there is a framework that then you can put the complicated does this fit, does that not fit, into that framework. Am I correct in that, Dr. Mitus?

Dr. MITUS. Absolutely.

Mr. GRIFFITH. Dr. Smith?

Dr. SMITH. I might add, if you would let me. I think that we if we whisk overprescribing this framework, and I think at some point there is a role for not drawing the sharpest of line, but to give latitude to the bedside where the patient and physician can decide whether technology is appropriate in use, as opposed to trying to draw one line for the broad population.

Mr. GRIFFITH. And I think we all want to see this technology being used. It is great stuff and whatever we can do to encourage folks to use it, but I do think there is a difference if—in the case of a picture of a mole, if the mobile app is actually running it through a computer and telling you it is cancerous or not cancerous, then yes, I want the FDA looking at that. If the mobile app is getting that to an expert doctor to take a look at it, I don't see that as being a medical device, and if there is a problem with the diagnosis—and I would think that Mr. Waxman would appreciate this—there are a slew of trial lawyers who would be more than

happy to help you figure out what you need to do next if there is a misdiagnosis. So I think we go from there.

I am concerned that the FDA sometimes tends to be slow, and if we have got something that doesn't fit the norm, obviously if it is something serious like the app is making the decision on whether or not that mole is cancerous, yes, then I want that top thing and I kind of like the framework that you pointed out, Dr. Mitus. If we don't have that kind of a framework and they decide to review everything, wouldn't you all—and I guess I will ask Dr. Mitus and Dr. Smith this question, and Mr. Bialick and others can chime in if they wish. But isn't there a real concern that the slowness of the FDA, particularly if you are looking at something that just transmits the data, can actually slow down innovation in this area where we really want the innovation to go forward? Dr. Smith?

Dr. SMITH. So you know, as a practicing cardiologist, I would often get records to make decisions based on transmission through a fax machine, and at that time, it was difficult to tell the difference between a three, a five, and an eight. And so one could make wildly different decisions based on that communication transfer, which no one regulates. Now that we make it so crisp and so clear and so error-free, now I don't believe is necessarily the time to regulate that particular flow of information. I think the market has served the need in this case, and so if it is really just about transmission of information, it is difficult to see even though that information may be clinically relevant, that that is necessarily something that requires FDA oversight.

Mr. GRIFFITH. It is funny how sometimes people can interpret old rules with new technology and get it wrong or get a different answer. In my law practice, if I had a book, I got taxed on it. If it was a disc, it didn't get taxed. If I could subscribe to an online site, it didn't get taxed. But if it was a book, by golly, I had to pay tax on that book.

Let me ask this about the smaller creative entrepreneurs, Mr. Bialick.

Mr. BIALICK. Bialick.

Mr. GRIFFITH. Bialick, thank you. In your opinion, if the FDA is successful in classifying all these medical apps, those particularly that I know we are talking about data are essential data's medical devices, do you think that might discourage some of the app makers to go into something that is easier to get their capital back out, or a quicker return on their investment?

Mr. BIALICK. Absolutely. The threshold for a blockbuster app is gigantic now. I mean, it is millions of dollars, and so even to get the investment now to—let's say you are going to develop it beyond just in your garage and have a large scale launch. The concern that you will have the potential for or if it is known that you will have additional regulation on top of that cuts out the bottom line, so there is an investment side to it, too.

Mr. GRIFFITH. So they are more likely to try to find the next Angry Bird as opposed to finding the next Angry Mole?

Mr. BIALICK. Well said.

Mr. GRIFFITH. And last—and I only have a couple of seconds left. I am just going to make a statement. I think a lot of us on this committee feel that the FDA is not only risk averse, but they are

at the point of no risk. We don't want to approve something if there is any risk, and obviously every human being is a little bit different and whatever you do, there is going to be at least some risk. And so I would just encourage the FDA to work with you all and hopefully we will pass that framework that you want and get it done.

Thank you, sir, and I yield back.

Mr. PITTS. Chair thanks the gentleman, and now recognizes the gentleman from Texas, Mr. Green, for 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman. I would like to thank our witnesses for appearing today.

As mobile technology has gotten more sophisticated, applications relating to health have become more complex, but also hold more potential. The possibilities of innovation are tremendous, but there is potential risk to health safety as well. Mobile applications such as glucose monitors are being sold as a way to monitor critical health issues, or other applications having direct effect on health should be regulated in a way that ensures their effectiveness and trustworthiness.

Regulation through the FDA comes with challenges. The agency is oftentimes far too slow. Obtaining approval can be costly. I worry about stifling innovation and bringing in unnecessary levels of regulation onto clever people with limited startup capital, but unlimited potential. However, even big companies have made high profit mistakes developing mobile apps. Had the recent mishap with a mapping software been a glucose monitor, there could have been serious consequences. But we must protect patient and consumer safety at all costs, but properly determining what poses as a safety risk may prove difficult.

Dr. Mitus, the Bipartisan Center framework focuses on clinical and nonclinical software. It also recognizes the role for FDA oversight for medical device software. Do you agree with that approach and that FDA does have a role for the oversight of riskier MMAs?

Dr. MITUS. Yes, absolutely.

Mr. GREEN. OK. In what ways can the FDA regulate mobile medical applications as mobile devices without slowing innovation?

Dr. MITUS. We believe that if a device, again, is defined as something that directly touches a patient or independently acts on a patient, that is a medical device and the software that runs that device would be considered a medical device, and subject to the current regulatory process. I think it is very important to distinguish that from the vast bulk of health IT, which is really not best categorized as a medical device.

Mr. GREEN. OK. Dr. Classen, a lot has been discussed about risk-based framework for regulation. As I read it, there are a lot of similarities between FDA's and the Bipartisan Policy Center's approaches. In what ways do the BPC recommendations differ from the draft guidance issued by the FDA?

Dr. CLASSEN. The guidance that we focused on in our report at the Institute of Medicine, a lot of the FDA guidance excluded what we were focused on there from their oversight on mobile medical apps, and we had recommended that a new framework be created for oversight of these areas. So we would agree with BPC Center approach and framework as a next step, creating more specificity around a future framework as we have outlined.

Mr. GREEN. I do have concerns about the capacity of the FDA to properly and efficiently regulate mobile apps. This is a topic that deserves more scrutiny by Congress and the FDA. We must find a way to ensure that the safety and effectiveness of the applications regulate only the application that posed a risk, and do so in a way that is efficient and effective.

Mr. Chairman, members of Congress always doesn't do things that are efficient and effective, but in this case, because it affects the health care and how we can deliver and monitor health care in the future, it is so important not only for our subcommittee, but the full committee and Congress.

Thank you, Mr. Chairman. I yield back my time.

Mr. PITTS. Chair thanks the gentleman and now recognizes the gentleman from New Jersey, Mr. Lance, for 5 minutes for questions.

Mr. LANCE. Thank you, Mr. Chairman, and good morning to you all.

I have heard from at least one app developer in my district who has been attempting to work with the FDA to approve the medical app. This involves a smartphone and corresponding app that helps patients with diabetes monitor the diabetes and so they can track their glucose levels. It is my understanding that while the procedure is currently under review at the FDA, the approval process is slow moving and there are some levels of uncertainty as to how the agency can address or regulate the technology. Your testimony this morning has involved this type of discussion. Do you believe that the experience of companies such as the one with whom I have been speaking in my district are common experiences that companies have, and should we be concerned about the FDA as it goes forward to regulate mobile apps as medical devices? To whoever wishes to respond to the question.

Dr. SMITH. So I do believe it is about clarity and speed, and I think we are in part here today because it was in the middle of 2011 when draft guidance was issued in this space, and we still don't have the clarity and certainty of even that guidance, which by itself, still has elements in it which maintains some vaguery. And so, I believe we are suffering the confusion of successive clarification, as opposed to enjoying the speed of appropriate regulatory efforts. And so I think it is both slow for the folks who are engaged, but perhaps even slower for those who are hesitating to engage and are finding other things to do with their time, treasure, and talent. And so I think it is fundamentally about clarity and speed, and at times, even willing to accept the imperfect now as opposed to waiting interminably for some other perfected notion of regulation.

Mr. LANCE. Of course.

Mr. BIALICK. I would like also just to say, I won't comment on the frequency with which that is a common occurrence, but I would like to say that that viewpoint and the experience of a developer like that is critical to this process. We talk about large apps, we talked about the apps that are being developed in a garage or a basement or an attic. We want to also make sure that those that are going to be engaging in this process and those that have made this market so dynamic, their viewpoint and their experience is brought into the process as well.

Mr. LANCE. It is clear to me that this would be helpful to those who have the condition of diabetes, and this is a well-respected group and wants to move forward in a medically responsible way. What would you suggest that we as the legislative branch do to help the FDA move through this situation to benefit the American people, particularly as it relates to such health concerns as diabetes?

Dr. MITUS. We would like to reiterate what you have just articulated so well. There is a risk, barriers to entry and to this important space, the delay of important advances into health care, and really we support a risk-based approach where we continue to manage devices as they are today, and then develop other mechanisms for the important oversight of health IT that is not a device.

Mr. LANCE. Yes, Dr. Smith?

Dr. SMITH. I would like to draw attention to the impact that the delay between draft guidance and formal, permanent guidance provides. So it goes well beyond the current issue. The next draft guidance offered, if there is a doubt that that will become final, you will have no movement based on the draft. No companies will engage based on those recommendations, for fear that that process will be again derailed. And so imperfect as it may be, I think there is a value proposition that says fulfill that draft promise, or else we risk the notion that the regulatory cloud becomes even larger. And so I think there is a calculus to be performed here, but one that has implications well beyond the current discussion.

Mr. LANCE. Thank you. Let me say, I do not view this as a partisan issue, and I want to work in a bipartisan capacity with colleagues on the other side of the aisle, as well as with those on this side of the aisle which I am involved, because we want to do this in a responsible way, making sure that the American people can have access to these marvelous new portions of improving the health of the Nation.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. PITTS. Chair thanks the gentleman and now recognizes the gentleman from Maryland, Mr. Sarbanes, for 5 minutes for questions.

Mr. SARBANES. Thank you, Mr. Chairman. This is a fascinating hearing.

When we were doing the health care reform effort here, which resulted in the Affordable Care Act, one of the things that I was most excited about was this turn in the direction of prevention with our health care system and trying to come up with a system that is a health care system, rather than a sick care system, which in many ways is what we had until now. But the promise of it is that patients can become full partners in their care, and at a time when we worry about whether there is going to be enough caregivers to provide the services out there, if you begin to identify the patient themselves as a potential caregiver, you get a little less anxious. Now, you have to approach that in a sensible way, but if we are focused on so the acute care side of things, I can't help my surgeon perform surgery on me, but I can certainly help my primary care physician make me more sensible about prevention. So I really become a partner in that, and this technology holds that real promise.

There was—Dr. Francis Collins, who is the director of NIH, recently highlighted the results of a mobile health clinical trial in his personal blog, and this was a trial conducted over a year by University of Maryland School of Medicine, which utilized a diabetes mobile health technology of a company that I am very familiar with called WellDoc, which is based in Baltimore. And they showed that these patients were able to demonstrate a reduction in terms of the percentage result on their blood sugar test that they would take on a regular basis, and the same system was studied in a demonstration project of Medicaid patients, where patients used this diabetes self-management system, with the result of reducing the number of diabetes-related hospital admissions and emergency room visits among that population that was using it by approximately 57 percent, which is really incredible. And a lot of times people do end up in the hospital because they have missed some basic precaution they need to be taking in their own self-management, so it just shows how important these opportunities to use technology are in terms of self-management by patients, and you have all spoken to that.

My question, and I offer it to anyone here on the panel, is as we continue this effort to reduce our health care costs, and there is real potential using this technology to do that, can you point to instances where federal programs are beginning to adopt these validated technologies across the spectrum of government health care? And you can—if you want to point to Medicaid and Medicare, please do, to the Federal Employees' Health Benefits Program, TRICARE, Veterans' Affairs, what have you, because obviously we are very interested in that, given the cost and scope of those programs.

Ms. BECHTEL. So I will start, and I say that I think it is a terrific question, and my testimony really focused on the Meaningful Use Program in Medicare and Medicaid, because of the work that it is doing to make patients full partners in their health. Giving patients access to electronic tools is really making them members of the care team now. We are moving from a point where we used to do things to patients and for patients to now doing things with patients, and that is essential to lowering costs and making care better for them. And the online tools are really facilitating important things like shared decision making, population health outreach so that we can get reminders about being overdue for a mammography screening or immunization or—whether it is pneumonia or flu shot or something like that. And it is also facilitating the provision of education resources for patients that are very specific to their needs. So we are moving to a health care system that is much more customized and personalized and engaging for patients and families, and so that is why I think that it is essential as we move forward in the Meaningful Use Program to really keep up the pace. In the next phase, we are going to give patients online access that they can download their health information and transmit it to other care providers who need it. We are going to give them the ability to securely send an e-mail to their doctor. I mean, there are some really important advancements that are coming down the pike if we just keep our foot on the gas pedal.

Mr. SARBANES. Mr. Chairman, would you indulge one more response from Dr. Smith?

Mr. PITTS. Go ahead.

Dr. SMITH. So I point to the VA here. Adam Darkins runs the VA telehealth program. In 2012, I think there were 1.5 million telehealth visits. The net impact of that at 150 VA medical centers is to drop emergency room visits by 40 percent, hospital admissions by 63 percent. Patients experienced a 60 percent reduction in hospital days. Nursing home admissions dropped by 63 percent, and patients reported a 95 percent satisfaction rate with their care. And that is the largest functioning telehealth program that we have in the country, and it is run by the Veterans' Administration. I think it is one of the best kept secrets of excellence inside the Veterans' Administration, and it speak to the potent opportunity that this has when we align the incentives system so that this technology is fully realized.

Mr. SARBANES. Thank you. Those are powerful statistics. I yield back.

Mr. PITTS. Chair thanks the gentleman and now recognizes the gentlelady from North Carolina, Mrs. Ellmers, for 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman, and thank you to all of our panelists today for this very important subcommittee hearing.

First I would like to just say that across the board, health IT is so important. We have got to do everything we can to make it move forward quickly for our patients. As you all have pointed out, the very helpful information that we are gaining from it and how this truly will improve upon health care in this country, with all the hurdles that it has faced. However, having said that, I think it is incumbent upon myself to point out that it isn't quite the nirvana that has been discussed here. For instance, when we are talking about the Meaningful Use, as Ms. Bechtel, you had cited some of the statistics, the number of physicians, the number of hospitals, however, we do have to remember that this is a mandate that was put forward and physicians are participating in it because if they do not, they will receive a Medicare reimbursement cut. So it is not only very beneficial and very important; however, it is very costly and at a time in this economy when you see what we are faced with, physicians being small business owners themselves, hospitals having difficulty functioning, physicians—tens of thousands of dollars that they are having to incur to put this into place, hospitals, millions of dollars. It is a challenge. And again, the importance being duly noted, however, very difficult for many physicians to be incurring this cost.

With that, I do have a question. Ms. Bechtel, you had mentioned that this situation—that we are moving forward and it is very important, and that there are many of these physicians, but you do acknowledge the fact that it is a mandate?

Ms. BECHTEL. Absolutely, and I think it points to the problem that we have in the larger system, which is a complete lack of payment, that really drives quality and the development——

Mrs. ELLMERS. Absolutely.

Ms. BECHTEL [continuing]. Of functionality, as you well know, and I know you are a big supporter of health IT, when we have fee-for-service, of course we are going to see the proliferation of billing systems, and we have no problems in interoperability or adoption rates of billing systems that are designed to really focus on services.

Mrs. ELLMERS. And two, this is my next question. We had also discussed the fact—and I think you had mentioned that at some point in the future, patients will be able to download their own information. Now, there again, I see a big problem and this feeds into the reason that we are having this subcommittee hearing, which is the future, where are we going to go, how is FDA regulation going to affect these things, how is medical device tax going to keep technology from innovating and moving forward?

One of the issues that I continuously hear about is the fact that communication or software is different, the different systems that physicians, hospitals, and others use, so there really is a communication problem right now. What timeline do you—number one, do you acknowledge that, and two, what timeline do you see that happening for patients to be able to download information on their own so that they can be partners in this?

Ms. BECHTEL. So you can do this if you are a veteran through the VA right now, or through the Medicare program. The ability to do it through the Meaningful Use Program, which will be from the EHRs, is going to start in October of this year for hospitals, and in January for physicians.

Mrs. ELLMERS. But do you—have you also heard that there is a communication problem between different facilities, physician offices and hospitals, different health care——

Ms. BECHTEL. Yes. It is one of the most common complaints we hear from consumers is the lack of coordination and the lack of communication. They say over and over again, I just want my doctors to talk to each other. The problem is they are not paid to talk to each other, so Meaningful Use has done a couple of things. One is there is an open standard now called the Direct Protocol, which is essentially like secured g-mail. Physicians and soon patients can actually use it right now to talk to each other, so you can have a hospital send a care summary to a primary care clinician——

Mrs. ELLMERS. OK. Can I just—I need—I only have 30 seconds left here, and I do have a question for Dr. Mitus. Now, you had mentioned that doctors are not paid to talk to each other. How do you describe that?

Ms. BECHTEL. Because they are not paid for care coordination, they are paid on volume for services and procedures. So my doctor doesn't get reimbursed for picking up the phone and calling my cardiologist and coordinating——

Mrs. ELLMERS. So you are basing that on payment?

Ms. BECHTEL. Under fee-for-service.

Mrs. ELLMERS. OK, fee-for-service, oK.

Dr. Mitus, and again, I apologize because this is such an important issue for me. The Commonwealth Alliance that you put together, what do you see Meaningful Use not doing that you feel is an issue that needs to be addressed? In other words, where are your areas of concern and the Commonwealth Alliance's concern?

Dr. MITUS. May I take a few moments to answer?

Mr. PITTS. You may proceed.

Mrs. ELLMERS. Thank you.

Dr. MITUS. Thank you for raising an issue that we are very proud of, that we announced with an intention to launch, led by McKesson, Athena Health, Allscripts, Cerna, and Greenway. We are really trying to create to solve the very difficult problem of disparate health systems and the ability to communicate across those health systems. It is one thing to gather data from an electronic medical record within an individual physician's office, but that ability to aggregate information from all the sites of care is a tremendous problem. We are attempting to solve that and create interoperability and seamless communication by setting standards and creating an infrastructure to support those important processes.

Mrs. ELLMERS. Is there a government HHS or any other agency that is hampering this availability that you are aware of?

Dr. MITUS. Not that I am aware of.

Mrs. ELLMERS. OK. Thank you so much, and again, thank you, Mr. Chairman, for indulging me for a few moments.

Mr. PITTS. Chair thanks the gentlelady and now recognizes the gentleman from Georgia, Dr. Gingrey, for 5 minutes for questions.

Mr. GINGREY. Mr. Chairman, thank you very much.

This is really for all of the panelists. Some have suggested that the mobile apps may be a game changer for health care delivery and consumer engagement. Do you agree with that statement, or do you believe they have already changed? Why don't we start at the end and——

Dr. SMITH. It would be sad if where we are is where we are going, and so I have to believe that we are looking at the front end—on the cusp of a transformation in health care where engaged consumers work with a coordinated and integrated health care system, and so we can realize the important benefits of having ambient health care as opposed to having the model of health care delivery that we have been living with since my grandparents.

Mr. GINGREY. Sure, thank you.

Mr. BIALICK. I 100 percent agree with that, absolutely agree with that.

Dr. MITUS. I support the comments of my colleagues.

Dr. CLASSEN. And I would agree.

Mr. GINGREY. All right. Excuse me, I didn't realize my phone was alive. I apologize for that, panelists.

Dr. Smith, who makes mobile apps? It is sophisticated, big developers or are we talking about the little developer working out of the garage, the entrepreneur types, or is it both engaged in this activity?

Dr. SMITH. So over the last 3 years, I have probably met with 1,000 companies that are interested in this space, all small, all largely unaware or incompletely aware of the regulatory framework that they are kind of naively entering, and find a bit of frustration as they realize that there is this other burden that they are not yet aware of. It is not enough to solve the problem; one must then engage a system with its own set of rules. And so it is often a fresh graduate out of graduate school, or even an undergrad who identi-

fied a problem in his family, the health care that they see, and are trying to figure out a way to solve it.

Mr. GINGREY. The next question is for Mr. Bialick. Today, there are roughly 97,000—I can't believe that, but this is a statistic that I have. Today, there are roughly 97,000 medical apps in the Apple app store, 97,000. These apps have generated more than three million free downloads. If the FDA regulates medical apps as medical devices and these products have to go through regulatory review at the agency and then they become subject to the 2.3 percent medical device tax, how likely do you believe it is that these apps will remain free to the public?

Mr. BIALICK. I would just say that any additional costs added to the development process is going to change the marketing approach for them. This is a very capitalist market that we have created in health care apps. I would say that if you are going to increase the startup cost, if you are going to recoup that cost within a reasonable amount of time, you are likely going to have to change how money is coming in, and so that is either going to be to stop offering them for free, or require that end users pay for additional functionality within the app itself.

Mr. GINGREY. Well sure, exactly, and I will stay with you, Mr. Bialick. The death toll for chronic conditions is a staggering number. More than 10,000 people die every day because of chronic conditions. Not only is the human toll large, but of course, the economics behind it are driving up health care costs, they are harming our household and national finances, and as these costs for health care go up, more money is diverted from other programs. It is diverted from job creation, indeed, from consumers' pockets. How can health information technologies such as medical apps or electronic health records, if not classified by the FDA as medical devices, how can they address these problems and how do we accelerate their use?

Mr. BIALICK. So to address the—let's look at a really high cost problem specifically to get to your question, which would be something like dually eligible beneficiaries between Medicare and Medicaid programs. Even if you target a specific issue like using these mobile apps to provide very high touch care, so we are not talking about managed care, but rather, we are talking about a direct way for the patient to be reminded for something, like imagine, taking their medication, some of these issues that could avoid the number of costly returns to the hospital. That is a very direct and tangible way that people can interact with their health care. That is what should be accelerated.

Mr. GINGREY. Well, and that is the point I wanted to make to the witnesses and to my colleagues on the subcommittee. These devices, these medical apps, they don't draw blood. They don't take a biopsy. They are not invasive. They are just giving information to people in a timely fashion, and if permitted, to members of their family so that they know what is going on with mom or dad who 5,000 miles away and maybe very elderly, or maybe even in a nursing home. I mean, this is a hugely important subject and I commend the chairman for assembling this panel of witnesses and discussing this subject.

So Mr. Chairman, I thank you for letting me go over a little bit, but I appreciate it and I yield back.

Mr. PITTS. Chair thanks the gentleman, and now recognizes the gentleman from Florida, Mr. Bilirakis, for 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it very much. Thank you to the panel for their testimony. I was over in VA. I apologize, but that is very important as well.

I want to—question to Mr. Smith. You mentioned in your testimony the potential cost savings benefits of telehealth. Do you believe it is feasible to expand the use of telehealth to Medicare to effectively lower its costs?

Dr. SMITH. It is a simple word, absolutely. I could go on, but we have seen the impact of telehealth and telemedicine—New England, the Health Care Institute, the VA program, there is a rich history of information, some of which I provided in my written testimony, about the beneficial impacts not only on outcome but also on costs. And so it seems obvious that we can extend that to patients struggling with chronic disease, independent of how their health care bills are paid.

Mr. BILIRAKIS. Very good, thank you.

Follow up again to Mr. Smith. With doctors showing an increase of reluctance to accept new Medicare patients, for obvious reasons, do you believe that allowing doctors to use telehealth will enable them to expand their reach in not only treating existing patients, but also increase access by enabling them to treat new beneficiaries? If you could elaborate a little bit.

Dr. SMITH. Sure. I think the technology obviously enables that notion of care at a distance in ways that are much more efficient than, say, in addition to the costs associated with travel, say, many of the costs associated with—in unnecessary or untimely ER visits or doctor's office visits. But I think it is not enough to have the technology enabled, we also have to have payment mechanisms that provide appropriate incentives for use. And so I was talking to a colleague who is a dermatologist and I asked about this—the world of teledermatology. And he says, it is never going to take off because I don't get paid for it. I think that is an unfortunate, but rational, statement.

Mr. BILIRAKIS. Very good. Anyone else on the panel wish to comment?

Mr. BIALICK. I would like to just specifically on that point about taking on more Medicare providers. I think that when we talk about telemedicine, we think about it in a traditionally rural setting, so it is the idea of someone that lives in the country that doesn't have access to advanced care facility that is using telemedicine to connect to that. But especially from what we have learned from the VA around telestroke interventions as well as a number of other occupational therapy style interventions that you are able to do via telemedicine, this is absolutely something that can be leveraged to not only increase—improve outcomes, but save money in the urban setting as well.

So we shouldn't be thinking about this as a purely rural situation, but this is also something that can be done in an urban situation as well, and still much like we are talking about with the idea of regulation of apps, there are major regulatory barriers in place that are limiting the amount that Medicare providers are able to do that.

Mr. BILIRAKIS. Thank you. Anyone else?

Thank you very much. I yield back, Mr. Chairman. I appreciate it.

Mr. PITTS. Chair thanks the gentleman. That concludes the questioning.

At this time, I would like unanimous consent to place two documents into the record. The first is a letter from Kevin McCarthy, the second is a statement from the Bipartisan Policy Center. I think you have seen these. So without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. This has been a very interesting hearing, very important issue, very informative. We would like to thank all the witnesses for taking time and presenting testimony and answering all the questions. Members may have follow-up questions. I will remind members they have 10 business days to submit questions for the record, and I ask the witnesses to respond to the questions promptly.

With that—and members should submit their questions by the close of business on Wednesday, April 3. With that, thank you very much. Without objection, the subcommittee is adjourned.

[Whereupon, at 12:00 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. PHIL GINGREY

Mr. Chairman, Thank you for calling this hearing today, and I commend the committee looking at the benefits that health information technologies can provide to the practice of medicine. The possibility that these emerging technologies may encourage higher patient engagement and ultimately better health outcome is impossible to ignore.

An impediment to innovation continues to be the uncertainty regarding the regulation of these technologies. We must seek a balance between patient safety and innovation. An overly restrictive regulatory process will stifle innovation and ultimately lead to erosion in the quality of care that a patient may receive. We need to work together to develop a framework that minimizes risk to a patient, but limits the regulatory hurdles so that future innovation will continue to change health care delivery and a patient's access to their health information.

Mr. Chairman, I look forward to working with the Committee to develop this framework. I still believe in the amazing potential that health information technologies will have on the practice of medicine, and I will continue to work to allow the market to develop breakthroughs to the benefit of patients.

Thank you and I yield back.

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March 20, 2013

Dear Chairman Upton and Chairman Pitts,

I would like to thank you for holding this week's series of hearings on Health Information Technology (IT) and mobile medical applications. As the hub for this industry, with the largest number of digital health investment deals in 2012, it is a topic of utmost economic importance to California. More important is the promise it holds of improving the health of all Americans.

Mobile electronic devices have already revolutionized the way we receive our news and communicate with one another. Industries such as banking and retail services have been transformed, with billions of secure transactions occurring seamlessly in cyberspace each day. Our global leadership in wireless devices and networks is unrivaled, and it is essential to put America's innovation engine to work for patients. This is critical to reining in the runaway costs of medicine by creating a modern, efficient, personalized, and patient-centered healthcare system.

My state stands ready with the bright minds and great ideas necessary to empower and inform patients using the devices they carry in their pocket. My district covers a vast and often remote landscape. The ability of patients to use their wireless device to consult their physician or update them on their latest blood pressure readings would be transformative. It would eliminate the costly and sometimes life-threatening barriers of time and distance that separate patients and healthcare in the Central Valley.

In 2012, there was $1.4 billion invested into the digital health sector, a 46 percent increase over 2011.[i] The market for mHealth app services is now in the commercialization phase and is expected to reach $26 billion globally by 2017.[ii] The growth potential for this industry is impressive; unfortunately, there is increasing concern from both innovators and those who invest in them, that it will be hindered by undue Food and Drug Administration (FDA) involvement.

I commend the Energy and Commerce Committee for holding hearings on this important subject. Given the significance of these technologies to patients, we must take the appropriate steps to support medical innovation and ensure that the regulatory burdens of the FDA and medical device tax of Obamacare do not hinder their promise.

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I look forward to continuing to work with you on protecting and cultivating innovation. This priority is of utmost importance to the economic and physical well-being of my constituents and all Americans.

Sincerely,

Kevin McCarthy
House Majority Whip

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[i] Rock Health, *2012 Digital Health Funding Report,* January 3, 2013, available at http://www.slideshare.net/RockHealth/2012-year-end-funding-report.

[ii] Jahns, Ralf-Gordon, *The market for mHealth app services will reach $26 billion by 2017,* Research2Guidance, March 3, 2013, available at http://www.research2guidance.com/the-market-for-mhealth-app-services-will-reach-26-billion-by-2017/.

BIPARTISAN POLICY CENTER

Written Statement of
The Bipartisan Policy Center

For the Energy and Commerce Subcommittee on Health
U.S. House of Representatives

March 20, 2013

The Bipartisan Policy Center (BPC) commends the Energy and Commerce Subcommittee on Health's exploration of the unique role that health information technologies have played in advancing the health and well-being of patients nationwide, as well as the public dialogue which it has initiated on the regulatory framework that should be applied to such technologies.

Today, health care costs constitute 18 percent of our nation's gross domestic product and the quality of care remains uneven. Rapidly emerging delivery system and payment models designed to improve quality, reduce costs, and improve the patient's experience of care require a strong information technology (IT) foundation to be successful. Several studies have shown that health IT, if effectively designed and implemented, has a positive impact on patient safety, the efficiency and effectiveness of care, and patient and provider satisfaction.[1]

Building upon numerous legislative proposals with bipartisan support over the last decade, the Health Information Technology and Economic and Clinical Health (HITECH) Act of 2009 brought about new authorities, standards, and investments in health IT. As a result of federal, state, and private-sector action, the number of clinicians, hospitals, and other providers across the United States who have adopted health IT to improve the quality, safety, and efficiency of care has significantly increased.

The widespread adoption of health IT largely stems from recognition of the important role that it plays in improving health care quality and safety. Policies are now being developed by the Department of Health and Human Services (HHS) to use health IT to make health care safer and continuously improve the safety of health IT.

Through a five-month, collaborative effort drawing upon the expertise and experiences of more than 100 leaders representing clinicians, consumers, health plans, hospitals, patient safety organizations, academic and research institutions, and software and technology companies, as well as experts in patient safety and health IT, BPC developed a set of principles and recommendations for assuring patient safety in health IT. The BPC report containing these principles and recommendations, An Oversight Framework for Assuring Patient Safety in Health Information Technology, was released to the public on February 13, 2013.

Through this process, BPC identified several factors associated with health IT that led to the development of a set of principles that should be applied to any oversight framework.

1. **Any framework for safety should recognize and support the important role that health IT plays in improving the quality, safety, and cost-effectiveness of care, as well as the patient's experience of care.**

   Research shows that health IT has a positive impact on the quality, safety, and cost-effectiveness of health care.[2] While the widespread adoption of health IT largely stems from recognition of the important role that it plays in improving health care quality and safety, there are also instances in which it can create harm if not effectively developed, implemented, or used.

   Because of the significant role that health IT plays in improving the quality, safety, and cost-effectiveness of care, as well as the patient's experience of care, any framework for safety should both recognize and support innovation in and adoption of health IT.

2. **Assuring patient safety, along with enabling positive patient outcomes, is a shared responsibility that must involve the entire health care system.**

   Assuring patient safety in health IT is a shared responsibility among the many stakeholders within the health care ecosystem. As noted in the recent IOM report, safety is part of a larger sociotechnical system that takes into account not just the software, but also how it is used.[3] This larger system includes technology, people, processes, organizations, and the external environment.[4]

   The level of safety in health IT depends on how the technology is designed, customized, implemented, used, maintained, and incorporated into clinical workflows. The quality of data, the interoperability of IT systems, and the appropriateness of clinical interventions also have an impact on health IT safety. Additionally, education, training, and proficiency of users can play a critical role. Finally, health IT supports—but does not replace—the judgment of clinicians.

   Any oversight framework for safety in health IT should have strong support from and involvement of all stakeholders, including patients.

3. **Any framework for patient safety in health IT should be risk-based, flexible, and should not stifle innovation.**

   The scale and scope of oversight requirements intended to ensure patient safety in health IT should be correlated to the potential risk of harm to patients.

   Health care is a continually evolving ecosystem that is now undergoing considerable change. Health IT plays a foundational role for rapidly emerging new models of delivery and payment that promise to improve the quality, safety, and cost-effectiveness of care, such as accountable care arrangements and the patient-centered medical home.

   Health IT must evolve to support rapidly emerging changes in the health care system and must continually be upgraded and/or customized to address the ever-changing needs of those who deliver, manage, pay for, and receive care. Innovation is needed to continually drive improvements in the cost, quality, and patient experience of care.

Any framework for safety in health IT must be flexible and promote—not stifle—the innovation needed to drive further improvements in health and health care. Current regulatory frameworks that are oriented toward turnkey devices that change infrequently and are often not customized based on the needs of the user, do not align well with the current and anticipated nature of health IT.

4. **Existing safety and quality-related processes, systems, and standards should be leveraged for patient safety in health IT.**

   Policies, processes, and systems associated with assuring safety in health IT should be aligned with and integrated into well-established patient safety and quality programs, including those that involve accreditation, certification, and reporting.

   Quality management and safety principles, processes, and standards, which are well-established and common to other industries, should also be leveraged for assuring patient safety in health IT.

   Health IT is an essential component of a comprehensive approach to improving patient outcomes and assuring the quality, safety, and efficiency of health care. Any oversight framework for health IT should align with and leverage existing processes, systems, and standards in health care, and should discourage or prevent duplicative or inconsistent requirements.

5. **Reporting of patient safety events related to health IT is essential; a non-punitive environment should be established to encourage reporting, learning, and improvement.**

   Any framework for patient safety in health IT should be data-driven. It should support and promote reporting, sharing, and analysis of patient safety events in a non-punitive environment that maintains confidentiality and enables learning and improvement.

   Reporting of patient safety events by users, developers, implementers, and patients is essential to both gaining an understanding of the nature and magnitude of health IT-related safety events and developing and implementing strategies to address risks. Aggregation and analysis of events and timely feedback to developers, implementers, and users are also crucial, so that necessary changes can be made to address identified issues and to mitigate future risk.

   Existing reporting processes and bodies, such as those created by the Patient Safety and Quality Improvement Act, should be leveraged. Reporting efforts should be coordinated. They should take into account existing work flows, and the burden of reporting should be minimized. The use of consistent formats for reporting should be encouraged so that data can be easily aggregated and analyzed to support learning and improvement.

   Reporting policies should encourage reporting for learning and improvement. As noted in the recent IOM report, "in other countries and industries, reporting systems differ with respect to their design, but the majority employs reporting that is voluntary, confidential

and non-punitive."[5] Lessons learned from such other approaches should be integrated into any oversight framework for health IT.

In summary, assuring patient safety in health IT is best accomplished through an oversight framework that is risk-based and reflects shared responsibility, promotes innovation, is flexible enough to accommodate a rapidly changing health care system, supports learning and improvement, and leverages existing safety and quality-related processes, systems, and standards.

Further, any oversight should contain the following key components:

1. Agreement on and adherence to recognized standards and guidelines for assuring patient safety in the development, implementation, and use of health IT.
2. Support for the implementation of standards and guidelines as well as development and dissemination of best practices through education, training, and technical assistance.
3. Participation in patient safety activities, including reporting, analysis, and response, by those who develop, implement, and use clinical software, while leveraging patient safety organizations.
4. Creation of a learning environment through the aggregation and analysis of data to identify and monitor trends, mitigate future risk, and facilitate learning and improvement.

As the Subcommittee engages in public dialogue regarding a regulatory framework for health IT, we urge you to consider and draw upon the collaborative report released by the Bipartisan Policy Center in February 2013.

About the Bipartisan Policy Center

Founded in 2007 by former Senate Majority Leaders Howard Baker, Tom Daschle, Bob Dole and George Mitchell, the Bipartisan Policy Center (BPC) is a non-profit organization that drives principled solutions through rigorous analysis, reasoned negotiation and respectful dialogue. With projects in multiple issue areas, BPC combines politically balanced policymaking with strong, proactive advocacy and outreach. www.bipartisanpolicy.org

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[1] Buntin M.B., Burke M., Hoaglin M., and Blumenthal D. (2011). The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results. *Health Affairs*, 30(3): 464–471.

[2] Ibid.

[3] Institute of Medicine. (2012). *Health IT and Patient Safety: Building Safer Systems for Better Care.* Washington, D.C.: The National Academies Press.

[4] Ibid.

[5] Ibid.

Response to Questions for the Record

Joseph M. Smith, MD, PhD
Chief Medical and Science Officer, West Health Institute

Before the
Subcommittee on Health, Committee on Energy and Commerce,
U.S. House of Representatives

Hearing on:
"Health Information Technologies: How Innovation Benefits Patients"
March 20, 2013

The Honorable Michael C. Burgess

1. **Mr. Smith, you mention the term clinical decision support. Is this something where there already are FDA regulations or just an area where FDA is contemplating a new regulatory regime?**

   Clinical decision support (CDS) is a logical framework for guiding clinical decisions and is most often embodied as a type of healthcare-related software. FDA oversight of such software spans decades and major FDA milestones related to software include draft software policy (1989 and subsequent withdrawal in 2005), pre-market software guidance (1991), off-the-shelf software guidance (1999), general principles of software validation (2002), cybersecurity software guidance (2005), medical device data system rule (2011) and mobile medical applications draft guidance (2011).

   FDA regulates some kinds of clinical decision support today; however, the exact parameters of what CDS is regulated are unclear. As a result, innovators, investors, and developers lack the certainty and predictability of whether their products will be regulated and, if so, what regulatory requirements apply. In September 2011, FDA offered a preliminary definition of CDS as software that converts information into patient-specific actionable results by any means including algorithms, formulae, database look-up, or comparisons or rules and associations. This definition is broad and seems to include a wide-range of CDS products that involve varying degrees of risk to patient safety. BMI calculators, for example, may meet this CDS definition but do not involve the same risk as radiation dose calculators. FDA has indicated that factors to consider for CDS regulatory oversight include the level of impact on subject health condition or disease, degree of acceptance in clinical practice and the relative transparency and documentation of internal algorithms used to provide decision support, and the ease with which erroneous output can be identified.

   As the agency aims to clarify uncertainties surrounding CDS, we believe the approach should be to focus on high-risk products.. This is in keeping with the agency's proposed approach for mobile medical applications. The mechanism to share FDA's thinking on CDS would be issuance of draft guidance. We encourage FDA to adopt a regulatory framework that is tailored to risks and clearly delineates areas of regulation, enforcement discretion and no regulation. It is our hope that the

recommendations of the external stakeholder working group convened under Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA) adequately address CDS within its proposals for an appropriate, risk-based regulatory framework pertaining to health information technology

Is medication management software considered clinical decision support?

It depends. Medication management software is an example of why it is important to specifically define what constitutes CDS and clarify what will be regulated, not regulated or subject to enforcement discretion based upon risk to the patient. Some medication management software may help automate workflow. Others may include recommendations for medications that are widely accepted, with medical references or sources readily available in the software. Still others may recommend dosages for treatment of serious conditions that are based on complex calculations that are not transparent to the user. In each of these scenarios, the risk to the patient is different and warrants different regulatory treatment.

a. **What about software created by a hospital to follow the care protocols of patients. Would those be considered decision support?**

As with medication management software, specific functionality determines whether it would be deemed CDS. Functionality limited to documenting and monitoring compliance would not likely be construed as CDS, whereas functionality intended to generate new diagnoses and treatment recommendations would be considered CDS. Clarification of what constitutes CDS, and its commensurate regulatory framework, would help alleviate uncertainty. As described above, a factor to consider in determining appropriate oversight is whether the decision-making process is sufficiently transparent to allow the clinician-user to make an informed decision.

b. **How about software that might help health information exchanges collect information for a patient, is that something FDA is saying it would regulate?**

No. I am not aware of any attempt or plan by FDA to regulate aspects of health information exchanges.

c. **Does FDA have expertise of information system types of software?**

FDA's long history of software expertise pertains more to medical devices than information systems. Although the agency has been regulating software and various medical device technologies for over 20 years, the current pace of innovation and increasing sophistication of products is creating new challenges that will require a collaborative approach among government agencies (FDA, FCC and ONC), advisory groups, and other experts to ensure we take full advantage of the opportunities presented by health information technology. For example, ONC, which supports adoption of health IT and promotion of nationwide health information exchange, has deep expertise in information systems software. Through the Section 618 process, we believe the agencies will have the

opportunity to further their collaboration and leverage each other's expertise. However, it is important to note that this collective effort with the necessary expertise must share the goal of developing a regulatory framework that eliminates duplication, delay and uncertainty. Clear, predictable, and transparent regulatory guidance - that is adaptable to the rapid pace of innovation - is required to ensure health information systems flourish.

2. **Mr. Smith, you mention burdens posed by HIPAA regulations. Can you describe a few examples?**

Confidence in the security and privacy of one's personal information is a cornerstone of health information exchange and true healthcare transformation. The final omnibus HIPAA rule announced January 17, 2013 enhances patient privacy protections, provides individuals new rights to their health information, strengthens the government's ability to enforce the law and increases penalties for noncompliance.

Unfortunately, these regulations are a complex set of rules that create administrative and compliance burdens that often lead to misinterpretation of the rules. This ultimately frustrates efforts to coordinate care and share information.

For example, the audit trail for protected health information (PHI) is one challenge. Insufficient data capture from traditional log files and systems leaves gaps, particularly around the explanation of why data was accessed. This gap may leave companies, especially smaller businesses, with greater exposure to steep noncompliance penalties. Some providers have "over-protected" patient information out of fear of fines to which they would be subjected if they shared information with an unauthorized person or entity. This has led to frustration for individuals trying to access their own information or that of loved ones. The continued increase in use of personal mobile devices for clinician-clinician and clinician-patient communications requires administrative, physical and technical measures to safeguard PHI. Unfortunately, these measures can impede the convenience of this communication modality.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

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April 10, 2013

Mr. Jim Bialick
Executive Director and Co-Founder
Newborn Coalition
750 9th Street, N.W., Suite 750
Washington, D.C. 20001

Dear Mr. Bialick:

Thank you for appearing before the Subcommittee on Health on Wednesday, March 20, 2013, to testify at the hearing entitled "Health Information Technologies: How Innovation Benefits Patients."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, April 24, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Sydne.Harwick@mail.house.gov and mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr. Ranking Member, Subcommittee on Health

Attachment

In Response to the Honorable Joseph R. Pitts:

Question 1: During the hearing you said that regulation of mobile medical applications disproportionally affect certain patient groups. Would you please elaborate?

Newborns will be disproportionately affected by the regulation of mobile medical applications.

The development of traditional medical devices for newborns is a relatively small market. Technologies and devices designed specifically for newborns are inherently higher risk and are subject to significant regulatory oversight. Developers of these technologies incur non-trivial costs during the FDA regulatory process, which increases the up-front investment required to bring a product to market and lengthens the timeline for a product to become profitable.

The high costs associated with bringing newborn-specific products to market have caused many medical device manufacturers shy away from designing products specifically for newborns. It is often the case that the exact same product can be brought to market with lower regulatory costs if the product is designated for use in adults.

An example is the pulse oximeter, a FDA regulated medical device that is used to measure the level of oxygen in a patient's blood. This technology has an array of uses in newborns including the identification of hypoxia, neonatal sepsis, and congenital heart defects. To date, fourteen states and the District of Columbia have passed laws that require all newborns be screened using a pulse oximeter before they are discharged. However, despite the common use of this technology since its advent in 1972, it was not until 2012 that FDA cleared a pulse oximeter specifically designed for use in newborns. The forty years without newborn-specific pulse oximeters was not do to lack of demand, but rather it was because adult pulse oximeters could be used on newborns, albeit not as accurately, and the developers could bring the product to market with less regulatory scrutiny.

In the absence of a product that has been developed specifically for newborns, families and providers have come to rely on technologies for which there is a market such as consumer-focused information and communication tools such as apps on smartphones and tablets. The question is not if some mobile applications should be regulated, certain mobile applications do present very real patient safety issues, but rather if all mobile applications should be regulated in the same way.

My concern is if mobile medical apps are regulated the same way as medical devices are currently, then we can likely expect to see a reduction in the number of mobile medical apps that are designed specifically to serve newborns and their families. As demonstrated by the pulse oximeter, where there is a need the market will respond, but if there is an opportunity for a

higher rate of return elsewhere, we must expect investment to flow to those areas first and that means fewer tools available to those that need them.

Question 2: You stated in response to a question there are non-reimbursement barriers to telemedicine services that preclude their widespread use. Please specify what these non-reimbursement barriers are and how they might be addressed.

Telemedicine has the ability to transcend geographic barriers but is often limited by bureaucratic issues such as state licensing. Currently providers have to be licensed in every state where they practice medicine, including telemedicine. If a provider physically located in the state where he or she is licensed, that provider cannot treat a patient via telemedicine that is located across state lines without first being licensed in both states.

Telemedicine is a way for a provider to make a house call regardless of where the patient is located. The United States has long faced provider shortages in rural communities and we are now seeing shortages in the urban setting as well. Medicare beneficiaries will become increasingly aware of these shortages as more and more seniors seek healthcare and they are unable to find a provider.

This problem can be solved by pursuing an approach similar to what the Veterans Administration and Department of Defense have done to address provider shortages great success: allow VA and DOD providers to treat patients regardless of where they are located.

Something similar can be devised to address shortages in Medicare by allowing Medicare providers to treat their patients (those with whom they already have a relationship), regardless of where the patient located, and allow these providers to do so with their current state license.

The Honorable Michael C. Burgess

Question 1: The Health Information Management Systems Society Recommends that FDA not define "medical device" to cover software or hardware that provides clinical decision support, EHRs, simply transmits or allows other parties to read information originally sent from a medical device, or technologies that are widely used in other industries. These seem like a strong request that FDA not use mission creep to go into areas for which it has little expertise and little ability to properly review.

a. How would FDA use a clinical trial system for clinical decision support?

The process of using clinical trials to regulate clinical decision support (CDS) tools would be complex. The trial would have to be designed to investigate the efficacy of different kinds of CDS tools both as standalone interventions and as a part of a system.

The issue of "mission creep" will become more apparent as CDS tools become more advanced and rely on individuals personalized health information instead of more fixed information sets such as drug formularies.

The concern here is that a CDS tool will have to be regulated as though it is a standalone medical device. This becomes increasingly complicated when we think of the EHR as being the central control for many CDS tools; the tools would then not only have to be individually regulated but also regulated as a device designed to work in concert with others.

In this instance the regulation of CDS tools would likely extend to EHR developers as well if their systems use regulated CDS tools, because the system itself may be subject to additional regulation. CDS tools are already required for certification in the Meaningful Use program and have widely been incorporated into EHR systems. The concern here being that what began as the regulation of CDS tools may quickly lead to the regulation of the Electronic Health Record systems that Medicare providers have been required to purchase by the HITECH Act.

April 24, 2013

RESPONSE TO QUESTIONS FOR THE RECORD
HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
HEARING ON
HEALTH INFORMATION TECHNOLOGIES: HOW INNOVATION BENEFITS PATIENTS
MARCH 20, 2013

RESPONSE SUBMITTED BY
JACQUELINE MITUS, MD
MCKESSON CORPORATION

Question from Representative Michael Burgess:

The Health Information Management Systems Society recommends that FDA not define "medical device" to cover software or hardware that provides clinical decision support, EHRs, simply transmits or allows other parties to read information originally sent from a medical device, or technologies that are widely used in other industries. These seem like a strong request that FDA not use mission creep to go into areas for which it has little expertise and little ability to properly review.

a. **How would FDA use a clinical trial system for clinical decision support?**

Response:

We concur that medical devices, currently regulated by the FDA, are fundamentally different and distinct from clinical decision support in two important ways.

First, the safety of a medical device is almost entirely dependent upon how it is manufactured. The safety of health IT on the other hand hinges upon how it is developed and, perhaps more importantly, on how it is deployed. Thus, health IT safety cannot be ensured simply through good manufacturing practices.

Second, medical devices, unlike health IT, are directly involved in the treatment of a patient, with little if any opportunity for a clinician to intervene. The majority of medical software does not directly or independently act upon a patient, but rather provides data and guidance. The ability of a "learned intermediary" to utilize professional judgment distinguishes this technology from traditional medical devices.

Consequently, clinical decision support, and health IT more broadly, is distinct from medical devices. The traditional paradigm of FDA regulation of medical devices is therefore not well suited to health IT, and a risk-based regulatory system similar to that advocated by the Bipartisan Policy Center is more appropriate.

In the context of the oversight of health IT, clinical decision support systems refer to software applications which gather, present, and, to varying degrees, interpret and act upon information to assist clinicians in the diagnosis and treatment of patients. This is very different from more administrative software such as clinical trial software which may provide registries of clinical trials or which may manage eligibility and/or registration into trials.

In some instances, physicians may utilize a clinical decision support system in the care of a patient who is participating in a clinical trial. It also is foreseeable that a clinical decision support system may utilize information obtained as a result of clinical trials, such as drug interactions or treatment recommendations associated with a medical device or pharmaceutical compound. However, it is difficult to envision a situation where the FDA would use a clinical trial system for clinical decision support in the context of the health IT discussion.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

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April 10, 2013

Dr. David M. Classen
CMIO, Pascal Metrics
Associate Professor of Medicine and
Consultant in Infectious Diseases
Utah School of Medicine
1025 Thomas Jefferson Street, N.W., Suite 420 East
Washington, D.C. 20007

Dear Dr. Classen:

Thank you for appearing before the Subcommittee on Health on Wednesday, March 20, 2013, to testify at the hearing entitled "Health Information Technologies: How Innovation Benefits Patients."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr. Ranking Member, Subcommittee on Health

Attachment

Additional Questions for the Record

The Honorable Michael C. Burgess

1. In recommendation 9a of the report you cite, IOM states that if there is not sufficient progress, FDA should regulate electronic health records, health information exchanges, and personal health records. I want to ask about your understanding about why the IOM committee felt these items are medical devices within the purview of FDA.

    a. Let's start with health information exchanges. What about health information exchanges are medical devices? Is your view that devices that exchange medical records are medical devices within the purview of FDA?

    Please see response to 1b.

    b. I am really trying to understand if the IOM believes that the entire health information architecture is a medical device. Can you start to tell me what software the committee did not consider a medical device?

    The IOM committee was asked to look specifically at "health IT-assisted care," defined by ONC as including "care supported by and involving EHRs, clinical decision support, computerized provider order entry, health information exchange, patient engagement technologies, and other health information technology used in clinical care."

    The IOM committee states on page 164 "health IT has multiple different characteristics [from conventional, out-of-the box, turnkey devices], suggesting that a more flexible regulatory framework will be needed in this area to achieve the goal of product quality and safety without unduly constraining market innovation" and calls for a "phased, risk-based approach" to regulation. The current model of medical device regulation, according to the committee, is insufficient for such complex products as health IT products.

    c. When the IOM Committee cites health information exchanges, what part of the definition of medical device is the Committee referring to? For example, are they saying a health information exchange is intended for use in the diagnosis of disease or other conditions? Or in the cure, mitigation, treatment, or prevention of disease?

    See response to 1b.

2. Page 140 of the IOM committee report states "The committee could not identify any definitive evidence about the impact regulation would have on the innovation of health IT." Yet the committee appears to recommend that FDA could jump in and regulate electronic health records, health information exchanges, and personal health records.

   a. What evidence is there about the impact that implementation of this recommendation would have on innovation in these areas?

      The IOM Committee believed that the evidence about the impact of regulation on health IT is unclear and could not be extrapolated from the literature in other fields. The committee underscores the importance of protecting patient safety as the reason for making this recommendation and expresses the need for regulation to not restrict positive innovation or flexibility, but instead to maximize transparency.

3. The IOM committee recommends an HIT error reporting system. There does not appear to be any discussion as to whether it is good to try to separate HIT issues from general care delivery system errors.

   a. Where is there evidence that you can separate HIT-related safety events from a category just called safety events? Is there not a danger in such separation of losing an understanding of the real causes and solutions for such errors?

      The scope of the IOM Committee report was health IT-related patient safety events, so the intent was not to create separate systems. The committee states on page 163 "If a broader system for all adverse events is created, the spirit of the committee's recommendations should be recognized and considered."

   b. Can you give me an example of what you mean by an HIT-related safety error and how that does not involve non-hit issues?

      The IOM Committee believed that HIT-related safety errors are adverse events that are related to the design, implementation, and/or use of a health IT product. An example of an HIT-related safety error is presented on page 125: "a new kind of error that can occur with IT which did not occur previously is the 'adjacency error,' in which a provider selects an item next to the one intended from a pulldown menu, for example picking 'penicillamine' instead of 'penicillin.'" Other examples from the report include:

      - *pick-list problem: selection of the wrong item from a menu of options, whether it be a patient, test, or drug per the above example of penicillamine/penicillin*
      - *alarm/alert problem: ignored alarms of potential problems*
      - *availability problem: system outages (e.g., during a prolonged power failure) where the EHR or other health IT products are unavailable*

- *interoperability problem: inverted images where the image of a right arm looks like that of a left arm*

○