HEARING ON PROMOTING THE ADOPTION AND USE OF HEALTH INFORMATION TECHNOLOGY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

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CONTENTS

July 24, 2008

HEARING ON PROMOTING THE ADOPTION AND USE OF HEALTH INFORMATION TECHNOLOGY

THURSDAY, JULY 24, 2008

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:05 a.m. in room 1100, Longworth House Office Building, Hon. Fortney Pete Stark (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
July 17, 2008
HL–28

CONTACT: (202) 225–3943

Hearing on Promoting the Adoption and Use of Health Information Technology

House Ways and Means Health Subcommittee Chairman Pete Stark (D–CA) announced today that the Subcommittee on Health will hold a hearing on promoting health information technology. **The hearing will take place at 10:00 a.m. on Thursday, July 24, 2008, in the main committee hearing room, 1100 Longworth House Office Building.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Adoption and use of comprehensive, fully interoperable health information technology (IT) can be a critical tool in efforts to improve clinical outcomes and reduce costs in the health care system. The Congressional Budget Office said in a recent report, "Health information technology has the potential to significantly increase the efficiency of the health care sector. . . . It could also improve the quality of health care and, ultimately, the outcomes of that care for patients."[1] In purely financial terms, the RAND Corporation estimates that widespread adoption of health IT has the potential to reduce system-wide health care spending by up to $80 billion annually.[2] At the same time, health IT could improve clinical outcomes by preventing medical errors, improving the practice of evidenced-based medicine, reducing disparities in the delivery of care, eliminating redundant tests and procedures, and generating data for health care research.

But these potential benefits come with a cost. Studies indicate that the total investment needed to achieve a nation-wide health IT network could be more than $100 billion.[3]

Though the United States has consistently been a leader in the field of information technology, this country lags 5 to 15 years behind countries like Australia, Canada, Germany, Norway and Great Britain in terms of the dissemination and use of interoperable health IT systems.[4] The time has come for the American health care system to get serious about fully utilizing this important tool.

Key issues to be discussed include: (1) the potential costs and benefits associated with the adoption of health IT, (2) options to ensure adoption through effective incentives, (3) ensuring that incentives are tied to systems that are fully interoperable and have necessary clinical capabilities, and 4) protecting patient privacy and the security of health information.

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[1] http://www.cbo.gov/ftpdocs/91xx/doc9168/05-20-HealthIT.pdf.
[2] http://www.rand.org/pubs/monographs/2005/RAND_MG410.pdf.
[3] Kaushal and others "The Costs of a National Health Information Network" Annals of Internal Medicine 2005. Walker and others "The Value of Health Care Information Exchange" Health Affairs 2005.
[4] Anderson, Frogner, Johns and Reinhardt, "Health Care Spending and Use of Information Technology in OECD Countries" Health Affairs 2006.

In announcing the hearing Chairman Stark said, **"In many ways America has the most advanced health care system in the world. But the way medical records are stored and transferred in this country is right out of the 19th Century. If we create a system where an emergency doctor in St. Louis has instant access to the medical records of a patient who lives in Oakland, we will dramatically improve the quality of care while simultaneously reducing costs. It's a win-win situation. But the lack of progress to date shows the need for strong federal leadership and real investment in order to realize those benefits."**

FOCUS OF THE HEARING:

The hearing will focus on options to encourage the adoption and use of a secure, clinically comprehensive, and fully interoperable health information technology system.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "110th Congress" from the menu entitled, "Committee Hearings" (*http://waysandmeans.house.gov/Hearings.asp?congress=18*). Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Follow the online instructions, completing all informational forms and clicking "submit". Attach your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business **Thursday, August 7, 2008**. Finally, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov*.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman STARK. If our guests could find a seat, then we will begin the hearing today to discuss the importance of electronic medical records, and the need to promote their adoption and use by the medical community.

There is little doubt that the U.S. health care system is among the most advanced in the world, in terms of diagnosing and treating disease. But when it comes to medical records, we are stuck in the 19th century. This IT shortfall hampers our ability to provide the best care when people are ill.

In my former life, as near as I can remember, when I was banker I helped to create the way financial information was stored and electronically transmitted for credit cards in this country. You can go to virtually any ATM in the country and instantly withdraw money or, as I do, get notice that I am overdrawn, and I can deposit money in a different bank, or see certain account information. This technology now allows me to receive and pay bills online. We still can't do the same with our medical records.

I am not in the habit of using props, but one of the members of our staff gave me a copy of 2 years—this is a young man behind me—2 years of his medical records. This is it. It's over 500 pages, weighs 5 pounds, and it cost more than $6 to ship it. Getting these records required our staff person to make several phone calls to his doctor, pay a medical records company $127 to copy and print it. Yet, this is the only way he could get his records from one physician to another, and because they're not stored electronically.

As I say, that is—it's just a useful illustration of some of the problems that our medical providers face in trying to do that. I would hate to look and go back starting, I guess, in the Air Force, when I started getting medical records. I will bet mine are a couple of feet high.

The widespread use of electronic medical records holds promise for increasing the quality of health care and bringing down costs. EMR's, electronic medical records, by themselves may have little impact on the cost. But they would allow us to proceed with comparative effectiveness research, put emphasis on disease management through primary care, and it has the potential to save our Nation's health care system billions—perhaps hundreds of billions—of dollars.

Despite its promise, we are years behind other countries in terms of getting doctors, hospitals, other providers to use modern technology. In Germany, they began an effort back in 1993. Canada started in 1997. Britain began its work in 2002. These countries have also invested billions of dollars in government funds toward developing their systems. By contrast, we are stuck in a rut.

We guess that perhaps 10 to 20 percent of the physicians in this country have a meaningful electronic medical records system, and the adoption rates of hospitals is probably not much better than 20 or 30 percent.

It wasn't until 2004 that the Federal Government realized the need for leadership on this issue, when President Bush said that every American should have an electronic medical record by 2014. By executive order, he established an office within Health and Human Services to lead this effort.

While the President and I happen to agree on this important issue—and we don't agree on much—I would point out that Health and Human Services has moved rather slowly since the President's request. The Agency seems more concerned with the vendors and other entrenched interests than in getting the job done. The lack of progress to date is why we have called this hearing, and it is why we will introduce legislation designed to promote—and I want to underline promote—the adoption and use of electronic medical records while protecting patient privacy. I would just like to emphasize that.

This should not be seen as an effort to slow down other commendable legislative efforts in this area. The opposite is true. Our bill would be designed to speed up the development of electronic medical record technology, covering three major points: to ensure that the Federal Government continues to promote development of a comprehensive, fully interoperable electronic medical records system; provide meaningful financial incentives through the Medicare Program that will, hopefully, overcome barriers to adoption; and take the necessary steps to protect the security and privacy of patient records, by giving individuals the right and ability to sue for damages when their records are breached.

We can continue this discussion after we have heard the testimony. I would like to recognize Mr. Camp for comments that he would like to make.

Mr. CAMP. Well, thank you very much, Mr. Chairman. I want to thank all the witnesses for being here.

Paper-based records are an expensive, antiquated relic from the last century. Paper records harm patients, increase costs, and lead to lower quality care. For the 21st century, we need electronic health records.

The question that needs to be answered is not whether we need to have better health information technology. We all know the answer to that is a resounding yes. The real and more difficult question is, how can we achieve that goal, and what role the Federal Government should play in getting physicians and hospitals to adopt health IT.

Should Congress provide physicians and hospitals with Federal subsidies to speed adoption, or are there smarter approaches that we can pursue? Should the Federal Government pick which information system wins the standard sweepstakes, or should a public-private partnership establish an interoperability framework that vendors would have to meet?

How can we ensure that patients' privacy is protected, while making sure that physicians have access to the medical data they need to make an informed decision?

I have introduced a bill that attempts to strike a balance between these competing schools of thought. The Promoting Health Information Technology Act would establish a public-private entity to develop and recommend interoperability standards, would increase the business depreciation expense to facilitate adoption, and allow hospitals and group practices to provide needed software to physicians, and protect the HIPAA privacy standard, and commissions a study to determine whether extra protections might be needed.

This approach will speed the adoption of workable electronic health records that will enable physicians and hospitals to provide better value to their patients. In addition, it will assist health care providers in avoiding unnecessary procedures, encouraging the timely utilization of preventative care, and empowering patients to take a more active role in their own health care.

I think it is very important to hear what is happening in the private sector. Due to the weather last night, Douglas Reding, a physician from the Marshfield Clinic in Marshfield, Wisconsin, was unable to be here. He was going to be a part of the panel, and was going to testify on that important aspect. We have agreed that this testimony will become part of the record.

Chairman STARK. Without objection.

[The prepared statement of Mr. Reding follows:]

Prepared Statement of Douglas J. Reding, MD, MPH, FACP, Vice President, Marshfield Clinic, Marshfield, Wisconsin

This testimony is presented on behalf of the physicians and staff of Marshfield Clinic, who thank you for conducting this hearing on promoting the adoption and use of health information technology. We appreciate the opportunity to share our views regarding the potential for HIT to revolutionize health care and provide the necessary decision support to incorporate evidence based decision making into clinical care processes. We recognize that there is a large public and clinical education gap that must be bridged for Congress to begin to address the quality and financial challenges facing health care delivery. We appreciate the difficulty of the representational issues you must address.

This document will summarize the following: (1) After nearly 40 years of IT development work and expenses approximating three to four percent of its annual budget (currently at $950 million/year) Marshfield Clinic has completely converted to an electronic record format and is paperless in all of its 43 facilities. (2) Marshfield Clinic invested in the technology out of a conviction that the pace of scientific discovery, the pressure for increased productivity, and the intellectual demands of the practice of medicine vastly exceed any individual's capacity for the timely processing of all the pertinent clinical information about a patient, and the provision of state of the art care. To provide anything less would compromise patient safety and care. (3) While we see the expenses associated with the implementation of HIT as a necessary part of the cost of doing business, the federal Medicare practice expense formulas for reimbursing physicians for the cost of patient care have never adequately covered the cost of providing services to Medicare patients, especially those costs associated with HIT, and this has had a limiting impact on the proliferation of HIT throughout the medical community. (4) We have shown through participation in the CMS Physician Group Practice Demonstration that our electronic medical record and the associated databases empower our physicians and their staff to improve patient care outcomes and reduce costs to the Medicare program. (5) We recommend that Congress provide incentives for the utilization of HIT and care management systems that add value to patient care. At a minimum HIT must facilitate meeting the Institute of Medicine's aims for health care delivery assuring that care is safe, timely, efficient, effective, patient centric and equitable.

Marshfield Clinic (the "Clinic") is the largest private group medical practice in Wisconsin and one of the largest in the United States. It is one of only a few large

independent not-for-profit, tax-exempt medical clinics in the United States. The Clinic is engaged in providing quality health care, health care education, and medical research. The Clinic owns and operates outpatient clinical, educational, and research facilities with its main clinical facilities and administrative offices located in Marshfield, Wisconsin. The Clinic currently employs more than 780 physicians and 6500 additional staff. The Clinic has 42 regional centers in addition to the Marshfield location and operates in 35 Wisconsin communities throughout Central, Western, and Northern Wisconsin, which is a predominantly rural area. Marshfield Clinic has developed and acquired sophisticated tools, technology, and other resources that complement and support the population health management mission and strategy of the Clinic. These include an electronic medical record, a data warehouse, an immunization registry, and an epidemiological database that enable enhanced definitions of disease states, diagnoses or conditions, and cost analysis of CPT level interventions. Marshfield Clinic's 43 regional centers are linked by common information systems. With this infrastructure, the Clinic is presently publicly reporting clinical outcomes, and providing physicians and staff quality improvement tools to analyze their clinical and business processes, eliminate waste and unnecessary redundancies, and improve consistency while simultaneously reducing unnecessary costs. The Clinic's largest facilities are adjacent to St. Joseph's Hospital of Marshfield, Inc., a 524 approved-bed acute care and teaching hospital, which is owned and operated by Ministry Health Care, Inc., a tax-exempt organization, headquartered in Milwaukee, Wisconsin.

We believe that health information technology has the potential to significantly increase clinical care efficiency by reducing costs and increasing value (defined as quality/cost) by enabling providers to manage information. To the extent that a provider can manage what he/she can measure, HIT enables performance measurement and the improvement of patient care outcomes. In many, but not all avenues, improvement in patient care also leads to efficiencies and savings, primarily through reductions in hospitalizations, readmissions, and the utilization of intensive services.

For this reason we believe that the Federal Government should stimulate the adoption, and utilization of HIT. As the Congressional Budget Office has recently shown, 85 percent of Medicare expenditures are concentrated among 25 percent of beneficiaries, and CMS has shown us that this population is predominantly individuals who have four or more chronic conditions. We recommend that Congress should initially subsidize the use of HIT through the Medicare program to promote rapid assimilation of the skill sets that are associated with the management of chronic disease. While the time factor associated with this cultural change in the practice of medicine may be protracted, ultimately it may be appropriate for the Federal Government to phase out the subsidies and impose penalties on providers who fail to achieve defined standards of professionalism in their utilization of health informatics resources.

Marshfield Clinic has long used information systems to facilitate care process redesign for patients with chronic illnesses, and the organization expanded its efforts after becoming a participant in the Center for Medicare and Medicaid Services (CMS) Physician Group Practice (PGP) Demonstration project. As a result of these expanded efforts, Marshfield Clinic enhanced access to care, reduced hospitalizations and costs, and became one of two PGP sites (out of 10 total) to earn a performance bonus from CMS in FY 2007. Results of the second year of the demonstration are forthcoming in the next few weeks, but we are embargoed under CMS' terms and conditions of the demonstration from discussing the results. Leave it to say that we are confident that care management works, and may be enhanced through HIT applications.

Description of the Marshfield Clinic electronic medical record

Marshfield Clinic is unique in that is has developed its own electronic health records and ancillary reporting systems over the last thirty years. The system, called Cattails MD, was the first internally-developed system to gain CCHIT certification last year, and has recently been made available for resale in the EHR marketplace.

The clinic first implemented an EMR in 1985, and over time the practice has promoted adoption of the full functionality of the system. Since 2003, Marshfield Clinic has been deploying portable wireless tablet computers that led to a chartless medical environment by the end of 2007. All physicians and their support staff now use the tablet computers, which are linked to the Clinic's sophisticated electronic medical record. With wireless computers, providers can instantly access confidential medical history, radiology reports and images, test results and expert opinions. They

can take notes, enter orders and write prescriptions electronically. Our physicians say that their practice is much more organized and efficient with the use of the tablet. It brings what previously was only available at our desktop into the exam room.

Our physicians can track blood pressure readings and lab results on tablet computers and check which preventive screenings, such as mammography or colonoscopy, are due. They can show their patients diagrams or streaming video of procedures they may undergo.

Storing, retrieving and updating paper charts is time-consuming and costly. Exam room access to electronic records enhances patient security, reduces errors and eliminates duplicate tests, all of which allows us to provide better care. We estimate that the elimination of pulling paper charts alone has resulted in a $7 million savings annually. Patient medical records are accessible to those who need to know throughout the Marshfield Clinic system, and will be available at the Clinic's affiliated hospitals.

Providers can instantly print out patient educational materials rather than leaving the exam room to search for information. When a provider can take the time to educate patients about diseases, risk factors and recommendations to improve their health, patients are more likely to comply. The ability to quickly get information clearly improves the quality of the patient visit.

Imagine your elderly mother has chest pain in the middle of the night. You bring her to the emergency department of your hospital. She can't remember the medications she takes. If she is a Marshfield Clinic patient her medical record is instantly available to the emergency room physician caring for her. Her medications, allergies, X-rays, electrocardiogram and notes from past medical exams are available electronically. The physician has instant access through a wireless computer tablet linked to Marshfield Clinic's sophisticated, integrated electronic medical record.

If your mother needs additional diagnostic tests, referral to a Marshfield Clinic specialist, or a follow-up visit with her family physician, she has access to all of those services at our Regional Medical Centers. Details of her emergency room visit will be available immediately to all of the providers on campus and throughout the Marshfield Clinic System. This promotes communication about her condition, and minimizes the need to repeat studies.

In order to assist with our quality performance, the Clinic developed a comprehensive package of initiatives that leverage the electronic technologies to redesign care for chronically ill patients, to identify improvement opportunities, collect needed information at the point of care, and report performance back to physicians.

For example, our PreServ (Preventive Services) System is able to alert physicians when preventative services are due for a patient during a visit with a primary care manager. In PreServ, the EMR generates a preventive services (PRESERV) list on the dashboard of each electronic patient record. This box compares the patient's clinical profile with evidence-based clinical practice guidelines formed from a number of sources including the ADA and input from endocrinologists at Marshfield, and highlights (in red) gaps in care related to preventive services, immunizations, routine screening, and diabetes care needs; eventually, this functionality will be expanded to cover additional disease states. The system prompts the physician to provide or schedule needed preventive services during the patient visit. In contrast to disease-specific programs and care registries, this list allows physicians to proactively plan and coordinate needed preventive, screening, treatment, monitoring, and education across a spectrum of diseases for each individual patient.

Our EMR also includes a system for flagging high-priority patients. A "hierarchical defect recovery list," which acts as a safety net, includes high-risk patients with multiple chronic conditions that are in need of immediate attention. High-risk patients with serious gaps in care (e.g., diabetes patients who have not made appointments for annual eye and foot examinations and whose hemoglobin A1c level is above goal) appear at the top of the list; physicians and staff use this list to work with the patient to provide or schedule needed care immediately. When a diabetic patient visits a physician for example, he or she is notified of the need to conduct a foot exam. Physicians are then provided "Clinical Storyboards" showing their performance with selected quality measures such as foot exam compliance. Since starting to measure and report these key quality areas, we have seen increases in percentage of patients at goals, that are specified in public reporting and efforts such as the PGP Demo, for key areas such as hypertension, diabetes, congestive heart failure, and coronary artery disease.

We have also implemented an anticoagulation care management system. All patients who take the drug, Warfarin, which is a high-risk medication with a narrow therapeutic threshold, are managed under a single set of protocols. Under this nurse-managed, physician-directed telephonic management program, nurses place outbound calls to patients to discuss their anticoagulation management and check

on their general health. As needed, nurses adjust dosing based on written protocols and enter updates into the EMR.

The Clinic has also implemented electronic prescribing to enhance safety. Physicians use tablet PCs for electronic prescribing, with prescriptions printed by computer, thus reducing the potential for medication errors.

We have implemented a 24-hour nurse line. Patients have access to a 24-hour telephone number staffed by nurses. Nurses listen to the patient's concerns, refer to the EMR for background data and care plan, offer advice, and triage patients for physician appointments using physician-approved guidelines. An automated e-mail system notifies physicians whose patients have called the nurseline and provides a hyperlink to the patient's medical record.

The Clinic is also utilizing the system to facilitate ongoing quality improvement efforts including continuing medical education, online provision of care guidelines, feedback and education by quality improvement medical directors and clinical nurse specialists, and sharing of comparative data on performance and best practices. The EMR facilitates many of these efforts by allowing physicians to collect data on quality thereby providing timely, actionable feedback on individual performance.

A key component of the CMS demonstration project was to show an overall decrease in cost in comparison to other regional healthcare providers. Marshfield Clinic was one of only two practices to accomplish this. One way we leveraged our information systems to help reduce costs and hospitalizations was to identify patients who are not well managed in one or more critical quality areas. To address this problem Marshfield Clinic developed a software tool called "iList" (Intervention List), which is used in primary care including Internal Medicine, Med-Peds and Family Practice departments. iList originates from the electronic medical record and provides a list by provider of patients who have one of three chronic illnesses—diabetes, heart failure or hypertension—and who do not meet all of their recommended health goals. iList is a tracking tool intended to help providers identify and reach out to patients who are overdue for services and are not meeting their quality of care goals. iList proactively assures that our patients get the care they need to try to help provide better control of their chronic medical conditions. Our physicians and their assistants use iList to be sure patients, especially those with diabetes, have lab work and follow-up visits when needed. In the past, patients might not have understood they needed to come in more frequently because they have diabetes. iList is a highly sophisticated reminder system, and can help physicians examine their practices realistically and take action to improve care where there may be gaps. Our physicians have found that using it has been an eye-opener as far as putting a face on those patients who could be slipping through the cracks. Physicians are typically trained to take care of an individual patient and are not typically trained in the management of populations of patients. Using tools such as iList have allowed us to improve our performance on the quality metrics reported and more importantly the health of our patients as evidenced by decreased hospitalizations in some chronic conditions. For Marshfield Clinic to be competitive on the basis of results, we need to know what our results are. This helps bring results to a patient level and lets us know where we stand on quality measures.

iList is not a registry. Patients who are on target for their health goals do not appear on iList and it is not a registry of all of a provider's patients or a listing of all patients with a specific condition. Only patients who have not achieved a specific quality measure or who don't have a future appointment will show up at any given time, and once they meet their goals they are removed from the list. iList may be viewed as being a subset of a registry, which would include all of a provider's patient population. The patients listed on iList are patients not on target for their monitored quality health metrics.

Provider-approved protocols make iList unique. Key to understanding iList's potential, and part of what makes it different from other Information Systems tools, is provider-approved protocols built to accompany the application. The step-by-step written protocols—derived from evidence-based medicine in the Marshfield Clinic guidelines for hypertension, heart failure and diabetes—delegate interventions and actions to be carried out by medical assistants and other support staff.

The protocols may be used as part of a patient-specific plan of care from the patient's primary care provider. With protocols providing direction, support staff may review the list and initiate actions to help patients reach their goals. Per protocol, for example, support staff may call a diabetic patient to schedule an overdue fasting lipid panel or foot exam. This promotes a team-based approach in the patient care process.

iList exclusions—Certain patients with chronic conditions may be excluded from the iList application by the provider for reasons such as advanced age, terminal illness or contraindications to the usual care. This ability allows the iList application

to individualize care for patients while considering population based measures for quality.

Potential to track other conditions

Development of iList was hastened due to Marshfield Clinic's participation in the Centers for Medicare and Medicaid Services (CMS) Physician Group Practice Demonstration project which began in 2004. In order to improve our performance in the demonstration, our providers wanted the ability to look more closely at overdue services for patients with the three chronic conditions previously mentioned.

Implementation of iList may provide the opportunity to address the way care teams handle planned care workflows. Planned care visits allow for results to be available at the time of a patient's visit to allow direct immediate direction and changes to the patient's care plan. This immediacy decreases the need for repeat visits and decreases rework (letters, telephone calls for communication of results) and for the patient and the practice after the visit. iList makes it easier to provide support to practices to help plan care for patients. This tool takes a huge step in that direction.

The Clinic has also developed additional reporting mechanisms to identify patients at risk of hospitalization (for example, congestive heart failure patients) who qualify to be added to the disease-management program. Once a patient is identified through criteria-driven data-mining, Care-Management staff review the patient's electronic chart and make a determination if the patient meets criteria to be added to the disease-management system. This system provides a worklist and documentation capabilities for the clinical staff to monitor at-risk patient populations, and escalate a patient's condition to a physician if required.

While most of the groups participating in the CMS PGP program also have electronic medical record systems, Marshfield Clinic is unique in that it has developed its own systems and data warehouse. This has allowed the group to customize its software as required and react quickly to meet reporting needs. We went through the typical quality reporting progression: denial that the results are accurate, improvements to data collection, improvement in acceptance of the results, improvements in process and outcomes resulting in clinicians wanting more data, faster. Because we have developed our own systems and data warehouse, we are able to react quickly and fine-tune as required to continually improve our data accuracy and timeliness.

Recently, Ministry Health Care, the predominant hospital provider in the Marshfield Clinic service area agreed to use CattailsMD, an electronic medical record software suite developed by Marshfield Clinic, in most of its hospitals and Ministry Medical Group.

The agreement will create the largest patient database in Wisconsin. Under the agreement, more than 1,000 providers in the Marshfield Clinic system, at Ministry Medical Group and Ministry hospital locations, will share access to 2.5 million patient records.

The implementation of Cattails within Ministry Health Care will take place over 3 to 5 years. CattailsMD, now used by more than 13,000 healthcare providers, is the first provider-developed ambulatory electronic medical record to achieve Certification Commission for Healthcare Information Technology certification.

With CattailsMD, caregivers will have immediate access to all patient medical information, including lab results and radiology images, over their computers—no matter where they are located. The electronic records provide care and security advantages over paper charts that must either be retrieved from a central storage area or be physically taken from one location to another within a healthcare system.

As part of the CattailsMD implementation, Marshfield Clinic will provide planning, project management, training, and technical support to Ministry Health Care. From a technology standpoint, the CattailsMD system stood out because its physicians liked the tablet platform and had witnessed its success at one Ministry health clinic. Physicians like the CattailsMD system because it's delivered as a service where Marshfield Clinic hosts the data and manages the applications.

Marshfield Clinic has a very mature data warehouse infrastructure and a world-class bioinformatics research group. Some organizations have gone through very expensive and time-consuming EMR implementation efforts, but when they were done, they still had nothing in terms of data warehousing and the tools they need to manage clinical outcomes. Ministry's goal was to be proactive and take advantage of the benefits evident in the EHR as seen in the Marshfield Clinic system of care. Rather than wait for the patient to show up in the examination room, with CattailsMD their providers will be able to see which diabetic patients, for example, are overdue for their eye or foot exam screenings.

Diabetes mellitus is a rapidly increasing and costly public health problem. Large studies are needed to understand the complex gene-environment interactions that lead to diabetes and its complications. The Marshfield Clinic Personalized Medicine Research Project (PMRP) represents one of the largest population-based DNA biobanks in the United States. As part of an effort to begin phenotyping common diseases within the PMRP, we have reported on the construction of a diabetes case-finding algorithm using electronic medical record data from adult subjects aged 50 years living in one of the target PMRP ZIP codes. Based upon diabetic diagnostic codes alone, Clinic scientists observed a false positive case rate ranging from 3.0% (in subjects with the highest glycosylated hemoglobin values) to 44.4% (in subjects with the lowest glycosylated hemoglobin values). They developed an improved case finding algorithm that utilizes diabetic diagnostic codes in combination with clinical laboratory data and medication history. This algorithm yielded an estimated prevalence of 24.2% for diabetes mellitus in adult subjects aged 50 years.

Marshfield Clinic has also embarked on a novel project to match genetic information from Alzheimer's patients with environmental factors that may contribute to the disease. The 2-year project is the first to tap the more than 18,000 DNA samples Marshfield Clinic has gathered for its Personalized Medicine Research Project, one of the nation's largest bio-banking efforts. Capitalizing on Marshfield's extensive database of electronic medical records, the project aims to develop a set of genetic markers that would allow doctors to screen a person early in life to determine their risk for the disease.

The study will focus on four specific genes and their connection to the disease. In addition to the patient's DNA, we have a complete medical record. We know the medications they have been taking and what diseases they have been diagnosed for. We have also some environmental factors. Consequently we can perform genetic analysis and look at genes and the DNA with the phenotypes we have. No other projects to date has made that critical phenotype-genotype link that is the subject of this Alzheimer's project within the Marshfield Clinic Personalized Medicine Research Project. The study is focusing on patients who are at least 70. Researchers will study 150 people who have Alzheimer's disease and about 300 people who do not. They will be re-contacting people they believe do not have Alzheimer's to confirm that, doing what are called mini mental exams, basically short lists of questions that are commonly used in clinical settings to confirm that the person truly does not have the disease. The project will also include a study of statins, which are one of the most commonly used medications to lower cholesterol and may actually protect a person from developing Alzheimer's. The project also will study the effects of smoking on the brain.

Protecting Privacy and the Security of Health Information

Marshfield Clinic has long been a proponent of HIT implementation, and federal policy reforms that would enable broad proliferation of an IT infrastructure necessary to sustain and improve the quality of health care services. The Clinic's electronic medical record is an essential tool for patient care that our physicians and care providers have utilized in the CMS Physician Group Practice Demonstration to identify sick and chronically ill patients and assure that they receive necessary primary and preventive services in a timely manner to avoid intensive specialty procedures and hospitalizations. We strongly recommend that Congress provide incentives for the utilization of HIT and care management systems that add value to patient care. We urge you to structure incentives in the Medicare program to hasten the objective of broad proliferation of HIT throughout the medical community. We have concerns, however, about proposed legislation that would change the current Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules that strike a necessary balance between protecting the privacy and sanctity of a patient's medical information and ensuring that necessary information is available for vital health care functions.

On many levels we believe that H.R. 6357, the "Protecting Records, Optimizing Treatment and Easing Communications through Health Care Technology Act of 2008" is important legislation that offers incremental improvements to the policy landscape regarding the promotion of Health Information Technology and the protection of patient's personal health information. We have concerns, however, about several provisions of the legislation. We are concerned that this bill will increase the costs of providing health care and the cost of implementing electronic medical records without any measurement of the problem it is trying to solve.

H.R. 6357 codifies ONCHIT, provides grants and loans for HIT, but most importantly the bill creates new privacy and security provisions which require notification of breaches of PHI by covered entities and business associates. The bill also includes

restrictions on certain disclosures of PHI allowing patients to request that their information not be released to health plans in certain circumstances.

Currently the HIPAA Privacy Rule permits providers and health plans that receive protected health information from a patient to share that patient's information with other providers/health plans for treatment purposes without the patient's authorization. In addition, covered entities can share with others the minimum amount of such information necessary for payment and for the entity's operations, such as quality improvement activities. Beyond that, authorization from a patient must be secured before sharing the patient's information. The Privacy Rule requires that health care providers and health plans use the minimum necessary amount of personal health information to treat patients and pay for care by relying on patients' "implied consent" for treatment, payment of claims, and other essential healthcare operations. This model has served patients well by ensuring quick and appropriate access to medical care, especially in emergency situations where the patient may be unable to give written consent. For all other types of uses and disclosures, including for marketing purposes, covered entities must obtain prior written consent.

The PROTECHT Act requires covered entities to make a reasonable effort to restrict the use, disclosure, or request of PHI to a "*limited data set*" of information as defined in regulation. If the limited data set is insufficient, the covered entity must restrict the use, disclosure, or request of PHI to the minimum necessary to achieve the purpose. The PROTECHT Act encourages the use of "the limited data set," which strips identifiers such as the name, medical record numbers, images, biometric identifiers and social security number of the patient. *It also includes a new consent provision that requires additional patient consent if the PHI is utilized in operations, such as peer review, quality review, standard of care review, malpractice review, or best practices analysis*.

The requirements for a "limited data set" could be particularly onerous because it is impossible to know in advance what information is needed for most services. The "minimum necessary to achieve the purpose" makes it cumbersome to evaluate unexpected findings that were not anticipated. The question arises: Who will make this determination and at what cost? Consultations could become 20% opinions rather than second opinions based on a keyhole view of the potentially relevant data. The size of the keyhole will be limited by the imagination of the sender and will likely force duplication of effort by the receiver. The requirement to track releases between covered entities could inhibit the willingness of entities without advanced computer systems to share patient information. It is in the nature of free text that any given note will be a mixture of information, some relevant and some not; and the same could be said of many laboratory tests. Should we be required to black out items that someone doesn't think are useful? Who will provide this censorship service? Are we to make separate requests for information for different specialists seeing the same patient? Will this curtail the use of shared electronic medical records among entities?

We are also concerned about additional patient consent if the PHI is utilized in health care operations, such as utilization review or best practices analysis. This will be an obstacle for quality improvement. Although the bill may be referring to "outside" review, the problem with "outside" is intractable, because almost all of our patients are hospitalized "outside" of the Marshfield Clinic at the hospitals where our physicians have admitting privileges. This will complicate collaborative efforts between the Clinic and the hospitals for quality improvement.

Section 312: This section would prohibit the Clinic from sharing PHI about a specific service with a patient's insurance company, if a patient elected to pay cash and not submit the service for payment by the insurance company. This may be difficult in an electronic medical record setting as the bill would require that medical records be segregated so that medical records for cash services are never sent to or viewed by the insurance company. At Marshfield Clinic, patient medical records are often sent electronically to third party payors and at times, payors may be granted electronic access to certain patient medical records as necessary to process claims. If H.R. 6357 were enacted, we would have to institute additional processes to segregate electronic medical records for services that are billable to the insurance company and those that the patient elects to pay cash for so that certain records are neither sent to the insurance company whether electronically or via paper. The Clinic will also need to ensure that the insurance company is never given electronic access to the electronic medical records for such health care that was not reimbursed by the insurance company. This may also negatively impact a health plan's ability to monitor the health of its enrollees and to offer preventive care services, as there will be gaps in data that is provided to the insurance company about health care that has been provided to their enrollees.

Requiring an accounting of disclosures for all disclosures of PHI, including for treatment, payment, and healthcare operations will be difficult. We currently do not log all these disclosures and it would be difficult to capture all since many times records are released directly by providers for treatment purposes, the billing office for payment etc. These disclosures are not logged or accounted for—as the law does not currently require this. In order to log all these disclosures, it is likely that any and all requests for PHI would have to be handled by our Health Information Management department and our release of info staff. *This requirement could add 10–30% to the cost of implementing a robust EMR.*

Requiring patient consent before a disclosure can be made for health care operations in an electronic medical record would likely require that each patient whose PHI is in the EMR sign such a release in advance. Each of health care providers who participate in the Clinic's shared electronic medical record have access to all the PHI contained in the electronic record, therefore they can use the PHI as necessary for treatment, payment, healthcare operations without notifying the other providers whose medical records are being accessed in the shared EMR. So long as there is a shared patient relationship, such access is currently permissible under HIPAA without the patient's authorization. In addition, the Clinic routinely uses its own medical records for healthcare operations such as quality review, peer review, malpractice claims handling, risk management, etc. It would be burdensome to obtain patient authorization each time their record was accessed for such purposes. Many patients would object and thus the records could not be used for these important health care purposes.

The proposed HIPAA privacy rule was first published on November 3, 1999. During the rulemaking process, the proper role for consent was carefully debated and considered. After drawing more than 50,000 comments from interested parties, the modified final version of the privacy rule was published August 14, 2002. During this time, requiring providers to obtain consent to use and disclose protected health information for treatment, payment and health care operations specifically was rejected based on the comments that HHS received. The "most troubling" and prevalent concern, based on their assessment, was that "health care providers would not have been able to use or disclose protected health information . . . prior to their initial face-to-face contact with the patient, something which is routinely done today to provide patients with timely access to quality health care."

What is considered a "health care operation" under the HIPAA Privacy Rule?

As defined by the privacy rule, health care operations includes the following activities:

- Conducting quality assessment and improvement activities, including: outcomes evaluation and the development of clinical guidelines; population-based activities to improve health or reduce costs, such as infection surveillance or sentinel event root cause analysis; participation in quality reporting, such as to Joint Commission or the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) initiative; protocol development; case management and care coordination; contacting providers and patients with information regarding treatment alternatives;
- Reviewing competence of health care professionals, including: practitioner and health plan performance evaluation; training programs for health and non-health care professionals; accreditation, certification, or licensing.
- Conducting or arranging for medical review or auditing functions such as fraud and abuse detection and HIPAA compliance programs.
- Business management and general administration, including: formulary development and administration; development or improvement of methods of payment or coverage policies; customer service activities; creating de-identified health information for purposes of research.

In order to achieve the potential benefits of health information technology (HIT), providers and other entities must be able to use it as a tool to improve the quality and efficiency of health care delivery. For example, greater adoption of HIT could improve the management of chronic disease through better coordination of care and the development of best practices. However, generating the processes and protocols to make this a reality will require providers to conduct activities, such as analyses of data collected via HIT, considered health care operations under the Rule. Requiring consent for these types of essential activities would severely hinder these types of crucial functions needed to reap the much-touted advantages of HIT.

For other types of uses, such as for population-based activities aimed at outcomes improvement or participation in quality reporting programs, requiring consent would prevent entities from securing the needed-threshold for meaningful success. For example, creating de-identified or limited data sets for the purposes of research

requires that the population on which it is based meet critical parameters that could be difficult to meet if it omits certain categories of patients. In the most serious instances, providers could be penalized significantly for failing to obtain affirmative consent for some types of operations. For instance, hospitals that could not obtain consent to use patient information for the purpose of reporting on quality measures for participation in the RHQDAPU initiative would receive a reduction of two percentage points in their Medicare annual payment update.

For these reasons, even proposed provisions that would require only a one-time or "blanket" consent for uses or disclosures of information for health care operations, would become unworkable in practice. A failure to obtain consent from even a fraction of a given population would preclude providers and other covered entities from conducting essential quality improvement and research functions. Likewise, provisions that would allow an individual to retract consent would impose an additional layer of burden by requiring covered entities to track information that was previously used or disclosed and retroactively remove the effects of various transmissions.

Summary

It is extremely important that legislation focused on the adoption and use of safe and secure electronic health information systems be adopted as soon as possible, as such systems will be the foundation for essential improvements in quality and access to care, movement in the direction of evidence-based medicine, expanded access, and value-based purchasing. A robust HIT system enhances physicians' ability to take care of populations of patients without losing sight of the individual needs of patients. It is important, however, to keep in mind that change in a culture of autonomy takes time. The use of an electronic health record is necessary but not sufficient to affect change.

There is no question that HIT is expensive, and perhaps cost-prohibitive. Physicians and providers are expected to pay for it, funding and maintaining the infrastructure of systems that utilize population-based information to improve patient health. There is a very small return on the investment in HIT to the physician, which is a return in efficiency and time. The significant benefits accrue to the patient and the payor, whether it be employers or the government. If Congress mandates changes such as imposing restrictions on the utilization of patient information for operations as proposed in H.R. 6357, we estimate that the cost of HIT will increase dramatically, undermining the return on investment that should accrue to patients and payors.

We would like to acknowledge the contribution that Dr. Peter Orszag and the Congressional Budget Office have made in calling attention to the research in variations in treatment and outcomes conducted at the Dartmouth Medical School under the guidance of Drs. Jack Wennberg and Elliott Fisher. Considering the rapid expansion of new medical knowledge occurring today, it might be reasonable to expect this continuing variability in care. The accelerating growth in new medical knowledge, coupled with the birth of new sciences, such as genomics and personalized medicine, suggests that physicians, nurses, and other health care professionals will invariably continue to fall further and further behind in their ability to keep up with the latest discoveries and approved treatments. As information technology has sparked this explosive growth in knowledge, only information technology can provide an adequate response. By using evidence-based knowledge embedded in clinical decision support deployed within a well-designed workflow, physicians can manage the ever changing and growing knowledge base critical to the delivery of effective and efficient healthcare.

Health IT on a broad basis is still in its infancy. Health care organizations have not developed IT to its full potential. Current costs may seem too high for what we are getting in return. Looking at what our costs today are is not the point. Start up costs will always be high. Looking to what can be achieved in the future due to implementation of these systems should be our focus.

Mr. CAMP. With the debate over health IT moving forward, there has been considerable attention placed on privacy and security. I agree that we must consider these important issues, and we must be cautious, however, that in a desire to complete an HIT bill, any HIT bill, that we do not limit the ability of health care workers and facilities to actually provide the proper health care.

Congress must encourage providers to make this transformation, not over-burden them with a new, unworkable set of regulations. At the risk of taking a well-known phrase, the remedy cannot be worse than the disease.

Earlier this week I read that the Chairman hopes to introduce a health IT bill in coming weeks. I sincerely hope that the Chairman will accept my offer to work in a bipartisan manner, just as the Energy and Commerce Committee is doing on health IT legislation. It is an important issue. With that, I yield back the balance of my time.

Chairman STARK. Thank you, Mr. Camp. At this point, we will proceed with our panel. It will be led off by Dr. Peter Orszag, who is the director of the Congressional Budget Office, with whom we constantly battle over numbers and procedures.

I warn the rest of the witnesses, he used electronic prescribing to get a gallon's worth of high-test caffeine in front of him instead of water, so he should be ready to really zero in on us.

I am going to ask Dr. Yul Ejnes, who is the Chairman of the medical services Committee of the American College of Physicians; Ms. Deven McGraw, who is the director of the Health Privacy Project at the Center for Democracy and Technology; Dr. Matthew King, who is the chief medical officer at Clinica Adelante, Incorporated, of Surprise, Arizona; Mr. LeRoy Jones, of GSI Health of Philadelphia, Pennsylvania; and Mr. David Whitlinger, director of healthcare device standards and interoperability at the Intel Corporation will lead off, and ask each of the witnesses to summarize or expand on their written testimony in any manner that they are comfortable. Then we will let the panel expand through questions.

Dr. Orszag, would you like to lead off?

STATEMENT OF PETER R. ORSZAG, PH.D., DIRECTOR, CONGRESSIONAL BUDGET OFFICE

Mr. ORSZAG. Mr. Stark, Mr. Camp, Members of the Committee, I guess I will hope to escape this battle without too much carnage, with the defense of my caffeine. But let me try to focus in on what I consider to be the largest inefficiency in the economy, which is our health care system.

Credible estimates suggest that as much as $700 billion a year in health care services are delivered that do not improve health outcomes. That is 5 percent of GDP, 30 percent of what we spend on health care, $700 billion. That number comes from a variety of calculations, including the very substantial variation that we see across the United States in the intensity of services provided without any corresponding benefit, in terms of the quality or outcomes that result from the higher spending regions.

It is striking, for example, that among Medicare beneficiaries in the last six months of life who are treated at UCLA Medical Center, the average cost is roughly $50,000 a year. Among those beneficiaries in the last 6 months of life who are treated at the Mayo Clinic, the average cost is about $26,000 a year.

I cannot tell you—and I don't believe that there is a person in this country who can tell you—what we are getting in exchange for the extra money at UCLA Medical Center. So, why is this happening?

I think there are a variety of explanations. But technology and incentives are among the most important. Let's start with incentives. We have incentives for more care, rather than better care. Guess what? We wind up with more care. But in order to alter that system of incentives, we need to know what better care is. That brings me to the second point, which is that we need more information on what works and what doesn't, specifically at the clinical level. That will require a very much expanded set of health information technology.

So, one can think of health information technology as the foundation or the gateway to capturing that $700 billion opportunity. It will not be sufficient by itself, but it is necessary to put in place a more universal system of health information technology in order to capture the opportunities that we have before us. I would emphasize I think this is, by far, not even close, the most important fiscal question that we face: improving the efficiency of the nation's health system.

So, how do we do that? There are a variety of approaches, and I am going to leave to my fellow panelists the important questions surrounding privacy, security, interoperability, and just focus in on, assuming that we can come up with acceptable answers to those questions, how do we spur adoption? Because as you have already noted, only 10 to 20 percent of providers have such systems.

Basically, there is either the carrot or the stick. The carrot could take the form of a bonus or a tax incentive for adoption. That can help to increase adoption among providers. But, typically, policy makers want to limit the budget costs involved, and typically, the subsidy is, therefore, pretty small. What you are, therefore, doing, is only affecting those entities that were close to adopting voluntarily.

So, a provider or a doctor or a hospital will look at the cost of putting in the system, and then the benefits to the doctor or the hospital, and adopt if they think it's beneficial, and not, if not. What you're doing is only pushing over the line those folks who were close anyway, with a modest subsidy. Plus, you're buying out the base, or providing a subsidy to all the entities that would have adopted anyway.

So, in general, a subsidy approach, unless you're going to spend lots and lots of money, is not going to affect that many people, and it's not that cost effective, because you're going to be buying out some people who would have done it anyway.

The alternative is a stick. The stick would take the form of the Federal Government saying you have three or four—some years, or some period of time to adopt a health IT system that meets the following standards, or meets the standards set by a public-private partnership. If you have not done so, you would not be reimbursed under Medicare or Medicaid.

I will say, very bluntly, that if we want to get to universal or nearly universal health IT in the very near term at reasonable budget cost, I do not see an alternative to the stick. One can combine these two approaches, like you did in the prescribing piece of the legislation that you've recently adopted, and provided a subsidy for some period of time, and then a penalty thereafter.

I will note that CBO did score a $2 billion savings to the e-prescribing provision in the recent Medicare legislation, both because we assumed, or we projected that it would lead to increased take-up of generic drugs, but also because there would be some penalties imposed, the point being that, if done right, and done in the right structure, health IT can save money.

On a broader basis, I would just say again, coming back to the main point, it's necessary but not sufficient. You also need changes in incentives and comparative effectiveness. But it is a foundation, and the gateway or the key to capturing that $700 billion opportunity, and we could get there with a combination of carrots and sticks. Thank you very much.

[The prepared statement of Mr. Orszag follows:]

Prepared Statement of Peter R. Orszag, Ph.D., Director, Congressional Budget Office

Congressional Budget Office

Testimony

Statement of
Peter R. Orszag
Director

Evidence on the Costs and Benefits of Health Information Technology

before the
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives

July 24, 2008

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CONGRESSIONAL BUDGET OFFICE
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Note

This statement reprises the Congressional Budget Office's May 2008 report *Evidence on the Costs and Benefits of Health Information Technology*.

Evidence on the Costs and Benefits of Health Information Technology

Chairman Stark, Mr. Camp, and Members of the Subcommittee, I am pleased to appear before you today to discuss the costs and benefits of health information technology (health IT). Information plays a key role in health care. Providers such as physicians and hospitals generate and process information as they provide care to patients. Managing that information and using it productively pose a continuing challenge, particularly in light of the complexity of the U.S. health care sector, with its many different types of providers, services, and settings for care. Health IT has the potential to significantly increase the efficiency of the health sector by helping providers manage information. It could also improve the quality of health care and, ultimately, the outcomes of that care for patients.

Introduction and Summary

The term "health IT" generally refers to computer applications for the practice of medicine. Those applications may include computerized entry systems for physicians' ordering of tests or medications, support systems for clinical decisionmaking, and electronic prescribing of medications. (The appendix provides more information about the different types of health IT and the terminology used in the field.) Some or all of those components are housed in the electronic medical record (EMR). The electronic health record (EHR) is the primary health IT package commonly purchased by a provider. It is an EMR with the capacity to send and receive data electronically and meets the requirements for interoperability.[1]

When used effectively, EHRs can enable providers to deliver health care more efficiently. For example, they can:

- Eliminate the use of medical transcription and allow a physician to enter notes about a patient's condition and care directly into a computerized record;[2]
- Eliminate or substantially reduce the need to physically pull medical charts from office files for patients' visits;
- Prompt providers to prescribe generic medicines instead of more costly brand-name drugs; and
- Reduce the duplication of diagnostic tests.

The adoption and proper use of EHRs could also improve the quality of health care. Among other things, they could:

- Remind physicians about appropriate preventive care;
- Identify harmful drug interactions or possible allergic reactions to prescribed medicines, and
- Help physicians manage patients with complex chronic conditions.

1. Interoperability describes the capacity of one health IT application to share information with another in a computable format (that is, for example, not simply by sharing a PDF [portable document format] file).

2. Many physicians use voice dictation to document and report the results of examinations and procedures. Medical transcription is, in its simplest sense, the process whereby those dictated notes about a patient's care are converted into a typewritten format.

Box 1.

The Office of the National Coordinator of Health Information Technology

The Office of the National Coordinator of Health Information Technology (ONC) manages the federal government's activities in two main areas: the development of standards necessary to achieve the interoperability of the large number of varying applications of health information technology (health IT) and the facilitation of information exchange.

Developing Standards to Ensure Interoperability

To establish processes for identifying standards with which health IT systems must comply and for certifying that the standards are being met, the Department of Health and Human Services (HHS), through ONC, set up the Health Information Technology Standards Panel (HITSP). The panel's overarching task is to promote interoperability in health care—the ability of systems and applications to communicate with each other. HHS also awarded a three-year contract to the Certification Commission for Healthcare Information Technology (CCHIT) to develop and evaluate certification criteria and create an inspection process for health IT.

As the standards process is currently set up, the HITSP develops industrywide health IT standards and recommends them to the Secretary of Health and Human Services, who first "accepts" them and then one year later officially "recognizes" them for use in federal health IT applications. (Such applications include those used by the federal government—for example, in the Veterans Health Administration—and by federal contractors.) The panel uses the one-year period to refine the instructions given to vendors for complying with the standards. The standard-setting process is designed to minimize the number of unworkable standards that are issued rather than to maximize the speed with which standards are set. Private-sector health IT users are not required to comply with the federal standards; nevertheless, the federal standards have become the de facto industry measure for achieving interoperability.

Health IT vendors who wish to have their products certified as compliant with new federal standards can submit those products for examination by CCHIT. Certified electronic health record products should be able to communicate and operate with other similarly certified systems.

Facilitating Health Information Exchange

To ease the electronic exchange of health-related information, HHS funded the creation of prototypes for organizing the components of the National Health Information Network (NHIN). ONC describes the NHIN as a "network of networks," built out of state and regional health information exchanges (and other networks) to link those various networks and the systems they in turn connect. The NHIN's mission is to develop a national capability to exchange standards-based health care data in a secure computer environment.

Many analysts and policymakers believe that health IT is a necessary ingredient for improving the efficiency and quality of health care in the United States. Despite the potential of health IT to increase efficiency and improve quality, though, very few providers—as of 2006, about 12 percent of physicians and 11 percent of hospitals—have adopted it.[3] An important question for policymakers, therefore, is whether—and if the answer is yes, how—the federal government should stimulate and guide the adoption of health IT.

The Bush Administration has set the goal of making an EHR available for most Americans by 2014. In 2004, it established the position of the National Coordinator for Health Information Technology in the Department of Health and Human Services to help bring about the broad adoption of health IT (see Box 1). Other federal agencies that finance health care or provide it directly have also taken steps to encourage adoption or to use health IT in their own clinical operations. Proposals before the Congress would expand the federal government's current activities by, among other things, mandating the use of some types of health IT, such as electronic prescribing ("e-prescribing"); offering financial incentives to providers who use health IT; and increasing the funds available for grants to purchase systems for providers.

This Congressional Budget Office (CBO) analysis focuses on evidence about the benefits and costs of health IT and identifies and analyzes barriers to its adoption. Research indicates that in certain settings, health IT appears to make it easier to reduce health spending if other steps in the broader health care system are also taken to alter incentives to promote savings. By itself, the adoption of more health IT is generally not sufficient to produce significant cost savings.

The most auspicious examples involving health IT have tended to be connected to relatively integrated health systems. For example, Kaiser Permanente is a large integrated delivery system in which the health plan (primarily a health maintenance organization, or HMO) and the providers (physicians and most hospitals and ancillary service providers) exclusively contract with one another to provide care to the health plan's enrollees. For such a system, reducing the number of unnecessary office visits (for patients' concerns or issues that could be handled to their satisfaction through telephone or e-mail consultations), for example, benefits the providers, the health plan, and the patients: It may lower the plan's costs for providing health care—and thus improve its "bottom line"—while minimizing inconvenience for patients. Kaiser has implemented a systemwide EHR in its facilities in some regions. In those areas, physicians have used such consultations to reduce the number of unnecessary office visits (compared with the number in regions without electronic systems).

A number of integrated delivery systems, including Intermountain Healthcare, Geisinger Health System, and Partners HealthCare, have also implemented EHRs across their organizations, and officials believe that as a result the systems have improved the efficiency and quality of the care they provide.[4] Some integrated systems have worked with health IT for decades. Intermountain Healthcare and the Department of Veterans Affairs (VA), for example, both began using computers to help manage clinical data in the 1970s. The VA has successfully implemented a systemwide EHR in a health care system that serves nearly 6 million patients in more than 1,400 hospitals, clinics, and nursing homes (Department of Veterans Affairs, 2008). According to the agency, its use of health IT has reduced its costs and greatly improved the quality of its care. (A recent Congressional Budget Office report [2007a] discusses the VA system in greater detail.)

For providers and hospitals that are not part of integrated systems, however, the benefits of health IT are not as easy to capture, and perhaps not coincidentally, those physicians and facilities have adopted EHRs at a much slower rate. Office-based physicians in particular may see no benefit if they purchase such a product—and may even suffer financial harm. Even though the use of health IT

3. Rates of adoption vary by the definition of health IT used in a particular survey. The rates given here are based on the adoption of health IT systems that include all or most recommended functionalities—such as electronic documentation of providers' notes, electronic viewing of laboratory and radiological results, electronic prescribing, computerized physician order entry, clinical decision support, and interoperability.

4. Those organizations differ from Kaiser in that they generally do not have exclusive contractual relationships with providers. In a typical integrated delivery system, providers are either salaried employees or operate in a close contractual partnership with the organization. Such a system often has a health plan that covers a substantial percentage of its patients but also treats patients who are insured through other, competing plans. Kaiser's exclusive contractual relationship with its providers is uncommon: The arrangement creates financial incentives that more closely resemble those of a staff-model HMO than of a typical integrated delivery system.

could generate cost savings for the health system at large that might offset the EHR's cost, many physicians might not be able to reduce their office expenses or increase their revenue sufficiently to pay for it.

For example, the use of health IT could reduce the number of duplicated diagnostic tests. However, that improvement in efficiency would be unlikely to increase the income of many physicians because laboratories and imaging centers typically perform such tests and are paid separately by health insurance plans. In cases in which a physician performs certain diagnostic tests in the office, reducing the number of duplicated tests would reduce his or her income. As a result, the capacity to avoid duplicating tests might not spur many physicians to invest in and implement a health IT system. Indeed, physicians might have a more powerful financial incentive to purchase additional office diagnostic equipment, for example, than to purchase a health IT system.

The search for improved efficiency in delivering health care has prompted numerous proposals for increasing the adoption of health IT. Two recent studies, one by the RAND Corporation and one by the Center for Information Technology Leadership (CITL), have estimated that about $80 billion in net annual savings is potentially attributable to such technology. Those studies have received significant attention, but for a number of reasons they are not an appropriate guide to estimating the effects of legislative proposals aimed at boosting the use of health IT. To take the RAND study as an example:

- The RAND researchers attempted to measure the *potential* impact of widespread adoption of health IT—assuming the occurrence of "appropriate changes in health care"—rather than the *likely* impact, which would take account of factors that might impede its effective use. For example, health care financing and delivery are now organized in such a way that the payment methods of many private and public health insurers do not reward providers for reducing costs—and may even penalize them for doing so.

- The RAND study was based solely on empirical studies from the literature that found positive effects for the implementation of health IT systems; it excluded the studies of health IT, even those published in peer-reviewed journals, that failed to find favorable results. The decision to ignore evidence of zero or negative net savings clearly biases any estimate of the actual impact of health IT on spending.

- The RAND study was not intended to be an estimate of savings measured against the rates of adoption that would occur under current law, but rather against the level of adoption in 2004. That is, the researchers did not allow for growth in adoption rates that would occur without any changes in policy, as CBO would do in a cost estimate for a legislative proposal.

One significant potential benefit of health IT that has thus far gone relatively unexamined involves its role in research on the comparative effectiveness of medical treatments and practices. Widespread use of health IT could make available large amounts of data on patients' care and health, which could be used for empirical studies that might not only improve the quality of health care but also help make the delivery of services more efficient.

By making clinical data easier to collect and analyze, health IT systems could support rigorous studies to compare the effectiveness and cost of different treatments for a given disease or condition. Then, in response to the studies' findings, they could aid in implementing changes in the kinds of care provided and the way those services were delivered, as well as track progress in carrying out the changes. Such comparative effectiveness studies could lead to reductions in total spending for health care because of the tendency in the current health care system to adopt ever more expensive treatments despite the lack of solid evidence about their effectiveness. The likelihood of such reductions in spending could be increased if the studies' findings were linked to the payments that providers received or the cost sharing that patients faced, particularly if sufficiently strict cost-effectiveness thresholds were used (Congressional Budget Office, 2007b).

If the federal government chose to intervene directly to promote the use of health IT, it could do so by subsidizing that use or by imposing a penalty for failing to use a health IT system. From a budgetary perspective, the subsidization approach is less likely than a penalty to generate cost savings for the federal government because of the costs of the subsidies: Payments would end up going to those providers who would have adopted a health IT system even without a subsidy as well as those providers for whom the subsidy made the difference in their decision to adopt one. However, providers may respond differen-

tially to a subsidy or a penalty depending on how those interventions are presented.

Evidence on the Adoption of Health Information Technology

A well-functioning EHR—comprising electronic documentation of providers' notes, electronic viewing of laboratory and radiological results, e-prescribing, and an interoperable connection via a health information exchange with all other providers and hospitals in a community—could have a significant impact on medical practice (Jha and colleagues, 2006). For example, consider a physician without a health IT system. The physician has a paper chart for each patient, and the following steps may then be involved in the patient's care:

- For each visit, the physician writes notes in the chart—or dictates them for later transcription—about the patient's condition and treatment. The nurse who takes the patient to the exam room records vital statistics (pulse, blood pressure, and temperature) in the paper chart. The physician writes out any needed prescriptions and gives them to the patient to fill at a pharmacy. If the chart contains information on the patient's allergies, the physician might check it to make sure the prescribed drug will have no adverse effects.

- If the physician decides to refer the patient to a specialist for a consultation, a portion of the patient's chart will go to that provider in the form of a letter. In many instances, however, the specialist does not receive a letter and has no information other than what might be noted in a referral form. The patient must then fill out a medical history and other forms required by the specialist. Moreover, unless the referring physician includes results from recent lab and radiology procedures, the specialist may well order similar diagnostic tests. If the physicians are both part of a multispecialty medical group that sees patients in multiple locations, the entire medical chart may need to be delivered to the specialist's office for the visit, risking the loss of the chart.

- Following the patient's visit, the specialist sends a letter back to the referring physician, detailing the results of the encounter. If the condition is serious, the specialist will probably communicate by telephone.

By contrast, consider a physician who uses an EHR. In that case:

- The physician might use a "drop-and-click" menu to note some elements of the patient's condition, reducing the need for handwriting or dictation and eliminating the delay—typically at least a week—in getting the transcribed notes into the chart.

- The EHR would automatically check any prescriptions for errors in dosing, allergies, and drug interactions; if the patient's health insurance plan included a formulary (a list of prescription drugs approved for use), the physician could discuss information about prices and copayments while the patient was still in the office. The EHR might also have a feature that could suggest a drug that might be a better choice, given the specifics of the patient's condition. The prescription would then be delivered electronically to the patient's pharmacy.

- A referral to a specialist would also be handled electronically. The clinical information necessary for the visit to the specialist would be automatically transmitted to that office and would include the results of any diagnostic procedures that the referring physician had ordered, including digitized images from radiological procedures.

- Following the consultation with the specialist, that physician's notes and recommendations would be electronically transmitted back to the referring physician's office, where they would become part of the patient's chart. Ideally, the EHR would substantially simplify operations in physicians' offices; it would have a similar if not a stronger impact in hospitals, given their more complicated care and treatment regimens.

As interest in health IT has grown, several surveys have attempted to measure current levels of its adoption.

- A survey sponsored by the Robert Wood Johnson Foundation (and summarized in Jha and colleagues, 2006) estimated that 24 percent of office-based physicians used an EHR of one type or another.[5] Physicians who worked in solo practices were less likely to have a health IT system than were physicians who worked in

5. The full report of the survey is at www.rwjf.org/files/publications/other/EHRReport0609.pdf.

larger offices (adoption rates of 16 percent versus 39 percent, respectively).

- A 2006 survey of nonfederal office-based physicians by the National Center for Health Statistics reported that 12.4 percent of them used a comprehensive health IT system, and an additional 16.8 percent said they used some type of system.[6]
- Another study, by the Center for Studying Health System Change, compared rates of health IT adoption for two periods: 2000 to 2001 and 2004 to 2005. The study found that adoption of health IT by large practices continued to exceed adoption by smaller practices by as much as 38 percentage points (Grossman and Reed, 2006).

The rates of adoption of EHRs by hospitals appear to be similar to those of physicians, according to recent analyses:

- Although the Robert Wood Johnson Foundation study mentioned above did not estimate the prevalence of EHRs in hospitals (because the available evidence was too limited), it concluded that only 5 percent of hospitals used computerized physician order entry (CPOE) systems, which are a key component of hospital EHRs (George Washington University, Massachusetts General Hospital, and Robert Wood Johnson Foundation, 2006).[7]
- That conclusion is consistent with the findings of a 2005 study by Cutler, Feldman, and Horwitz, which found that 4 percent of hospitals were in full compliance with standards for CPOE, although an additional 17 percent of hospitals had made progress toward obtaining the technology. The Cutler team concluded that hospitals' profitability was not associated with the use of CPOE—a possible reason for the low adoption rates.
- A more recent survey by the American Hospital Association, reported in 2007, found that 11 percent of nonfederal hospitals had fully implemented EHRs. Such hospitals were more likely to be large urban or teaching hospitals than to be small community facilities.

Some international comparisons are available that measure investment in health IT and other parameters, such as rates of adoption and the functionalities that implemented systems provide. That research suggests that the United States lags behind other Western countries (specifically, the United Kingdom, Germany, Australia, the Netherlands, and New Zealand) although perhaps not dramatically, if the measure being used is the adoption of sophisticated IT systems. In several of those countries, rates of adoption of health IT systems among physicians are at or above 80 percent (Schoen and others, 2006). Although the data show that U.S. physicians are far less likely than physicians in those countries to use EHRs in their offices, they are just as or even more likely to use more-sophisticated electronic functions—such as accessing their patients' records remotely. That finding points to the difficulty of comparing rates of adoption—some countries may report high rates, but it is not clear whether their systems are particularly sophisticated or fully utilized (Schoen and others, 2006). In most countries in which rates of adoption are high, the government has heavily subsidized the acquisition of health IT systems by providers (Anderson and others, 2006).[8]

Evidence on the Benefits of Adopting Health Information Technology

No aspect of health IT entails as much uncertainty as the magnitude of its potential benefits. Some analysts believe that the adoption of such systems could provide substantial savings by lowering the cost of providing health care, eliminating unnecessary health care services (such as duplicate diagnostic tests), and improving the quality of care in ways that might reduce costs (by diminishing the likelihood of adverse drug events, for example). Other analysts expect little effect on costs but some improve-

6. In the survey, reported by Hing, Burt, and Woodwell in 2007, an EMR system was deemed comprehensive if respondents answered "yes" to questions about computer applications for ordering prescriptions and tests and for test results and clinical notes.

7. Computerized physician order entry systems are electronic applications that physicians use to order medications, diagnostic tests, and other services.

8. Some analysts point to those trends as indicating that the U.S. government could increase adoption of health IT systems through subsidization but that such support would not necessarily result in the adoption or use of those systems' more sophisticated features. See the later discussion on the question of a potential role for the federal government in speeding adoption of health IT.

ment in the quality of care. Another school of thought holds that health IT could bolster the quality of care but also increase expenditures on health care services—because improvements in quality would stimulate demand for additional services.

Wider adoption of health IT has the potential to generate both internal and external savings:

- Internal savings are those that can be captured by the provider or hospital that purchases the system; they are most likely to be in the form of reductions in the cost of providing health care—that is, improvements in the efficiency with which providers and hospitals deliver care.
- External savings are those that the provider or hospital that purchases the system cannot realize but that accrue to another such provider or perhaps the relevant health insurance plan or even the patient. Such savings might arise, for example, from the newfound ability of participants in the health care sector to exchange information more efficiently.

For integrated systems (such as Kaiser Permanente and the VA), more savings are internal than would be the case for providers that are not part of an integrated system. For example, integrated systems often have contracts with health insurance plans entailing that the systems assume the financial risk for the cost of prescription drugs and diagnostic tests, among other things, for the patients covered by those plans. As such, the systems can capture the savings from shifting their prescribing patterns toward generic drugs and reducing the number of duplicated diagnostic tests.

Different reimbursement arrangements might also shift savings from the external to the internal category in instances in which a provider is not part of an integrated system. A provider who was not affiliated with an integrated system but who treated HMO patients might be similarly rewarded for appropriate formulary management, which would shift those savings from being external to internal. But if the provider was paid purely on a fee-for-service basis, the savings would remain an external benefit.

The extent to which the use of health IT generates savings and how those savings are distributed across the health care sector can greatly influence the speed of broader adoption and use of those technologies. If health IT's adoption primarily produced internal savings for the providers and hospitals that purchased the systems—that is, if the purchasers of the systems were able to capture most of the cost savings that arose from using the technology—then the adoption of health IT would probably proceed apace without any need for intervention by the federal government. But if health IT appeared primarily to provide external savings—that is, if those who adopted the systems were unable to garner a sizable share of the benefits—then the adoption of such systems might proceed very slowly without additional governmental support.

Of the research to date, most studies examine how health IT might make the delivery of health care services more efficient, and they tend to focus on a particular clinical practice or area of potential savings. The evolving nature of the U.S. health care marketplace and of health IT has made it difficult to apply the results of such research to national estimates of the impact of health IT on the costs and quality of care. The few studies that have attempted to do so appear to have substantial shortcomings that limit their usefulness in analyzing legislative proposals. And some potential areas of research and analysis remain largely unexamined. They include the ways in which the delivery of health care services might change in response to the efficiencies that health IT offers and how the large amounts of clinical data available through EHRs could contribute to analyses of the comparative effectiveness and cost-effectiveness of different treatments.

Underlying any consideration of the potential benefits of health IT are the financial incentives that influence the behavior of health care providers, hospitals, health insurance plans, and patients. The use of information technology might lead to greater efficiency in delivering health care and to higher-quality services, but financial incentives could constrain many of those positive changes. For example, EHRs could provide physicians with a useful tool for reducing the number of unnecessary or duplicated laboratory tests that they ordered, but the likelihood of such reductions could depend on factors such as whether physicians were compensated for controlling the use of laboratory testing (as in some managed care plans) or whether they derived income from ordering more tests. How well health IT lives up to its potential depends in part on how effectively financial incentives can be realigned to encourage the optimal use of the technology's capabilities.

A general indication of health IT's usefulness in improving efficiency and quality can be seen in the adoption of such applications by integrated health care delivery systems (such as staff-model HMOs). By their nature, those types of systems are able to garner more of the benefits of health IT than nonintegrated providers can. Not surprisingly, such entities have relatively high rates of adoption of health IT.

Estimates of the Potential National Savings from Widespread Adoption of Health IT

Two studies, one by the RAND Corporation and one by the Center for Information Technology Leadership, report estimates of the potential net benefits that could arise nationwide if all providers and hospitals adopted health information technology and used it appropriately. (For the RAND research, see Girosi, Meili, and Scoville, 2005; and Hillestad and others, 2005. The CITL study is reported by Walker and colleagues, 2005, and Pan and others, 2004.) Both studies estimated annual net savings to the health care sector of about $80 billion (in 2005 dollars), relative to total spending for health care of about $2 trillion per year. The studies, however, measured different sources of such savings. The RAND research focused primarily on savings that the use of health IT could generate by reducing costs in physicians' practices and hospitals, whereas the CITL study limited its scope to savings from achieving full interoperability of health IT, explicitly excluding potential improvements in efficiency within practices and hospitals.

Neither the RAND nor the CITL study, however, is an appropriate guide to the budgetary effects of legislative proposals aimed at increasing the use of health IT. For example, both studies attempt to measure the *potential* impact of widespread adoption of health IT, not the *likely* impact; a CBO cost estimate, by contrast, would estimate the likely effect. And whatever the net savings to the health care system as a whole, the impact on the federal budget would be far smaller than that. Medicare and the federal share of Medicaid together account for only about one-fourth of total spending for health care services. Moreover, some types of savings, such as those from improved efficiency within a physician's office, could not be realized by Medicare without revising payment rates to physicians, which usually requires legislation. There are also other reasons, discussed in detail below, that the studies are not appropriate for estimating the impact of a legislative proposal. The bottom line is that both studies appear to significantly overstate the savings for the health care system as a whole—and by extension, for the federal budget—that would accrue from legislative proposals to bring about widespread adoption of health IT.

The RAND Analysis. The RAND analysis itself notes that its estimate is of health IT's potential savings and costs: "We use the word *potential* to mean 'assuming that interconnected and interoperable EMR systems are adopted widely *and used effectively* [emphasis added].' Thus, our estimates of potential savings are not predictions of what will happen but of what could happen with HIT [health information technology] *and appropriate changes in health care* [emphasis added]" (Hillestad and others, 2005, p. 1104). By incorporating the assumption of "appropriate changes in health care," the study's estimate deliberately does not take into account present-day payment incentives that would constrain the effective utilization of health IT, even if the technology was widely adopted. A key reason for the currently low rate of adoption of health IT may be that, given the way health care financing and delivery are now organized, the payment methods of both private and public health insurers in many cases do not reward providers for reducing some types of costs—and may even penalize them for doing so. Most providers are paid on a fee-for-service basis; if they were to reduce health care costs by providing fewer or less expensive services, they would have to submit lower charges to insurers, and as a result, their payments would decline. If technologies were adopted without changing those incentives, then the RAND estimate would be too high because the "appropriate changes in health care" assumed in the study would not have been made.

Another issue raised by the RAND study is that it was based solely on empirical studies from the literature that found positive effects for the implementation of health IT systems. Researchers offered this rationale: "We chose to interpret reported evidence of negative or no effect of HIT as likely being attributable to ineffective or not-yet-effective implementation" (Hillestad and others, 2005, p. 1105). However, a number of studies of health IT published in peer-reviewed journals have failed to find favorable results (for example, Garrido and others, 2005; Overhage and others, 2001). Consequently, the decision to ignore evidence of zero or negative net savings clearly biases—possibly quite substantially—any estimate of the actual impact of health IT on spending.

The methods researchers used in the RAND study would not be appropriate for assessing the savings that a legislative proposal would generate because, unlike the procedures used for a CBO cost estimate, savings were not measured relative to a current-law baseline. Instead, RAND researchers used the level of health IT adoption in 2004 as a baseline and assumed for comparison purposes that adoption remained at that level during the period over which they projected savings. A CBO cost estimate, however, would reflect the continuing growth in health IT adoption that would occur without any change in law. To the extent that health IT adoption has grown since 2004 and will continue to grow, that growth reduces the possible cost savings, compared with RAND's estimate, that could come about by encouraging wider adoption.

In several specific parts of the RAND analysis, the savings that would accrue from widespread adoption of health IT appear to be overstated. For example, it is likely that the RAND researchers significantly overestimated savings for health IT from reductions in the average length of stay in a hospital.[9] The RAND researchers assumed that reductions in lengths of stay would result in proportional reductions in costs. They noted, though, that health IT would primarily reduce lengths of stay by speeding up how quickly procedures were performed. If that is the primary channel through which lengths of stay are reduced, at least some costs will simply be shifted to earlier days in the stay and not eliminated—which argues for a reduction in costs that is less than proportional to the reduction in the average length of stay.[10]

The RAND estimate also failed to take into consideration that hospitals often achieve reductions in their average-length-of-stay measures by shifting patients to another health care site, such as a skilled nursing facility. That practice produces fewer net savings because although such shifts reduce costs in the hospital sector, they increase them in the skilled-nursing sector.

Another issue raised by the RAND analysis is the method that the researchers used to estimate savings from eliminating or reducing the use of paper medical records: They based their findings on the experiences of recent adopters of electronic medical record systems and then applied the savings to all physicians' offices. Yet that assumption might not be realistic for small practices (those that have fewer than four practitioners) because the same person who pulls charts in those offices typically also schedules appointments, administers billing, and performs other administrative tasks. Thus, although the overall workload of such staff might be diminished, those practices would find it difficult to reduce their costs by eliminating support staff positions. About half of physicians are in small practices; consequently, RAND's estimate of savings in this area is probably overstated.

Finally, the RAND study did not consider the broader impact that reducing at least some types of health care costs would have on the utilization of services. If the widespread use of health IT reduced the cost of health care services, that decline would eventually be reflected in lower prices and copayments for patients—and as prices fell, patients would demand more care. Even if the researchers' underlying assumptions about savings are accurate, the net effect of more use of health IT would probably still be lower overall costs than would otherwise be the case—but the reduction would not equal the amount that the RAND analysis has suggested.

The Study by the Center for Information Technology Leadership. Many of the same concerns raised by the

9. The study also makes what are probably optimistic assumptions about the savings from more efficient use of prescription drugs (for example, from switching to generic medications). It relies on the results of three studies of the effects of health IT on drug utilization, each of which has significant drawbacks. Two of the studies were conducted by a private consulting firm and were not published in a peer-reviewed journal; one of those studies was based on the experiences of only one clinic, and the other was an estimate of potential savings from using a particular vendor's e-prescribing product. The third study was based on the opinions of an expert panel, which estimated savings only for capitated plans and not for fee-for-service plans. (In capitated plans, providers give specified services to patients for a fixed monthly fee, regardless of the amount of care each patient actually receives.) The RAND researchers implicitly assumed that savings in the fee-for-service sector would be the same as those in the capitated sector. That assumption probably overstates the impact of the use of health IT because it ignores the very different set of economic incentives that capitated providers face compared with those faced by providers who are paid on a fee-for-service basis.

10. Furthermore, the estimate of the reduction in the average length of stay was based on the average reduction reported in three studies. Two of them were single-hospital case studies that reported very different reductions—5 percent and 30 percent—in average stays; the third study was based on data from 1996, a period during which hospitals were significantly reducing their costs per admission in response to pressures from the spread of managed care. Today, more than 10 years after hospitals first experienced such forces, it is unlikely that additional savings would be as easy to obtain as they were during that earlier period.

RAND analysis apply to the study conducted by CITL. For one thing, the authors did not fully consider the impact of financial incentives in their analysis; they did not take into account the effect of those incentives on the use of health IT by providers, hospitals, and insurers or the effect on patients' demand for health care services in the event that health IT reduced the cost of care. The CITL analysis also estimated the $80 billion in potential savings against a baseline of little or no information technology use. Savings would come, the study suggests, by moving the U.S. health care sector from Level 1 (with completely nonelectronic data and with all information written down or shared verbally) to Level 4 (with all standardized machine-interpretable data). The impact of moving from the current level of adoption to Level 4 would be much smaller because many of the nation's health care providers already operate above Level 1 in their use of technology. (For example, Level 2 includes the use of fax machines, which are widely available in physicians' offices today.) As the report by Pan and others (2004) states, "the model [used in the study] does not account for the 'current state of affairs'" (p. 17).

Like the assumptions in the RAND analysis, some of those that the CITL study used appear to be overly optimistic:

- The CITL study estimated that the administrative cost of a laboratory test (encompassing both the provider's and the lab's expenses) was about $40 and that widespread interoperability could save about $38 per test—producing estimated national savings on lab tests of about $25 billion annually. However, the results of another analysis (Baker, 2005) raise doubts that the administrative cost of a lab test could possibly be as high as $40 to begin with.

- The CITL researchers assumed that fully interoperable health IT systems would eliminate 95 percent of avoidable tests, resting that assumption on the belief that physicians would choose to override the system's warnings on such tests only 5 percent of the time. Other estimates of avoidable tests typically report higher override rates, however (Bates and colleagues, 1999b).

- The CITL study also assumed that at the highest level of health IT adoption, only 0.001 percent of prescriptions would require a phone call between a pharmacist and a prescribing physician. Certainly, greater implementation of health IT could significantly reduce the number of those telephone calls, but the reduction that the CITL researchers assumed does not appear to be attainable.

Evidence on Improvements in Efficiency from Adoption of Health IT

The potential of health IT to reduce spending for health care depends in large part on its ability to make care more efficient by cutting the cost of delivering services, avoiding redundant services, and improving providers' productivity. Evidence from the literature on health IT, however, does not uniformly support the possibility of such savings. The potential for savings appears to depend heavily on their source and whether that source is in a hospital or in an ambulatory care setting (such as a clinic or a physician's office). In addition, savings are difficult to assess because the trimming of costs in one area of a physician's practice, for example, may be offset by increased costs or reduced efficiency in another area.

Estimating the impact of some potential sources of savings, especially those arising from greater exchange of information among providers, insurers, and patients, is especially difficult because health IT networks are in an early stage of development. Furthermore, health care providers and hospitals that were early adopters of health IT may have been motivated by particular characteristics of their organizations or operations that made them more likely than nonadopters to achieve benefits from health IT—in which case the outcomes they have seen might not be generalizable. Evidence of savings in the health care sector as a whole from adopting health IT is also limited.

Nevertheless, savings could accrue in a number of areas: the handling of medical records, the redundancy of diagnostic tests, the prescribing and use of drugs, the productivity of caregivers, and the length of hospital stays. Savings could also arise if a comprehensive interoperable health IT system, including a health information exchange that facilitated the sharing of health care information, was implemented.

Eliminating Paper Medical Records. Providers typically adopt EHRs with the intention of replacing their paper medical record systems. Research has shown that physicians' offices can realize savings from reducing the pulling of paper charts and the use of transcription services (Wang and others, 2003). Those savings might not apply

in very small practices, however, because such offices typically have low but relatively fixed costs related to medical records and the physicians who work there are much more likely than those in larger practices to write notes manually in the charts. Savings from less pulling of charts is typically accomplished by reducing the number of staff required to do so. But that type of staff reduction may be impossible in a small practice if the employee who pulls charts also performs other tasks (such as scheduling and billing), as is usually the case.

The extent of savings to be gained from eliminating paper medical records would also depend on how well a physician used the new system. For example, most EHRs allow physicians to create templates that can significantly reduce the amount of time spent typing in notes, ordering medications, and so forth. But making effective use of templates and other features of EHRs would require a physician to make a substantial up-front investment in time to create templates suited to his or her style of practice and to learn how to use them effectively.

Moreover, many physicians would have to alter the way they practiced medicine to make a health IT system work for them, and not all physicians appear willing to make such changes. For example, some providers who have already installed EHRs continue to maintain paper charts; Miller and colleagues (2005) noted that 10 of 14 practices they examined stopped pulling charts—which implies that 4 practices still did not. Presumably, as physicians became more accustomed to the new electronic systems, they would stop using paper charts.

Avoiding Duplicated or Inappropriate Diagnostic Tests. The possibility of duplicating diagnostic tests arises when patients are seen by different physicians in multiple facilities or when records make it difficult to discern which tests have or have not been administered. Inappropriate testing can also occur because of a physician's habits or preferences, and a pattern of such testing may be easier to identify and change if information is in an electronic format. For the most part, any savings from avoiding duplicate or inappropriate diagnostic tests would be realized primarily by a health insurance plan, not a health care provider. Thus, the extent to which savings in this area would actually benefit providers is unclear.

Despite somewhat mixed results, most evidence suggests that EHRs have the potential to reduce the number of inappropriate laboratory tests. Bates and colleagues (1999b) found that providers canceled 69 percent of lab tests when alerted by an electronic notice that a test appeared to be redundant. That result, when combined with a related estimate that 9 percent of all lab tests appeared to be redundant (Bates and colleagues, 1998b), implies that EHRs with a notice of redundancy could reduce the number of laboratory tests by about 6 percent (69 percent of 9 percent). Consistent with this estimate, research by Tierney and others (1987) found that showing physicians information about a patient's previous lab work when they ordered a test in a clinic's order entry system and reminding them of the date of the patient's last test reduced the volume of tests ordered by about 6 percent. A second study reported by Tierney and colleagues in 1988 found a drop of about 9 percent in lab charges. The Tierney research, however, is based on data collected in the mid-1980s, and its applicability in today's health care environment is questionable.

By contrast, an evaluation of laboratory services in the outpatient facilities of two separate Kaiser Permanente regions that adopted health IT systems did not find a difference in the number of duplications as a result (Garrido and others, 2005). It is unclear what specific methods the systems used to prevent the duplication of tests and whether using the same methods shown to be effective in other studies would also have been effective for the Kaiser facilities. Moreover, as a fully integrated HMO, Kaiser may have already used non-health IT methods to reduce the number of unnecessary tests. For that reason, the results of the study may not be applicable to the non-HMO health care sector.

Reducing the Use of Radiological Services. Less information is available about the impact of EHRs on the use of radiological services. The Garrido team's 2005 study of Kaiser facilities also examined imaging and, as was the case with laboratory testing, found no change following the adoption of health IT. A study by Harpole and others (1997) found that providing physicians with evidence-based critiques of certain types of imaging at the point at which a provider orders a radiological study (that is, providing a clinical decision support system) had no significant effect on whether or not a test was ordered but did influence the types of radiological images that were taken. Health IT thus appears to ease the job of monitoring the use of radiological services, but there is little evidence that it helps control costs.

Promoting the Cost-Effective Use of Prescription Drugs. Evidence suggests that in hospitals, features of EHRs—specifically, clinical decision support (CDS) and computerized physician order entry—could help reduce the cost of prescription drugs by prompting providers to use generic alternatives, lower-cost therapies, and, for more complex drug regimens, cost-effective drug management programs (Mullett and others, 2001; Teich and others, 2000). In outpatient settings such as clinics and physicians' offices, health IT—specifically, e-prescribing—could alter prescribing practices in the direction of lower-cost drugs.[11]

Little empirical evidence exists, however, on the effectiveness of health IT to help manage the use of prescription drugs in either hospital or outpatient settings. One factor limiting cost savings is that physicians generally do not benefit financially from effectively managing the utilization of drugs. Instead, any financial gain is usually realized by health plans or pharmacy benefit management companies (PBMs). Moreover, because of their strong incentives to hold down costs, health plans and PBMs may already be capturing a substantial portion of those savings.

Improving the Productivity of Nurses and Physicians. Several analyses have investigated whether EHRs in hospitals and outpatient facilities might increase the productivity of nurses and physicians. A 2005 summary of research by Poissant and others suggests that when health IT systems were in use, nurses in hospitals saw drops in the time required to document the delivery of care but physicians saw increases in documentation time. That finding implies that hospitals might be able to reduce their spending on nurses but not necessarily on physicians. Those studies, however, may have identified a short-term effect among physicians—that is, before providers had become accustomed to the new system and incorporated the new methods into their daily routine. In addition, most studies have examined health IT in teaching hospitals, and the generalizability of their results to more typical community hospitals may be limited.

Few studies have measured the effect of EHRs on physicians' efficiency in outpatient settings, and those that have show mixed results (Pizziferri and others, 2005; Overhage and others, 2001). The lack of demonstrated gains in productivity as a result of implementing health IT systems may be partially due to some providers' tendency to duplicate the system's functions by continuing to do some tasks manually, such as maintaining paper records (Gans and others, 2005; Overhage and others, 2001). Physicians that eliminate or reduce their use of transcription services by adopting a health IT system may see savings, though. Intermountain Healthcare maintains that its savings from reducing transcription costs alone (as high as $12,500 per year for some physicians) contributed substantially to paying for its EHR, which cost about $2,500 per physician.[12]

The measures of productivity that researchers have used in such studies are relatively narrow and do not exhaust the ways in which the use of health IT might affect health care workers' productivity. For example, the improvements in documentation that EHRs provide might help physicians improve their caregiving: If such systems led providers to spend more time documenting the care they delivered, the end result might be higher-quality care. Health IT systems might also enable a physician to provide other services for patients, such as helping them get appropriate preventive care, providing better education about their health, and assisting them in making choices from among an array of treatment options.

Reducing the Length of Hospital Stays. Some research (Mekhjian and others, 2002) suggests that health IT could reduce the average length of a hospital stay by 5 percent or more by speeding up certain hospital functions (such as ordering and completing tests, ordering and administering medications, and collecting information and preparing for patients' discharge) and by avoiding costly errors (such as adverse drug reactions that could lead to delays in discharging patients). Other research has produced mixed results.

11. Wang and colleagues (2003) estimate that health IT systems in the offices of primary care physicians could save 15 percent of total drug costs per year in capitated plans, but that number is based on the opinions of an expert panel and not on actual data. Given that capitated plans already have a powerful incentive to encourage the use of less expensive drugs, an effect of 15 percent may be overly optimistic. Some research also indicates that some providers apparently have trouble using the prescribing functions in health IT systems (Wang and others, 2003; Grossman and others, 2007).

12. Personal communication to CBO from Len Bowes, Senior Medical Informaticist, Intermountain Healthcare, May 18, 2008; Clayton and others (2005).

As discussed earlier with regard to the RAND study, reductions in the average length of hospital stays are unlikely to result in cost savings of a similar proportion to the reduction in average length of stay, such as that found by the Mekhjian research team (that is, of 5 percent or more). In particular, reductions in stays that stem from performing various hospital functions more quickly are not likely to cut costs as much as will reductions that result from improving care—for example, by diminishing the number of adverse drug reactions. Reducing the length of time required to process a lab test or diagnostic image from the time it is ordered to the moment the results are delivered only speeds up the delivery of care; it does not necessarily reduce the amount of care provided or its associated cost.

Moreover, the promise of shortening the average length of time that a patient stays in the hospital might not be very compelling to a typical institution because it already faces a sizable financial incentive to pare its costs per admission. Payment incentives in the Medicare program that encourage hospitals to reduce their per admission costs have been in place since the early 1980s; the average length of stay has fallen steadily since then, although recently, the downward trend has slowed (National Center for Health Statistics, 2007). In all likelihood, the majority of hospitals have already made most of the changes necessary to maximize their payments for the care of Medicare patients, and the additional money they would get from the next increment in reducing the average length of stay might not be worth the additional investment in health IT needed to produce it. Moreover, the payment methods for hospital stays that are common among private health plans—per diem payments (that is, a set fee per day in the hospital)—may work against shortening those stays.

Evidence on Improvements in the Quality of Care from Adoption of Health IT

The use of health IT applications has the potential to increase patients' safety within the overall health care system and improve the quality of the care that physicians and other caregivers provide. When used for prescribing medications, EHRs and their computerized physician order entry features can help prevent costly medical errors by checking patients' medical records and the list of medications they are taking, screening the list for possible drug allergies and drug interactions, and alerting physicians to any potential conflicts. The quality of health care could be improved through the use of clinical decision support systems to remind physicians to schedule tests, help diagnose complicated conditions, and more effectively implement appropriate protocols for treatment. In addition, the extensive data about patients that the use of EHRs generates might allow researchers to inform evidence-based guidelines and compare the effectiveness of different treatments for different patients as well as the effectiveness of different designs for the delivery of care.[13]

Like the benefits from delivering care more efficiently, however, benefits that stem from improving the quality of care—and the potential cost savings that accompany them—are primarily realized by patients and insurers rather than the providers who generally make the investment in health IT that leads to those benefits. Seldom are providers directly compensated for improvements in the quality of their care. Indeed, if those improvements, for example, cut down the number of hospitalizations and office visits, they might actually reduce a provider's compensation, especially in the case of providers paid on a fee-for-service basis (as is commonly the case). Improvements of that kind might enhance a provider's reputation and thereby attract more patients over the long run. But those outcomes would not necessarily increase a provider's income or lower his or her costs. (Also, some providers might discount the value of those benefits because they already had what they considered to be a sufficient number of patients and felt no need to add new ones.)

A possible benefit of improving care through the use of health IT, however, might be to lower malpractice insurance costs for providers. A number of firms that sell liability insurance for physicians are beginning to offer discounted premiums to practices that use EHRs.[14]

Avoiding Adverse Drug Events. One of the most common types of medical error—and a focus of much research—is a so-called adverse drug event, in which a patient has an adverse reaction from being administered an inappropriate medication. Research examining serious errors in the medications that patients receive in hospitals has shown that such mistakes are both common and potentially expensive and that they could be substantially reduced

13. Evidence-based guidelines are recommended methods of treatment that are based on empirical research.

14. Personal communication to CBO staff from Mark Leavitt, Executive Director, Certification Commission for Healthcare Information Technology, February 7, 2008.

through greater use of health IT. Studies have found potential reductions in error rates from the use of health IT of between 50 percent and over 90 percent (Potts and others, 2004; Bates and others, 1999a, 1998a; Evans and others, 1998).[15] In a few other studies (Han and others, 2005; Nebeker and others, 2005; Upperman and others, 2005), researchers did not find that the rate of adverse drug events was lowered—although that result might have had more to do with the quality of the health IT systems being used than the performance of such systems in general.

Much less evidence is available on how EHRs affect adverse drug events in outpatient settings. One study (Gandhi and others, 2005) found no evidence of reductions in such errors but qualified those findings by pointing out the lack of sophistication of the systems used by the physicians in the study.

By maintaining a list of a patient's allergies and current medications, a health IT system makes it easier for doctors to check for drug and drug-allergy interactions and for contraindications (stemming, for example, from the results of a laboratory test) to prescribing a particular medication. Health IT systems can also speed providers' access to lists of possible side effects of particular drugs, which allows physicians to quickly verify whether a drug is appropriate for a given patient. Most EHRs (with or without a CPOE feature) automatically check for allergy and drug interactions and for the appropriateness of a particular medication and warn the physician of potential conflicts. Such systems can also provide doctors with standardized dosing amounts or recommended dosing guidelines that can help prevent errors in overmedicating and undermedicating patients. Further, the automated prescribing practices possible with CPOE features may help reduce errors resulting from miscommunication among physicians, pharmacists, patients, and nurses.

Because medical errors can lead to the use of additional health care services, health IT systems that successfully reduce such errors may also diminish expenditures on health care. The effectiveness of health IT in reducing errors, however, depends largely on the type, setting, and quality of the systems. One study (Jha and others, 2001) found that 1.4 percent of hospital admissions were caused by adverse drug events, and 28 percent of those were considered preventable. The average cost of treating the consequences of a preventable adverse drug event, researchers estimated, was more than $10,000. Another study (Honigman and others, 2001) determined that adverse drug reactions that arose through care provided at an outpatient facility and that required hospitalization occurred at an average annual rate of 3.4 for every 1,000 patients. Avoiding even a fraction of the errors that now occur in inpatient and outpatient settings could yield significant savings.

Some of the potential savings from errors originating among outpatient providers, however, are probably already being realized by existing electronic systems. Even though today very few prescriptions (an estimated 7 percent in 2008) are handled exclusively through electronic means, some aspects of prescribing are almost universally electronic. For example, nearly all pharmacies connect electronically to health plans when they enter a patient's prescription into their computer system. At that point, the health plan has data on most if not all prescriptions that the patient has—and the pharmacist has that information through the health plan's system—and both the health plan's and the pharmacy's systems typically check for drug interactions and possible allergic reactions. (If a PBM is also involved, it may undertake some checking as well.) A provider's health IT system might still contribute to improving the quality of a particular patient's care if, for example, the patient had a result from a recent lab test that might suggest something about his or her response to a particular medication—although it is becoming more common for health plans also to have access to lab results (SureScripts, 2007).

Expanding Exchanges of Health Care Information. The adoption of interoperable health IT systems could ease exchanges of health care information, which might not only improve the quality of care but also reduce costs. The effects of expanding such exchanges include:

- Lessening the duplication of diagnostic procedures (because results could more easily be made available to other providers);
- Preventing medical errors (because providers would have more accurate and more complete information about the patients they are treating); and

15. Not all serious medication errors, however, lead to adverse drug events. About 57 percent of all such errors have no adverse effect on the patient; they are often called "potential adverse drug events" (Bates and others, 1998a).

- Lowering administrative costs (because automated transfers of test results, clinical information, and prescriptions among health insurers, physicians' offices, hospitals, laboratories, imaging facilities, pharmacies, and public health agencies would be less costly than manual transfers).

The realization of other benefits from greater exchange of information, such as the availability of more data for medical research, lies further in the future (see the later discussion).

An increased capability to exchange information is not sufficient, however, to reduce costs and improve the quality of health care because existing mechanisms for paying providers do not create incentives to reduce costs by acting on that information. Indeed, in some cases, those mechanisms create incentives that discourage efforts to cut costs. For example, a provider who is paid on a fee-for-service basis might refrain from ordering a diagnostic test if the results of the same test recently ordered by another provider were in the patient's EHR (owing to health information exchange); however, that fee-for-service physician would have no financial incentive to do so. Moreover, if the physician could perform the diagnostic test in his or her office by using office-based equipment (such as an X-ray machine), the stronger financial incentive would be to ignore the previous test's results.

One potential source of empirical evidence on the benefits of health information exchange is the experience of integrated health systems that use systemwide EHRs—although separating out the impact of expanded information exchange from other health IT-related effects is difficult. The case of the VA illustrates some of the empirical challenges. The agency reports that its cost per patient has stayed relatively flat over the past several years, which it attributes in part to reducing the number of full-time-equivalent employees per 1,000 patients by 37 percent at the same time that the cost of medical care has been rising by about 6 percent per year (Evans, Nichol, and Perlin, 2006). After an adjustment for changes over time in the mix of patients that the VA sees, its spending per enrollee grew by a total of 1.7 percent in real terms from 1999 to 2005 (0.3 percent annually)—a rate significantly below Medicare's real rate of growth in costs per capita of 29.4 percent (4.4 percent per year) over the same period (Congressional Budget Office, 2007a).

Those results cannot be attributed solely to the impact of the VA's health IT program, however, because the VA differs in many ways from Medicare and other parts of the health system. In addition, the VA adopted other efforts to control costs during the 1999–2005 period; for example, it switched from a labor-intensive inpatient system to a system of outpatient clinics.

Expanding the Practice of Evidence-Based Medicine. Part of the motivation for the broader adoption of health IT has come from evidence of deficits in the quality of health care in the United States and large unexplained geographic variations in the utilization and cost of care (McGlynn and others, 2003; Congressional Budget Office, 2008).[16] Many health IT systems have some type of clinical decision support function—such as automated reminders about preventive care—that could help physicians adhere to evidence-based guidelines, avoid preventable errors, reduce the use of procedures that have no demonstrated clinical value, ultimately improve the quality of the care that they provide, and possibly cut costs. Measuring the effects of using clinical decision support on the costs and outcomes of care for patients is difficult, though. At this stage, empirical research has shown that the use of health IT in general and CDS features in particular can improve the quality of patients' care, but it has not shown that improving care can, in turn, improve patients' health or reduce costs.

Several studies suggest that CDS features can improve the quality of health care:

- Garg and colleagues (2005) reviewed studies on clinical decision support and found that most such functions improved the performance of practitioners. Reminders about using established guidelines for preventive care were found to be the most effective feature. However, few of the studies that Garg reviewed also reported improved outcomes for patients.

- Asch and others (2004) found that the quality of care received by patients in the VA system, which uses an EHR that includes CDS tools, was superior to that received by a nationally representative sample of the

16. For example, the rate of back surgeries varies by state from just under 2 per 1,000 Medicare enrollees in Hawaii to more than 9 in Wyoming.

- population.[17] The VA practitioners' adherence to recommended-care guidelines was greatest for indicators of quality care that were associated with a VA performance measurement program (in which the care that practitioners provide is tracked and monitored and feedback is given to each practitioner about his or her performance). However, as CBO's 2008 report on geographic variation in health care spending notes, the VA medical system varies substantially across the nation in patterns of clinical practice, despite the fact that managers track providers' compliance with national guidelines for the treatment of many medical conditions.

- Consistent with the results from the VA, recently released data from a Medicare demonstration project of the Centers for Medicare and Medicaid Services (CMS) suggest that practitioners respond to rewards for high-quality care (Lindenauer and others, 2007). In that study, researchers coupled a CDS system with incentives to achieve a higher level of quality.

Yet a CDS capability does not always improve the quality of patients' care, and even if it could, that improvement might not have the desired effect on costs. According to a broad range of research (Crosson and others, 2007; Linder and others, 2007; Sequist and others, 2005; Tierney and others, 2005, 2003; Murray and others, 2004; Subramanian and others, 2004; Harris and others, 1998), CDS functions have failed to increase physicians' adherence to evidence-based standards of treatment for a wide variety of conditions, including chronic obstructive pulmonary disease, heart disease, diabetes, coronary artery disease, chronic heart failure, chronic renal insufficiency, and hypertension.

The failure to find positive effects from the use of CDS tools for those conditions could be due more to misaligned financial incentives than to limitations in the technology itself, or it could be attributable to the poor quality of some CDS features. Like all aspects of health IT, such tools are not uniform, nor are they all used equally well. The systems have been variously criticized as "cookbook" medicine, as not fitting well with the particular patterns of work in a given practice, or as unable to positively affect providers' behavior (Frisse, 2006; Sittig and others, 2006; Bates and others, 2003). With time, the quality of such systems may improve, and users may be better able to routinely achieve the positive effects noted in some studies.

Better CDS tools could also boost spending in some ways. For example, the use of some features (such as reminders to practitioners about screening tests and other preventive services) could increase spending for health care by encouraging the utilization of some additional services. Moreover, physicians might order some recommended preventive treatments that were not cost-effective—because even though such practices might improve the health of patients, their costs might not be completely offset by reductions in future health care spending.

Generating Data for Research on Comparative Effectiveness and Cost-Effectiveness of Treatments. Proponents of the adoption of health IT note its potential to provide a massive source of new health care data—once patients' identifying information has been removed and the data have been standardized and assembled in a repository—for research on the comparative effectiveness and cost-effectiveness of medical treatments. The data could provide more-comprehensive information about the health histories of different patients and about the outcomes of their treatments than has previously been available. And the depth and breadth of the data would make it easier to take into account the differences among patients who receive different treatments and allow researchers to assess a broad set of outcomes.

Some work of that nature is being conducted through the HMO Research Network and through a broader network of centers having access to electronic databases that was established in 2005 by the Agency for Healthcare Research and Quality (Congressional Budget Office, 2007b). The knowledge gained from such studies could:

- Improve treatment protocols and methods,

- Lead to better outcomes for patients,

- Lower costs for health care,

17. Judged on the basis of 348 indicators used to assess the treatment of 26 conditions, best-practices care was provided for 67 percent of VA patients compared with 51 percent of non-VA patients. Particularly large differences between the two kinds of patients were seen in quality measurements of chronic disease care and preventive care.

- Improve postmarketing surveillance of pharmaceuticals (to ensure that a drug is effective and has no unexpectedly harmful side effects) that have been approved by the Food and Drug Administration,
- Help target public health efforts, and
- Support early detection of outbreaks of diseases.

The Costs of Implementing Health Information Technology

Implementing a health IT system, whether in a single physician's practice or in the multiple venues of an integrated health care delivery system, involves significant expenditures. Total costs for a health IT system include:

- The initial fixed cost of the hardware, software, and technical assistance necessary to install the system;
- Licensing fees;
- The expense of maintaining the system; and
- The "opportunity cost" of the time that health care providers could have spent seeing patients but instead must devote to learning how to use the new system and how to adjust their work practices accordingly.

The costs of implementing health IT systems vary widely among physicians and among hospitals, depending on the size and complexity of those providers' operations and the extent to which a system's users wish to perform their work electronically.

Owing in part to the wide variation in costs, evidence on expenditures for implementing health IT systems tends to be limited and somewhat conflicting. The initial investment and the cost of maintenance can be fairly easily determined—providers can obtain bids for a system from one or more vendors and thus have a relatively accurate estimate of what those costs will be once they have selected a vendor. Much less predictable is the productive time lost in learning to use the system and in adjusting patterns of work. Yet that nonmonetary investment may be an important factor in whether providers will be able to use the system effectively.

Social costs may also be a factor in providers' adoption and use of health IT, and one such potential cost is the risk of lost privacy. Purchasers of health IT systems, which must comply with stringent federal and state rules and standards intended to protect patients' privacy, bear the monetary costs associated with such protection. Given the ease with which information can be exchanged between health IT systems, patients whose physicians use them may feel that their privacy is more at risk than if paper records were used. (Health IT might also, though, support efforts to strengthen privacy by making it easier to track who accesses a patient's medical record.)

The Cost of Health IT Systems for Physicians' Offices

Estimating the total cost of implementing health IT systems in office-based medical practices is complicated by differences in the types and available features of the systems now being sold and differences in the characteristics of the practices that are adopting them. Many existing studies of the costs of implementing such systems lump together all direct costs (for hardware, software, licensing fees, installation, and training), do not include estimates of indirect costs (for example, practitioners' reduced productivity during the early stages of adoption), and spread the costs of implementation over different time frames.

The few detailed studies available report that total costs for office-based EHRs are about $25,000 to $45,000 per physician (Gans and others, 2005; Kibbe and Waldren, 2005).[18] Estimates of annual costs for operating and maintaining the system, which include software licensing fees, technical support, and updating and replacing used equipment, range between about 12 percent and 20 percent of initial costs, or $3,000 to $9,000 per physician per year (Miller and others, 2005; Wang and others, 2003).

Those studies indicate that smaller groups of physicians typically pay more per physician than do larger offices to implement health IT systems (Gans and others, 2005). Other possible savings may not depend on the size of a practice. Nearly all physicians already use information technology to manage the business side of their practices. Thus, many offices may already have much of the hardware necessary to operate a health IT system and need only purchase the software.

18. The studies that CBO examined commonly report costs on a per-physician or per-hospital-bed basis. Some costs may vary in a given setting along those dimensions; others are more fixed.

Moreover, the prices of health IT products appear to be falling (Kibbe and Waldren, 2005). In particular, some Internet-based applications that are becoming available might substantially limit costs to an annual subscription fee that could be as low as $2,000 per physician.[19] (However, extremely low prices might signal lower quality and fewer components or features.) If prices continue to fall over time, the quantity and quality of the health IT systems that are purchased should increase.

Physicians who implement health IT systems typically experience an initial loss in productivity as they learn how to use the system and adjust the ways in which they practice. In a survey of health IT adoption conducted by Gans and others (2005), many physicians' practices reported that after they implemented a system, productivity in their offices dropped by between 10 percent and 15 percent for at least several months. A study by Miller and colleagues (2005) found that among a sample of 14 small physicians' offices implementing a health IT system, the average drop in revenue from that loss of productivity was about $7,500 per physician. That amount may understate the actual loss in productivity, however, because in some practices, physicians worked longer hours to keep the practice's income the same as it was before the adoption.

The Cost of EHR and CPOE Systems for Hospitals

A few studies have examined the cost of implementing EHR and computerized physician order entry systems in hospitals.[20] Such calculations are difficult: Hospitals vary widely in size and type; a variety of different health IT applications may be implemented, and there is a general lack of data on costs. Those challenges limit the generalizability to other institutions of any single hospital's experience in implementing a health IT system.

For example, two studies—one in 2003 by First Consulting Group and the other reported in 2006 by Kaushal and colleagues—were carried out in teaching hospitals, making their results potentially unrepresentative of what would happen in a typical community hospital. First Consulting Group researchers used case studies of five hospitals or multihospital groups to develop a model for estimating hospitals' costs for adopting a CPOE system. According to that model, a large 500-bed hospital would incur initial costs of $7.9 million and annual operating costs of about $1.35 million; a smaller 250-bed hospital would incur initial costs of about $3 million and annual operating costs of approximately $700,000. On average, implementation costs for the health IT system amounted to about $14,500 per bed, and annual operating costs were about 19 percent of those one-time costs, or $2,700 per bed.

The study by the Kaushal research group considered the cost of implementing a CPOE system at Brigham and Women's Hospital, a 720-bed academic hospital in Boston affiliated with Harvard Medical School. That study reported costs totaling about $16,000 per year per bed for both implementation and maintenance between 1993 and 2002.

Researchers from the RAND Corporation (Girosi, Meili, and Scoville, 2005) estimated the costs of implementing CPOE systems using data from 27 teaching and nonacademic hospitals. That study reported a considerably higher average cost—nearly $63,000 per bed. The RAND researchers estimated that annual costs for maintaining and updating the system would equal 30 percent of acquisition costs—a figure that is higher than the corresponding proportion in other estimates and that adds $18,900 per bed per year. Although the RAND study used observations from a larger group of hospitals than the investigations discussed earlier, its sample was still quite small, and its estimates, as well as those of other researchers with small samples, should be viewed with caution.

Other factors may contribute to the variation in estimated costs for implementing hospitals' health IT systems. They include differences in the amounts and types of associated training and labor costs (for operating the system) that researchers may take into account and differences in the years from which the data are taken (because of changes from year to year in the technologies, in costs, and in other factors). The RAND analysts observed a relatively linear relationship between the number of beds in a hospital and the hospital's costs for implementing a health IT system and posited that health IT costs were budget driven; that is, such costs are influenced by the amount of money that the hospital has allocated for spending on health IT in general, and various projects,

19. A list of those products and their prices as of September 2006 is available at www.physicianspractice.com/files/pdfs/theGuide_sep06.pdf.

20. EHR systems in hospitals generally include a CPOE component, so discussions of health IT in hospitals may use the two terms interchangeably.

including an EHR or CPOE system, are funded as they rise to the top of the hospitals' list of priorities. Budgets for information technology for hospitals typically range from 1 percent to 3 percent of overall operating expenses. Hospitals that are part of integrated delivery systems with very sophisticated clinical IT capabilities (including those in outpatient settings) may have budgets for information technology that equal or exceed 4 percent.[21]

Possible Factors to Explain the Low Rates of Adoption of Health IT

In spite of the seeming advantages that health IT offers to physicians and hospitals, the proportion of those providers that actually use such systems is relatively small. Several factors may explain the low rate of adoption, including the challenges that arise in implementing the systems, the inability of providers to capture all of the financial returns of the health IT systems that they purchase, the possibility in the case of health insurance plans that the efficiencies they garner through the use of health IT will benefit their competitors, and uncertainty about the value of the advantages to be gained from adopting a health IT system and the evolution of laws affecting its acquisition and financing.

Challenges in Implementing Health IT Systems

Adopting a health IT system involves more than just deciding to spend money; it is a major organizational commitment that, for hospitals in particular, will probably last for several years. To take full advantage of such a system may require physicians to substantially redesign the way they practice medicine. EHRs are only as helpful as the information that goes into them. Some of that information is part of the system when it is purchased, but much of the technology's value comes when physicians devote considerable time to training, to personalizing the system, and to adapting their work processes to achieve the maximum benefits. Not surprisingly, the adoption rates for health IT systems are higher among younger physicians, who in general are more familiar with computers than their older colleagues (who were trained with paper charts as an integral part of patients' care and who may be more comfortable using such tools in their practices; Grossman and Reed, 2006).

In implementing a health IT system, providers must choose from among a wide array of vendors and options. With so many choices (for example, more than 40 different EMR vendors) and rapidly developing technologies, many providers may be concerned about buying the wrong kind of system for their practice, acquiring technology that has already become outdated, or purchasing a poor-quality system. They may wish to postpone the decision until more of their colleagues have purchased systems, allowing them to benefit from others' experience. Research suggests that providers who have purchased an EHR system tend to be in practices in which at least one physician is technically savvy and able to champion the cause of health IT (Miller and Sim, 2004). But relatively few practices include such a physician, which may lead many providers to wait until the systems become more standardized and demand coalesces around fewer but better-known choices. The large number of vendors and products may slow down adoption in the short run, but the winnowing process that occurs as some vendors leave the market is likely to identify the products that deliver the greatest value per dollar spent.

As noted earlier, the prices of health IT systems are falling, and over time that decline should lead to an increase in purchases. One question is whether such increased demand would be constrained by supply problems for qualified technicians to install and maintain the systems. Indeed, hospitals and large provider groups have already begun to complain about the difficulty of finding qualified technicians to maintain their systems.

Providers' Inability to Capture Financial Returns from Health IT

Many, if not most, providers would like to make more use of health IT in their practices, recognizing the technology's potential to improve the quality of the care they provide, increase convenience for their patients, and perhaps reduce costs in their office. But many of those benefits accrue to others rather than to the providers who purchase the health IT system. As a result, many providers cannot generate the additional income necessary to justify the significant investment in time and money that the adoption of such a system would require.

Some benefits to be derived from health IT increase in value as the network of those using the technology expands—that is, as other providers also purchase health IT systems. Providers who can perform functions electronically (such as communicating with each other, send-

21. Personal communications to CBO staff from James Walker, Chief Information Officer, Geisinger Health System, May 19, 2008; and Len Bowes, Senior Medical Informaticist, Intermountain Healthcare, May 18, 2008.

ing and receiving medical records, prescribing medications electronically, and ordering laboratory and imaging procedures) gain when other providers develop similar electronic capabilities. For example, the cost to a primary care physician of sending medical data to a consulting specialist is far lower with a health IT system—as long as the consulting specialist has an interoperable system that can receive the data electronically. However, some so-called network benefits accrue mainly to patients or health insurance plans and only indirectly to providers. Examples include less duplication of diagnostic tests or increased availability of patient data in accessible repositories, which could lead to more research on the best practices for treatment and care.

Health IT can contribute to improvements in the quality of health care that providers deliver, but it is relatively rare for providers to be compensated for such improvements. Pay-for-performance programs are in effect in some managed care plans in the Medicaid program and as pilot programs in the fee-for-service sector of Medicare. Such programs do not create a strong incentive to invest in health IT systems, though, because the payments are fairly modest. Another approach that Medicare has adopted is to *not* pay for poor performance in some areas. CMS recently began a program under which it will not pay for certain occurrences that it calls "never events" or "serious preventable events" (Department of Health and Human Services, 2008). Never events include such incidents as leaving an object in a patient's body during a surgery; operating on the wrong patient or on the wrong body part of the right patient, or performing the wrong surgery; precipitating an air embolism as a result of surgery (in general, an air embolism is a bubble of air in a blood vessel that may cause trouble if it moves to the heart or brain); and providing incompatible blood or blood products. Never events occur rarely, and not paying for a service that leads to such an event is unlikely to have a big effect on providers' behavior in adopting health IT.

Other than through such programs, the financial rewards for physicians and hospitals from improving the quality of their care (or avoiding the provision of poor-quality services) are indirect. A physician's reputation for providing high-quality care might improve as a result of investing in health IT, and patients might want to see a physician who uses an EHR because they believe they will get better-quality care. Health plans, in recruiting doctors for their networks of physicians, might eventually find that doctors who used health IT systems were more attractive to patients than physicians who did not—provided that the plans could determine whether those doctors actually helped them attract and retain enrollees or lowered the cost of treating them.

Most networks of physicians today, however, cover nearly all the doctors in a given area, so physicians who were considering an investment in health IT would probably not include in their calculations whether their use of the technology would make their services more attractive to health insurers. They would also probably not expect to increase their income by improving the quality of the care they provided; thus, that factor would probably not be a key consideration for them. However, they might change their thinking if they knew that they would be directly compensated for implementing a health IT system or if they could report data on the quality of care that they provided—data for which they were being compensated—only by using such a system.

Other benefits, such as lower costs for maintaining medical records and transcribing clinical data, clearly accrue to the provider who purchases the health IT system. For example, Intermountain Healthcare reports that its savings from reducing transcription costs alone (as high as $12,500 per year for some physicians) contributed substantially to paying for its EHR, which cost about $2,500 per physician.[22] But many providers, especially primary care physicians in small practices, might gain relatively little from implementing such a system because their practice would be too small to benefit from the efficiencies it would create. (For example, many providers would not save on transcription costs by purchasing a health IT system because they were not using transcription to begin with.)

Competition Among Health Insurance Plans

Health insurance companies may have an incentive to help providers acquire health IT systems: The technology could help lower the companies' costs by improving both the quality of the care that providers deliver and patients' health. But competition may limit the amount of assistance insurers give to providers to implement health IT systems because the same savings and improvements in quality that such a payer might reap if providers used a

22. Personal communication to CBO from Len Bowes, Senior Medical Informaticist, Intermountain Healthcare, May 18, 2008; Clayton and others (2005).

health IT system could also benefit competing health insurance plans.

For example, suppose Plan A paid an additional amount per unit of service to providers who used EHRs in their offices. That additional payment would probably be determined by the benefit per patient that the plan expected to receive from the physician's use of the system (a benefit that the physician could not capture). But Plan A could not realize all of that benefit, either because some of it would go to other payers—for example, Plan B, a competitor of Plan A, whose participants were seen by the same physician. If Plan B contracted with the same physicians that Plan A used but made no additional payment for the adoption of health IT, it would obtain the same benefit that Plan A obtained from improved quality and lower costs but would not have to pay for it. Thus, even though payers might gain many of the benefits that providers are unable to garner, a payer's inability to prevent competitors from also gaining those benefits may limit the assistance it is willing to give providers to obtain the technology.

Health insurance plans might also hesitate to help pay for the adoption of health IT systems by providers because they cannot fully capture the returns from improving the quality of health care services that such systems may bring. Health plans undergo open enrollment each year, and many enrollees switch from one plan to another during that time. Unless the improved quality of care yielded savings quickly, it would probably do little to motivate insurers to help providers adopt health IT. In fact, health care plans largely address the quality of health care services only to the extent that the employers who purchase coverage for their employees demand it. Many employers are beginning to ask plans to take steps to improve the quality of health care. However, even very large employers may have little leverage with insurance companies to encourage improvements because their workers are usually dispersed across the country. And few employers have enough employees in any one community to enable them to demand changes. In addition, the outcomes for people's health that improvements in the quality of care might provide are still unknown in many cases because not enough research has been done.

Rather than help providers obtain EHRs for their offices, some insurers use other types of electronic records, such as personal health records (PHRs) and payer-based health records (PBHRs). The PHR is controlled by the patient, the PBHR by the health insurance plan (see the appendix for additional information). Both types of electronic record deliver at least some of the network benefits to payers that would be available if physicians used health IT systems, and they present fewer issues related to competition. For example, even though the information in PBRs and PBHRs is not at the same level of detail as the data in EHRs, such records could still help eliminate duplicate diagnostic tests and identify current medications and medical conditions through the data on insurance claims that they do include—information that would be helpful, for example, in a hospital emergency room. But even these alternatives to EHRs have encountered obstacles to implementation related to competition. Payers in some markets have been reluctant to share claims data and other information, fearing that competitors could use it to their detriment.

Worries that the use of health IT will benefit competitors are not limited to health plans. Hospitals and other providers may be concerned that such systems will cause them to lose some degree of control over what they may consider to be proprietary information: the information in their patients' charts. Patients always have the right to access their medical records, but if the records are paper, the impediments to doing so (including the need to make copies) naturally limit the number and nature of the inquiries they are likely to make. Medical data that are stored electronically, however, coupled with the growing availability and popularity of personal health records, imply less control of health data by providers and more control by patients—and potentially greater access to those records by other providers and health plans.

The increased availability of that information through the use of EHRs improves the quality of care for patients. (For example, a hospital emergency room with access to a patient's primary care physician's medical record can better treat that patient, and researchers have more data for evaluating the effectiveness of various medical treatments.) But some providers could lose patients to competitors; the fact that electronic medical records can be so easily transferred makes it easier for patients to change physicians. Providers might also worry that the ease of documentation and emphasis on greater transparency could have a negative impact if it showed them to be less competent than other competing providers.

Box 2.

The Federal Government's Activities as a Payer

The federal government can influence the development and growth of health information technology (health IT) through its operation and management of federal programs that finance health care—in particular, Medicare, which accounts for about 20 percent of all third-party (insurance) payments in the United States, and Medicaid, a joint program with the states for which the federal government's share of spending accounts for 8 percent of third-party payments. In addition to those two programs, the federal government pays for or provides health care through the Military Health System, the Veterans Health Administration, the Indian Health Service, and the Federal Employees Health Benefits Program.

What exactly the government should require of health care providers in those programs is beyond the scope of this analysis. It is reasonable, however, to expect that the government would ask the same questions asked by private health insurance plans about the costs versus benefits of various health IT systems and that it would either encourage or require participating providers to use systems that are consistent with sound management of federally managed or funded health care programs. Because the government is not concerned about competitive issues, its efforts with regard to health IT are not constrained by fears of benefiting health insurance plans in the private sector.

The Centers for Medicare and Medicaid Services (CMS), which runs Medicare, has undertaken a number of initiatives and programs that encourage the adoption of health IT:

- The Medicare Care Management Demonstration provides financial incentives to medical practices on the basis of their performance on 26 measures of clinical quality. Physicians who use an electronic health record (EHR) certified by the Certification Commission for Healthcare Information Technology and who submit performance data to CMS electronically receive additional payments.
- In another demonstration announced in October 2007, CMS will make bonus payments to small physician practices that use certified EHRs. All participating practices will be required to use a certified EHR to perform specific functions, such as clinical documentation and electronic ordering of prescriptions (e-prescribing), that can positively affect the quality of patients' care. The core incentive payment to the practices will be based on their performance on measures of quality, with an enhanced bonus based on how well integrated the EHR is in helping physicians manage care.
- In accordance with a recently passed law, CMS is implementing the Physicians Quality Reporting Initiative, through which physicians receive extra compensation for submitting data to CMS on the quality of the care they deliver. (Although physicians are not required to use health IT systems to prepare and transmit those reports, such systems facilitate that reporting.)
- CMS is working with Medicare Advantage plans, the program's managed care option, to encourage them to offer personal health records (described in the appendix) to their members.

Continued

Box 2. Continued

The Federal Government's Activities as a Payer

- CMS published a rule in 2006 and recently proposed another that would establish standards for e-prescribing for the Medicare program. The rules do not require providers to use e-prescribing in their practices; however, if providers are planning to use such an application to prescribe medication for their Medicare patients, they must abide by the CMS standards.

In addition to creating payment incentives to encourage providers to adopt health IT, CMS is working—as are a number of private health insurance plans—to develop policies for the use of health IT and standards for the systems. For example, CMS is a member of the American Health Information Community (a federal advisory committee established by the Department of Health and Human Services, or HHS) and participates in many of its working groups. In 2007, CMS administered a total of $98 million in grants to states for the Medicaid Transformation program; the bulk of those grants were focused on implementing e-prescribing, EHRs, and the capability for health information exchange. CMS also provides technical assistance to small and medium-sized physician practices to help them obtain health IT systems and coaching for practices that acquire health IT practice management systems.

Other federal agencies that purchase health care are also involved in efforts to further the development and broad adoption of health IT. The Department of Defense (DoD), the Department of Veterans Affairs (VA), and the Office of Personnel Management (OPM) have worked with HHS to adopt health information standards for use by all federal health agencies. As part of the Consolidated Health Informatics initiative, more than 20 federal agencies have agreed to endorse standards that enable information to be shared among agencies and that can serve as a model for the private sector. OPM has agreed to create incentives aimed at encouraging providers to adopt health IT in its contracts with insurers that participate in the Federal Employees Health Benefits Program.

The VA and DoD are both extensive users of health IT. For several years, the VA has used an EHR, the Veterans Health Information Systems and Technology Architecture (VistA), in providing care to U.S. military veterans and, according to some empirical studies, has improved the efficiency of its health care delivery and the quality of the care it provides. The VA has made VistA an "open source" system—available to the public at no charge—thereby lessening the cost to providers of adopting health IT.[1] DoD has developed and is in the process of implementing an EHR—known as AHLTA [armed forces health longitudinal technology application]—for its health care system. Currently, AHLTA gives health care providers access to data about the conditions that beneficiaries are being treated for and their prescriptions and diagnostic tests, as well as additional information. DoD is also working with the VA to develop a way by which health information can be transmitted seamlessly and instantaneously between the two agencies.

1. The open-source version of VistA is known as WorldVistA. Although it is free, it is a relatively sophisticated system that may be intimidating for providers who have little experience with computers. An additional drawback for such providers is that WorldVistA may not come with the same level of on-call technical support and other similar types of assistance that are typically part of the EHR products of for-profit vendors.

The perceived loss of control of health data that makes some providers reluctant to adopt health IT may also make them hesitate to share information if they implement EHRs in their practice. Such reluctance has been a major stumbling block in efforts to establish and maintain regional health information organizations and to support greater exchange of health care information.[23]

Regulatory Impediments

State and federal regulations regarding health IT are evolving. One major issue concerns federal rules related to donations of health IT that hospitals and other large providers may want to make to providers with whom they work. Recent changes in such rules have created so-called safe harbors that allow those donations to take place without violating prohibitions on physician self-referrals. But some providers, payers, and other participants in the health care sector may be reluctant to make or accept donations until the rules regarding them are clearer.

The Departments of Health and Human Services (HHS) and Justice have attempted to clarify those rules, but other agencies, including the Internal Revenue Service (IRS), are still developing their regulations. The IRS has addressed the question of nonprofit hospitals' donations of health IT to physicians, but it is still studying related issues, such as the tax-exempt status of regional health information organizations and of organizations formed by payers and others to promote the adoption of health IT.

A major aspect of policymaking in regard to health IT has to do with ensuring that proper safeguards are in place to protect confidentiality and patients' privacy. The ability of health IT systems to speed the exchange of data and expand the amount of information that is shared also increases the risk that the confidentiality of personal health care information could be compromised (although in one sense EMR and other systems could lessen that risk by making it easier to monitor who accesses a person's medical record). Efforts to clarify and update federal and state laws regarding privacy are well under way, but the final form of those laws is uncertain—another factor that could be constraining the widespread adoption of health IT.

23. More information on the challenges in establishing regional health information is available at www.ehealthinitiative.org/toolkit/allfin/VSMFiles/HRSA_CCBH_Report_Summary.pdf.

The Federal Role in Implementing Health Information Technology

The federal government is both a purchaser of health care services and a regulator of health IT. As a purchaser, the government has an interest in improving the quality and the value of the care provided by Medicare, Medicaid, and other federal health care programs (which together account for about one-third of total national expenditures on health care). If, indeed, health IT improves the quality of care while lowering its costs, then the federal government as a payer might consider actions that would facilitate the adoption of health IT, as long as the costs of those actions did not exceed the savings expected from them or the value of the improvements in care. (Box 2 on page 22 describes federal activities relating to the government's role as a purchaser of health care services.)

As a regulator, the government is helping coordinate and facilitate the development and use of health IT. In general, its regulatory actions have been limited to functions (such as developing standards for interoperability) that would appear to be more difficult, more time-consuming, or more costly than those that the private sector could deal with on its own. (Box 3 describes federal activities relating to the government's role as a regulator.)

Issues for Consideration

As the prominence of health IT has grown—in terms of its potential for increasing the efficiency and improving the quality of health care—policymakers have debated the appropriateness of the federal government's being involved in stimulating and guiding its adoption. Two factors lend support for such a role. The first is the federal government's position as a major purchaser of health care services through such programs as Medicare and Medicaid. As the manager of those programs, the government is responsible for running them efficiently and maintaining a level of quality in their services that reflects the views of the electorate as expressed by policymakers. As a payer, the federal government assesses the benefits and costs of health IT in its various forms, determines which elements of the technology should be required to run federal health care financing programs efficiently and at the desired level of quality, and takes appropriate steps to achieve the level of use of health IT that meets those criteria.

The second factor lending support to possible federal intervention in furthering adoption of health IT is that the technology has some characteristics of a public

Box 3.

The Federal Government's Activities as a Regulator and Funder

The Department of Health and Human Services (HHS), through the Office of the National Coordinator for Health Information Technology (ONC), leads the federal government's efforts to encourage the adoption of health information technology (health IT). ONC's primary responsibilities are to coordinate the development of standards for health IT systems to ensure interoperability (the systems' capability to communicate with each other) and the development and implementation of a national health information network through which interoperable health information can be exchanged. (For additional information, see Box 1 on page 2.)

To help spur adoption of health IT, HHS has established a new rule—which was developed by the Centers for Medicare and Medicaid Services and the HHS inspector general—to make it easier for hospitals and other entities to give health IT systems to physicians. (The incentive for a hospital to provide health IT equipment and technical assistance to physicians who are associated with it is that such interoperable health IT systems may enable the hospital to better control its costs and improve the quality of the care it provides.) The new rule creates two new exceptions to a so-called physician "self-referral" law, which prohibits a physician—unless an exception applies—from referring Medicare patients for certain designated health services to entities with which the physician has a financial relationship. The two new exceptions are as follows: First, entities that furnish the designated health services may give to physicians interoperable electronic health record (EHR) software, information technology, and training services; and second, hospitals and other entities may provide physicians with hardware, software, or other information technology and training necessary and used solely for the electronic prescribing of medications. The rule also specifies that recipients of such health IT donations pay at least 15 percent of the price of the system.

HHS has also supported the development of health IT through grants administered by ONC and the activities of other HHS agencies. The department has funded efforts to enhance the privacy and security of personal health information, promote antifraud activities for EHRs, support the development of standardized measures of adoption for such records, and organize groups of qualified experts to advise the federal government in its activities concerning the clinical decision support feature of many EHRs. The Agency for Healthcare Research and Quality within HHS funds research and development to support and stimulate investment in health IT, especially in rural and underserved areas. The agency also created the National Resource Center for Health Information Technology, which provides technical assistance on health IT. The Health Resources and Services Administration within HHS provides technical assistance as well to health centers and other grantees in adopting model practices and technologies.

HHS has also provided funds to other entities. In 2005, it established the American Health Information Community (AHIC), a federal advisory committee made up of public- and private-sector leaders who represent a broad spectrum of health care stakeholders. AHIC was established to make recommendations to the Secretary of Health and Human Services on how to make health records digital and interoperable and ensure that the privacy and security of the records are protected; it is charged with accomplishing those goals by relying as much as possible on the private sector. (Other private-sector entities established with the assistance of HHS funding include the Health Information Technology Standards Panel and the Certification Commission for Healthcare Information Technology; see Box 1 for additional information.)

good—that is, a good that would be provided in a less-than-optimal amount by private markets if the government did not intervene. A fundamental characteristic of a public good is the presence of a free-rider problem, whereby some of the parties that directly benefit from the good are able to secure its advantages without being charged for them. Such goods are undersupplied because the receipts that they generate for their producers do not adequately represent their value to individuals (because consumers of the good can obtain its benefits without paying for them).

One feature of health IT that may qualify as a public good is the wealth of information that can be captured through EHR systems. (As discussed earlier, if researchers combined data from the EHRs of the population, they might be able to understand the spread and prevention of various diseases and injuries—and eventually develop cures and treatments; assess the effectiveness of various treatments; and more readily detect potential treatment hazards.) Some analysts contend that because such information is a public good—once generated, it would not be feasible to restrict its use—it is unlikely to be produced without the government's intervention. According to that argument, the government has an interest in the adoption of health IT systems that could readily generate such data and therefore a reason to become involved in standardizing coding systems and methods. In addition, the government would want to encourage the recording of such information and subsequent analytical studies as well as the dissemination of results.

Health IT also resembles a public good because of its network effects: Some of its benefits increase in value as more providers purchase and use interoperable systems. Those benefits include, for example, being able to exchange relevant medical information electronically, a less expensive option than the use of paper. The additional user of health IT provides a benefit to existing users in the community that is available to all of them at little or no additional cost and from which it is difficult to exclude an existing user. Because a would-be purchaser of health IT fails to account for the value of the network's expansion in calculating the benefits to be gained from implementing such a system, too few people (relative to the number that would enhance overall economic well-being to the greatest degree) will purchase health IT systems.

Given that the returns of health IT to the providers who invest in such systems are less than the returns to society as a whole, an argument could be made that the federal government's intervention is necessary to raise the rate of the technology's adoption to be more in line with its total returns. But the fact that health IT has some characteristics of a public good does not necessarily mean that the federal government must intervene, nor does it prescribe an appropriate form of intervention. Another alternative for enhancing adoption might be private-sector cooperative arrangements to help providers purchase systems that would be jointly funded by the participants and that would benefit the market as a whole. Some areas of the country, such as Indiana, boast successful regional health information organizations that, without federal assistance, facilitate the broad exchange of health care information within a community. Similarly, markets for products that have networklike benefits have developed in other cases without the government's help. The market for fax machines, a product that provides network benefits, is an example.

Relying on private markets to act, however, would probably lead to a slower rate of adoption than if the federal government intervened. Private-sector participants would have to engage in time-consuming negotiations to reach agreements acceptable to most parties. By contrast, the government could either limit its intervention to such activities as setting standards and supporting the development of regional networks for health information exchange or act more broadly to encourage health care providers and payers to purchase health IT systems.

The government may also have a special interest in protecting individuals' rights with respect to health information, especially in regard to privacy and people's access to personal health records. Competing interests are involved in relation to privacy issues. On the one hand, people expect and hope that their individual privacy will be protected in electronic transactions regarding their health care. On the other hand, researchers seeking to improve health care outcomes would like relatively free access to health care data for use in their work. Many analysts believe that given those competing interests, the government's involvement is critical in developing rules to protect individuals' privacy in health care transactions but still facilitate relatively unfettered access to personal health records for the purposes of research.

Options for Federal Efforts to Promote Adoption of Health IT

If the federal government chose to intervene directly to promote the use of health IT, it could do so by subsidizing that use or by requiring it. Steps might include, for example, having Medicare pay an additional amount per billed service to providers who used EHRs or requiring that providers who wished to participate in Medicare obtain an EHR by a specified date or pay a penalty. From a budgetary perspective, the subsidization approach is less likely to generate cost savings for the federal government because of the direct budgetary costs of the subsidy.

Paying a bonus to providers that used health IT (in an amount less than or equal to the value of the providers' use of the technologies) would enable practitioners to capture more of the benefits that their use of health IT would produce and give them a stronger financial incentive to invest in a system. But that approach would be likely to lead to a net cost for the government—and possibly a large one. Even a small bonus could be expensive because it would be paid not only to those providers who newly purchased health IT but also to providers who already had such systems. Because a small bonus would attract relatively few takers, the bulk of the bonus would be paid to providers that already had health IT. A large bonus would entice more new purchasers, but it would add further to the overall net cost of the federal subsidy. (An alternative approach might be to target a subsidy to various types of providers, the amount of which would depend on their ability to capture the financial benefits of health IT. Thus, providers who were associated with staff-model HMOs and other highly integrated organizations would receive relatively small subsidies, whereas solo providers would receive relatively larger amounts.)

A mandate to purchase health IT, or to purchase a particular functionality such as e-prescribing, by contrast, would probably induce nearly all providers to adopt it at a small cost to the government, and might produce net savings in health care spending. The requirement could be enforced either by not paying providers who failed to adopt such a system for other health care services that they delivered, or by imposing a specific penalty on those who did not comply. A less prescriptive version would involve paying providers without a health IT system less for any given procedure than providers with a health IT system were paid, which would create an implicit penalty for failing to adopt the technology. Either of those approaches, though, would come at a cost to providers, and that cost would be greatest for providers who were least able to capture the financial benefits of health IT systems. If policymakers are interested in promoting health IT, some version of a requirement or an explicit or implicit penalty for providers who fail to adopt health IT is likely to be more cost-effective for the federal government than a subsidy.

Appendix: Common Terms in Health Information Technology

Health information technology (health IT) is a broad term that is commonly used to describe the use of computers and electronic applications in providing and documenting medical care. The most common health IT terms include several types of health records—the electronic medical record (EMR), the electronic health record (EHR), and the patient health record (PHR)—as well as computerized physician order entry (CPOE), clinical decision support (CDS), electronic prescribing (e-prescribing), and interoperability. EMRs, particularly those in hospitals, in many cases include CPOE and CDS applications. Also part of the health IT landscape are the health information exchanges (HIEs) and regional health information organizations (RHIOs).[1]

The *electronic medical record* is equivalent to the paper-based medical record that a health care provider maintains for a patient. The National Alliance for Health Information Technology defines it as "[a] computer-accessible resource of medical and administrative information available on an individual collected from and accessible by providers involved in the individual's care within a single care setting." The EMR contains demographic information and clinical data (related to the practice of medicine) on the individual, including information about medications, the patient's medical history, and the doctor's clinical notes (Moshman Associates, Inc., and Booz Allen Hamilton, 2006). The EMRs currently in use vary considerably. Basic systems include patient information, doctors' clinical notes, and results from diagnostic tests. Systems that are more sophisticated also include such features as e-prescribing and warnings about drug and allergy interactions. The most advanced EMRs add CPOE (see below), registry functions that support population management, and clinical decision support.[2] The variation in what different EMRs can provide has complicated measurements of the rate of their adoption and led to seemingly contradictory estimates.

An *electronic health record* is defined as "[a] computer-accessible, interoperable [see below] resource of clinical and administrative information pertinent to the health of an individual." An EHR differs from an EMR in that information is drawn from multiple clinical and administrative sources and used primarily by a broad spectrum of clinical personnel involved in the individual's care, enabling them to deliver and coordinate care and promote the person's wellness. Any ambulatory-care EMR that meets the certification requirements of the Certification Commission for Healthcare Information Technology (see Box 1 on page 2 for more information) and that includes access to data sources beyond the physician's office would be termed an electronic health record with the EMR embedded in it. Despite their differences, the terms "EMR" and "EHR" are often used interchangeably.

A *personal health record* is another type of electronic record that is distinguished in part by who controls it: A PHR is controlled by the patient, whereas the EHR is controlled by the provider. The PHR is defined as "[a] computer-accessible, interoperable [see below] resource of

1. The definitions included here draw heavily on an interim draft document prepared by the National Alliance for Health Information Technology, with guidance from BearingPoint, Inc. The effort is funded by the Office of the National Coordinator for Health Information Technology to achieve consensus on definitions for five health IT terms: electronic health record, electronic medical record, personal health record, regional health information organization, and health information exchange.

2. Registries generally track patients who have a particular disease or who have received a specific treatment. They collect additional information (such as measures of health status or test results) that is typically not contained in insurance claims records.

pertinent health information on an individual. Individuals manage and determine the rights to the access, use, and control of the information. The information originates from multiple sources and is used by individuals and their authorized clinical and wellness professionals to help guide and make health decisions." In contrast to the EHR, in which providers enter data, people who use a PHR manage the data contained in it. As a result, the quality and comprehensiveness of the information in a PHR vary considerably, depending on how much effort the patient wishes to expend and his or her access to data.

PHRs may and frequently do include data on insurance claims for medical services that the patient has received. (Some health insurance plans now provide PHRs to their members and insert their claims data.) By comparison, EHRs typically contain data that are more clinical in nature, such as the physician's notes on treatment or services provided. (They may also contain data from other providers if the patient was referred to a specialist.) In essence, the PHR's data are broad but not especially deep, whereas the EHR's data are less broad but much deeper. The PHR, however, has the potential to be the basis for the electronic health record, the repository for all health data on a particular patient.

Many health plans and some employers now offer the use of PHRs to their members or employees, but while such a record can be a benefit to consumers, it may also raise questions about who owns the record, how it can be used, and whether the data in the record can be transferred if the person switches health plans or employers. Firms such as Google and Microsoft are now (or soon will be) offering a PHR product.

A *payer-based health record* (PBHR), yet another type of electronic health record, is owned and administered by a health plan. It includes whatever data are available to the health plan but primarily those related to claims. It may also include demographic information provided by the patient at the time of enrollment. It does not contain clinical notes; however, owing to the increasing amount of data required in submitting claims to payers, a PBHR may comprise laboratory results, radiological readings, prescriptions, and complete reports for inpatient and outpatient hospital care, as well as other types of information. A PBHR may be useful—for example, when a patient visits a hospital emergency room—because hospital staff can access the record to obtain critical data on the patient, such as information that could help prevent adverse drug events.

Computerized physician order entry systems are electronic applications that physicians use to order medications, diagnostic (laboratory and radiology) tests, and ancillary services (Poon and others, 2004). Typically, such systems are used in hospitals, often with an EHR; however, many outpatient EHRs also provide CPOE functions. Because EHRs and CPOE are so often connected in hospitals, a facility's health IT system may be described as either an EMR, an EHR, or a CPOE system, adding to the confusion over what system the hospital is actually using. (Studies that examine the effects of health IT in hospitals often measure reductions in duplicate orders for laboratory tests, and those reductions are possible only if the hospital has both an EHR and a CPOE system.)

Clinical decision support systems are often used in combination with CPOE functions in hospitals to assist physicians with decisionmaking by providing reminders, suggestions, and support in diagnosing and treating diseases and conditions. The range of features that CDS systems offer includes drug-dosing assistance, checks for drug allergies and drug-drug interactions, access to the latest evidence-based protocols, reminders about preventive-medicine tests, and guidance for complex antibiotic management programs. Both CPOE and CDS systems vary considerably in their complexity and capabilities.

E-prescribing is the electronic transfer of a prescription from the prescribing physician's office to the pharmacy, which allows a patient to make only a single trip to the pharmacy to pick up the prescription once it has been filled. E-prescribing has received a great deal of attention but is not very common. Many physicians who have EHRs in place could easily generate prescriptions using the electronic record—and thus benefit from the CDS function that many EHRs include—but in the end they often print out a prescription for the patient to take to the pharmacy. Using the EHR to generate a paper prescription may reduce transcription errors and reduce the physician's time and effort, but the patient must still deliver the prescription to the pharmacy.

Interoperability describes the capacity of one health IT application to share information with another in a computable format (that is, for example, not simply by sharing a PDF [portable document format] file). Sharing information within and across health IT tools depends on

the use of a standardized format for communicating information electronically—both among the components that constitute a doctor's office EHR (clinical notes, lab results, and radiological imaging and results) and among providers and settings that use different health IT applications. An interoperable health IT system would allow a hospital physician to view the contents of an EHR from a patient's primary care physician and enable the primary care physician in turn to view all notes and diagnostic tests from the patient's hospital visit. Interoperability is the feature that would allow the creation of a single comprehensive medical record that could follow a person throughout his or her life and from one geographic area to another.

A key component of interoperability is the establishment of a *health information exchange*, an "information highway" of sorts. An HIE is defined as "the electronic movement of any and all health-related data according to an agreed-upon set of interoperability standards, processes and activities across nonaffiliated organizations in a manner that protects the privacy and security of that data; and the entity that organizes and takes responsibility for the process." Without such an arrangement, a physician could still receive lab results in a computable format and use e-prescribing, but a hospital could not, for example, access information on a patient that is stored in the physician's office EHR. Health information exchanges are even less common than EHRs; however, some integrated health care delivery systems, such as Intermountain Healthcare in Utah and southern Idaho and the Veterans Health Administration, share information within their networks and operate much like health information exchanges. However, because they have access only to data within the network, they may not have a comprehensive view of a patient's record.

A *regional health information organization* is defined as "a multi-stakeholder governance entity that convenes nonaffiliated health and healthcare-related providers and the beneficiaries they serve, for the purpose of improving health care for the communities in which it operates. It takes responsibility for the processes that enable the electronic exchange of interoperable health information within a defined contiguous geographic area."

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Chairman STARK. Thank you.
Dr. Ejnes.

STATEMENT OF YUL D. EJNES, M.D., CHAIRMAN, MEDICAL SERVICES COMMITTEE, AMERICAN COLLEGE OF PHYSICIANS

Dr. EJNES. Thank you, Chairman Stark and Ranking Member Camp. My name is Yul Ejnes, M.D. FACP. I serve on the American College of Physicians Board of Regents. I am a general internist in private practice in Cranston, Rhode Island, and I am also a Member of the medical faculty at Brown University.

Representing 126,000 internal medicine physicians and medical students, we share your optimism that health information technology can improve health care. Many studies have found that full adoption and utilization of HIT can improve quality and reduce high medical costs. Patients who are fortunate enough to have a physician who is supported by electronic health records and other information systems are more likely to receive better coordinated care, and be less likely to be exposed to medical errors.

Duplicate tests and drug interactions can be prevented. Better coordinated care supported by HIT enables physicians to partner with their patients to prevent complications that lead to avoidable hospital admissions, particularly for patients with multiple chronic illnesses.

My 50-physician group practice has an electronic health record, or EHR. Our practice leadership is tech-savvy, and we're fortunate to have received some support from a forward-looking private payer. So, with these favorable factors, you would think that our decision to implement an EHR was simple. On the contrary, it took us 10 years. We have been using our EHR for two years now, and have found that the challenges associated, especially the cost and impact on workflow, and the lack of true interoperability to be very substantial.

The other challenges are not nearly as great as they are for physicians in smaller practices. Of the ACP Members involved in direct patient care after training, approximately 20 percent are in solo practice and 50 percent are in practices of 5 or fewer physicians. Three-fourths of all Medicare recipients receive their outpatient care from smaller physician practices. These are the physicians who already lag in HIT adoption, and are least likely to have the necessary capital on board to invest in technology.

Acquisition costs can average up to $44,000 per physician. The average annual ongoing costs are about $8,500 for a physician. For many of those practices, the business case for making such a large investment simply doesn't exist. Public and private payers, not the physicians, realize much of the savings from physician investment in acquiring the necessary HIT.

Mandating use of HIT, especially in the absence of positive financial incentives and lack of uniform standards of interoperability and functionality will likely drive the physician practices we need the most out of business. Positive incentives are the answer.

ACP specifically recommends that Congress build into the Medicare physician payment system an add-on code for office visits and other services when supported by certified HIT. The amount of the add-on should relate to the complexity of HIT adopted by the prac-

tice, similar to how bridges to excellence provides increasingly higher payments to practices as they acquire and use more advanced information systems. Congress should continue to support the establishment of the standards needed to allow true interoperability.

For example, while my EHR has provided great benefit, we can't yet incorporate test results from outside laboratories in electronic searchable form, due to lack of interoperability. Congress should continue to advance the patient-centered medical home, or PCMH model, as a means of rapidly driving primary care practices to acquire the information systems and other capabilities needed to provide patient-centered and coordinated care.

We appreciate the support of Chairman Stark and other Members of this Subcommittee for the increased funding for the Medicare medical home demo that was included in H.R. 6331, and for the inclusion of provisions in the CHAMP Act to further advance this model.

NCQA has developed a qualification process to provide an independent assessment of the capabilities of practices to provide coordinated care, including the degree by which they are using HIT in order to participate in a medical home demo. This process, for instance, looks at whether a practice has registry systems to track patients by disease conditions, or to generate patient reminders.

ACP specifically recommends that Congress transition from the limited medical home demonstration in eight states to a national pilot, as the Medicare payment advisory Committee has recommended.

Should the pilot show that the medical home model can improve quality, achieve savings without compromising quality, or both, Congress should require the Secretary of HHS to develop and implement a new payment system for any practice that has the capability to be a medical home. This would consist of a monthly risk-adjusted care management fee that would take into account how a practice is advanced in acquiring HIT, continued fee-for-service payments for visits, and a performance-based component for reporting on quality.

We also encourage Federal support for regional and statewide HIE, health information exchanges. Many of the potential benefits of physicians adopting EHR's won't be realized until we do so.

So, in summary, we commend Chairman Stark and Members of the Committee for holding this important hearing. ACP believes that Congress should build into Medicare payment policy, increased payments for practices that acquire and use HIT to improve quality, especially those that demonstrate the capability of being a medical home, and provide access to Federal funding for initial acquisition costs.

Without financial incentives, small practices and their patients will be left behind the technological curve. Thank you.

[The prepared statement of Mr. Ejnes follows:]

Prepared Statement of Yul D. Ejnes, M.D., Chairman, Medical Services Committee, American College of Physicians

I am Yul Ejnes, MD, FACP. I am a practicing general internist in Cranston, Rhode Island. I am a member of the medical faculty at Brown University and serve on the Board of Directors of the Rhode Island Quality Institute, the state's Regional

Health Information Organization (RHIO). I am also a member of the Board of Regents of the American College of Physicians (ACP), and chair of the College's policy committee that has overall responsibility for both payment-related policies and health information technology (HIT). I am pleased to present ACP's views on the adoption and use of HIT.

ACP, representing 126,000 internists and medical students, is the largest medical specialty society and the second largest medical organization in the United States. ACP commends Subcommittee Chairman Fortney "Pete" Stark and Ranking Member Dave Camp for holding this hearing on the adoption and use of HIT. We share the optimism conveyed in the announcement of this hearing by Chairman Stark, that HIT has the potential to improve quality of health care and reduce costs. We commend the Subcommittee for specifically focusing on the need for incentives to facilitate HIT adoption and use.

Introduction

The Institute of Medicine's (IOM) 2001 Report, "*Crossing the Quality Chasm—A New Health System for the 21st Century*," suggested that up to 98,000 Americans die each year as a result of medical errors. The report introduced the notion that many of these lives could be saved through information technology. Since then, numerous studies and other policy experts have confirmed that full adoption and utilization of HIT has the potential to result in major gains in health care quality of care and patient safety.[1] Some studies have also concluded that HIT can achieve very substantial reductions in health care costs.[2] Even skeptics who are less certain about the ability of HIT to lower costs recognize that providing physicians and other clinicians with access to information systems to help them manage and coordinate patient-centered care, especially for patients with multiple chronic diseases, offers the potential of achieving gains in quality and overall savings.[3]

The Congressional Budget Office (CBO) May 2008 paper "Evidence on the Costs and Benefits of Health Information Technology" states that HIT generally refers to the use of computer applications in the practice of medicine. It notes that those applications (including clinical decision support and electronic prescribing) can be housed in an electronic health record (EHR).[4] While physicians can use individual HIT applications independent of an EHR, use of an EHR is often used to measure HIT adoption.

Benefits of Health Information Technology

The benefits of HIT that are most often cited are: avoidance of medical mistakes; storage and preservation of medical data; avoidance of medical errors; reductions in malpractice premiums; and improved quality outcomes.[5] We elaborate on each of these benefits below.

- *Medical Mistake Avoidance/Provision of Recommended Care:* The use of clinical-decision support tools at the point of care has the potential to offer a tremendous advantage to both physicians and their patients by facilitating recommended evidence-based preventive, acute, and chronic care. Examples of this benefit include alerts about vaccinations, anti-coagulation reminders, diabetes, hypertension, thyroid and anemia screening in the elderly, health maintenance and preventive care measures. HIT can also be an important conduit for providing clinicians with unbiased information on the comparative effectiveness, clinical as well as cost, of different treatments, a topic that the ACP has addressed in some detail in a new position paper on comparative effectiveness.
- *Storage of Other Encounter Data:* An often-cited example is the disappearance of paper medical records and charts following Hurricane Katrina. Having medical data stored electronically assures the safe keeping of complete med-

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[1] DesRoches, Catherine, et al., "Electronic Health Records in Ambulatory Care—A National Survey of Physicians", New England Journal of Medicine, July 3, 2008.

[2] RAND Health, "Health Information Technology: Can HIT Lower Costs and Improve Quality?," Research Highlight, at http://www.rand.org/pubs/research_briefs/RB9136/RAND_RB9136.pdf.

[3] Sidorov, Jaan, "It Ain't Necessarily So: The Electronic Health Record and the Unlikely Prospect of Reducing Health Care Costs," Health Affairs, July/August 2006.

[4] Evidence of the Costs and Benefits of Health Information Technology, Congressional Budget Office, May 2008.

[5] Sidorov, Jaan, "It Ain't Necessarily So: The Electronic Health Record and the Unlikely Prospect of Reducing Health Care Costs," Health Affairs, July/August 2006.

ical histories that can be difficult to duplicate from memory. In addition, when patients become incapacitated, storage of the data can be critical.

- *Medication Error Avoidance:* The use of electronic prescribing (e-prescribing) offers promise because it eliminates problems with handwriting legibility and, when combined with decision-support tools, automatically alerts prescribers to possible interactions, allergies, and other potential problems. E-prescribing can also increase appropriate use of generic drugs. We note, however, the e-prescribing systems will be more effective if they are integrated with fully functional electronic health records.
- *Quality Improvement, Patient-Centeredness, and Care Management:* As noted earlier, HIT offers the potential to help physicians improve overall health care quality by having evidence-based clinical decision support at the point of care, generating patient reminders, providing access to more complete information, and reducing drug interactions. It can also have the benefit of preventing unnecessary and duplicative testing, helping patients achieve improvements in their own health care, delivering patient centered services (such as remote monitoring, secure access to email consultations), and reducing fragmentation in health care services that may increase costs and result in poorer outcomes. Further, it can shorten hospital stays or help avoid them altogether. It also enhances the ability of physicians to track and measure the quality of care they provide to their patients.

Status of Physician Health Technology Use

Despite the tremendous upside associated with HIT, relatively few physician practices have it—with small practices having the lowest rates. A 2006 review by the Robert Wood Johnson Foundation found that approximately 24% of physicians in ambulatory practice have an EHR, with a solo physician practice adoption rate of only 13% to 16%.[6] A 2006 ACP member survey demonstrated that practices with five or fewer physicians have a significantly lower EHR adoption rate (18%), than practices with 20 or more physicians (58%).[7] Other studies have shown that while EHR use is rising slowly, adoption by small practices continues to lag.[8]

Barriers to Physician Health Information Technology Use

The barriers to the acquisition and use of HIT, especially for small physician practices, are numerous, with the major obstacles described below.

- *Substantial Cost in Acquiring and Maintaining the Technology:* Depending on the size of the practice and its applications, acquisition costs, on average, $44,000 per physician. The average annual ongoing costs of maintenance and support are about $8,500 per physician.[9] Physicians cite these costs are the largest adoption barrier.[10] In addition, there are costs associated with training and lost productivity. In a 2005 study, 14 small practices implementing a HIT system experienced a decline in revenue because of lost productivity of $7,500 per physician.[11] Collectively, investment and maintenance is a financial commitment that spans the life of the practice. This obstacle is especially acute for physicians in small practices, where three-fourths of all Medicare recipients receive outpatient care.[12]
- *HIT Savings Accrue to Others and Not the Physician Making the Investment:* Public and private payers generally realize the financial benefit associated with HIT use, which can come in the form of a reduction in duplicative or unnecessary care, the avoidance of costly medical errors, a reduction in hospital days, an improvement in quality outcomes, and lower administrative costs.

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[6] The Robert Wood Johnson Foundation (2006), Health Information Technology in the United States: The Information Base of Progress, chapter 3, p. 26.

[7] American College of Physicians, E-Health and Its Impact on Medical Practice. Philadelphia: American College of Physicians; 2008: Position Paper.

[8] Jha, Ashish K., Ferris, Timothy G., et al., "How Common Are Electronic Health Records in the United States? A Summary of the Evidence," Health Affairs, web exclusive October 11, 2006.

[9] Miller, Robert, West, Christopher, et al., "The Value of Electronic Health Records in Solo or Small Group Practices." Health Affairs, Vol. 24, No. 5, September/October 2005.

[10] DesRoches, Catherine, et al., "Electronic Health Records in Ambulatory Care—A National Survey of Physicians", New England Journal of Medicine, July 3, 2008.

[11] Miller, Robert, West, Christopher, et al., "The Value of Electronic Health Records in Solo or Small Group Practices." Health Affairs, Vol. 24, No. 5, September/October 2005.

[12] Center for Studying Health System Change, "Most Medicare Outpatient Visits Are to Physicians With Limited Clinical Information Technology," July 2005.

- *Lack of True Interoperability:* Physicians lack confidence that an EHR will be able to communicate with an information system used by another clinician, hospital, laboratory, or other entity. Manual integration of information from disparate sources requires additional work and prevents full using EHRs to their full capability. This situation discourages EHR adoption.
- *Medicare and Other Payment Systems Generally Incentivize Volume over Quality:* Paying physicians on a per-procedure or per-service basis encourages volume and actually may act as a disincentive to acquire information systems that can result in the more efficient provision of services. For example, a physician receives less financial compensation if he or she refrains from conducting a test known to be duplicative because of HIT. Medicare payment policies for the most part are, at best, neutral on acquisition and use of HIT, except for some limited reporting of "structural" measures in the Physician Quality Reporting Initiative (PQRI) and several Medicare demonstration projects that provide reimbursement incentives for HIT. Medicare also systematically undervalues primary care services, making it particularly difficult for primary care doctors whose practices may be struggling and near the breaking point to spend the money needed to acquire HIT.
- *Uncertainty Surrounding Medicare Physician Payments:* The flawed mechanism for updating Medicare payments to physicians, the Sustainable Growth Rate (SGR) system, is a complicating factor. The system—and its need to be perpetually corrected, makes planning for significant practice investment a challenge. We appreciate the congressional action, despite the budget challenge and other obstacles, to avert what would have been a devastating 10.6% across-the-board cut in physician payments that was set to begin on July 1, 2008 and substituting the additional 5.4% cut slated for 2009 with a 1.1% increase. This action provides some stability and buys time to fashion a long-term legislative solution. The relatively modest increase, especially considering rising practice costs, and the uncertainty regarding payment updates beyond 2009 make it difficult for practices to make the investment in EHR and other HIT. ACP also recognizes and appreciates that the Children's Health and Medicare Protection (CHAMP) Act—reported out of the Ways and Means Committee, with the support and leadership of Chairman Stark, and that passed the House of Representatives in 2007—would have provided further relief from the SGR cuts and improved payments for primary care services had it become law.

In sum, for many physicians, the business case to invest in EHR/HIT simply does not exist. Even so, there are physicians who have become early adopters even though the economic case for doing so is poor.

I have had an EHR in my own medium-sized practice for the past two years and have been writing prescriptions electronically for the past five. I made this investment because I felt it was in the best interests of my patients, even thought it was not necessarily in the best interest of my practice's "bottom line." But, I fully understand why so many of my colleagues have deferred making such an investment given the poor business case to support it and the lack of any reimbursement incentives for doing so.

The Need for Congressional Involvement

The complex issues surrounding financing, assistance with redesign of practice workflow, and ongoing technical support and training must be recognized and addressed for the goal of widespread adoption and use HIT to be realized. ACP strongly believes that the Congress has an important role to play in overcoming the challenges posed by these issues, particularly pertaining to physicians in small practices.

Both Medicare and the private sector have recently provided some incentives to facilitate HIT adoption and use. Unfortunately, the programs are limited to far too few physicians. These experiences do, however, demonstrate physician interest and provide reasonable assurance the physicians will respond to adequate incentives. This should provide Congress with a level of comfort that physicians will use incentives if they are made available to more physicians.

The Bridges to Excellence (BTE) program that encourage practices to maintain structural capability, including HIT components, aimed at improving patient care provides an example of physician practices responding to financial incentives. BTE is a coalition that encourages leaps in quality of care by recognizing and rewarding health care providers who demonstrate that they provide safe, effective, efficient, and patient-centered care. The BTE program pays physicians who are recognized under the National Committee for Quality Assurance (NCQA) Physician Practice

Connections Physicians Office Link (PPC–POL) program as having the systems to improve care up to $50 per patient per year. Over 1,500 physicians are recognized through the NCQA PPC program, with an average practice size of 5 physicians. This shows that small physician practices are responsive when financial incentives are aligned with the transition to this type of care.

Beginning January 2008, BTE started to make bonus payments to practices in eligible areas that earn NCQA PPC–POL or PPC Patient Centered Medical Home (PPC–PCMH) recognition, plus the required recognition for other condition-specific modules (e.g. diabetes, heart/stroke). This is evidence of the growing interest of the PCMH and the willingness of the private sector to provide incentives to encourage practices to pursue PCMH recognition.

Recommended Financial and Other Incentives

Many physicians' small practices will be unable to acquire and use HIT without sufficient financial assistance from the Federal Government. Leaving behind these practices, from which the majority of Medicare beneficiaries receive their care, will prevent the goal of widespread use of fully integrated technology from becoming a reality.

We caution Congress, though, against trying to mandate HIT use, especially given the lack of financial incentives to help practices. For many small practices, an unfunded mandate to acquire and use HIT could literally put them out of business. It is also does not make sense to mandate HIT given that issues relating to interoperability, standards, and functionality have yet to be fully resolved. Mandates are not sensitive to differences in practice resources, patient case mix, staffing ratios, geographic locations, ownership, and a myriad of other factors that will affect the ability of practices to acquire and use HIT. A practice that is part of a large academic system, large group practice, or owned by a hospital is very different from a small physician-owned practice.

We instead recommend that Congress establish targeted financial incentives aimed at facilitating HIT in small practices. Specifically, ACP recommends that the Congress take the steps below to provide the financial incentives necessary to facilitate widespread HIT adoption and use.

- *Establish an Add-on Payment for Evaluation and Management Services:* The College recommends establishing an add-on code for office visits and other evaluation and management (E/M) services when the visit is supported by qualified HIT systems. The payment mechanism should make it possible for the physician to report that the E/M service was supported by HIT. The amount of the add-on should relate to the complexity of HIT adopted by the practice. For example, Medicare could establish three levels or tiers of HIT adoption, similar to the NCQA PPC–POL module. The level of the add-on then would depend not only on whether the physician had the information systems in their office, but how those systems are used to improve patient care. A practice that had only a simple stand-alone e-prescribing system and patient registry would be paid less than one that had a fully functional EHR with e-prescribing, patient reminders, clinical decision support at the point of care, and the ability to measure and report on clinical performance measures imbedded in the system.
- *Include Reporting of Structural HIT Measures in Quality Reporting Programs:* Medicare should reward physicians who incorporate either some or all aspects of HIT and participate in reporting on endorsed quality measures as part of the PQRI. We note that the PQRI currently includes a small number of structural measures, and beginning in 2009, Medicare will begin providing bonus payments to physicians who are able to report that they are using an e-prescribing system.
- *Pay Physicians a Care Coordination Fee if they Acquire and Use the Information Systems Needed to Function as a PCMH and Regularly Report on their Performance.* The ACP recommendations on the PCMH are discussed in depth later in this testimony.
- *Assist Small Physician Practices with the Initial Investment to Acquire HIT:* Congress should make available grants, loans, and/or tax credits to help practices currently least able to purchase the necessary HIT hardware and software. ACP notes, however, that the impact of these incentives is limited absent changes in Medicare payment policies to create incentives for HIT use.
- *Ensure Clear Guidance on the "Safe harbor" Exception to the Self-referral Prohibition:* The law allows hospitals and other entities to assist physicians in acquiring HIT. The CBO May 2008 paper, "Evidence on the Costs and benefits of Health Information Technology", notes that three federal agencies are

establishing rules related to this safe harbor and the lack of present clarity can be an impediment to HIT expansion.

- *Explore Mechanisms to Assist Practices in Implementing HIT:* Physicians face significant challenges in selecting, integrating, and optimizing HIT. The National Ambulatory Medical Care Survey (NAMCS), an annual, government-funded, nationally representative survey of all ambulatory visits to physicians whose practices are not hospital-based, includes questions about EHR use. While the NAMCS found nearly 24% of physicians using EHRs, further analysis determined that only 9% are using an EHR with at least the four key functionalities identified by the IOM.[13] Congress should facilitate resources that provide support throughout the HIT implementation continuum that will make selection less daunting, minimize productivity throughout implementation, and result in optimal use. The College urges Congress to review the recommendations/options in the October 2007 "eHealth Initiative Blueprint: Building Consensus for Common Action," which is available at *http://www.ehealthinitiative.org/blueprint/eHiBlueprint-BuildingConsensusForCommonAction.pdf*.
- *Support the Establishment of Standards to Facilitate Interoperability and Reporting Quality Data:* ACP strongly supports efforts by those in the Administration and the Congress to speed the adoption of uniform standards for HIT. In order to oversee the ten-year initiative to achieve widespread adoption of EHRs that President Bush announced in 2004, the Administration created the Office of National Coordinator for Health Information Technology (ONC). ONC and related initiatives are working toward establishing the standards necessary to provide physicians with confidence that their investment in HIT will be supported by sustainable processes and infrastructure that enable them to use HIT to the optimal benefit of the patient and system efficiency.
- *Support for Information Exchange Projects that Promote Interoperability:* Congressional support for state and regional health information exchange efforts will move toward the true interoperability needed for physicians to use EHR products to their maximum potential and to achieve the greatest benefit to the health care system.

Patient Centered Medical Home as a Means to Facilitate HIT and its Associated Goals

ACP, like many others, believes that use of HIT alone will not enable the health care system to deliver improved quality in a way that maintains or lowers costs to its full potential. The College believes that HIT in the context of a Patient Centered Medical Home will yield the greatest benefit. ACP worked with the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and the American Osteopathic Association (AOA) to jointly establish principles that define the PCMH. The PCMH is a delivery model that involves a patient with a relationship with a personal physician who works with a practice team to provide first contact, whole-person, continuous care. The PCMH model is based on the premise that the best quality of care is provided not in episodic, illness-oriented care, but through patient centered care that emphasizes prevention and care coordination. A PCMH practice must demonstrate that it has the infrastructure and capability to provide care consistent with the patient's needs and preferences. The PCMH joint principles call for enhanced payment to support the practice transformation and increased value to the patient and the health care system.

ACP, AAFP, AAP, and AOA, as the four organizations that represent a significant number of primary care physicians, worked with the National Committee on Quality Assurance (NCQA) to establish an independent process by which physician practices can be recognized as a PCMH. The NCQA established process, the Physician Practice Connections-PCMH (PPC–PCMH) module, requires practices to meet core requirements and attain a minimum score to be recognized as a medical home. Practices that meet these core requirements and achieve at or above the minimum total score are identified as one of three progressive levels of PCMH. The highest level of medical home, a Tier 3 PCMH, is generally associated with the greater use of HIT.

Having a process by which an independent, third-party determines whether a physician practice is a PCMH is one reason why the model has gained considerable traction over the past few years. Assurance that practices are transforming to meet the full needs of patients has contributed to the decision of many employers, health

[13] Institute of Medicine, "Key Components of an Electronic Health Record System: Letter Report," July 2003.

plans, consumer organizations, policymakers, and other health care stakeholders to embrace the model. It is our understanding that CMS intends to use a recognition process to identify the medical home practices that participate in the Medicare medical home demonstration project authorized by Congress in 2006 and enhanced through the Medicare legislation that become law earlier this month.

In its June 2008 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended that it establish a robust PCMH pilot project that focuses on practices that use significant HIT.

We appreciate the Congress's support of the PCMH and urge it to consider additional payment reforms that incentivize the adoption and use of HIT in the context of the PCMH. We specifically recommend that Congress:

- *Provide Additional Funding to the Centers for Medicare and Medicaid Services (CMS) to Expand the Medicare Medical Home Demonstration to More Practices and States.* ACP appreciates the $100 million in increased funding for the Medicare Medical Home Demonstration that was included in H.R. 6331 but believe that even higher funding levels would enable the PCMH model to be expanded nationwide and evaluated as a national pilot rather than a limited demonstration project. We also believe that Congress should consider working from the medical home demonstration language and funding that was in the CHAMP Act as a basis for expanding the model into a national pilot. ACP cautions the Subcommittee, however, not to delay the existing demonstration even as it considers additional legislation to expand and test the PCMH on a national scale.
- Require that the Secretary Transition to a New Payment Methodology for Qualified PCMH, should the Medicare Medical Home Demonstration be Successful in Improving Quality or Achieving Savings or Both: The alternative PCMH payment structure should pay PCMH recognized practices, including practices recognized through the NCQA PPC–PCMH voluntary recognition process or other equivalent process as determined by the Secretary, for the clinical work and practice expenses associated with providing care coordination services, consisting of the following:
- Prospective, risk-adjusted per beneficiary per month PCMH fee for each beneficiary that chooses that practice as their PCMH to cover the work and practice expenses involved in providing care consistent with the PCMH model (e.g. increased access, care coordination, disease population management and education) that are not currently covered under the Medicare Physician Fee Schedule. Such prospective, risk-adjusted per beneficiary payment should be set at a level and magnitude that is sufficient to support the acquisition, use and maintenance of clinical information systems needed to qualify as a PCMH and that have been shown to facilitate improved outcomes through care coordination.
- The Secretary should consider the impact of qualified PCMHs on reducing preventable hospital admissions, duplicate testing, medication errors and drug interactions, and other savings in Medicare Parts A, B (including Part B services not included in the Medicare Physician Fee Schedule) and apply a portion of the aggregate estimate of such savings to determining the aggregate amount of payment for the PCMH fees that would then be provided to qualified practices. Should aggregate actual savings after three years be higher than the estimate, the Secretary should apply a portion of such additional aggregate savings to fund the PCMH fee.
- Performance-based bonus fee determined by meeting specified clinical, patient satisfaction and efficiency benchmarks.
- Continued fee-for-service payment for evaluation and management services.
- *Require Separate Medicare Payment for Designated Primary Care Services and Services and Capabilities that Promote Patient-centered Care:* Congress should mandate that the Secretary pay for care coordination services provided by a primary or principal care physician to a beneficiary. Medicare should make separate payment for a comprehensive care coordination service described in a yet-to-be-defined procedure code(s). Medicare should also make separate payment for discrete services defined by existing procedure codes that describe a clinical interaction with a beneficiary that is inherent to care coordination, including interactions outside a face-to-face encounter. These services should include:

- Care plan oversight;
- Evaluation and management provided by phone;
- Evaluation and management provided using internet resources;

- Collection and review of physiologic data, such as from a remote monitoring device;
- Education and training for patient self management;
- Anticoagulation management services; and
- Current or future services as determined appropriate by the Secretary.

Estimating Savings from HIT Use and Other Promising Projects

ACP believes that much of the additional expense involved in funding the financial incentives it recommends in this statement can be covered by the anticipated savings that the improved care can generate. Congress should develop a mechanism to assess the system-wide savings that HIT and other innovative delivery and payment reforms, such as the PCMH, that aim to improve quality generate. Savings can be used to help fund Medicare's assistance to physicians with initial HIT investment and on-going maintenance.

In addition, we are encouraged that the Department of Health and Human Services is in the process of assessing the system-wide savings expected to be generated through the EHR demonstration project and the Medicare medical home demonstration project. HHS intends to fund the enhanced payments to physicians participating in the EHR demonstration project through the system-wide savings that it expects it to generate. HHS is determining the savings it expects the improved interventions that result from the Medicare medical home demonstration project will generate. It will use the expected savings to fund payments to individual physicians in PCMH practices for the enhanced services they provided to better coordinate patient care. Congress should monitor these important efforts to assess the impact of HIT and other promising reforms across the entire Medicare program, as opposed to the historical tendency to assess changes within individual components of the Medicare program.

We are troubled, however, by the CBO view, expressed in its May 2008 paper, that HIT will not likely reduce overall health care spending and that incentives may actually increase spending in the absence of mandates. This position goes against the views of many other experts who believe that HIT, especially if used to support patient-centered care coordination by primary care physicians, can improve quality and achieve efficiencies that decreases overall spending. The CBO position may itself become one of the greatest barriers to HIT adoption if it results in Congress being unwilling to provide the financial incentives needed to support HIT.

We also note that most other industrialized nations have decided that it is necessary and appropriate to make large public investments in HIT. ACP recently published a position paper in the College's peer-reviewed journal, the *Annals of Internal Medicare*, that compared the United States' health care system with those of other industrialized countries. Citing data from the Commonwealth Fund and other sources, the paper found that compared with countries with well-performing health care systems, the United States lags seriously in the implementation of EHR systems in office practice. Compared with primary care doctors in six other countries, U.S. physicians are among the least likely to have extensive clinical information systems. In 2006, nearly all primary care doctors in the Netherlands (98%), and 79% to 92% of doctors in Australia, New Zealand, and the United Kingdom, have EHR systems, while the rate was only 28% in the United States (and 23% in Canada). Most doctors in countries with high rates of EHR systems routinely use them to electronically order tests, prescribe medications, and access patients' test results. Compared with doctors in the U.S. doctors in these countries are more likely to receive computerized alerts about potential problems concerning drug dosages and interactions, have reminder systems to notify patients about preventive or follow-up care, and (except for the Netherlands) receive prompts to provide patients with test results. More than 60% of the doctors in the four countries with high EMR use, as well as those in Germany (where 42% have EMR systems), say it is easy to generate lists of patients by diagnosis or health risk; in contrast, only 37% of U.S. doctors say it is easy, and 60% say it is somewhat difficult or worse to generate such lists. Likewise, doctors in countries with high rates of EMR systems are two-to-four times as likely to say it is easy to generate lists of patients who are due or overdue for tests or preventive care; only 20% of doctors in the United States report that it is easy.[14]

[14] "Achieving a High-Performance Health Care System with Universal Access: What the United States Can Learn from Other Countries," ACP position paper, *Annals of Internal Medicine*, January 2008.

Privacy and Security Concerns

ACP recognizes that patients have a basic fundamental right to privacy that includes the information contained in their own medical records—whether in electronic or paper form. ACP has long recognized the need for appropriate safeguards to protect the privacy and security of patient data. Trust and respect are the cornerstones of the patient-physician relationship and are key to quality health care. Patients who trust their physician are more like to fully participate in their treatment and comply with their care plan.

We strongly believe that physicians—already governed by strict ethical codes of conduct, state professional disciplinary codes, and the Hippocratic oath—have a duty and responsibility to protect patient privacy. Patients need to be treated in an environment in which they feel comfortable disclosing sensitive and confidential health information to a physician they can trust. Otherwise, there may be a chilling effect for patients to fully disclose the most sensitive of information (conditions or symptoms), thereby reducing the effectiveness and timeliness of treatment, or, they may avoid seeking care altogether for fear of the negative consequences that could result from disclosure. While physicians must have access to clinically relevant information to safely and effectively treat patients, patients must have assurances that adequate firewalls against unauthorized individuals gaining access to sensitive data are in place. Congress must ensure these safeguards are present.

Conclusion

The barriers to HIT adoption in physician practices can best be overcome by building financial incentives into Medicare and other programs. Supporting small practices with their initial acquisition costs and including an add-on payment for services documented and facilitate by an EHR will provide an infusion of funding that small practices need to invest in and maintain HIT. It also sends a signal that the Federal Government is committed to facilitating this goal. Financial incentives to facilitate the promising PCMH delivery model provide a mechanism to further HIT adoption and use in the context of an improved delivery system that further achieves these goals. PCMH practice recognition that is inherent in the model provides assurance that the practice has acquired and uses HIT in an optimal manner. Collecting, analyzing, using, and reporting how care compares to vetted measures of clinical quality is also inherent in the PCMH model.

ACP is pleased that the House Committee on Ways and Means Health Subcommittee on Health is examining the issues pertaining to HIT option and use. We strongly believe Congress has a very important role in promoting HIT adoption and providing the necessary initial and ongoing funding mechanisms to assist small physician practices. The benefits of full-scale adoption of interoperable HIT will be significant, leading to a higher standard of quality in the health care system. Unfortunately, without adequate financial incentives, small physician practices will be left behind the technological curve and their patients with them.

Chairman STARK. Thank you, Doctor.
Ms. McGraw.

STATEMENT OF DEVEN MCGRAW, DIRECTOR, HEALTH PRIVACY PROJECT, CENTER FOR DEMOCRACY AND TECHNOLOGY

Ms. MCGRAW. Thank you, Chairman Stark, Ranking Member Camp, and the members of the Subcommittee. Deven McGraw, director of the health privacy project at the Center for Democracy and Technology, CDT.

CDT is a non-profit public interest organization with more than 15 years of expertise on Internet and information privacy issues. The health privacy project, which was once an independent organization, has more than a decade of experience in advocating for health privacy protections—again, for health information. The two organizations merged just this year, to combine the expertise which

is particularly timely, given the focus now on electronic and Internet-based records.

CDT supports—CDT absolutely supports—efforts to expand the adoption of health information technology and health information exchange. Too often I think privacy advocates get labeled as trying to place obstacles to getting health IT in place. In fact, the opposite is true. We think that privacy and security protections are enablers to health IT. We believe that, in fact, those solutions, as Peter Orszag referred to, are actually obtainable in this congress and in subsequent congresses.

We need to do this, because people do want electronic health records. But surveys show that, time after time, about two-thirds are concerned about the privacy and security of health information. Technology actually enhances our ability to keep records private and secure. At the same time, it also magnifies the risks. You only have to think about the risks of a box of records being left open on a table, versus a laptop with thousands of records being stolen out of the trunk of someone's car.

So, to really build public trust in these systems, we need a comprehensive privacy and security framework that is based on fair information practices, which is typically what we look to in developing policies to protect personal information in a whole range of contexts. The good news is that we don't have to start from scratch.

First of all, we have the HIPAA privacy and security rules, which are based on fair information practices, and provide us with a foundation of protections that govern the use of information by health care organizations. We can build on this foundation, filling in the gaps to create, again, this comprehensive policy framework.

There is also the common framework developed by the Markle Foundation's multi-stakeholder Connecting for Health Initiative. So, we have lots that we can draw on.

So, we are really calling on Congress to think big, and have a comprehensive vision on privacy and security. But we know this is a complex topic. So, in order to get it right and still facilitate the flow of information that is necessary to improve health care, you really need to think about this, take some incremental steps. So, think big, act incrementally, and we're happy to work with you all along the way.

So, in our written testimony, we have actually suggested a number of areas that Congress might think about, in terms of filling these gaps in HIPAA, and looking at the new players in the environment. When I talk about new players, I am focusing in particular on personal health records, PHRs, that are being offered by employers and Internet companies. They are not covered by HIPAA.

But we don't want you to address this policy vacuum by taking HIPAA and having it cover these entities. We don't think that's the right approach. Instead, we recommend tasking HHS and the Federal Trade Commission, which has lots of experience in regulating Internet-based companies, to jointly come up with recommendations to protect privacy and security of information in personal health records.

HIPAA was really designed for health care system entities. Understanding health care system needs for information to flow, that

doesn't fit very well, in terms of a regulatory framework when you're talking about entities that have a completely different business model, and where the revenue basis is likely to be based on advertising and commercial use.

Again, we don't have to start from scratch here, with respect to PH.R.s. This is another place where the Markle Connecting for Health Initiative has come up with a common framework.

Enforcement is another area that we hope that Congress will pay attention to. As is pretty common knowledge now, I think, the HHS office of civil rights has not imposed a single civil monetary penalty for violations of HIPAA. To our knowledge, the Justice Department has only prosecuted a handful of criminal violations. We make recommendations in our written testimony for some tweaks in the HIPAA statute that will make it easier for the Secretary to follow Congress's intent to make sure that penalties are imposed in cases of the most egregious HIPAA violations: knowing violations and violations of willful neglect.

But we also think that a significant shortfall in HIPAA is the absence of any way for the consumer whose privacy is violated to pursue meaningful recourse and be made whole. So, we do encourage Congress to look at creating a private right of action, not for every HIPAA violation, but at least for the most egregious types. The government can pursue these penalties today, but they don't go to the individual who is actually—if they are harmed—are really left holding the bag.

Again, there are workable ways to do this. It won't be easy. We are happy to work with you to find that way. But we think it's important to begin developing a way to ensure that covered entities are accountable to consumers for the most egregious violations of their privacy. Thank you.

[The prepared statement of Ms. McGraw follows:]

Prepared Statement of Deven McGraw, Director, Health Privacy Project, Center for Democracy and Technology

Chairman Stark, Ranking Member Camp, and members of the Subcommittee, thank you for holding this hearing on promoting the adoption and use of health information technology and for the opportunity to testify today.

CDT is a non-profit public interest organization founded in 1994 to promote democratic values and individual liberties for the digital age. CDT works to keep the Internet open, innovative and free by developing practical, real-world solutions that enhance free expression, privacy, universal access and democratic participation. The Health Privacy Project, which has more than a decade of experience in advocating for the privacy and security of health information, was merged into CDT earlier this year to take advantage of CDT's long history of expertise on Internet and information privacy issues and to come up with workable solutions to better protect the privacy and security of health information on-line and build consumer trust in e-health systems.

CDT recently released a comprehensive paper calling on Congress to enact—and all stakeholders to adopt—a comprehensive privacy and security framework to cover electronic health information. Some of the points raised in that paper are highlighted in this testimony today, but I also request that the full copy, which is attached and can be found at www.cdt.org/healthprivacy/20080514Hpframe.pdf, be entered into the hearing record.

Privacy and Security Protections are Critical to Health IT

Health information technology (health IT) and electronic health information exchange can help improve health care quality and efficiency, while also empowering consumers to play a greater role in their own care. Survey data shows that Americans are well aware of both the benefits and the risks of health IT. A large majority

of the public wants electronic access to their personal health information—both for themselves and for their health care providers—because they believe such access is likely to increase their quality of care. At the same time, people have significant concerns about the privacy of their medical records. In a national survey conducted in 2005, 67% of respondents were "somewhat" or "very concerned" about the privacy of their personal medical records.[1] In a 2006 survey, when Americans were asked about the benefits of and concerns about online health information:

- 80% said they are very concerned about identity theft or fraud;
- 77% reported being very concerned about their medical information being used for marketing purposes;
- 56% were concerned about employers having access to their health information; and
- 55% were concerned about insurers gaining access to this information.[2]

Health IT has a greater capacity to protect sensitive personal health information than is the case now with paper records. Digital technologies, including strong user authentication and audit trails, can be employed to limit and track access to electronic health information automatically. Electronic health information networks can be designed to facilitate data sharing for appropriate purposes without needing to create large, centralized databases that can be vulnerable to security breaches. Encryption can help ensure that sensitive data is not accessed when a system has been breached. Privacy and security policies and practices are not 100% tamperproof, but the virtual locks and enforcement tools made possible by technology can make it more difficult for bad actors to access health information and help ensure that, when there is abuse, that the perpetrators will be detected and punished.[3]

At the same time, the computerization of personal health information—¾ in the absence of strong privacy and security safeguards—¾ magnifies the risk to privacy. As the recent spate of large-scale privacy and security breaches demonstrates, serious vulnerabilities exist now. Tens of thousands of health records can be accessed or disclosed through a single breach. Recent headlines about the theft of an NIH laptop loaded with identifiable information about clinical research subjects underscore these concerns, and this is just one of numerous examples. The cumulative effect of these reports of data breaches and inappropriate access to medical records, coupled with a lack of enforcement of existing privacy rules by federal authorities, deepens consumer distrust in the ability of electronic health information systems to provide adequate privacy and security protections.[4]

With rare exception, national efforts to advance greater use of health IT have not adequately or appropriately addressed the privacy and security issues raised by the movement to electronic health records. While some persist in positioning privacy as an obstacle to achieving the advances that greater use of health IT can bring, it is clear that the opposite is true: enhanced privacy and security built into health IT systems will bolster consumer trust and confidence and spur more rapid adoption of health IT and realization of its potential benefits.

Protecting privacy is important not just to avoid harm, but because good health care depends on accurate and reliable information.[5] Without appropriate protections for privacy and security in the healthcare system, patients will engage in "privacy-protective" behaviors to avoid having their personal health information used inappropriately.[6] According to a recent poll, one in six adults (17%)—representing 38 million persons—say they withhold information from their health providers due to worries about how the medical data might be disclosed.[7] Persons who report that they are in fair or poor health and racial and ethnic minorities report even higher

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[1] National Consumer Health Privacy Survey 2005, California HealthCare Foundation (November 2005) (2005 National Consumer Survey).

[2] Study by Lake Research Partners and American Viewpoint, conducted by the Markle Foundation (November 2006) (2006 Markle Foundation Survey).

[3] See For The Record: Protecting Electronic Health Information, Committee on Maintaining Privacy and Security in Health Care Applications of the National Information Infrastructure, Computer Science and Telecommunications Board, National Research Council (National Academy Press, Washington, DC 1997) for a discussion of the inability of systems to be 100% tamperproof.

[4] See http://www.cdt.org/healthprivacy/20080311stories.pdf for stories of health privacy breaches and inappropriate uses of personal health information.

[5] See Janlori Goldman, "Protecting Privacy to Improve Health Care," Health Affairs (Nov-Dec, 1998) (Protecting Privacy); Promoting Health/Protecting Privacy: A Primer, California Healthcare Foundation and Consumers Union (January 1999), http://www.chcf.org/topics/view.cfm?itemID=12502 (Promoting Health/Protecting Privacy).

[6] Protecting Privacy; Promoting Health/Protecting Privacy; 2005 National Consumer Survey.

[7] Harris Interactive Poll #27, March 2007.

levels of concern about the privacy of their personal medical records and are more likely than average to practice privacy-protective behaviors.[8]

The consequences of this climate of fear are significant—for the individual, for the medical community, and for public health:

- The quality of care these patients receive may suffer;
- Their health care providers' ability to diagnose and treat them accurately may be impaired;
- The cost of care escalates as conditions are treated at a more advanced stage and in some cases may spread to others; and
- Research, public health, and quality initiatives may be undermined, as the data in patient medical records is incomplete or inaccurate.[9]

It is often difficult or impossible to establish effective privacy protections retroactively, and restoring public trust that has been significantly undermined is much more difficult than building it at the start. Now—in the early stages of health IT adoption is the critical window for addressing privacy.

We Need a Comprehensive Privacy and Security Framework That Will Build Public Trust, Advance Health IT

To build public trust in health IT, we need a comprehensive privacy and security framework that sets clear parameters for access, use and disclosure of personal health information for all entities engaged in e-health. In developing this comprehensive framework, policymakers, regulators, and developers of HIT systems need not start from scratch. A framework for HIT and health information exchange already exists, in the form of the generally accepted "fair information practices" ("FIPS") that have been used to shape policies governing uses of personal information in a variety of contexts—most notably the privacy regulations enacted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), which established the first federal health privacy framework.[10] While there is no single formulation of the "FIPs," the Common Framework developed by the Markle Foundation's multi-stakeholder Connecting for Health initiative, would:

- Implement core privacy principles;
- Adopt trusted network design characteristics; and
- Establish oversight and accountability mechanisms.[11]

In particular, the core privacy principles of the Connecting for Health Common Framework set forth a comprehensive roadmap for protecting the privacy and security of personal health information while still allowing information to be accessed and disclosed for legitimate purposes. Those core privacy principles are:

- **Openness and Transparency:** There should be a general policy of openness about developments, practices, and policies with respect to personal data. Individuals should be able to know what information exists about them, the purpose of its use, who can access and use it, and where it resides.
- **Purpose Specification and Minimization:** The purposes for which personal data is collected should be specified at the time of collection, and the subsequent use should be limited to those purposes or others that are specified on each occasion of change of purpose.
- **Collection Limitation:** Personal health information should only be collected for specified purposes, should be obtained by lawful and fair means and, where possible, with the knowledge or consent of the data subject.
- **Use Limitation:** Personal data should not be disclosed, made available, or otherwise used for purposes other than those specified.
- **Individual Participation and Control:**
- Individuals should control access to their personal health information:
- Individuals should be able to obtain from each entity that controls personal health data, information about whether or not the entity has data relating to them.
- Individuals should have the right to:

[8] 2005 National Consumer Survey.

[9] Id.

[10] Other potential sources for policy recommendations include the GAO, the National Center for Vital Health Statistics and the National Governor's Association State Alliance for eHealth.

[11] See *www.connectingforhealth.org* for a more detailed description of the Common Framework.

- Have personal data relating to them communicated within a reasonable time (at an affordable change, if any), and in a form that is readily understandable.
- Be given reasons if a request (as described above) is denied, and to be able to challenge such a denial.
- Challenge data relating to them and have it rectified, completed, or amended.
- **Data Integrity and Quality:** All personal data collected should be relevant to the purposes for which they are to be used and should be accurate, complete and current.
- **Security Safeguards and Controls:** Personal data should be protected by reasonable security safeguards against such risks as loss, unauthorized access, destruction, use, modification or disclosure.
- **Accountability and Oversight:** Entities in control of personal health data must be held accountable for implementing these information practices.
- **Remedies:** Legal and financial remedies must exist to address any security breaches or privacy violations.

The HIPAA privacy and security regulations include provisions that address each of these categories—but, as discussed in more detail below, the rules are insufficient to cover the new and rapidly evolving e-health environment. To build consumer trust in e-health systems and ensure that health IT and electronic health information exchange move forward with sufficient protections for privacy and security, Congress should consider: strengthening HIPAA for records kept by traditional health system participants; filling gaps in HIPAA's coverage where appropriate; and establishing additional legal protections to reach new actors in the e-health environment and address the increased migration of personal health information out of the traditional medical system.

Strengthening HIPAA Privacy and Security Rules to Meet New Challenges

The HIPAA privacy and security regulations that took effect in 2003 reflect elements of a comprehensive framework and provide important privacy protections governing access, use and disclosure of personally identifiable health information by some entities in the health care system. The HIPAA Privacy Rule was a landmark in privacy protection, but as noted above, the regulation does not adequately cover the new e-health environment. For example:

- State and regional health information organizations or health information exchanges (also known as RHIOs or HIEs), which may aggregate and facilitate exchange of personal health information, are often not covered by HIPAA privacy and security regulations. Personal health records and other consumer access services now being created by third parties, including companies such as Google and Microsoft, as well as by employers usually fall outside of the HIPAA rules.
- Personal health data is migrating onto the Internet through an exploding array of health information sites, online support groups, and other on-line health tools, regulated only through enforcement by the Federal Trade Commission (FTC) of the general prohibition against unfair and deceptive trade practices, such as a failure to follow promised privacy policies.
- HIPAA has never required that patients receive notice when their personal heath information is inappropriately accessed or disclosed.
- While the Privacy Rule includes criteria for de-identifying data, new technologies are making it much easier to re-identify once de-identified health information and to combine it with personal information in other databases, making it more likely that sensitive health information will be available to unauthorized recipients for uses that have nothing to do with treatment or payment.
- The HIPAA rules have never been adequately enforced. The Office for Civil Rights (OCR) in the U.S. Department of Health and Human Services (HHS), charged with enforcing HIPAA, has not levied a single penalty against a HIPAA-covered entity in the nearly five years since the rules were implemented, even though that office has found numerous violations of the rules.[12]

Historically, states have filled the gaps in federal health privacy laws by enacting legislation that provides stronger privacy and security protections for sensitive data, such as mental health and genetic information. The states continue to have an im-

[12] "Effectiveness of medical privacy law is questioned," Richard Alonso-Zaldivar, Los Angeles Times (April 9, 2008) http://www.latimes.com/business/la-na-privacy9apr09,0,5722394.story.

portant role to play, but relying on the states to fill deficiencies in HIPAA's Privacy Rule—or to regulate entities outside of the traditional healthcare sphere—does not provide a comprehensive, baseline solution that gives all Americans adequate privacy and security protections, and does not offer all the entities in the e-health space a predictable and consistent policy environment.

Although it is desirable for Congress to enact legislation that fills some of the gaps in HIPAA and to enact a general privacy and security framework to govern health IT, we caution against a "one-size-fits all" approach that treats all actors that hold personal health information the same. The complexity and diversity of entities connected through health information exchange, and their very different roles and different relationships to consumers, will often require precisely tailored policy solutions that are context and role-based and flexible enough to both encourage and respond to innovation. For example, it makes little sense to have the same set of rules for "personal health records," which are often created by and controlled by patients and held by third party data stewards outside the healthcare system, and for "electronic health records," which are created and controlled by health care providers for purposes of treatment and care management. To take another example, rules for use of personal health information for treatment need to be quite different than rules for marketing or other secondary uses. Rules regarding use of health information for research need to be separately considered as well. Therefore, a second major challenge for Congress is to decide what can be legislated and what must be delegated to agency rulemaking—and what areas are best left to be developed and enforced through industry best practices.

Below we discuss in detail two critical areas that we do believe need attention from Congress: establishing privacy protections for personal health records offered by entities not currently covered by HIPAA and strengthening HIPAA enforcement. But CDT also recommends Congress address the following, either through express legislation language or by tasking HHS to modify the HIPAA privacy and security rules (or a combination of both approaches):

- Clarify how the new entities that facilitate the electronic exchange of personal health information—including HIEs (Health Information Exchanges), RHIOs (Regional Health Information Organizations), and E-Prescribing Gateways—are covered by HIPAA (for example, by making them HIPAA covered entities or requiring them to have business associate agreements with the entities that exchange health information through them).
- Establish a federal right for patients to be notified in the event of a breach of identifiable health information.
- Tighten the definition of "marketing" in the HIPAA privacy rules to make clear that covered entities cannot use a patient's protected health information to send a communication recommending a product or service without that patient's prior authorization.
- Make clear that when entities use electronic medical records, their patients have the right to receive an electronic copy of their health information, and establish a right for patients to monitor who has accessed their health information through audit trails.
- Ensure that covered entities holding protected health information access, use, and disclose only the minimum necessary amount of information when engaging in activities related to payment and health care operations [13] and require entities to use information stripped of common patient identifiers when it is possible to do so and still accomplish the legitimate purpose for which the information was accessed.[14]
- Explore whether the current HIPAA de-identification standard—now five years old—needs to be updated given the increased public availability of data on-line and the possible greater potential for re-identification of de-identified data.

Establishing Privacy Protections for Personal Health Records

Personal health records and other similar consumer access services and tools now being created by Internet companies such as Google and Microsoft, as well as by employers, will not be covered by the HIPAA regulations unless they are being offered to consumers by covered entities. In this unregulated arena, consumer privacy will be protected only by the PHR offeror's privacy and security policies (and poten-

[13] See 45 C.F.R. 164.501 for a definition of "health care operations."

[14] For example, HIPAA rules provide for the use of a limited data set—information stripped of certain patient identifiers—for certain purposes, but its use is neither required nor expressly encouraged. See 45 C.F.R. 164.514(e).

tially under certain state laws that apply to uses and disclosures of certain types of health information), and if these policies are violated, the Federal Trade Commission (FTC) may bring an action against a company for failure to abide by its privacy policies. The policies of PHR vendors range from very good to seriously deficient.[15] The absence of any clear limits on how these entities can access, use and disclose information is alarming—and has motivated some to suggest extending the HIPAA Privacy Rule to cover PHRs. But we believe that the Privacy Rule, which was designed to set the parameters for use of information by traditional health care entities, would not provide adequate protection for PHRs and may do more harm than good in its current scope. Further, it may not be appropriate for HHS, which has no experience regulating entities outside of the health care arena, to take the lead in enforcing consumer rights and protections with respect to PHRs.

We believe tasking HHS and FTC with jointly developing recommendations for privacy and security requirements for PHRs is the right approach for ultimately establishing comprehensive privacy and security protections for consumers using these new health tools. For PHRs offered by entities that are not part of the traditional health care system, it is critical that regulators understand the business model behind these products, which will largely rely on advertising revenue and partnerships with third-party suppliers of health-related products and services. Relying solely on consumer authorization for use of information shifts the burden of protecting privacy solely to the consumer and puts the bulk of the bargaining power on the side of the entity offering the PHR. For consumers to truly trust PHRs—and for these tools to flourish as effective mechanisms for engaging more consumers in their health care—clear rules are needed regarding marketing and commercial uses that will better protect consumers.

Congress Should Also Consider Strengthening HIPAA Enforcement

When Congress enacted HIPAA in 1996, it included civil and criminal penalties for failure to comply with the statute—and these penalties applied to the subsequent privacy and security rules implemented years later. Unfortunately, the HIPAA rules have never been adequately enforced. As noted above, HHS has not levied a single penalty against a HIPAA-covered entity in the nearly five years since the rules were implemented.[16] The Justice Department has levied some penalties under the criminal provisions of the statute—but a 2005 opinion from DOJ's Office of Legal Counsel (OLC) expressly limits the application of the criminal provisions to covered entities, forcing prosecutors to turn to other laws in order to criminally prosecute certain employees of covered entities who have criminally accessed, used or disclosed a patient's protected health information.[17]

A lax enforcement environment sends a message to entities that access, use and disclose protected health information that they need not devote significant resources to compliance with the rules. Without strong enforcement, even the strongest privacy and security protections are but an empty promise for consumers. Further, even under the existing enforcement regime, there is no ability for consumers whose information is accessed or disclosed in violation of HIPAA to seek redress or be made whole.

Below are a number of incremental steps that Congress can take this year to improve enforcement of HIPAA.

Accountability for Business Associates

Under current rules, business associates who access, use and disclose protected health information on behalf of covered entities are accountable for complying with HIPAA privacy and security regulations only through their contracts with covered entities. If the covered entity does not take action to enforce the contract, there is no other mechanism for ensuring that the business associate complies with the applicable rules. Further, HHS can only hold the covered entity responsible for the ac-

[15] The HHS Office of the National Coordinator commissioned a study in early 2007 of the policies of over 30 PHR vendors and found that none covered all of the typical criteria found in privacy policy. For example, only two policies described what would happen to the data if the vendor were sold or went out of business, and only one had a policy with respect to accounts closed down by the consumer.

[16] Just last week, HHS announced that Seattle-based Providence Health & Services agreed to pay $100,000 as part of a settlement of multiple violations of the HIPAA regulations. But the press release from HHS made clear that this amount was not a civil monetary penalty. http://www.hhs.gov/news/press/2008pres/07/20080717a.html.

[17] See http://www.americanprogress.org/issues/2005/06/b743281.html for more information on the OLC memo and the consequences.

tions of business associates if the entity knew of a "pattern of activity or practice of the business associate that constituted a material breach or violation" of its agreement with the covered entity, and the covered entity doesn't take action to cure the breach or terminate the contract.[18] Of interest, if the covered entity decides that terminating the contract is "not feasible," the covered entity is required to report the problem to the Secretary.[19] But the regulations do not give the Secretary any further authority to enforce HIPAA against the business associate or hold the covered entity responsible for the violation. Congress should take action to ensure that business associates can be held legally accountable for complying with HIPAA regulations.

Strengthening the Statutory Provisions Authorizing Civil and Criminal Penalties

Penalties for Criminal Violations. As noted above, the HIPAA statute provides for criminal penalties for intentional violations; but a DOJ Office of Legal Counsel Memo expressly limits the application of these provisions to covered entities. According to this memo, DOJ cannot prosecute employees of covered entities or their business associates for intentional violations of HIPAA unless these persons are carrying out a specific policy or business practice endorsed by the covered entity. Congress should make it clear that penalties can be assessed against covered entities, business associates, and their employees for violations of HIPAA.

Civil Monetary Penalties—Part I. The statute prohibits the Secretary of HHS from imposing civil monetary penalties if the HIPAA violation is "an offense *punishable*" under the criminal provisions of the statute.[20] A reasonable interpretation of this provision is that if a HIPAA complaint indicates a possible criminal violation, the Secretary of HHS cannot launch a civil investigation or pursue civil monetary penalties, even if DOJ decides not to prosecute the case. To avoid having the most egregious HIPAA violations go unpunished, Congress should act to give the Secretary clear authority to investigate and pursue civil monetary penalties unless DOJ decides to pursue criminal penalties.

Civil Monetary Penalties—Part II. The civil penalty provisions of the statute envision three types of HIPAA violations: those that the entity was not aware of (or could not have been aware of exercising reasonable diligence); those due to reasonable cause; and those due to willful neglect.[21] The statute also prohibits the Secretary from imposing civil monetary penalties in cases of lack of knowledge or due to reasonable cause, unless the entity is unable to correct the violation within a 30-day time period (with discretion to extend this time period).[22] The statute also gives the Secretary authority to provide compliance assistance to help the covered entity correct a violation due to reasonable cause and to waive or reduce a penalty in cases of reasonable cause if the penalty would be excessive relative to the compliance failure involved.[23] The statute requires that the Secretary impose civil monetary penalties for HIPAA violations;[24] the statute does not give the Secretary discretion to give a covered entity a chance to correct the violation or the authority to waive or reduce penalties in cases of willful neglect. The HIPAA enforcement regulations, however, require the Secretary to first try to informally resolve *all HIPAA complaints*—which means there is never an investigation into whether or not the violation rises to the level of willful neglect (and thus should be subject to civil monetary penalties). Congress should act to clarify that the Secretary must investigate all complaints for which a preliminary inquiry into the facts indicates possible willful neglect and pursue civil monetary penalties in willful neglect cases.

Establishing Penalties for Re-identification of De-identified Data

Health information that is de-identified is not covered by the protections of HIPAA. Thus, covered entities can provide de-identified data to other persons or entities without regard to the requirements regarding access, use and disclosure in the HIPAA regulations, and these entities can use this data as they wish, subject only to the terms of any applicable contractual requirements (or any state laws that

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[18] 45 C.F.R. 164.504(e)(ii).
[19] Id.
[20] Section 1176(b)(1) of the Social Security Act.
[21] See Sections 1176(b)(2)–(3) of the Social Security Act.
[22] Id.
[23] Sections 1176(b)(3)–(4) of the Social Security Act.
[24] See Section 1176(a) of the Social Security Act (". . . The Secretary shall impose on any person who violates a provision of this part a penalty of not more than $100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000").

might apply). If one of these persons or entities then re-identifies this data—for example, by using information available in a public database—that re-identified information would not be subject to HIPAA regulations unless the person or entity holding the data was a covered entity. Earlier in this testimony we suggest examining the current HIPAA de-identification standard to ensure that it continues to provide robust protection for patient-identifiable data. But Congress could also protect individual privacy by enacting prohibitions (and penalties for) the unauthorized re-identification of de-identified data.

Other Ways to Improve Accountability under HIPAA

A significant shortfall in HIPAA is the absence of any way for the consumer whose health information privacy has been violated to pursue meaningful recourse and be made whole. CDT believes that a private right of action should be part of any enforcement scheme. We recognize that providing a private right of action to pursue every HIPAA complaint no matter how trivial would be inappropriate and disruptive, but Congress should further consider giving consumers some right to privately pursue recourse where there are intentional violations of the law, or in circumstances of willful neglect. As noted above, the HIPAA statute already provides for criminal and civil monetary penalties in such cases—but these penalties do not currently go to the consumers whose privacy was violated, and as structured may not be sufficient (at least with respect to civil penalties) to provide meaningful recourse for individuals.

Structuring an effective private right of action will take careful thought and consideration. Given the dwindling number of legislative days left in the year and political circumstances, we recognize that it is unlikely we can pursue implementing such a right this year. But we urge Congress to hold hearings on this issue to begin to develop a workable way to ensure that entities covered by HIPAA are directly accountable to consumers for the most egregious violations of their privacy. In the meantime, the recommendations we set forth above are ones that can be put into legislation this year and if implemented will greatly improve HIPAA enforcement.

Congress should also consider authorizing State Attorneys General to also enforce HIPAA. The HHS Office of Civil Rights is significantly under-resourced, and expressly authorizing state authorities to enforce HIPAA puts more hands on the enforcement deck. Currently, only those State Attorneys General who expressly have the authority to enforce federal law in their state authorizing statutes are able to enforce the federal HIPAA provisions. State authorities are able to enforce their own state health privacy laws, but in only a handful of states are those laws are as comprehensive as HIPAA. Congress should consult with State Attorneys General about providing them with express authority to enforce HIPAA and consider taking future action in this area (particularly if the enforcement "fixes" recommended earlier in this testimony are not successful in actually improving HIPAA enforcement).

The Appropriate Role of Consumer Consent

Recently, public debates about how best to protect the confidentiality, privacy and security of health information have focused almost exclusively on whether patients should be asked to authorize all uses of their health information. The ability of individuals to have some control over their personal health information is important, and a comprehensive privacy and security framework should address patient consent.[25] A number of states have passed laws requiring patient authorization to access, use and disclose certain sensitive categories of health information, and federal law prohibits the disclosure of substance abuse treatment records without express patient authorization. HIPAA Privacy Rules currently prohibit the use of certain types of information, such as psychotherapy notes, or prohibit use of information for certain purposes, such as marketing, without express patient authorization, and the Rules provide individuals with the right to object to certain uses and disclosures (such as in facility directories or to family members). The Rules also allow covered entities to give consumers greater rights to restrict uses and disclosures of their information. Health information systems must be structured in a way that allows these consents to be honored and appropriately and securely managed.

But patient authorization is not a panacea, and as appealing as it may appear to be in concept, in practice reliance on consent would provide weak protection for consumer's health information. If health privacy rules fail to address the range of

[25] Much more should be done to improve the way in which consent options are presented to consumers in the healthcare context. Internet technology can help in this regard, making it easier to present short notices, layered notices and more granular forms of consent.

privacy and security issues through concrete policies, and instead rely only (or significantly) on giving individuals the right to consent to multiple uses and disclosures of their personal health information, the result is likely to be a system that is *less* protective of privacy and confidentiality.

Among other reasons, a consent-based system places most of the burden of privacy protection on patients at a time where they may be least able to make complicated decisions about use of their health data. Most don't read the details of a consent form and those that do often do not understand the terms. Many wrongly assume that the existence of a "privacy policy" means that their personal information will not be shared, even when the policy and the accompanying consent form say just the opposite.[26] If mere patient authorization is all that is needed to share data with third parties, highly sensitive patient information will be disclosed to entities that are completely outside the scope of the HIPAA privacy regulation. If consent becomes the focus of privacy protection, it is clear that patients will be exposed to unregulated and potentially uncontemplated uses—and misuses—of their data. Further, if policymakers rely on consent by an individual for any particular use of his or her information as the key to privacy protection, the healthcare industry will have fewer incentives to design systems with stronger privacy and security protections.

In contrast, a comprehensive approach—which puts clear parameters around who can access, use and disclose a patient's personal health information and for what purposes—puts the principal burden on the entities holding this information by placing clear enforceable limits on the collection and use of personal health information and backs it up with strong enforcement.[27]

Conclusion

Thank you for the opportunity to present this testimony in support of strengthening privacy and security protections for personal health information, which will build consumer trust and enable health IT and electronic health information exchange to move forward. I would be pleased to answer any questions you may have.

Attachment

Comprehensive Privacy and Security: Critical for Health Information Technology Version 1.0—May 2008

In this paper, CDT calls for the adoption of a comprehensive privacy and security framework for protection of health data as information technology is increasingly used to support exchange of medical records and other health information. CDT believes that privacy and security protections will build public trust, which is crucial if the benefits of health IT are to be realized. In CDT's view, implementation of a comprehensive privacy and security framework will require a mix of legislative action, regulation and industry commitment and must take into account the complexity of the evolving health exchange environment.

Privacy and Security Protections are Critical to Health IT

Health information technology (health IT) and health information exchange can help improve health care quality and efficiency, while also empowering consumers to play a greater role in their own care. At the federal and state levels, policymakers are pushing initiatives to move the health care system more rapidly into the digital age.

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[26] See "Stopping Spyware at the Gate: A User Study of Privacy, Notice and Spyware" (with Nathan Good, Rachna Dhamija, Jens Grossklags, Steven Aronovitz, David Thaw and Joseph Konstan), presented at the 2005 Symposium on Usable Privacy and Security (SOUPS), also in ACM INTERNATIONAL CONFERENCE PROCEEDING SERIES; VOL. 93, PROCEEDINGS OF THE 2005 SYMPOSIUM ON USABLE PRIVACY AND SECURITY, Pittsburgh, Pennsylvania (2005); 2005 National Consumer Survey; "Research Report: Consumers Fundamentally Misunderstand the Online Advertising Marketplace," Joseph Turow, Deidre K. Mulligan and Chris Jay Hoofnagle, survey conducted by University of Pennsylvania Annenberg School for Communications and UC-Berkeley Law School's Samuelson Law, Technology and Public Policy Clinic 2007.

[27] By contrast, a comprehensive approach puts the principal burden on the entities holding personal health information to protect privacy by placing clear enforceable limits on the collection and use of personal health information and backs it up with strong enforcement. See Beyond Consumer Consent: Why We Need a Comprehensive Approach to Privacy in a Networked World, http://www.cdt.org/healthprivacy/20080221consentbrief.pdf.

However, health IT initiatives pose heightened risks to privacy. Recent breaches of health information underscore that the risks are real. At the same time, there is widespread confusion and misinterpretation about the scope of current health privacy laws. Some are pushing for quick "fixes" to try to address the public's privacy concerns, but fully resolving these issues requires a comprehensive, thoughtful and flexible approach.

While some persist in positioning privacy as an obstacle to achieving the advances that greater use of health IT can bring, it is clear that the opposite is true: enhanced privacy and security built into health IT systems will bolster consumer trust and confidence and spur more rapid adoption of health IT and realization of its potential benefits.

Survey data shows that Americans are well aware of both the benefits and the risks of health IT. A large majority of the public wants electronic access to their personal health information—both for themselves and for their health care providers—because they believe such access is likely to increase their quality of care. At the same time, people have significant concerns about the privacy of their medical records. In a national survey conducted in 2005, 67% of respondents were "somewhat" or "very concerned" about the privacy of their personal medical records.[28] In a 2006 survey, when Americans were asked about the benefits of and concerns about online health information:

- 80% said they are very concerned about identity theft or fraud;
- 77% reported being very concerned about their medical information being used for marketing purposes;
- 56% were concerned about employers having access to their health information; and
- 53% were concerned about insurers gaining access to this information.[29]

Appropriate privacy protections must be incorporated from the outset in the design of new health IT systems and policies. It is often difficult or impossible to establish effective privacy protections retroactively, and restoring public trust that has been significantly undermined is much more difficult than building it at the start. Now—in the early stages of health IT adoption—is the critical window for addressing privacy.

As an Internet policy organization and privacy advocate, CDT brings a unique perspective to these issues, based on our experience in shaping workable privacy solutions for a networked environment. In this paper, we describe why it is necessary that all parties—from traditional health care entities and new developers of personal health records, to legislators and regulators—address privacy and security in health IT systems. We emphasize that all stakeholders need to begin immediately to implement and enforce a comprehensive privacy and security framework in all of the various tools and processes of health IT.

The Consequences of Failing to Act

Protecting privacy is important not just to avoid harm, but because good health care depends on accurate and reliable information.[30] Without appropriate protections for privacy and security in the healthcare system, patients will engage in "privacy-protective" behaviors to avoid having their personal health information used inappropriately.[31] According to a recent poll, one in six adults (17%)—representing 38 million persons—say they withhold information from their health providers due to worries about how the medical data might be disclosed.[32] Persons who report that they are in fair or poor health and racial and ethnic minorities report even higher levels of concern about the privacy of their personal medical records and are more likely than average to practice privacy-protective behaviors.[33]

People who engage in privacy-protective behaviors to shield themselves from stigma or discrimination often pay out-of-pocket for their care; ask doctors to fudge a diagnosis; switch doctors frequently to avoid having all of their records in one loca-

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[28] National Consumer Health Privacy Survey 2005, California HealthCare Foundation (November 2005) (2005 National Consumer Survey).

[29] Study by Lake Research Partners and American Viewpoint, conducted by the Markle Foundation (November 2006) (2006 Markle Foundation Survey).

[30] See Janlori Goldman, "Protecting Privacy To Improve Health Care," Health Affairs (Nov–Dec, 1998) (Protecting Privacy); Promoting Health/Protecting Privacy: A Primer, California Healthcare Foundation and Consumers Union (January 1999), http://www.chcf.org/topics/view.cfm?itemID=12502 (Promoting Health/Protecting Privacy).

[31] Protecting Privacy; Promoting Health/Protecting Privacy; 2005 National Consumer Survey.

[32] Harris Interactive Poll #27, March 2007.

[33] 2005 National Consumer Survey.

tion; lie; or even avoid seeking care altogether.[34] The consequences are significant—for the individual, for the medical community, and for public health:

- The quality of care these patients receive may suffer;
- Their health care providers' ability to diagnose and treat them accurately may be impaired;
- The cost of care escalates as conditions are treated at a more advanced stage and in some cases may spread to others; and
- Research, public health, and quality initiatives may be undermined, as the data in patient medical records is incomplete or inaccurate.[35]

Health IT Can Protect Privacy—But Magnifies Risks

Health IT has a greater capacity to protect sensitive personal health information than is the case now with paper records. For example, it is often impossible to tell whether someone has inappropriately accessed a paper record. By contrast, technologies, including strong user authentication and audit trails, can be employed to limit and track access to electronic health information automatically. Electronic health information networks can be designed to facilitate data sharing for appropriate purposes without needing to create large, centralized databases of sensitive information that can be vulnerable to security breaches. Encryption can help ensure that sensitive data is not accessed when a system has been breached. Privacy and security policies and practices are not 100% tamperproof, but the virtual locks and enforcement tools made possible by technology can make it more difficult for bad actors to access health information and help ensure that, when there is abuse, that the perpetrators will be detected and punished.[36]

At the same time, the computerization of personal health information—in the absence of strong privacy and security safeguards—magnifies the risk to privacy. As the recent spate of large-scale privacy and security breaches demonstrates, serious vulnerabilities exist now. Tens of thousands of health records can be accessed or disclosed through a single breach. Recent headlines about the theft of an NIH laptop loaded with identifiable information about clinical research subjects, and the accidental posting of identifiable health information on the Internet by a health plan, underscore these concerns, and are just two of numerous examples. The cumulative effect of these reports of data breaches and inappropriate access to medical records, coupled with the lack of enforcement of existing privacy rules by federal authorities, deepens consumer distrust in the ability of electronic health information systems to provide adequate privacy and security protections.[37]

Elements of a Comprehensive Privacy and Security Framework That Will Build Public Trust, Advance Health IT

A comprehensive privacy and security framework must be implemented by all stakeholders engaged in e-health efforts. Such a framework, as outlined by the Markle Foundation's Connecting for Health, would:

- Implement core privacy principles;
- Adopt trusted network design characteristics;
- Establish oversight and accountability mechanisms.

Congress should set the framework for national policy through legislation. Ensuring and enforcing adequate protections for privacy and security also will require coordinated actions on the part of key regulatory agencies, as well as industry best practices. The framework should be implemented in part by strengthening the HIPAA Privacy Regulation for records kept by the traditional health system participants, but also needs to address the increased migration of personal health information out of the traditional medical system.

Notwithstanding the urgent need to address privacy, health information policy initiatives—both legislative and administrative—are moving forward without addressing privacy and security at all, or they are taking a piecemeal approach that

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[34] Protecting Privacy; 2005 National Consumer Survey; Promoting Health/Protecting Privacy.

[35] Id.

[36] See For The Record: Protecting Electronic Health Information, Committee on Maintaining Privacy and Security in Health Care Applications of the National Information Infrastructure, Computer Science and Telecommunications Board, National Research Council (National Academy Press, Washington, DC 1997) for a discussion of the inability of systems to be 100% tamperproof.

[37] See http://www.cdt.org/healthprivacy/20080311stories.pdf for stories of health privacy breaches and inappropriate uses of personal health information.

too narrowly focuses on a single activity, such as e-prescribing, or on just one aspect of fair information practices, such as the appropriate role of patient consent.

In developing a comprehensive framework, policymakers, regulators, and developers of HIT systems need not start from scratch. A framework for HIT and health information exchange already exists, in the form of the generally accepted "fair information practices" ("FIPS") that have been used to shape policies governing uses of personal information in a variety of contexts, most notably the HIPAA Privacy Regulation, which established the first federal health privacy framework.[38] While there is no single formulation of the "FIPs," the Common Framework developed by the Markle Foundation's Connecting for Health initiative, which includes broad representation from across the health care industry and patient advocacy organizations, describes the principles as follows:

- Openness and Transparency: There should be a general policy of openness about developments, practices, and policies with respect to personal data. Individuals should be able to know what information exists about them, the purpose of its use, who can access and use it, and where it resides.
- Purpose Specification and Minimization: The purposes for which personal data is collected should be specified at the time of collection, and the subsequent use should be limited to those purposes or others that are specified on each occasion of change of purpose.
- Collection Limitation: Personal health information should only be collected for specified purposes, should be obtained by lawful and fair means and, where possible, with the knowledge or consent of the data subject.
- Use Limitation: Personal data should not be disclosed, made available, or otherwise used for purposes other than those specified.
- Individual Participation and Control:
- Individuals should control access to their personal health information:

§ Individuals should be able to obtain from each entity that controls personal health data, information about whether or not the entity has data relating to them.

- Individuals should have the right to:

§ Have personal data relating to them communicated within a reasonable time (at an affordable change, if any), and in a form that is readily understandable;
§ Be given reasons if a request (as described above) is denied, and to be able to challenge such a denial:
§ Challenge data relating to them and have it rectified, completed, or amended.

- Data Integrity and Quality: All personal data collected should be relevant to the purposes for which they are to be used and should be accurate, complete and current.
- Security Safeguards and Controls: Personal data should be protected by reasonable security safeguards against such risks as loss, unauthorized access, destruction, use, modification or disclosure.
- Accountability and Oversight: Entities in control of personal health data must be held accountable for implementing these information practices.
- Remedies: Legal and financial remedies must exist to address any security breaches or privacy violations.

The Connecting for Health Common Framework also sets forth characteristics for network design that can help ensure health information privacy and security.[39] These network design characteristics facilitate health information exchange not through centralization of data but rather through a "network of networks." Such a distributed architecture is more likely to protect information. Other key elements of such a system are interoperability and flexibility, which support innovation and create opportunities for new entrants.

The Role of HIPAA in the New Environment

The federal privacy and security rules that took effect in 2003 under the Health Insurance Portability and Accountability Act (HIPAA) reflect elements of this framework and provide important privacy protections governing access, use and disclosure of personally identifiable health information by some entities in the health care sys-

[38] Other potential sources for policy recommendations include the GAO, the National Center for Vital Health Statistics and the National Governor's Association State Alliance for eHealth.
[39] See www.connectingforhealth.org for more details on the Common Framework.

tem. The HIPAA Privacy Rule was a landmark in privacy protection, but it is widely recognized that the regulation is insufficient to adequately cover the new and rapidly evolving e-health environment. For example:

- State and regional health information organizations or health information exchanges (also known as RHIOs or HIEs), which may aggregate and facilitate exchange of personal health information, are often not covered by HIPAA's Privacy Rule.
- Personal health records and other consumer access services now being created by third parties, including companies such as Google and Microsoft, as well as by employers usually fall outside of the HIPAA rules.
- Personal health data is migrating onto the Internet through an exploding array of health information sites, online support groups, and other on-line health tools, regulated only through enforcement by the Federal Trade Commission (FTC) of the general prohibition against unfair and deceptive trade practices, such as a failure to follow promised privacy policies.
- While the Privacy Rule includes criteria for de-identifying data, new technologies are making it much easier to re-identify once de-identified health information and to combine it with personal information in other databases, making it more likely that sensitive health information will be available to unauthorized recipients for uses that have nothing to do with treatment or payment.

In addition, the HIPAA rules have never been adequately enforced. The HHS Office for Civil Rights (OCR), charged with enforcing HIPAA, has not levied a single penalty against a HIPAA-covered entity in the nearly five years since the rules were implemented, even though that office has found numerous violations of the rules.[40]

Historically, states have filled the gaps in federal health privacy laws by enacting legislation that provides stronger privacy and security protections for sensitive data, such as mental health and genetic information. The states continue to have an important role to play, but relying on the states to fill deficiencies in HIPAA's Privacy Rule—or to regulate entities outside of the traditional healthcare sphere—does not provide a comprehensive, baseline solution that gives all Americans adequate privacy and security protections, and does not offer all the entities in the e-health space a predictable and consistent policy environment.

National Conversations about Privacy and Security Have Been Too Focused on the Issue of Individual Consent

The ability of individuals to have some control over their personal health information is important, and a comprehensive privacy and security framework should address patient consent.[41] However, consent is not a panacea. If health privacy rules fail to address the range of privacy and security issues through concrete policies, and instead rely only (or significantly) on giving individuals the right to consent to multiple uses and disclosures of their personal health information, the result is likely to be a system that is *less* protective of privacy and confidentiality.

Among other reasons, a consent-based system places most of the burden of privacy protection on patients at a time where they may be least able to make complicated decisions about use of their health data. Most don't read the details of a consent form and those that do often do not understand the terms. Many wrongly assume that the existence of a "privacy policy" means that their personal information will not be shared, even when the policy and the accompanying consent form say just the opposite.[42] If mere patient authorization is all that is needed to share data with third parties, highly sensitive patient information will be disclosed to entities that

[40] "Effectiveness of medical privacy law is questioned," Richard Alonso-Zaldivar, Los Angeles Times (April 9, 2008) http://www.latimes.com/business/la-na-privacy9apr09,0,5722394.story.

[41] Much more should be done to improve the way in which consent options are presented to consumers in the healthcare context. Internet technology can help in this regard, making it easier to present short notices, layered notices and more granular forms of consent.

[42] See "Stopping Spyware at the Gate: A User Study of Privacy, Notice and Spyware" (with Nathan Good, Rachna Dhamija, Jens Grossklags, Steven Aronovitz, David Thaw and Joseph Konstan), presented at the 2005 Symposium on Usable Privacy and Security (SOUPS), also in ACM INTERNATIONAL CONFERENCE PROCEEDING SERIES; VOL. 93, PROCEEDINGS OF THE 2005 SYMPOSIUM ON USABLE PRIVACY AND SECURITY, Pittsburgh, Pennsylvania (2005); 2005 National Consumer Survey; "Research Report: Consumers Fundamentally Misunderstand the Online Advertising Marketplace," Joseph Turow, Deidre K. Mulligan and Chris Jay Hoofnagle, Survey conducted by University of Pennsylvania Annenberg School for Communications and UC-Berkeley Law School's Samuelson Law, Technology and Public Policy Clinic 2007.

are completely outside the scope of the HIPAA privacy regulation. If consent becomes the focus of privacy protection, it is clear that patients will be exposed to unregulated and potentially uncontemplated uses—and misuses of their data. Further, if reliance on consent by an individual for any particular use of his or her information is treated by policymakers as the key to privacy protection, the healthcare industry will have fewer incentives to design systems with stronger privacy and security protections.[43]

All Entities Should Adopt and Implement a Comprehensive Privacy and Security Framework

Regardless of whether or not Congress takes action to address these issues, states and entities developing health information exchanges and other health IT initiatives should commit to adoption of the comprehensive privacy framework outlined here. Guidance for policy development for health information exchanges can be found, for example, in the Common Framework developed by the Markle Foundation's Connecting for Health Project. Consumer access services such as PHRs must also implement the comprehensive framework through rigorous privacy and security protections.[44] Such entities should make their privacy commitment explicit in a published privacy notice. Consumers should look for these promises and should measure them against the framework. Once companies make a privacy promise, they will be bound to it under the Federal Trade Commission Act. In addition, consumer rating services can compare and assess privacy practices, measuring them against the principles outlined here.

Congress Should Establish a Comprehensive Health Privacy and Security Approach

Although states and the private sector should not wait for action by Congress to protect privacy, CDT believes that Congress should establish national policy to ensure that health information technology and electronic health information exchange is facilitated by strong and enforceable privacy and security protections.

According to recent surveys:

- 75% believe the government has a role in establishing rules to protect the privacy and confidentiality of online health information;
- 66% say the government has a role in establishing the rules by which businesses and other third parties can have access to personal health information; and
- 69% say the government has a role in encouraging doctors and hospitals to make their personal health information available over the Internet in a secure way.[45]

One of the major challenges in developing a comprehensive privacy and security framework is to integrate any new rules with the HIPAA privacy and security rules. Congress should consider both strengthening HIPAA where appropriate and establishing additional legal protections to reach new actors in the e-health environment.

Congress should set the general rules—the attributes that a trusted health information system must have—based on the Fair Information Practices discussed earlier. Further, Congress should hold a series of hearings on some of the more difficult issues to resolve and develop a full record that will serve as the basis for more specific legislative action. In particular, Congress should consider:

- The appropriate role for patient consent for different e-health activities;
- The ability of consumers to have understandable information about where and how their Personal Health Information (PHI) is accessed, used, disclosed and stored;
- The right of individuals to view all PHI that is collected about them and be able to correct or remove data that is not timely, accurate, relevant, or complete;
- Limits on the collection, use, disclosure and retention of PHI;
- Requirements with respect to data quality;

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[43] By contrast, a comprehensive approach puts the principal burden on the entities holding personal health information to protect privacy by placing clear enforceable limits on the collection and use of personal health information and backs it up with strong enforcement. See Beyond Consumer Consent: Why we need a Comprehensive Approach to Privacy in a Networked World, http://www.cdt.org/healthprivacy/20080221consentbrief.pdf.

[44] See, e.g. the Best Practices for Employers offering PHRs http://cdt.org/healthprivacy/20071218Best__Practices.pdf.

[45] 2006 Markle Foundation Survey.

- Reasonable security safeguards given advances in affordable security technology;
- Use of PHI for marketing;
- Other secondary uses (or "reuses") of health information;
- Responsibilities of "downstream" users of PHI;
- Accountability for complying with rules and policies governing access, use, and disclosure, enforcement, and remedies for privacy violations or security breaches; [46] and
- Uses and safeguards for de-identified information.

Congress Also Should Enact Legislation to Strengthen HIPAA For Health System Entities

With respect to the access, use and disclosure of electronic health information by the traditional players in the health care system, there are some immediate steps Congress could take to fill some of the gaps in HIPAA. For example, Congress can take a number of actions to secure more meaningful enforcement of the HIPAA rules, including:

- Strengthening Office for Civil Right's (OCR's) role by requiring it to conduct periodic audits of covered entities and their business associates to ensure compliance with the rules;
- Increasing the penalties associated with failure to comply with key provisions of the HIPAA rules;
- Increasing resources dedicated to HIPAA enforcement;
- Requiring OCR to report to Congress on a regular basis on enforcement of the rules; and
- Amending HIPAA to allow for enforcement of the rule by state authorities (such as attorneys general).

Congress should also consider enacting legislative provisions to:

- Establish notification requirements and penalties for data breaches;
- Strengthen the existing HIPAA rules requiring express authorization for use of patient identifiable data for marketing; and
- Require electronic health systems to provide consumers with access to their health information in an electronic format.

Although it is desirable for Congress to enact legislation that fills some of the gaps in HIPAA and to enact a general privacy and security framework to govern health IT, it will be impossible for Congress to legislatively adopt comprehensive rules that fit all of the various actors and business models in the rapidly expanding and evolving e-health environment. Therefore, a second major challenge for Congress is to decide what can be legislated and what must be delegated to agency rulemaking—and what areas are best left to be developed and enforced through industry best practices.

Strengthening Privacy and Security Will Also Require a More Tailored Regulatory Approach

While Congress should establish a strong framework for health privacy and security, it must avoid a "one size fits all " approach that treats all actors that hold personal health information the same. The complexity and diversity of entities connected through health information exchange, and their very different roles and different relationships to consumers, require precisely tailored policy solutions that are context and role-based and flexible enough to both encourage and respond to innovation. For example, it makes little sense to have the same set of rules for "personal health records," which are often created by and controlled by patients and held by third party data stewards outside the healthcare system, and for "electronic health records," which are created and controlled by health care providers for purposes of treatment and care management. To take another example, rules for use of personal health information for treatment need to be quite different than rules for marketing or other secondary uses. Rules regarding use of health information for research need to be separately considered as well.

Congress should not attempt to develop all of the details in legislation. Rather, Congress should enact legislation specifically recognizing the importance of the privacy rights in health information across technology platforms and business models, setting out principles and attributes to guide one or more regulatory agencies in de-

[46] See the Common Framework, www.connectingforhealth.org.

veloping detailed, context-specific rules for the range of entities that collect, use and distribute personal health information in the new interconnected healthcare system. One approach would be to direct the Department of Health and Human Services to strengthen the HIPAA regulations that apply to traditional players in the health system, while also directing HHS or possibly the Federal Trade Commission to issue regulations to govern the handling of personal health information by new players who are part of the broader Internet marketplace and not part of the healthcare system. If more than one agency is to be involved, Congress could require them to work together to avoid issuing conflicting rules (as the financial services regulatory agencies did in developing security rules for financial information).

Tasking HHS and/or the FTC with the responsibility for developing detailed regulations allows for:

- A more tailored, flexible approach that will ensure comprehensive privacy and security protections in a myriad of different e-health environments, and
- More regular, active monitoring of developments in the marketplace and a more rapid response to newly emerging privacy and security issues.

Congress should maintain strong oversight over the regulatory process by:

- Requiring regulations to be developed within a particular timeframe;
- Requiring satisfactory completion of the rulemaking before federal HIT grants can be made;
- Mandating reporting by the agencies on implementation and enforcement; and
- Vigorous oversight and reporting on implementation and enforcement.

Conclusion

To establish greater public trust in HIT and health information exchange systems, and thereby facilitate adoption of these new technologies, a comprehensive privacy and security framework must be in place. From traditional health entities to new developers of consumer-oriented health IT products to policymakers, all have an important role to play in ensuring a comprehensive privacy and security framework for the e-health environment. Congress should set the framework for privacy and security by strengthening enforcement of existing law and ensuring that all holders of personal health information are subject to a comprehensive privacy framework. Congress can also take immediate steps to strengthen existing privacy rules, for example, empowering consumers to play a greater role in their healthcare by mandating electronic access to their health records. Given the broad array of entities in the e-health arena, the technological changes in the marketplace today, and the prospects for rapid innovation, much of the details of that framework should be worked out through the regulatory process. The challenge for policymakers is to find the right mix of statutory direction, regulatory implementation, and industry best practices to build trust in e-health systems and enable the widespread adoption of health IT.

For more information please contact: Deven McGraw, Director, CDT's Health Privacy Project, 202–637–9800 http://www.cdt.org.

Chairman STARK. Thank you.

Dr. King.

STATEMENT OF MATTHEW KING, M.D., CHIEF MEDICAL OFFICER, CLINICA ADELANTE, INC., SURPRISE, ARIZONA

Dr. KING. Yes. Thank you, Chairman Stark and Ranking—Mr. Camp, and the rest of the Subcommittee Members. I am the chief medical officer of Clinica Adelante, which is a medium-sized community health center, which is located in Phoenix, Arizona. We have seven sites and a mobile clinic that serves remote areas of Maricopa County. Our clinic has 26 providers. We have 32,000 patients and 90,000 encounters a year. About half of our patients are uninsured. We wanted an electronic health record to help us in improving the quality of care, particularly around areas of chronic

disease management, and also to help us with preventative care management.

I think the reason why I am here is because we chose an open source electronic health solution that was based on the Veterans Administration VISTA system. It is called World Vista EHR, and it is CCH IT-certified. We chose it for two reasons. The first reason was because we believe that open source is a very viable paradigm to be used in health information technology. The second reason is because a review of the medical literature suggested Vista is associated with improved patient outcomes. This association is far stronger than with any other electronic health system.

So, open source software allows one to see the source code. It is also freely available. So, there is licensing, but the license is free. The important points that surround that particular paradigm is that innovations can come from many sources. World Vista has partnered at times with Veterans Administration, Indian Health Service, with private vendors, and with other funders to get projects done. Sometimes—many times—it's from volunteers. This collaborative development compounds the value and effectiveness of investments.

For us, the idea of no licensing fees up front was very good, because it cost less money to come to the table. The collaborate leveraging that you did around open source allows you to re-use interfaces that are open source that we developed with our practice management system and with our lab systems, for instance, can be re-used by other community health centers and offices, private offices, for just the cost of configuration and support.

Vendor competition in open source is probably the strongest reason. As you know, proprietary software basically has what they call vendor lock. Once you decide to go with them, you're pretty much stuck with them, even if you felt like it was a bad deal. It's very hard to walk away. In fact, I would say that open source is defined by the ability to have vendor competition, so that if I am not getting what I need from my vendor, I can walk away from that vendor but not walk away from my system. That is very important, I think, and is one of the main reasons why we drove to open source.

The other part was that physicians don't prescribe medicine based on what drug representatives tell them. They use an evidence-based approach. So, the Institute of Health Care Improvement suggests that up to one-third of medical errors can be reduced by appropriate application of technology.

So, I started to wonder if there was an aspirin of EHR's. To look for that, what I did was I did a literature research and found, hands down, that Vista has the strongest correlation between patient outcomes and improvements, and the use of electronic software.

What happened with us is—initially, this is—outcomes and cost productivity declined the first week to 50 percent. In 6 weeks it was back up to 90 percent. We are now at 100 percent productivity. We will have one year of production next month.

All the functionality we hope for, including registry use for diabetes and asthma, is functional. We have clinical reminders and other—in medication interaction and allergy interactions.

We're very cost conscious. We did this for $19,000, plus hardware costs, but that doesn't include my time and hiring a trainer, and it's not sustainable. What we believe is that sustainable costs would show a savings over proprietary systems of 30 to 50 percent, perhaps more if they were deployed in a networked environment, which we strongly favor.

So, in summary, Vista is the aspirin of electronic health records. If it were a drug, every provider would prescribe it. But, just like generic aspirin, there is no drug representatives or lobbyists to sell it. Its effectiveness is clearly supported in the literature, but administrators don't have time to read the literature, so they listen to the sales pitch and lobbyists. In the health care industry, that could cost lives.

I believe we should hold ourselves to the same standard we hold physicians, and use the evidence whenever possible to evaluate and select technology solutions, not advertising and marketing. That's why we chose the electronic health record that we chose. Thank you.

[The prepared statement of Dr. King follows:]

Prepared Statement of Matthew King, M.D., Chief Medical Officer, Clinica Adelante, Inc, Surprise, Arizona

Background

Clinica Adelante, Inc (CAI) is a Community Health Center located in the Phoenix, Arizona area. We have seven sites that serve both urban and rural populations and a mobile clinic that serves remote areas of Maricopa County. The clinic has 26 providers, including family practice, pediatricians, internists, OB/Gyn, mid-levels, and dentists. We see about 32,000 individual patients annually and about 90,000 encounters. 50% of our patients are uninsured, 40% Medicaid, 3% Medicare and the rest commercial insurance. We provide sliding fee services to those at 200% FPL or below.

In 2000, I took over as Chief Medical Officer for the clinic. CAI was engaged in National Chronic Disease Collaboratives sponsored by HRSA. We used Wagoner's Chronic Disease Management Model [1] to improve care for some of our diabetics and asthmatics, which has been successful in showing dramatic improvements in chronic disease outcomes. The model utilizes patient education, nationally recognized treatment guidelines, a rapid process change model known as PDSA cycles and a chronic disease registry. The registry is a critical piece of the model because it can be used to track the population and also provide a means for outreach. However, it is not designed to be used in the exam room with the patient, so the patient data needs to be entered manually into the registry later. This double entry of data—once in the exam room and once in to the registry—is error prone, time consuming and costly.

Our desire was to extend the model to everyone that walked into the door so that each patient could have their own personal health plan based upon their age, sex, risk factors and disease states. However, we faced two main challenges. First, because the registries required double entry, we estimated that we would need to hire 24 more data entry specialists; however, we did not have the funds to do so. Second, the time required to do the preventive health would have a negative impact on our revenue. We knew that we needed to find an EHR solution that was relatively inexpensive and could support data entry into a registry without double entry; because it could be used at the point of care.

The Search for an EHR Solution

We started a search for an EHR. The search was disappointing: The products were very expensive, between $200,000 to $500,000, and they really didn't perform chronic disease management out of the box well without expensive customization; and they were deployed in a consumer unfriendly environment that included con-

[1] Rothman AA, Wagner EH. Chronic illness management: what is the role of primary care. *Ann Intern Med* 2003;138: 256–61.

sumer hostile contracts, vendor lock, poor interoperability, and a licensing and support structure that negated the natural leverage of collaborative networks. Because of my prior exposure to Linux and other open source products, I wondered if there were open source solutions that would address the clinic's needs.

I would like to stop for a moment to discuss what Open Source means in the context of Health Information Technology (HIT). Open Source software allows one to see the source code and is freely available. The Open Source license used by organizations such as WorldVistA guarantees that not only is the code available to be examined, it is also available to be enhanced by the community and the enhancements cannot be lost or trapped in a proprietary product for the sole benefit of one vendor and its customers. Improvements must be donated back to the community of users. Enhancements to the code can come from volunteers, vendors, funded projects, IHS, VA, etc. These enhancements are checked by experts and only released after review. The important points here are that innovations can come from many sources, collaborative development compounds the value and effectiveness of investments, and the processes are transparent, organized and safe.

The following is a list of what we perceive through our direct experience to be some of the key benefits of the open source model in healthcare:

(1) Software quality and standardization accelerated by transparency—The transparency of the code assures better software quality and conformance to coding standards and security. Security flaws are more likely to be found and quickly addressed, often within hours of discovery. Non-conformance with open standards is not tolerated by both developers and users.

(2) Rapid innovation and improvement-The improvement cycle needed to keep the software current in response to the dynamically changing healthcare environment is much more rapid than in proprietary business models.

(3) Improvement driven by user needs—Enhancements and fixes are directly driven by what users need, not by marketing, shareholder or other non-healthcare related priorities. Community Health Centers, for instance, can drive changes to update their UDS reporting, while a proprietary vendor might not have the business case to make the code changes.

(4) Lower total cost of ownership—No licensing fees mean less upfront and lower total recurring costs.

(5) Competition focused on service excellence—Flexible support fees mean greater chances to leverage technology. For instance, if support fees are fixed by number of servers, not providers, every provider assigned to that server will spread the costs over more and more users. In the traditional model, every provider added to the system will cost another license and more support fees.

(6) Collaborative leveraging of resources to improve "products"—Open source means quality management tools, clinical tools, interfaces, training and deployment materials are all shared. Going forward, the costs to participate are less and less.

(7) The ultimate competitive free market economy—Vendor competition in open source is not distorted by the effect of vendor lock in. Open source prevents vendors from actively and purposefully using closed code to maintain their advantage over clients. Vendor competition encourages fair support pricing, great customer service and innovation. It also provides the consumer with a way out if the vendor goes out of business or is not responsive. Open source is a simple survival of the fittest business ecosystem which is driven and focused by evidence based improvement of both health quality and costs.

Taken in aggregate, these advantages create strong financial and quality incentives to join cooperative networks and collaborate. This in turn accelerates improvement of safety and quality through best practice sharing and reducing isolated islands of healthcare data.

Our search for an appropriate EHR led us to VistA in 2000, while researching open source alternatives. Unfortunately, at the time it was nowhere near ready for easy deployment outside the Veterans Administration (VA) so we continued to search for a solid EHR in the usual ways, but found the process disappointing. The process is not unlike being detailed by a pharmaceutical representative, so I started wondering what I could learn by comparing the two. Most physicians don't prescribe medicine based upon what the drug representatives tell them. Instead they use an evidence-based approach. This is now an expectation and considered a standard of care in medicine, because evidence-based medicine saves lives. According to the Institute for Healthcare Improvement, nearly one third of all medical errors could be

prevented by applying appropriate technology.[2] So applying technology can save as many lives as prescribing aspirin after a heart attack! I began to wonder, is there an aspirin of electronic health records? What does the evidence based literature say about EHR and impact on quality? Is there one in particular that stands out? Shouldn't applying the medical evidence to the choice of HIT be the standard of care since it, like aspirin, can potentially save so many lives? What I found in the literature shocked me.

It turns out that a search of the peer reviewed medical literature shows that the VA VistA EHR system is one of the only EHR systems that has been associated with improved outcomes. By contrast, the literature says almost nothing about proprietary systems and outcomes. Moreover, VA's costs only went up 0.8% between 1995 and 2004, while Medicare costs increased by over 40%.[3]

Once we understood the role of VistA in the VA's transformation and performance our search was over. In addition we also became aware of the CMS VistA Office EHR initiative, the WorldVistA not-for-profit and the efforts to adapt VistA for use outside the VA. This work would ultimately lead to WorldVistA providing a CCHIT version (WorldVistA EHR) licensed under an open source software license. The only open source EHR to achieve CCHIT certification is WorldVistA. . . . Suddenly the advantages of the open source model would be available using a CCHIT certified VistA clone!

Clinica Adelante's WorldVistA EHR Implementation Strategy

So after applying evidence-based studies and recognizing the importance of an open source model in healthcare, we chose WorldVistA to do a demonstration project. We developed a relationship with WorldVistA and became a development site during the CMS project. A key contribution our site made was to pilot a full open source platform which included the open source operating system Linux, and the open source database GT.M to further cut licensing costs.

We leveraged and made use of the extensive resources and documentation which the VA makes available through a number of public web sites such as the VistA University training materials. Other examples of leveraging the open source model include:

- modifying an installation checklist found on the VA documentation website for our use to direct our installation efforts
- developing an open source interface to our practice management system (PMS) for registration and scheduling
- integrating test ordering and results reporting with our external reference lab; our providers order labs in WorldVistA EHR and the results return as discrete data directly into WorldVistA EHR
- development of chronic disease registries that allow data to be entered at point of care and reported in many forms including a HIPAA-stripped form for uploading to state and national chronic disease databases
- implementation of real time drug order checks, automated clinical reminders and automated provider alerts
- development of pediatric templates, including state approved EPSDT forms

We formed four teams, using our staff and external consultants to help with the work and build buy in, including our key stakeholders early in the process. We hired a clinician to a training role and hired trainers to train him. The preparation phase took 8 months and we went live August 10, 2007 in Surprise, AZ at our busiest clinic.

Outcomes and Costs

Initially, as with any intervention of this magnitude productivity declined . . . in our case to 50% of our usual level in the first week, but it recovered to 85–90% in six weeks. We are now at 100% productivity at our first site. Our referrals department can now do 10–15 referrals per hour, compared to only 6 per hour before implementation. We don't lose medical records any more and they are always available for the patient visit when we need them. We lost no staff or providers as a result

[2] Crossing the Quality Chasm: A New Health System for the 21st CenturyCommittee on Quality of Health Care in America, Institute of Medicine, Washington, DC, USA: National Academies Press; 2001.

[3] Robert A. Petzel, Director, Veterans Integrated Services Network 23, Compelled to Act: it's called survival, Powerpoint presentation, slide 14, available at http://www.amq.ca/congres2006/pdf/Compelled__to__Act-Robert__Petzel.pdf.

of the project. Staff immediately loved the system, but the providers only tolerated it at first. Now, no provider desires to return to the old way or to paper charts.

Our registry functions also appear to be very successful. We now have two registries—one for diabetes and another for asthma—configured. Now 100% of qualified patients are selected automatically for entry by the computer. This will allow planned care to be scaleable to 100% of our patients without hiring extra data entry specialists. We will be able to provide outreach and improved chronic disease management to a much larger population of patients. For instance, when we used the registry that required double entry, we were only able to use Wagoner's model on about 800 diabetics. Now we can use it on all of our patients with Diabetes. That is over 3000 diabetic patients. We will also be able to extend the Chronic Disease Model to other types of chronic disease, like depression, coronary artery disease and hypertension. Eventually, we hope to give every patient their own personal health plan, using the VistA registry technology.

We were very cost conscious with the first implementation. We had no special grants. Our development costs were approximately $19,000 dollars, plus hardware costs. This does not include the salary of the trainer. Nor does it include lost revenue from staff meetings and lowered productivity, or my time as project leader. To achieve this, I spent most of my administrative time, evening and weekends working on the project. It is doubtful that others can expect to achieve what we did with the same budget, nor should it be so difficult to do the "right thing" by patients.

Since the demonstration project, we have also implemented our EHR at another site and also with the (mobile) rural health team. We are developing a 16 week implementation cycle that can be staggered to allow two implementations in different phases. We have started a network with two other community health centers and a small safety net non-federally qualified clinic. Although the demonstration project allowed us to show clinical success and estimate reduced costs compared to proprietary systems, the project has stalled without more funding. Our analysis of sustainable costs show a savings of 30 to 50% over proprietary systems, perhaps more as the network grows larger. Even so, this cost remains out of reach for most offices. Ultimately, we view the EHR as a tool to reduce medical errors, improve patient care and stabilize the costs of healthcare. Developing these strategies is possible with systems like WorldVistA EHR, but are unlikely to co-evolve on their own. Proper planning, adequate funding and well designed incentives are all necessary to drive projects like these forward. In fact, without more funding, we will not be able implement WorldVistA EHR across all our network sites. This network represents a quarter of a million patient visits a year—that is a lot of patients who we *could* be reaching and whose care we *could* be improving with health IT but which we cannot, because of lack of funding.

Based on our practical experience, our view is that VistA is hands down the best system available, is the only solution backed by solid scientific evidence to prove it, and costs 50–70% of the costs of comparable proprietary systems. The fact that it is open source and was developed by with taxpayers' money makes it a logical and very affordable choice for a large segment of the US health system.

Health Improvement through health IT and the need for incentives

Health improvement through health information technology is a tough sell to providers in general because it temporarily affects productivity as providers learn how to use the system. Moreover, any cost savings (like less ER visits because of better control of asthma) are realized downstream from the user and tend to accrue largely to the patient and the health care purchaser. Incentives are a very powerful tool to effect change that successful businesses use all the time. In this context, it is the fastest way to increase the rate of provider adoption for health IT.

Incentives certainly could increase the rate of adoption, but just giving incentives for EHR acquisition will not improve quality. Incentives must be tied to quality improvement or reporting clinical measures to have the desired effect. Connecting offices through networks tasked with quality improvement would work. The most innovative approach would be to move completely away from volume based reimbursement to value based pay. Pay for performance is a step in the right direction, but still relies on volume.

However, it is important to note that quality incentives need an adequate HIT infrastructure with enough connectivity and sufficient granularity to report clinical measures at the provider level. This is why as a first step, I believe it is important that provider incentives be tied to the adoption of EHR systems. I believe further that EHR systems should support these important clinical and quality reporting functions.

In addition, a provider might need time and support to get used to the system and learn to use it effectively. This is why I believe provider incentives should encourage network membership. Networks are better prepared than small offices—much less solo practitioners working on their own—to evaluate EHRs for the necessary functions, have the capital to customize them as needed and the expertise to deploy them, secure them and support them. Networks can also better connect with existing HIE, Medicaid transformation grant projects, labs and other ancillary services, etc. Provider support and clinical improvement will be greater with network formation and will also achieve the goals of better connectivity and improved quality.

Myths about VistA and open source applications

Before I conclude, I want to dispel the many myths floating out there about the VistA system and open source applications in general.

Myth #1: the M coding language is too old to be used in a modern healthcare system. This is false and most large proprietary healthcare vendors, Epic for example, use it. There are many innovations taking place outside the VA right now that show the robust and flexible nature of the M based code.

Myth #2: Open source is unfair in a competitive market. Open source stimulates competition unlike proprietary systems whose goal is to lock in users and monopolize the market. Proprietary systems are only in a competitive market until the client signs on the contract line. Then the relationship becomes very lopsided. I have been to many Health Information Conferences and have listened to the best speakers. They always say deciding on a healthcare vendor is like getting married, because it will be a long-term relationship. It is very difficult to change vendors because of vendor lock. Then they talk in the remaining hour about all the "pre-nuptials" you must get because you can't trust any of the vendors. Open source has competition at multiple levels, but primarily on support services and training which are the most important factors in successful and sustainable adoption of a solution. In the case of WorldVistA EHR both large and small companies can compete against each other with the same a high quality, CCHIT system. Large companies are definitely interested, too. For instance, a major US systems integrator has just won the contract to provide all of Jordan's public health system (46 hospitals, 500 clinics) with the WorldVistA EHR. With open source vendor competition, you reduce price, eliminate vendor lock and improve customer service. Open source is a true free market.

Myth #3: The VA code is too expensive to maintain. VistA, under the open source model has flourished. Clinica Adelante was able to fund an extraordinary amount of customization for a moderate amount of money. Moreover, these enhancements are available for other offices for the price of configuration and support. Some of the code done by WorldVistA has found its way back into the VA system. There is an extraordinary opportunity for governmental agencies like the VA and Indian Health Service to work with private businesses and not for profits to further their missions.

Myth #4: Open source applications are more vulnerable to security breaches. Because open source code is transparent, there is a myth that it is insecure. This has not proved true at all. Breaches are often a result of poor coding practices. The transparency of the code demands that peers code to the highest levels. Moreover, it is scrutinized by expert before it is released. The result is clear: Nobody runs antiviral software on (open source) Linux, nor do they need to. Everybody runs antiviral on Windows (closed code) and they would be crazy not to. Moreover, with so many eyes looking at the code, more security flaws are found before breach and more quickly corrected, often within hours.

VistA is the aspirin of EHRs

VistA is the aspirin of EHRs and if it was a drug, every provider would prescribe it. But just like generic aspirin, there are no "drug representatives" or lobbyists to sell it. Its effectiveness is clearly supported in the literature, but administrators don't have time to read the literature. So they listen to the sales pitch and the lobbyists. In the healthcare industry, that could cost lives. In healthcare, when lives are at stake, I believe we should hold ourselves to the same standard we hold our physicians and use the evidence whenever possible to evaluate and select technology solutions . . . not advertising or marketing hype. And that is why Clinica Adelante chose VistA EHR.

Chairman STARK. Thank you.
Mr. Jones.

STATEMENT OF LEROY JONES, GSI HEALTH, PHILADELPHIA, PENNSYLVANIA

Mr. JONES. Thank you, Mr. Chairman. My name is Lee Jones. I am the founder and chief executive of a company called GSI Health. It's a health IT consultancy based in Philadelphia. In that capacity, I am involved in a number of industry and government-sponsored initiatives to bring about large scale interoperability among health care applications and enterprises.

One role I currently hold is as senior advisor and architect for the New York e-Health Collaborative, which is building a statewide health information exchange, and has invested in excess of $100 million thus far to do so.

I am also the program director of the health information technology standards panel, which—sounds as though many of you are already familiar with. It's a Member organization that has over 400 organizations from various corners of the health care industry who have come together to select standards for interoperability. I am grateful for the opportunity to testify before you today.

As you noted, consumers in today's global economy have become accustomed to instant access to information, and have hit a speed bump, if you will, on the information super highway when it comes to their medical records. It's not as though the information doesn't exist. There is certainly electronic representations of clinical records and administrative records. But often they are not able to be brought to bear at the time and place that they are needed.

So, I have come to say today that that is changing. As you noted, Mr. Chairman, the Department of Health and Human Services has established several different initiatives in order to move this ball forward. They established American Health Information Community, which is a group of 18 government and business non-profit organization leaders fostering the adoption of interoperable electronic health records throughout the country.

In order to meet the community's objectives, there is also the office of national coordinator, which really is the implementation arm of what the community tries to do. The national coordinator has funded several initiatives which are well known at this point, and I will just name, so that we can get to my larger point.

The first is to harmonize all the electronic standards for health care in the country. The health information technology standards panel, which I am involved with directly, identifies and selects the necessary standards that will bring about an interoperable exchange of health care data. The panel then develops further guidance that we call interoperability specs, which really give instructions for different vendors to build independent "instantiations" of software that will, when brought together, be interoperable with one another.

So, without collusion, different vendors are able to be interoperable, and have some guarantee of interoperability. That's sort of the intention of the standard selection process.

The second key initiative is to ensure that the electronic medical record, or the electronic health record, has a proper floor

functionality, that it can be defined, if you will, and that there is a place that one can go to in order to verify correct implementation of health care standards.

So, the certification commission for health information technology does exist for that purpose. So, it is not enough to say these are the standards that one should adhere to. We have to have a system that allows the verification that a vendor, in fact, used those standards and used them correctly, so that we can ensure interoperability.

The third key initiative is to catalog all of the privacy and security paradigms that exist in different jurisdictions because, as we know, that is often a great barrier to interoperability, and there isn't a clear cut silver bullet solution to solving how we reconcile those differences.

So, the first step is at least to understand what those differences are, so that we can begin to understand how they might be harmonized. So, the health information security and privacy collaboration has been started by the Department of Health and Human Services to catalog those, and has spurred many efforts to remove key barriers to interoperability.

Then, last, there is an initiative to establish a real health information exchange network, which both demonstrates feasibility of implementing interoperability standards in an effective way, as well as propagates their use broadly by connecting real systems to each other. So the Nationwide Health Information Network, or NHIN, as it's sometimes referred to, orchestrates implementation of interoperable standards within the context of real world health delivery environments across different regions in the country.

These efforts have now been established, and are complementary, and are coordinated as one system. They have established a dominant design whereby interoperability will continue to be achieved in an ongoing fashion, whereas no such systems existed like that prior to AHIC and ONC's establishment.

We now have an accepted system in place to harmonize and advance appropriate standards. We now have an accepted system in place to verify correct implementation of those standards. We now have an accepted system in place to catalog our privacy and security differences. We now have an accepted system in place to identify and ultimately remove barriers posed by these different aspects.

Over the past few years, these initiatives have demonstrated that it matters how the Federal Government participates, and not just that it participates. So, leveraging the familiar paradigm of consensus-based development, we have found that when people come together and are partly owners of the solution, as opposed to having solutions foisted upon them, they actually are more receptive and likely to do a good job in implementation.

I think that the question before us is one of both supply and demand. On the demand side, there are many incentives that can be brought to bear in order to bring about—or to incentivize people to adopt technology. But demand increasing will increase supply in the market. However, we don't just want an increase in supply, we want the supply to increase in a way that fosters interoperability. So that requires coordination.

So, what we have been focused on is trying to coordinate the supply side of this, so that when that demand is increased through incentives and other things, we are able to, in fact, supply that in an interoperable way. I thank you.

[The prepared statement of Mr. Jones follows:]

Prepared Statement of LeRoy Jones, GSI Health, Philadelphia, Pennsylvania

Mr. Chairman and distinguished members of the Subcommittee, my name is Lee Jones, and I am the founder of GSI Health, a healthcare information technology consultancy. In that capacity, I am involved in a number of industry and government-sponsored initiatives to bring about large-scale interoperability among healthcare applications and enterprises. One effort I currently support is the very important work happening in New York State to create shared policies and technical protocols for interoperability. This effort has over $100 million invested in a statewide collaborative process to develop a standards-based health information exchange network among a number of regional efforts within the state. Additionally, I currently serve as the program director of the Healthcare Information Technology Standards Panel (HITSP), a volunteer-driven cooperative partnership between the public and private sectors that is working to ensure the interoperability of electronic health records in the United States. I am grateful for the opportunity to testify before you today on the need for harmonized electronic data exchange standards and infrastructure to empower patients and healthcare providers.

The Current Landscape of Healthcare Information Technology

Through my years of work in healthcare information technology, I know that patients are often treated by doctors with incomplete medical information. Patients often do not know their medications, their medical history or their latest laboratory results. Patients seek care from a wide variety of primary care providers, specialists, hospitals, clinics, laboratories, imaging centers and pharmacies—all of which have disconnected pieces of their medical record.

Patients, providers and payers believe that communication among caregivers is key to delivering quality, personalized medicine. Many think that electronic records shared across the entire community of clinicians is key to care coordination.

According to a national survey published earlier this month in *The New England Journal of Medicine*, only 17% of clinicians in the U.S. have a basic system of electronic health records in their offices. Among the doctors who have access to electronic health records systems, 97–99% report using all of the system's functions at least some of the time.[1] However, data does not flow among all these systems partly because of the inconsistent use of data standards, lack of a consistent architecture for exchange of data, the lack of a trusted means to validate consistent and compatible implementations of standards and architecture, and the lack of agreement on privacy policies held by different jurisdictions.

The Need for a Coordinated Approach Toward Interoperability Enablement

Consumers in today's global economy have become accustomed to instant access to information. News, music and movies can be accessed real-time on a handheld device. Products and services from multiple providers can be located, compared and purchased online. Financial accounts can be managed, bills can be paid electronically, and funds can be withdrawn at ATMs anywhere in the world.

When it comes to their personal health information, however, patients have felt a speed bump on the information superhighway. The records exist, but doctors, pharmacies, and insurance companies use disparate systems that make the exchange of information slow and cumbersome, thus retarding timely access to the information in the routine delivery of care.

But all of this is changing.

U.S. Department of Health and Human Services (HHS) Secretary Michael Leavitt has established the American Health Information Community (AHIC), a group of eighteen government, business, and non-profit organization leaders charged with fostering adoption of interoperable electronic records throughout the country. The AHIC has been essential to moving national interoperability efforts forward by ar-

[1] DesRoches et al (2008). "Electronic Health Records in Ambulatory Care—A National Survey of Physicians." *The New England Journal of Medicine*, Volume 359(1):50–60.

ticulating and prioritizing specific scenarios, often referred to as "use cases", which focused industry efforts on specific and tangible areas where healthcare interoperability is needed and can be achieved through concerted work. Equally as important, the AHIC has served as a conduit to the Secretary of HHS to identify the results of the industry's work to achieve interoperability in the areas of those use cases, so the Secretary can hold up said results for all Federal agencies and initiatives to leverage appropriately. These standards that the Secretary holds forth are known as "recognized standards" and have an appropriate lead time that enables testing and evaluation before achieving recognized status, which is when Federal partners are expected to use these standards. Thus, the first generation of recognized standards have had that status for only slightly more than 6-months, and so we anticipate increasing adoption and system interoperability as these standards are given a chance to be planned for and implemented in Federal and private-sector systems in an ongoing fashion over the coming months.

In order for the objectives of the AHIC to be met in a purposeful and directed way, the HHS-based Office of the National Coordinator for Health Information Technology (ONC) has funded a coordinated effort to accelerate electronic medical record interoperability efforts. This effort is comprised of several symbiotic initiatives, four of which I will mention here:

The first is to harmonize all the electronic standards for healthcare in the country. Currently there are more than a dozen organizations creating healthcare information standards in the U.S. These standards are at times redundant, competitive and non-interoperable. Further, sometimes there are no appropriate standards available to enable particular kinds of healthcare transactions. To achieve the kind of universal functionality our ATM cards provide today, the country must agree on a common set of healthcare information standards, implemented consistently by vendors and healthcare providers alike. The organization I support, the Healthcare Information Technology Standards Panel, or HITSP, has been sponsored by ONC to harmonize the relevant information standards, working with the various authoring organizations of these standards, industry stakeholders of all types, and affected Federal partners to disambiguate the use of standards when several compete, and to push for establishment of needed standards where none exist.

The second key initiative is to ensure electronic medical records provide the basic functions needed for a doctor to record and transmit patient medical information. The average patient over 80 years old has ten medications and three clinicians. Rarely is there any coordination of care among caregivers to assist these patients, and others, with bringing to bear a correct picture of their health status (history, treatments, medications, current issues, etc.) into each new healthcare encounter. But in order for care providers to more easily share patients' clinical information which may be held in their particular electronic health record systems, objective criteria to certify that an electronic record system meets the basic requirements for data capture and exchange is essential. The Certification Commission for Healthcare Information Technology, or CCHIT, provides certification and validation services that enable healthcare IT vendors and implementers of various kinds to verify the correctness of their implementations of interoperability standards and key system functions.

The third key initiative is to catalogue privacy and security policies across the nation toward the end of reconciling their variances in a manner that enables interoperability. In Massachusetts, for example, doctors cannot retrieve a complete electronic medical list from insurance companies, even with patient consent, if a medication related to mental health, substance abuse or HIV treatment is present. In Ohio, doctors must use a cryptographic electronic signature to prescribe medications electronically. In California, only paper signed consent forms (not electronic forms) are considered a valid patient consent. The laws that created many of these regulations were appropriate 30 years ago when electronic systems lacked the sophistication available today, but now are an impediment to delivering safe, patient focused care. The Health Information Security and Privacy Collaboration, or HISPC, has begun this cataloguing effort and has spurred many efforts to remove key barriers to interoperability related to divergent privacy and security practices.

The fourth key initiative I will discuss here is to ensure that a real health information exchange network is established which both demonstrates the feasibility of implementing interoperability standards in an effective way, as well as propagates their use broadly by connecting real systems. All standards are merely theoretically useful until proven through real implementation. The Nationwide Health Information Network, or NHIN, orchestrates implementation of interoperability standards within the context of real-world health delivery environments across different regions in the country. Often, these implementations involve a number of vendor prod-

ucts and platforms that adopt the desired standards through NHIN, and subsequently spread them through their normal channels in the marketplace.

These four ONC initiatives plus the AHIC are critical to the rapid advancement of healthcare interoperability for several reasons.

First, prior to the government becoming actively involved in this type of public/private partnership through the activities of ONC, interoperability efforts through the standards development organizations' activities alone led to a highly fractured system that was not converging in any meaningful way. Therefore, the Federal Government must stay involved in the process for ultimate success to be achieved in moving the entire industry.

Second, the model AHIC and ONC have been cultivating over the past few years has shown that it matters *how* the Federal Government participates, not just *that* it participates. Leveraging the familiar paradigm of consensus-based development and adoption of standards in the United States has led to wider participation and buy-in than has been achieved through other methods such as unassisted market forces or heavy-handed mandates. It is important to allow private sector entities have ownership in the process of developing the interoperability solutions they will need to implement. It is most effective when they can innovate around, and adopt standards and architecture in a manner where their incentives are aligned with the collective goals.

Third, these efforts have now established complementary and coordinated systems that have set the dominant design for how interoperability will continue to be achieved in an on-going fashion whereas there were no such systems prior to AHIC and ONC. We now have a system in place to harmonize and advance appropriate standards. We now have a system in place to verify correct implementation of those standards. We now have a system in place to develop and proliferate the technical network to interconnect healthcare partners. And lastly, we now have a system in place to identify and ultimately remove barriers posed by divergence in privacy and security practice.

Lastly, the efforts of the AHIC and ONC have inspired smaller-scale replicas to emerge around the country. The AHIC use cases are reused or customized for local interoperability efforts. The consensus processes used for standards harmonization are mimicked by regional efforts that need to arrive at their own technology blueprints. In the parlance of the internet community, the current national interoperability initiatives are "viral".

For the balance of this testimony, I will provide further details around the areas I am most involved in, namely establishing interoperable networks and architectures, and harmonizing interoperability standards. The intention here is to convey a greater insight into how these initiatives are operating to foster understanding of why the current efforts are working well.

Health Information Exchange Networks

I am currently involved in two significant efforts to establish networks that enable the exchange of healthcare information among various healthcare software applications. These efforts are to build the Statewide Health Information Network of New York, called the SHIN–NY (pronounced "shiny"), and the Nationwide Health Information Network, called the NHIN. These efforts are actually related inasmuch as the SHIN–NY is intended to be a microcosm of the NHIN in New York. The development of technical infrastructure through these projects is catalyzing the adoption of interoperability standards and actual data sharing among providers.

Building these networks is a complicated undertaking. Not only do different sets of standards need to be integrated, but additional elements beyond information standards need to be "standardized", such as technical methods associated with all networks (e.g.—ensuring the reliability of the and availability of the network). It involves deciding what technologies are ready for implementation, what level of backward compatibility will be supported, and what emerging technologies are likely to persist enough to include in the technical plan.

The NHIN has published a number of technical specifications regarding the detailed handling of not only healthcare standards, but also methods for communication in the transmission of messages, security techniques, as well as paradigms for distributing functionality across the network without centralized control (critical for quick adoption where policy hurdles regarding centralized control may abound). The NHIN has also established a shared testing environment that may be leveraged broadly to ensure accurate utilization of interoperability standards. There are over ten participating regions and entities in the NHIN, including Federal partners, volunteer organization, and regional teams funded by ONC. This pioneering is an important step in realizing ubiquitous interoperability.

The SHIN–NY is leveraging the work of a number of different efforts to achieve its goals in New York. It has modeled its local business cases on the published AHIC use cases, and has even extended them to encompass local concerns such as the utilization of Medicaid data in data exchange. It has also taken the HITSP interoperability standards and incorporated them into the design of statewide network, further entrenching these important specifications. New York is participating in an initiative sponsored by the Centers for Disease Control and Prevention to implement a biosurveillance system using the corresponding AHIC use case and HITSP standards, and this work is integrated into the SHIN–NY effort as well. And finally, as a participant in the NHIN, New York is leveraging the technical specifications, testing environment, and experience the NHIN has amassed over the past few years. In addition to all of this leverage of existing work, the SHIN–NY will contribute its own technical protocols and services that will be usable across New York and beyond.

These efforts both have designs to not only establish technology that will be interoperable, but also to serve as reference implementation models for other efforts to learn from and to reuse. The learning, including much of the design and some of the new software from these initiatives will be made available in the public domain. This will fuel the fledgling open source projects in healthcare as they are the most likely to leverage these new assets. Whether it is bolstering the open source assets, or transforming the landscape of commercial products as they integrate into the network, these significant initiatives to build networks for information exchange are propelling the industry forward into a more interoperable state.

The Role of the Healthcare Information Technology Standards Panel (HITSP)

"Within ten years, every American must have a personal electronic medical record . . ."

—President George W. Bush, April 26, 2004

When President Bush called for every American to have an electronic health record by 2014, he was outlining his vision for a healthier nation. To help make this vision a reality, the public and private sectors are working together to define and build an information network that would support the secure exchange of health data across the United States.

In the fall of 2005, the HHS Office of the National Coordinator for Health Information Technology (ONC) awarded multiple contracts to advance President Bush's vision for widespread adoption of interoperable electronic health records (EHRs). The contracts targeted the creation of processes to harmonize standards, certify EHR applications, develop nationwide health information network prototypes, and recommend necessary changes to standardized diverse security and privacy policies.

As coordinator of the U.S. voluntary consensus standardization system and proven provider of standards-based solutions to national and global priorities, the American National Standards Institute (ANSI) was selected to administer the standards harmonization initiative, in cooperation with strategic partners the Healthcare Information and Management Systems Society (HIMSS), the Advanced Technology Institute (ATI), and Booz Allen Hamilton. The resulting collaborative, known as the Healthcare Information Technology Standards Panel (HITSP), brings together representatives of the private and public sectors to make possible the interoperable exchange of health care data across the United States.

The Panel's work is driven by a series of Use Cases (i.e., business needs) that are issued by AHIC. Based on the needs outlined in each Use Case, HITSP develops guidance documents known as Interoperability Specifications (IS) that recommend the standards that will meet the defined clinical and business requirements for sharing information across organizations and systems. During this process, HITSP also identifies and documents any gaps in standards which must be resolved.

Once an IS is recognized by Secretary Leavitt, agencies administering or sponsoring federal health programs are required to implement the standards where applicable. These work products (IS) are intended to be supportive to the developing Nationwide Health Information Network (NHIN) for the United States and also to community and regional health information exchange networks.

HITSP is a volunteer-driven, consensus-based operation. The Panel's 480 member organizations represent consumers, health care providers, public health agencies, government agencies, standards developing organizations, and other stakeholders—all working together to identify the most appropriate standards for specific use cases involving patients, providers, and government agencies. HITSP is committed to an open and transparent mode of operation and to facilitating standards harmonization

efforts that support interoperability, accurate use, access, privacy and security of shared health information.

The Standards Harmonization Process

HITSP's most important work is the development of a well-defined, repeatable process to identify the most appropriate standards for each AHIC use case.

A standard specifies a well-defined approach that supports a business process and has been agreed upon by a group of experts, has been publicly vetted, provides rules/guidelines/characteristics, helps to ensure that materials, products, processes and services are fit for their intended purpose, is available in an accessible format, and is subject to an ongoing review and revision process. Harmonization is required when a proliferation of standards prevents progress rather than enables it.

In some cases, redundant or duplicative standards will be eliminated. In other cases, new standards may be established to span information gaps. In all cases, the resulting standards serve the consumer and other healthcare stakeholders by addressing issues such as data accessibility, privacy and security.

Our process to date is:

a. AHIC and its working groups develop Breakthroughs.

b. AHIC Working Groups or other customers prepare a HITSP Harmonization Request.

c. HITSP Technical Committees identify candidate standards, which are harmonized into a final list of standards. They also identify overlaps and highlight gaps. Gaps are forwarded to standards developing organizations for their guidance as to emerging candidate standards or new standards requirements.

d. HITSP Coordinating Committees provide technical committees with important background information to support their work, such as objective criteria to evaluate the appropriateness of standards for a given purpose.

e. The final chosen standards produced by the Technical committees are discussed and ratified by the full Panel.

f. These standards are made available for public comment and feedback.

g. Technical committees work with standards developing organizations and other groups to produce detailed specifications, an unambiguous "cookbook" for the implementation of chosen standards. HITSP provides a convening and facilitation function for this activity.

h. HITSP work products are delivered to AHIC for their endorsement.

i. After AHIC endorses HITSP work, the Certification Commission on Healthcare Information Technology will include HITSP specifications in its certification work. Hospitals and clinicians will be more likely to buy products, which are certified as interoperable. This will lead to increased success of vendors, which embrace standards and interoperability.

Progress to date and next steps

The first priorities assigned to HITSP were in the areas of Electronic Health Records (EHR) (e.g., the electronic delivery of lab results to providers of care), biosurveillance (e.g., data networks supporting the rapid alert to a disease outbreak), and consumer empowerment (e.g., giving patients the ability to manage and control access to their registration and medication histories). In January 2007, HHS Secretary Michael O. Leavitt accepted HITSP's recommended standards, known as "Interoperability Specifications (IS)", for a one-year period of implementation testing. In January 2008, the Secretary announced his formal recognition of the HITSP IS.

According to Executive Order 13410 signed by President Bush in August 2006, federal agencies administering or sponsoring federal health programs must implement any and all relevant recognized interoperability standards. These standards also become part of the certification process for electronic health records and networks.

Three additional sets of HITSP IS—Emergency Responder-Electronic Health Records; Consumer Access to Clinical Information; and Quality—were accepted by the Secretary for implementation testing in January 2008 and new IS on Medication Management was submitted to the Secretary for acceptance in Spring 2008.

New work is also underway to address interoperability needs in six additional areas: personalized health, transfer of care, remote monitoring, secure communications between patients and providers, public health case reporting, and immunizations and response.

The HITSP Education, Communications and Outreach Committee has strived to educate interested stakeholders on the future of healthcare information technology

and how the public can shape the standards that will promote interoperability. This summer, the Committee is sponsoring an educational webinar series that informs the public of the work that is currently underway to support the exchange of healthcare information in the U.S.

Beyond 2008, HITSP will continue to produce recommendations and reports in Interoperability Specifications and related Constructs. These work products are intended to be equally applicable to the developing Nationwide Health Information Network for the United States (NHIN) and also to community and regional health information exchange networks.

From consumers to doctors, nurses and hospitals; from those who develop health care IT products to those who use them; and from government agencies to organizations that are developing the standards upon which these new health systems are based—everyone has a role to play in shaping the new U.S. healthcare IT infrastructure.

Thank you very much for your attention, and I look forward to any questions you may have.

Chairman STARK. Mr. Whitlinger.

STATEMENT OF DAVE WHITLINGER, DIRECTOR OF HEALTHCARE DEVICE STANDARDS AND INTEROPERABILITY, INTEL CORPORATION

Mr. WHITLINGER. Thank you. Good morning, Mr. Chairman, and fellow Members of the Committee. My name is David Whitlinger, and I am the director of health care standards at Intel. I appreciate the opportunity to appear before your Committee to testify on promoting the adoption and use of health information technology.

Let me start by saying that I am honored to be here, representing Intel Corporation in this important health care information technology discussion.

As many Members of the Committee may know, Intel has been a major contributor to the worldwide information technology sector for 40 years now. As a corporation, we have participated in the transformation of countless industries as they have adopted PC's, data servers, high-speed communications networks, data visualization tools, wireless networks, and other information technologies to increase their productivity, improve efficiency, and thereby achieve greater quality in their products and services.

What industry sector is in greater need, if not dire need, of higher efficiency and productivity—and, perhaps most importantly, measurable quality—than the U.S. health care industry? As you are all well aware, our nation currently spends nearly two times as much as any other country in the world on health care, weighing in at roughly 16 percent of our gross domestic product, or $2.2 trillion. Without a dramatic change, we are on course to hit $4.3 trillion within 10 years.

Health care IT is obviously not the silver bullet that will singlehandedly overhaul our Nation's health care industry, but broad industry adoption of information technologies will improve efficiencies, increase productivity, reduce costs, and give us all quality measurements that we can be nationally proud of.

So, first, we commend Secretary Leavitt for his recognition and commitment to health IT by his development of a strategic plan that lays the groundwork for the transformation to higher quality,

more cost-efficient patient-focused health care through electronic health information.

We would like to see Congress provide a framework to ensure the continuation of the Certification Commission for Health Information Technology, known as CCHIT, and the Health Care Information Technology Standards Panel, known as HCITSP, and encourage industry organizations that are at the forefront of consumer or patient-centered health care, like the Continua Health Alliance.

The Continue Health Alliance is an industry-led consortium of over 160 companies that is driving personal health care interoperability through standards and certification testing for health devices like blood pressure cuffs, glucose meters, pedometers, weight scales, personal computers, and cell phones. These are the personal health devices that can help an individual become empowered to better manage their own health, thereby reducing their dependency on the health care system itself, and at the same time improving their overall health: empowered, informed, healthy citizens.

Second, we would strongly encourage Congress to develop financial incentive programs to jumpstart health care IT implementations across the nation. We commend the Ways and Means health Subcommittee for challenging the current system by considering direct incentives for providers of Medicare and Medicaid services to convert from the paper-based, inefficient, and at times dangerous systems, to using the technologies we take for granted in every other industry.

As a large self-insured employer, we are willing to step up, and we have in certain regions where we have large concentrations of employees. But we need government partnership to support more transformational programs, create the financial incentives to move the entire U.S. health care system to an electronic health care record that can help increase efficiency of the health care providers, increase accessibility of patient health data across providers, and provide a foundation for a quality measurement system.

How can we improve the quality of health care in our country, or even measure what we are providing our citizens for $2.2 trillion without data? Congress should explore reimbursement options for health care providers in the Medicare program that will facilitate the use of health information technology for quality improvement, and evaluate the benefits of providing grants and loans to providers to help reduce the barriers to investment and future health IT solutions.

Last, I would like to speak to you, as a large employer. With over 60,000 employees here in the United States, we, unfortunately, are on track to spend close to $1 billion on health care for our employees in the next couple of years if something doesn't change.

We look forward to working with Congress to improve the efficiency of our nation's health care system, to help keep U.S. companies competitive, and improve the quality of health care in this country to a level that we can all be proud of. Thank you.

[The prepared statement of Mr. Whitlinger follows:]

Prepared Statement of Dave Whitlinger, Director of Healthcare Device Standards and Interoperability, Intel Corporation

Thank You. Good morning Mr. Chairman and fellow members of the committee. My name is David Whitlinger and I am the Director of Healthcare Standards at

Intel. I appreciate the opportunity to appear before your committee and to testify on technology in U.S. healthcare.

The topic discussed today is of utmost importance. Not only does our nation currently spend almost two times our nearest competitor per capita on healthcare, but the costs are having a dramatic effect on the ability of U.S. businesses to remain competitive in an ever growing global economy. At approximately 16% of the GDP, we can no longer afford to move ahead with business as usual. Unless something is done soon to dramatically overhaul our broken healthcare system, the coming age wave and rise in chronic conditions will overwhelm our ability to pay for and provide the kind of care we expect in this country. Further, we do not get better results for our $2 trillion dollar spend. U.S. healthcare fails to stand up to comparison on a wide range of quality measures with other mature countries. Clearly something has to change. Spending more or providing less is not a solution. We need to provide better care at lower total cost.

I represent Intel, a large U.S. technology company which has helped transform countless other industries utilizing the power of information. Today, you and I reap the benefits of years of investment and work to put the power of information directly in the hands of consumers. It's hard for some of us to remember life before personal computers, cell phones, portable music players, and in-car navigation systems.

Additionally, Intel is a large U.S. employer with headquarters in the Silicon Valley which currently employs approximately 60,000 U.S. citizens. We are on a path to spend $1 billion annually on healthcare within the next few years. Just the annual cost of healthcare for an Intel employee and family of four exceeds the fully loaded cost (including salary and benefits) of one qualified engineer in many developing nations. Our employees are our greatest resource. We need the best and brightest minds working on the challenges of the 21st century.

Because we, as an employer, pay into the system in three ways via corporate taxes, employee benefits and the cost shift from the uninsured, we see healthcare as an issue that must be addressed and solved if U.S. business is to remain globally viable and able to provide quality jobs and benefits to our employees and beneficiaries.

Healthcare Missed the Revolution

Intel has been at the center of technology change for 40 years, driving efficiencies in every part of the economy. The PC and the Internet have literally changed the world—they have changed the way we communicate, the way we access information, the way we conduct business, and the way we entertain ourselves, except for one critical industry, healthcare. Paul Otellini, Intel's CEO, cites Intel's work in the health industry as a case in which our technology and leadership may help resolve some of society's thorniest issues. By reducing the cost of healthcare "the single biggest opportunity we have—to address the single biggest problem that certainly the U.S. and many of the Western countries are going to have—and ultimately the world."

Intel Employer Initiatives

Not only has Intel seen the value of investment in the infrastructure necessary to keep our products on the cutting edge of future demand, we also have seen the value of investment in our own people.

In 2005, Intel, Cisco and Oracle launched an effort to incrementally change the way employers pay for healthcare services for our employees. The program, known as the Silicon Valley Health IT initiative, is a collaborative effort among seven large IPA's (Independent Practice Associations) representing 25 distinct practice sites and more than 1,800 physicians. The goal is to help the system shift toward a more patient centered approach with rewards for the use of IT to provide better communication, care and follow-up.

Early data has shown promising results and each year the bar is raised to drive toward NCQA (National Committee for Quality Assurance) guidelines and patient satisfaction. We'll continue to look for ways to lead the change around how we pay for the care provided to our employees and their dependants.

As we know, action follows money. Different outcomes require that we rethink how we pay for care in the U.S. We need to transition from the fee-for-service treadmill that is driving more and more providers out of the profession. As funders of the system, the ones who actually write the checks, we have the power to work with the delivery system to help align the incentives and reward the right care. Simple examples are electronic prescriptions, electronic communication between patient and

clinician, remote diagnostics and monitoring, electronic health records, etc. Additionally, Intel has made the commitment to deploy on-site clinics for our larger facilities. We are combining these clinics with a renewed emphasis on employee health and wellness. While these clinics are not a new concept, we believe it is another step toward establishing a culture of wellness and convenience to our associates.

Dossia

Intel is also one of the founding members of Dossia, a non-profit organization initiated by a consortium of large U.S. employers for the purpose of creating a national system to deliver lifelong, personal, private, and portable health records for their employees. The focus is to leverage employers as the purchaser of healthcare services and place the health data into the hands of employees and their families with a strong firewall between the employee records and the employer. This will be a national platform that will provide personal control to the employee over an independent, non-tethered view of their patient information. With a complete picture of their health, employees will be free to exercise more choice and thus drive competition for the higher quality, patient-centric healthcare.

Federal Leadership

We believe government has to help lead the way toward systemic transformation, by developing new care paradigms and new financing alternatives.

Given the enormous technology advances in all other industries, it's time for healthcare to reap the same benefits and it will take leadership by the Federal Government partnering with private industry to provide funding, and standards to promote an open architecture for health IT interoperability. We commend Secretary Leavitt for his recognition and commitment to Health IT by developing a strategic plan that lays the groundwork for the transformation to higher-quality, more cost-efficient, patient-focused health care through electronic health information. We want to see Congress provide a framework to ensure the continuation of CCHIT and HITSP, organizations at the forefront of federal Health IT.

Congress has been actively engaged through the Senate HELP and House Energy and Commerce committees developing opportunities for loans, grants, and pilots to stimulate the deployment of electronic medical records. The Medicare Reform bill passed last week follows a path recommended by AHIC (American Health Information Community) to provide incentives for Medicare/Medicaid doctors to move electronic prescriptions.

With U.S. healthcare spending at $2.2 trillion, $7K/person, 16% GDP, and 4 times the spending on national defense, and 125 million citizens facing chronic disease, 60 million with multiple conditions, the state of the U.S. healthcare system demands a more comprehensive approach.

We commend the Ways and Means Health Subcommittee for challenging the current system by considering direct incentives for providers of Medicare and Medicaid Services to convert from the paper based, inefficient and inherently dangerous systems to using the technology we take for granted in every other industry. It's not just about routers, wireless Voice over IP (VOIP) and telehealth equipment and electronic medical records. Transitioning to a data rich environment provides an opportunity for improved tracking, analysis and understanding of expenses and outcomes that drive healthcare decisions. How do you track quality improvements without data? How do the oversight committees realistically appraise the state of healthcare in the U.S. or set benchmarking standards for reimbursement schedules without electronic medical systems? And more importantly, how are patients cared for without a holistic understanding of their diagnosis, testing and treatment?

Think Y2K, when the Federal Government working with industry, avoided a meltdown of the economy through funding and partnership in a highly technical area. Federal Government leadership played another key role in the healthcare industry when the Federal Government's decision to move to electronic billing records revolutionized not only the Medicare/Medicaid payment systems, but provided leadership for the private payers as well. Purchasing power of the Federal Government will move the meter nationwide.

Case Example: Banner Health IT

I'd like to share a case example of one hospital's experience after deciding to integrate technology in the construction and operation of their facilities. Banner Estrella Medical Center in Phoenix combined clinician-designed workflows, extensive training, with a cultural change to save the system $2.6 million through:

- Improvements in nurse retention
- Decreased incidence of adverse drug events
- Reduced length of stay
- Fewer patients leaving the ED without treatment
- Reduced days in A/R
- Decreased expenses

The patient experience improves dramatically as well. Patients aren't asked the same questions over and over again—the first clinicians to interview a patient chart the information, and everyone on the care team is able to review the information digitally. Clinicians don't waste time chasing after paper charts, and when they consult with other clinicians, each person can simultaneously access the charts. Clinicians use wearable Voice-Over-Internet Protocol phones (VoIPs), so patients' sleep isn't interrupted by frequent overhead pages. Nurses have a more comprehensive view of patients, so they are better able to develop a comprehensive plan of care to advance the patient in his or her recovery. Even many clinicians who were reluctant adopters of a paperless system now say they would never want to work in a paper-based hospital again.

Offering incentives to convert to a health IT platform for Medicare and Medicaid providers offers the opportunity to change the healthcare system in a dramatic way, both qualitatively and through cost savings. We urge the Ways and Means Committee to act now to find the right combination of payment incentives, tax benefits, pilot programs and low cost loans that will elevate the world's costliest system into the world's best healthcare system.

Value of Measurements and Interoperability

One of the critical gaps in today's existing health care IT is the lack of standards and interoperability. Hospitals and clinics have no shortage of expensive advanced technology, but often these devices do not communicate with each other. X-Rays and test records are not portable between doctors or health systems. Tests are often repeated unnecessarily, wasting money and time while the patient waits for a critical decision.

As President of the Continua Health Alliance, a worldwide non-profit, open-industry coalition of healthcare and technology companies, I am pleased with the progress our 250 members have made to voluntarily develop a system of standards that will promote harmonization of personal health products. We have just announced a set of Bluetooth standards that will promote wireless interoperability of these products.

Back to the Future—Home Centered Health Care

Over 70 million aging baby boomers could overwhelm the U.S. healthcare system and engulf the nation's tenuous economy, according to a new study, "Will the Boom Bust Health Care?," by management consulting firm Tefen USA. Internationally, the United Nations shows the number of people aged 70 and older doubling in 25 years to 1.2 billion in 2025.

Recognizing the impact of these demographics, Intel researchers launched an unprecedented study of seniors and chronically ill patients in 1999. Our ethnographic researchers have observed and interacted with more than 150 hospitals and clinics and 1,000 households in 20 countries. We became passionate about enhancing independence and finding solutions to help individuals, family members and caregivers stay in touch with the people they care about. We are learning that consumer education combined with home computers, wireless networks, televisions and cell phones offer new ways to increase prevention, early detections and caregiver assistance. We are designing systems that better connect to information interaction, safety and security, and health and wellness. Through ongoing monitoring and patient education, we can begin to shift the process of improving outcomes while keeping patients at home and independent.

While the bulk of health care today is delivered in hospitals and clinics, today's acute care-centered system is ultimately unsustainable in the future.

The old one-on-one physician to patient paradigm will not suffice. We need to move away from the physician-centered care delivery paradigm toward a patient centric model where delivery and funding are channeled via care teams with a community approach toward care. IT is a powerful enabler to help provide the care necessary to meet this tide head on.

Intel's goal for healthcare solutions is to connect people and information across the continuum of care to improve healthcare and quality of life. Interconnected personal health innovations will keep people healthy and living at home longer, and help individuals, families, and the extended healthcare community, and connect to

the right information at the right time. These new technologies will empower people to make better, more informed health decisions and become an integral part of the healthcare system.

Global Health Race

Between now and 2013 the EU and the private sector will invest more than €1bn in research and healthcare innovation for older people. Some €600m is to be invested in the ambient assisted living program, while a further €400m is included in the EU's latest research framework program. In addition, about €30m in research funds have been made available this year under the European Union's ICT Policy Support Program.

Through an unprecedented partnership with the Irish government Intel launched the TRIL (Technology Research for Independent Living) Centre creating one of the largest research centers of its kind. This active research collaboration between industry and academics drives knowledge transfer through the collective work of multidisciplinary research teams. The TRIL Center is building an open, sharable research platform and co-invents new technologies for older people and their families.

The U.S. shows evidence of quickly being left behind in this global marketplace largely ignoring, avoiding or under-investing in aging-in-place and home health R&D. One exception is the Oregon Health and Science University Biomedical Engineering Lab developing technologies for early detection and remediation of aging changes. The university is using biosensors to continuously monitor seniors' movements and develop new ways of detecting cognitive impairment. Another example is CAST, the Center for Aging Services Technologies, a partnership Intel co-founded with the not-for-profit long term care advocacy group AAHSA, the American Association of Homes & Services for the Aging. From the White House Conference on Aging to several demo days in the Senate, CAST, now with more than 500 care providers, technology companies, and universities involved, has brought national and international visibility to the needs of older people, their families, and their physicians.

By adopting a platform of innovation and care for the "age wave," U.S. businesses, governments, and NGO's have the opportunity to not only create centers of excellence but also provide a new economic frontier serving the U.S. and across the globe.

Once again, thank you for acknowledging the role of the Federal Government in accelerating the U.S. adoption of a robust and effective health IT ecosystem. We look forward to working with the Committee as you develop policy incentives to ensure that the U.S. becomes a center of excellence.

Chairman STARK. I want to thank the panel very much. This is a problem that actually has concerned some of us on the Committee for over 15 years. I think it was Mr. Gravitts and I who had talked about outcomes research more than 15, 20 years ago.

I have a feeling that that is impossible to develop, unless we have some kind of universal database, and we can find out what happens—not whether you survive a procedure, Dr. King, but what happens 5 years after the procedure? Which procedure is better? Unless we have some kind of database, we're just never going to know.

Peter, could you address the issue of the incentives that you think are necessary from two points? One, my sense is that doing it through the tax code leaves out the not-for-profit segment of the provider community. So, that leaves a big hole, if that's where we're going to do it. Second, the smaller providers, the solo practitioners, the small, very small groups—less than five, let's say—that Dr. Ejnes's group represents, don't see the same "savings" that Kaiser Permanente sees. I mean, Kaiser can use their own system, as they do now, and probably save a whole lot of money. But, for a solo practitioner, that's not as good.

Well, how could we incentivize these two different extremes? Can we do it any other way? You say the stick. I've suggested that we start with a supplement, and that means Dr. King and others who spent money already get some of it back. Because whatever system we pick isn't going to make—90 percent of the people are going to be unhappy because it isn't their system, and they're going to have to make some changes and adopt.

Those who don't have a system we'll front-end load it, and then glide down to zero subsidy and—in 5 years, say—and then in the subsequent 5 years, start penalties. So, you get 5 years and some money they get into the system, and then if you're not in it in 5 years, we start to penalize. It would be a system—could you comment on those ideas?

Mr. ORSZAG. Sure. First, I think it is, for context, important to realize that the entities that find it most beneficial—the integrated health plans—have already largely adopted. These institutions are behaving rationally. Those that see the largest benefits from this have been the leaders in adopting it.

With regard to the Tax Code, you're right that non-profits—you have to either be—leave them out, or be very clever about transferability, about clever—and it creates problems in the Tax Code—in extending benefits to non-profit entities. So, I will leave it at that, but you are right to identify that as a significant issue in any tax incentive that is intended to provide help to non-profits.

With regard to solo practitioners, I guess there is this tradeoff, which is unless you're going to provide massive subsidies—you know, $20,000, $30,000, $40,000 or more for those solo practitioners—you are going to wind up in a situation in which they are going to bear some costs that are not fully reimbursed, or fully offset, and it's really up to you.

I mean, I believe that the only way we're going to get to nearly universal adoption is ultimately with some stick, as it were, or some penalty, if you will, as the e-prescribing legislation did. You can easily, if you wanted to, offset most, if not all, of the costs up front. It's just you're going to be bearing larger budgetary costs in doing that. That's obviously a choice that would be up to you.

What I would say, though, is it seems unlikely that, unless you're going to have very, very large budget costs, that you're going to get nearly universal through purely the carrot approach.

Chairman STARK. Well, you are right. We have been faced recently with a series of ads—I'm not sure who is running them—in the Post showing us the "$1 billion profits" that some of these not-for-profit systems are making, and the $6 million and $8 million and $12 million annual paychecks that the chief executive officers of some of these large—you're not one of those, are you, Dr. King, getting——

Dr. KING. I'm wondering where I can apply.

Chairman STARK. Me too. But—and I suspect they're the ones that already have the system, and they can well afford it.

I wanted to go to Dr. King and maybe Mr. Whitlinger. I am happy to say, Mr. Whitlinger, I just found out that my Mac just crashed due to a RAM chip, but Intel didn't make it. We think Samsung did, but I will recommend to Steve Jobs that you make those chips, and then maybe the darn thing will work better.

But, Dr. King, you use Vista, that you just—the one that the Veteran's Administration has, and makes available for anybody for free?

Dr. KING. Well——

Chairman STARK. Or an iteration of it? I don't——

Dr. KING. An iteration. Basically, what happened is because it was developed by the VA, you can obtain Vista under the Freedom of Information Act. That particular—the way it is when it comes to you, it's not very practical. So——

Chairman STARK. Somebody said that somebody out there in the world is rewriting it, the Vista program, to bring it into—and here, my 13-year-old would have to explain to me the technology—but rewriting it in a form that would be usable in modern-day computers.

Dr. KING. Well——

Chairman STARK. It, too, will be available, free.

Dr. KING. Well, what happened was—it's sort of already happened—the CMS had a grant, and was able to take the Code and open source it through this grant, so it could be used in an office-based setting.

Chairman STARK. Okay.

Dr. KING. That was developed by World Vista——

Chairman STARK. Now, if I am a patient in your clinic.

Dr. KING. Yes.

Chairman STARK. I go to Kaiser in Oakland, can they access—they have IPIC, or something like that—could they access my record in your clinic, if I happened to be in Oakland and needed treatment?

Dr. KING. Today they could not, no.

Chairman STARK. It's my understanding that if I am a patient in the Veterans Administration, and I end up in an emergency room at Oakland, if they have my password and code, they can—the doctor in the emergency room at Pilot Hospital in Oakland—could get on the Internet and get my Vista records. Is that your understanding?

Dr. KING. My understanding is they could go and get the patient health record——

Chairman STARK. Yes.

Dr. KING [continuing]. That the patient actually has entered, but not the electronic health record that Vista has. In other words, there is a——

Chairman STARK. I thought they could, but I am——

Dr. KING. Only if they have access—that system is locked down pretty well.

Chairman STARK. Okay.

Dr. KING. Unless you have all the access, and—it would not work.

Chairman STARK. Would not something of that nature be desirable—and I ask the physicians on the panel—at some point for treating emergencies and/or treating people who move from a primary care doc to a specialist, to have, as Vista does, all the—imaging is electronic, so there is no paper image any more, but film images. You can just get all of this out of the ether. Would that not be an advantage to practitioners? Dr.——

Dr. EJNES. Yes, it would be. In fact, I would argue that the full potential of physicians adopting electronic health records will not be achieved until we get there. The—and this is what's going on—I mean, I'm involved—I'm also on the board of directors of the Rhode Island Quality Institute, which is a recently designated RHIO, and that's something we are trying to do within the state, is to get the hospitals, the labs, other physicians, to be able to exchange information.

It doesn't require everybody at the user end have the same software, just as you can access the web on your Mac and I can on my PC. But the concept of the exchange is key to our success.

Chairman STARK. Yes, I think you say it, and I would be concerned Mr. Jones's clients, and Mr. Whitlinger, while we—each person here—may have a different e-mail—I use AOL personally, but something else here in the House, but I can get to my AOL mail on a Mac or a PC in the airport, if I get into the—you know, borrow somebody's. So, it's—to that extent, that is my definition of—I can have a separate little program that either encourages pornography or sorts spam, or whatever it wants to do, but I can do that from any computer that is available. Is that what your clients—is that what you suggest to your clients, Mr. Jones?

Mr. JONES. Yes. We certainly try to bring about interoperability without reducing the freedom of choice of the particular end user point solution. I think that, you know, and electronic health record, in this regard, is sort of akin to that, an end user point solution.

Chairman STARK. Ms. McGraw, I am not avoiding you, but I know some of my colleagues know much more about the privacy law than I do.

Ms. MCGRAW. Okay.

Chairman STARK. Even—some of them went to law school, so they understand really the nuances of it, which I don't. As a banker, I sued George Schultz when he was Secretary of the Treasury, because he was trying to get into the bank records, and it went to the Supreme Court, and I lost. But nonetheless, that's the last time I got involved in privacy issues.

Are there any of the witnesses who feel that we could get to a database that I think we all desire for research, sanitized for privacy protection, and that would save the money that Dr. Orszag suggests that we could get, without the Federal Government—or perhaps AMA, I don't know—somebody saying, "This is the system in which everybody must participate?"

On the other hand, is there anybody who thinks that would be a disaster, in terms of free enterprise and getting where we want to get?

I can—anybody want to—that's my last question. Mr. Whitlinger, you're the biggest free enterpriser, next to Dr. Orszag here, in terms of money that you spend. How would Intel come up with that?

Mr. WHITLINGER. Well, certainly, there are interoperability standards being developed, and that are being implemented, that would allow us many, many systems across the nation that could be linked together and provide us the functionality that would be necessary to provide the physicians with the ability to transport

health records back and forth, in order to serve their patients and to also have a secure private network that you describe.

Chairman STARK. Dr. Ejnes.

Dr. EJNES. Yes, Sir. If you are referring to everybody adopting the same electronic health record application, for example, I think, based on what's out there today, and the needs of offices today, I think I would say disaster.

Having been through the process a couple of years ago of weeding through the hundreds of different products, it's very clear that if you've seen one practice you've seen one practice. Certain physicians want all the bells and whistles, others want "Bring it out of the box and let me use it." The types of practice, locations, and other needs really dictate which product is the best one. The certification commission has played a major role in helping to narrow down the choices for us, as well as have us poised for interoperability.

But I think, unless it were a product that didn't exist today, to have it be the universal one, even if it were inexpensive, would be problematic.

Chairman STARK. Let me follow that up, because I am afraid I don't have the vocabulary to adequately deal with this. But my assumption would be that I could get the entire organized medical fraternity and sorority to nod with me if we started with age, weight, blood pressure, cholesterol, all those kind of empirical things that we all have in our psyche, okay, or in our physiology. So, I don't think there is any quarrel there. We say, "Okay, every record has got to have my name, race, age, sex," you know, all the stuff. Okay?

Beyond that, I also think we could agree that, as Vista does, all the pictures, or whatever they take of us—CAT scans and all, x-rays and that sort of stuff, can be stored digitally. So, no quarrel there, right?

Dr. EJNES. Right.

Chairman STARK. Now, as to my program for—my schedule in Congress has a place where my wife can get in touch with my scheduler and add the shopping list for Fresh Fields that I am supposed to pick up on the way home. That might not be required in every system, but the ability to do it could very well be there without disadvantaging—can't we get to some level where—and then, let the specialities—it's my understanding that thoracic surgeons and the anesthesiologist do have a database of more than half of all the procedures performed in the last 5 years. That's pretty good. But I don't think there are many others that do that. Is that a——

Dr. EJNES. Yes. I think that's——

Chairman STARK. I mean, doesn't somebody have to outline——

Dr. EJNES. Yes.

Chairman STARK [continuing]. That system?

Dr. EJNES. Yes. I think what you are getting at is the development of standards.

Chairman STARK. Okay.

Dr. EJNES. I think we have made a lot of progress. This is not my field, but——

Chairman STARK. Then what I should say is somebody has to define the standard.

Dr. EJNES. Yes. I think we have. I mean, there are standards that exist for communicating a lab report, an image, you know, the patient—discharge somebody from the hospital, and that's come out of these different collaboratives that were described by the other panelists.

So, yes, I think that has to be the foundation for whatever then is acquired by the physicians, just as, you know, TCPIP is the way that we communicate data across the Internet. So, whether you have a Mac, a PC, a Blackberry, you're able to communicate.

Chairman STARK. Do you have a feeling on this, Mr. Jones? Your clients, what would they say about all of this? Or what do you say to your clients about all of this?

Mr. JONES. I think that the last point is exactly right, that we are—you know, if I made an analogy, we don't want to tell everyone they have to drive the same car, because some people—or the same motor vehicle—because some people need a pick-up truck and some people need, you know, to be compact, et cetera. But we do want to define what a car is, that it moves, it has wheels, it has a steering wheel, et cetera.

So, in that sense, I think that this system that you're describing is, in fact, the selection of standards that would govern how a car operates. You know, there could be enforcement about various things: You must have seatbelts for safety, you know, et cetera.

Chairman STARK. We don't have that yet, do we?

Mr. JONES. Well, what we do have is a number of different standards development organizations that all are trying to define that car. Sometimes they define slightly different cars.

So, what we have tried to do in HITSP is to bring them to the table and say, "You know, this is really—let's compromise, and this is really what the definition should be about a car." So, I think that there is not a lack of standards. In many cases, there may be "too many standards." So we need to select and harmonize them.

Chairman STARK. Would it be helpful for, say, the Federal Government to establish a standard and say, "Here it is, guys, and now let's all figure out how we can compromise to work on one standard?"

Mr. JONES. Well, I think that the Federal Government is doing that through the sponsoring of HITSP. The establishment, in this case, is to bring the Federal stakeholders and the private stakeholders together to agree and say it's not an option to not agree. "We will move forward, whether you are at the table or not, but you have the opportunity to come to the table, and we will agree that this"——

Chairman STARK. We have to complete that, then.

Mr. JONES. Absolutely.

Chairman STARK. Okay. Mr. Camp, would you like to inquire?

Mr. CAMP. Well, thank you. Being from Michigan, I certainly like these car analogies. I hope—and what my bill tries to do is actually codify what these groups are doing at HHS, and bring them together to come up with standards.

But also, I think it's important that we have the people who build cars at the table. So, we do need to have a viable private sector role in this. I don't think people in the government know how to define a car without the help of the people who build the cars.

So, that's why I think we are trying to strike this balance in the legislation that we have.

I do just want to mention that Dr. Reding, who was going to testify here on behalf of the Marshfield Clinic, they have 40 years of IT development at their—in their experience, and they didn't receive any direct Federal funding to pursue HIT. But they did express concerns about the privacy language, and the commerce bill, or the Protect Act that is moving through. Really, this idea that there is a limited data set of data that is moving forward, they believe would certainly affect peer review, quality review, quality improvement, standard of care review.

So I do think, while this privacy issue is a complex one, I think we have to make sure that we keep certain simple truths in place, and that is this idea that those involved in health care can consult with others in health care for the purposes of treatment, this implied consent issue, that we don't erode that to the point where we hurt those positive things that are moving forward.

But let me just say, Dr. Orszag, you know, from your testimony I got the sense you feel that society, as a whole, is spending enough on health care, in terms of a percent of our economy. Is that something that you—in your comments, that's what I drew, at least, a conclusion. Would that be a viable conclusion of your comments?

Mr. ORSZAG. Well, I don't know whether we're spending enough or not. What I do know is we could be getting a lot more from what we're spending.

Mr. CAMP. So, we are not getting value for what we are spending.

Mr. ORSZAG. We are not getting enough value——

Mr. CAMP. So, we are spending too much for what we get.

Mr. ORSZAG. That is correct.

Mr. CAMP. Now, you mentioned that—this idea of a non-integrated and integrated system—and for those of us who may not be the policy wonks that others are—traditional Medicare is a non-integrated system, correct?

Mr. ORSZAG. Traditional Medicare pays for non-integrated care——

Mr. CAMP. That's a yes?

Mr. ORSZAG. Yes.

Mr. CAMP. Medicare Advantage is an integrated system, correct?

Mr. ORSZAG. Medicare Advantage——

Mr. CAMP. Much like an HMO is an integrated system.

Mr. ORSZAG. Could be, yes. It depends on the exact definition of an integrated——

Mr. CAMP. So you would conclude that integrated systems, like health HMO's, better realize benefits from HIT than non-integrated systems like Medicare. That's a conclusion you draw in your report.

Physicians, you mention, have little incentive to adopt HIT. Should we incentivize them to do that?

Mr. ORSZAG. I am going to leave the "should" up to you. What I would say is if you want to capture this—you want to improve the efficiency in the health system, you need to get toward more universal health IT. You can do that, again, in a variety of ways. You can provide a positive or a negative incentive. I guess I could put it that way. But we do need to change the incentives.

Mr. CAMP. All right. Dr. King, the Marshfield Clinic believes that Congress should subsidize the use of health IT through Medicare, to promote the rapid adoption of those systems. You mentioned that just 3 percent of your health system patients are Medicare beneficiaries. So, this means that a clinic like yours would see very little support from health IT.

Is this a good use of taxpayer dollars, in your opinion, for——

Dr. KING. For the——

Mr. CAMP. The beneficiary?

Dr. KING. Yes. I think that incentives are extremely important to get adoption. However, I think you have to do it in a way that drives improvement of care at the same time. Just handing out money for people to buy electronic health records I think will lead to large failures, a lot of wasted money, and you won't get what you want.

Mr. CAMP. Dr. Orszag, if physicians were paid based on the quality and appropriateness of care they delivered, would they be more likely to see financial incentives associated with adopting health IT?

Mr. ORSZAG. Yes.

Mr. CAMP. That would be a good thing?

Mr. ORSZAG. Yes.

Mr. CAMP. All right. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Mr. Doggett, would you like to inquire?

Mr. DOGGETT. Thank you, Mr. Chairman, and thanks to each of our witnesses who have offered some valuable insights into this complex issue. I certainly agree with Dr. Orszag, that we cannot begin to get at—effectively—the $700 billion of waste in the system unless we have information technology. We won't get information technology unless part of the incentives are strong negative incentives. We will simply be encouraging people who are already moving toward health IT, and not getting at those who have been resistant to the idea.

My concerns, though—and I will address probably all my questions to Ms. McGraw—concern the question of privacy.

You are well aware that this is not the first time, as all our witnesses are, that this Committee has considered information technology. In 2006, I joined with Mr. Emanuel and some of our other colleagues in offering an amendment to the bill that was up then, designed to protect patient privacy. On the floor, I offered that language, and I have not seen anything since then.

In fact, quite a bit of evidence supporting our concern about patient privacy that would suggest that, in this legislation, we should lower the bar and denigrate the standard that was set in the Emanuel amendment, and the language that I offered on the floor.

I find that, despite the efforts yesterday of Congressman Ed Markey, that there are a number of provisions in the legislation approved in the Energy and Commerce Committee that are troubling. I thought, Ms. McGraw, that your point was well taken in your testimony, that proper standards for privacy are not an obstruction to information technology, which we want. They, in fact, can enable that.

Indeed, wouldn't you agree, Ms. McGraw, that, unless there are appropriate privacy safeguards in this legislation, we won't get the

kind of honest, complete data that we need, both from practitioners and from patients, feeling that they can have confidence in telling their physician what their situation is, particularly in the mental health area, unless they can be sure that their personal data is private, and shared only between medical health care practitioners, and not sold off to some data mining company?

Ms. MCGRAW. Right. No, of course, I completely agree with you. You know, one out of every six people in this country practice what are called privacy protective behaviors because of their fear about how their health information could be used to harm them. That is particularly true for people who are dealing with conditions that are frequently stigmatized, or have sought care that really, you wouldn't even want your neighbors to know about.

So, essentially what that means is that people either won't go to the doctor, they will lie to their doctor, or they will ask their doctor to be careful about what goes in the record, or they will see multiple providers to avoid all of the data being in one record. Of course, if we are going to all be electronically connected, that behavior obviously won't be as fruitful as it once was for people who are really concerned about their privacy.

The problem is that that person doesn't necessarily get good care, because the physicians and the providers who care for them need that information. So, there is bad data, essentially, in the record. That also hurts us in our efforts to measure care quality—and use of data for population health purposes, because you have some bad data streams in there.

So, I agree with you, that it's important to pay attention to this.

Mr. DOGGETT. Exactly. We want the data stream to go—to allow us to set good policy, to allow for treatment insuring between practitioners. But we don't want bad data that grows out of fear that privacy is being invaded.

I note that the bill that was approved in the Commerce Committee yesterday, though it makes repeated reference to privacy, does not define privacy.

Ms. MCGRAW. Yes. Well, to be quite frank, I think that the focus on a definition of privacy is, again, far less important than setting forth some very clear parameters on how information can be used by health care providers, and how it can't be used.

There is actually, within the privacy community, a great deal of difference of opinion on if you were to define what privacy is, what that would be. So, we could spend a lot of time debating that, and still not—you know, and not come up with a good set of privacy and security protections. I think our focus is better put on——

Mr. DOGGETT. Would you agree——

Ms. MCGRAW [continuing]. Setting that framework.

Mr. DOGGETT [continuing]. That, again, looking to the Commerce bill, that patients should be able to give consent before identifiable prescription records are shared with insurance and pharmaceutical companies?

Ms. MCGRAW. Well, again. We worry a bit that the focus on consent diverts us from the more important issues. Let me explain myself, because I—consent is an important part of a comprehensive privacy and security framework for protecting data. But it's only one part.

In fact, if we sort of pin all of our hopes or our plans for privacy and security on patient consent, we will, unfortunately, provide people with very weak privacy protection. Because, in the health care context, people don't actually have a right to say no. If you are coming to your health care provider and you need care, they need the information to treat you. It's not a situation where you can say, "Well, you can't use my information to do this."

It also puts all of the burden on the individual to protect their own privacy, counting on them to read the consent form, understand what it says, sign it at the bottom, and then hope that actually what they have signed at the end of the day actually does protect their privacy in ways that they think it does. There is plenty of research that shows that people actually completely misunderstand what they read.

I would much rather have a focus on creating some very clear rules about how providers can and can't use data, and penalties associated with the misuse of that data.

Mr. DOGGETT. Seeing the red light is on, and understanding that consent, by itself, may not be sufficient to protect privacy, it would appear that in the Commerce bill, that doctors, concerning certain procedures, must obtain consent from patients before sharing this data. Is that your reading?

Ms. MCGRAW. The—it is for health care operations——

Mr. DOGGETT. Right.

Ms. MCGRAW [continuing]. Which is a defined term in HIPAA, which isn't treatment and isn't payment, but is instead this sort of—I call it almost back office, things associated with treatment like a peer review, quality assurance——

Mr. DOGGETT. You agree with that consent requirement?

Ms. MCGRAW. I have some concerns about it, to be quite honest. Again, the focus—people will be—the consent forms, people—again, they don't read them, they don't understand them. What they end up being is potentially a shield for uses of data that would, again, be much better protected if we had some clear rules around how entities can and cannot use data. We worked with Committee staff to try to make that provision more clear, to make sure that it was linked to the minimum necessary rule. But, again, I still have some concerns about that provision in the bill.

But, having said that, CDT does support the Energy and Commerce legislation and moving it forward, because we think there are some very important privacy and security protections in there.

Mr. DOGGETT. But not necessarily without some changes. Okay.

Ms. MCGRAW. We would encourage some changes. But, again, our support was not qualified. I don't want to be misunderstood.

Mr. DOGGETT. Thank you.

Chairman STARK. Thank you. Mr. Johnson, would you like to inquire?

Mr. JOHNSON. Thank you, Mr. Chairman. You know, when you're following on that conversation, when you're talking with specialists—and there are a heck of a lot of them out there these days, as you know—the docs have to coordinate with one another. That information has to be passed.

You know, Dr. Orszag, you repeatedly state that physicians have little incentive to adopt health IT, and state that physicians may actually have a disincentive, because the systems can lead to a reduction in the number of unnecessary tests and services. You have been a proponent of that, and claim we're spending too much money.

If this is the case, then why are any physicians spending their own money to implement health information technology? There is a doctor practice in my district that was so motivated to implement an electronic health record, that they went from paper charts to paper free in three short months. They broke even on the investment in 18 months, and have reported a significant addition to physicians' annual income as a direct result of the technology. If they're doing fewer tests and services, which you state is the case, then they're making more money from something else. From all the conversations I have had with physicians who have adopted this technology, the scenario is not a one-time phenomenon. There happens to be 17 physicians in that group that did that.

Is this an inherent disincentive that dissuades physicians, or just that there isn't enough people out there, trying to get the equipment or associations or organizations spreading the good word of what technology can do for them? Do you have a comment on that?

Mr. ORSZAG. Well, Mr. Johnson, as has already been asserted by the Chairman, I suppose in some settings I am a strong believer in the power of incentives and free markets. I will just look at the evidence. Ten to twenty percent of physicians have adopted. So, yes, there are some that find it in their interest to do so. But the vast majority don't, under the current system.

The kinds of settings where there are—it is profitable to do so, there might be some losses from ordering fewer tests, but you save on administrative efficiencies. You may not need as many support staff to process things. You can often get internal efficiency benefits that offset any other effect.

I would just come back, though, to saying in the current system we are clearly not getting take-up rates that are anywhere near what most people believe would be optimal. I don't think that is from a lack of health IT providers or vendors, you know, going out there and saying, "We have these things that may help you." I think it is from complexity, and I think it's from a lack of direct incentives for especially small practitioners to adopt.

Mr. JOHNSON. Well, I think we could appeal to physicians as small businessowners, and let them use the Tax Code to deduct the cost of the technology if they wanted to, and perhaps entice them that way. But it sure is a lot simpler dealing with a doc that has got that kind of data. I know the docs here know that.

But you know, in Dallas, for example, you can—if you happen to have a doc that's got that IT installed, you can go to the hospital and you don't even have to fill out forms, because they can pop that stuff over there right now.

Mr. ORSZAG. I don't think there is a person on this panel or in this room who is not annoyed at how many times you have to fill out forms when you go see a new doctor. We all are——

Mr. JOHNSON. 18,000 times.

Mr. ORSZAG. Yes.

Mr. JOHNSON. Yes. It seems like the forms are duplicative. In the hospital, it is even worse, you know?

Mr. ORSZAG. Yes, Sir.

Mr. JOHNSON. There is a stack of them this high. So, if we can get rid of that, and the storage required for all that paper, it would be a marvelous improvement in our medical system, I think.

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

Chairman STARK. Thank you, Mr. Johnson. Mr. Thompson, would you like to inquire?

Mr. THOMPSON. I would. Thank you, Mr. Chairman. Thanks for holding the hearing, and thanks to the witnesses, for being here.

I have got some concerns about how we make health IT available in the areas that I represent, specifically our rural areas. Dr. Orszag, you referenced the Robert Wood Johnson work, and they mention the fact that rural hospitals are 50 percent less likely to be able to have health IT, and that solo practices, which are, more often than not, in rural areas, fall under some pretty heavy constraints. It's more than just coming up with the capital to put this in place. There is maintenance, there is constant upgrades. Small practices, rural practices, rural hospitals don't have the opportunity or the ability to have a full-time IT manager in place.

How do you—what recommendations do you suggest that we make sure we don't hurt these guys in our effort to help them, and help health care?

Mr. ORSZAG. Well, the report that you referenced, CBO's report, also mentions that one thing you could do is, if you are going to go with the carrot approach, or the subsidy approach, you can vary it.

So, for example, provide a larger subsidy to solo practitioners than to large practices. Or, I suppose you could also offer a larger subsidy to regional hospitals than to urban hospitals, for example.

But I would again come down to the fundamental problem here is there is a lot of the benefit that is going to accrue from having a more universal system of health IT that is not going to be capturable—or directly capturable—to, say, that regional hospital. There is a national benefit here, in terms of capturing efficiencies in health care that will not—it will be very difficult to have it flow back to that hospital.

So, there is this problem in that there is a national benefit and an overall benefit, and it's not exactly the same thing as the benefit to that regional hospital. That's just the way it is. It's very hard to come up with a way of returning that overall efficiency gain to all of the doctors that will be necessary in order to capture it.

Mr. THOMPSON. Well, I am very worried that we understand that, and even in regard to the carrot approach, that we don't think that we can give some sort of incremental increase in funding, based on visits or something to pay for that. Because the rural guys also don't have the amount of folks coming in for visits that more populated areas do.

Also, in the area—in the issue of interoperability, I would just be interested in hearing maybe Mr. Jones, if you could comment on this. In my rural district, I have doctors that—one doc will work

in three or four different hospitals in three or four different areas that will be out of county, out of city.

In your work in regard to interoperability, do you take this into consideration, and—the cross-jurisdictional boundaries?

Mr. JONES. Yes. I think that there are a few aspects to that. One is people are realizing these days that there was a lot of energy focused on trying to reconcile patient data, given that patients go to multiple places. But the same is true for providers.

So, I think that similar technology that allows you to reconcile who this patient is can also allow you to reconcile who the doctor is, so you can pull the information from——

Mr. THOMPSON. So, you would envision interoperability that crosses jurisdictional boundaries, and every city would have the same electronic ability, every county, every area where you would get this cross-pollenization?

Mr. JONES. I think, from a technology standpoint, yes. I think what starts to become the barrier are the policies that those different jurisdictions have to work out, in order to facilitate that.

Mr. THOMPSON. I have been involved in the—in California, in bringing technology forward for programs such as the welfare program in California. You couldn't get cities to agree—let alone counties to agree—on what type of technology you would use. I would just think it would be very difficult for individual hospitals, and especially individual hospitals run by individual companies, and operating in different geographical areas.

Mr. JONES. Yes. I think that it does require a focused set of policies for this purpose of interoperability. That's what we found in New York, for example, in some of the RHIO's. Hospitals may have different policies about how they correct errors in patient data. But when it came to the community-wide view of that data, they had to have a separate policy that allowed them to have a common understanding of how that data would be treated. So, I think it has to be purposeful in that way.

Mr. THOMPSON. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Mr. Becerra, would you like to inquire?

Mr. BECERRA. Thank you, Mr. Chairman. Thank you, to the panel, for your testimony.

Mr. King, let me start with you. My understanding is you have a very low percentage of your patients who pay through Medicare.

Dr. KING. About 3 percent. However, 40 percent is Medicaid.

Mr. BECERRA. Right. But Medicare is about 3 percent?

Dr. KING. That's correct.

Mr. BECERRA. How many patients would you say you see in a year in your different clinics, roughly?

Dr. KING. We see 32,000 total patients, individual patients——

Mr. BECERRA. Okay, and——

Dr. KING [continuing]. In all the clinics combined. Is that the question?

Mr. BECERRA. Yes, that's fine.

Dr. KING. Okay.

Mr. BECERRA. If we were to go toward a system to try to incent the institution of a HIT throughout the country, and certainly in your clinic—and while you have moved forward, chances are if

we're doing it through Medicare, you're going to get very little money back.

Dr. KING. That is correct, because we don't have a lot of Medicare patients.

Mr. BECERRA. But you do have a lot of Medicaid patients.

Dr. KING. Yes.

Mr. BECERRA. Do you get any SCHIP patients?

Dr. KING. We get some of those, as well.

Mr. BECERRA. Okay. Do you get any other form of government-subsidized payment for patients that you see?

Dr. KING. Off the top of my head—you're talking about Federal?

Mr. BECERRA. Or state.

Dr. KING. We get tobacco tax.

Mr. BECERRA. Okay.

Dr. KING. There is some, like, special programs, like well women programs and——

Mr. BECERRA. Well, there——

Dr. KING. We also have WIC.

Mr. BECERRA. There are programs sponsored, supported, subsidized by the government—Federal, state, and maybe local—that offer you some reimbursement for some of the patients which you see, because most of the folks you see, obviously, are modest income or uninsured.

Dr. KING. Absolutely. We have 50 percent uninsured.

Mr. BECERRA. Okay.

Dr. KING. For every dollar that we get for uninsured patients, we spend about $2 on them. So, we do that by leveraging the money we get from Medicaid, primarily.

Mr. BECERRA. Your clinic is like thousands of clinics throughout the country who provide care to some 16 million people in America who otherwise might not have access to good health care. So we thank you for that.

My question, then, is if we go toward a model that only seeks to use Medicare to try to provide the incentive for health IT, is that going to help the community clinic universe that's out there, providing care to some 16 million Americans?

Dr. KING. It would leave us out.

Mr. BECERRA. It would? Do you think there is any reason why we couldn't use Medicaid as a mechanism to try to offer incentives to adopt HIT?

Dr. KING. No, Sir. I think that's——

Mr. BECERRA. Can you think of any reason why we wouldn't want to consider using the SCHIP program to perhaps also adopt HIT?

Dr. KING. Perhaps it doesn't penetrate deep enough. That would be my only concern.

Mr. BECERRA. But we are providing it to some six million to seven million kids right now.

Dr. KING. Right.

Mr. BECERRA. If Congress is successful in overriding the President's veto, we would include another five million kids from modest-income families. So, that might be another mechanism?

Dr. KING. Makes sense, yes.

Mr. BECERRA. Okay. Dr. Orszag, is there any reason that you're aware of why Medicaid or SCHIP could not also be considered vehicles through which we would try to incent, positively or negatively, the adoption of HIT?

Dr. ORSZAG. No, I can't think of a reason. Indeed, it's not just community clinics, but also pediatricians and other parts of the medical system that would be left out in a Medicare-only approach.

Mr. BECERRA. You forecast my question to Dr. Ejnes, and that is, is there any reason, Dr. Ejnes, that you think that we should not consider using SCHIP or Medicaid, as well as Medicare, for potential vehicles to try to incent the adoption of HIT?

Dr. EJNES. No, I can't think of any reason. I think all payers have a stake in this.

Mr. BECERRA. Okay, good. Dr. Orszag, do you have a sense—and this may go beyond what you have examined—but do you have a sense of how much an incentive, positive or negative, and over what timeframe we would have to do this, in order to try to really capture the providers out there in America into this system of HIT?

Mr. ORSZAG. Well, I guess that's similar to a question—it depends on how deep an incentive you want to provide. It's similar to the question of how much it would cost to move towards universal health IT. The answer is, it depends on the systems adopted, but something in the range of tens of billions of dollars. In your head, if you want something, you know, $50 billion to $70 billion or so is the kind of number that you should have in your head.

You obviously don't need to pay—you don't need to fully subsidize that, if you don't want to, but that is the kind of range that one might want to have in your mind, if you are thinking about the total cost.

By the way, that—just coming back to the earlier question—that's for adoption, and then there are ongoing maintenance and other costs.

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

Chairman STARK. Thank you. Let's see, who—Mr. Emanuel, would you like to inquire?

Mr. EMANUEL. Thank you, Mr. Chairman. Dr. Orszag, if you look at IT, or look at your $700 billion of what you think are savings through efficiency in otherwise spent dollars, you have the chronic illnesses, wellness programs—the other side of that chronic illnesses—you have paying doctors for outcomes, rather than fee-for-service, you have IT.

Break down the parts—and I know this is a rough game—and I am a little confused, because some people are saying what you said, and then other people's testimony is slightly different, that IT kind of is the foundation to all these others. Then, you are saying that IT is just a piece of those, and—you know, the others—and it's just a composite.

So, is IT the essential combination to the lock of the whole $700 billion, or do you see it as just a part and parcel of other sets of pieces that would get us at that $700 billion?

Mr. ORSZAG. It unlocks one of the locks, but there is then a bolt and other things on the door, so there are many other things that have to happen in order for——

Mr. EMANUEL. Don't ruin a bad metaphor of mine, okay? It was horrible when it started. Please, don't do that. Go ahead.

Mr. ORSZAG. Health IT—so the report says, and in terms of foundations, think of health IT as necessary but not sufficient. You need to do it in order to get the data to do comparative effectiveness research, and then to pay for what works. That is crucial, including for those needing chronic care and those with multiple chronic conditions.

But by itself, if you just plop a health IT system into a fragmented system with distorted incentives, don't expect magic. You're not going to get the $700 billion by just putting health IT in.

Now, if you want to start breaking it down—the problem is, if we need to make three or four changes in order to capture that efficiency, and they're all necessary, you can't—I can't give you a breakdown on how much is coming from this piece versus that piece.

Mr. EMANUEL. Well, let me ask you this way. Tell me if this is right, that we spend about 60 percent of our dollars on chronic illness that, if those were managed better, you would see a reduction of health care costs.

Mr. ORSZAG. The majority——

Mr. EMANUEL. Close?

Mr. ORSZAG. It depends exactly, but yes. The majority of health care costs are going towards very seriously sick people. By the way, that's where a lot of this variation that is occurring across the United States is occurring, also.

Mr. EMANUEL. Let me understand, because I think one of the problems when I looked at the report also is about how much Germany has spent, Great Britain has spent, versus what we spend on a per capita basis. We're like in the pennies, and they're spending $21 a patient, et cetera.

We discussed this, Democrats on the Committee talking yesterday, on the IT space. You know, I noticed last time when we did a spectrum sale, we thought it would generate about $10 billion in revenue, and it generated $19 billion. Have you ever looked at using that type of revenue, of asset sales as—in a dedicated area that would go into a health IT? We can do it as a revolving fund, et cetera, as a way to leverage those dollars, but selling some type of asset to generate this—what you would call start-it-up capital for this specific space?

If you were to do that, what would be the first type of payments you would do, given what you said, you know, medical IT has to be in combination with other things?

Mr. ORSZAG. First, let me say on Federal assets, I think there is a substantial amount of Federal assets that could be better managed, and potentially sold in exchange for revenue that could be used for other things, and that—spectrum, by the way, if you move toward addressing climate change, you're also creating a very valuable commodity there. Federal properties and land and buildings, and what have you, there are all sorts of assets that we are not optimally managing, and that could be used for this sort of thing.

I have not actually thought about what would be at the top of the list for this specific application, but the general thought, I think, is a very good one.

Mr. EMANUEL. All right, thank you. Mr. Chairman, I yield back.

Chairman STARK. Thank you. Ms. Tubbs Jones, would you like to inquire?

Ms. TUBBS JONES. Mr. Chairman, thank you. To the speakers, thank you for coming this morning. This is significant, that we are talking about IT as we transform the delivery of health care from people who used to walk up to a doctor's door, and the doctor did everything that they needed to, large systems delivering health care.

I want to commend my staff, Athena Abdullah, for a wonderful opening statement. It's so good, that I am going to read a part of it before I ask you questions.

The requisite tools and technologies are viable if a company—let me back up and start from this page.

Our current care delivery model requires a myriad of Federal and state laws, and regulations that are difficult to understand and navigate for large payers and providers. Vulnerable and under-served populations rarely have the resources or tools to effectively understand and navigate the mix of Federal, state, and local entities engaged in providing their health care. The requisite tools and technologies are viable if a company by culturally, linguistically, appropriate outreach and educational initiative, advocacy and public policy strategies, work force development and training ventures, and concrete options for funding and sustainability.

A comprehensive approach will be required to bring under-served populations into our National HIT framework to achieve improved health quality and access for racial and ethnic minorities, and other under-served and vulnerable populations.

Health information technology is widely viewed as a tool to improve health quality and expand health access for consumers in the United States. Public, private, and community stakeholders have a vested interest in insuring that all communities participate fully in the benefits of health information and related technologies.

Just last evening, I held my first telephone townhall meeting with my constituents in the 11th congressional district of Ohio. What I found very interesting was the reception or receptivity of people to having access to that process. It made it a lot easier for seniors who may not get out of the house, who could do it by telephone, contact by telephone.

But the dilemma I see, and the dilemma I see as we walk our way through this whole technology piece, is the need to be inclusive of those who historically are not accessing computers, technology, who are afraid to even think about getting on a computer. I would be curious to give each of you the three minutes that I probably have left at this point to answer for me, how do we bring into this world the people who are not into technology, who also are not necessarily into accessing improved health care? They want better health care, but they don't always receive it.

I am going to start with Mr. Jones, and I am going to come to Dr. Orszag, and anybody else can pipe in. Mr. Jones, I picked you because I think you can help me answer that question. Go ahead, Sir.

Mr. JONES. Well, thank you. I think that a——

Ms. TUBBS JONES. Also, we might be related, you know, so we might as well take——

[Laughter.]

Mr. JONES. We may be. We may be. I think that the—a lot of what we're talking about is the ability for those who would assist those under-represented populations to be technology-enabled.

So, for example, in Philadelphia, where I live, there are several academic medical centers—University of Pennsylvania Hospital, Temple University Hospital System—who serve a lot of these who are disenfranchised. So, I have had talks with both of them—and I know that they have initiatives—in order to try to upgrade their IT capabilities, so that they can extend the benefit of that to the populations they serve, whether it's through their hospitals or their physicians, who are affiliated with the hospitals.

So, I think that is one way. If we can go to urban centers and other places where these populations are and empowered, the providers, to be able to access this technology, it would be helpful.

Mr. ORSZAG. Yes, if I could just add, I mean, this is related to the discussion we were having earlier about community clinics and other providers that are serving, disproportionately, those populations.

But let me back up and say I think an absolutely huge issue that has received far too little attention—we have heard a lot about inequality in income; we have heard far too little about inequality in life expectancy and other health outcomes. Life expectancy inequality in the United States is exploding by income.

So, at the top of the socio-economic distribution, life expectancy is going up much faster. At the bottom, it is either flat, or perhaps even declining. I think this is a major issue that has received very little attention.

Ms. TUBBS JONES. I appreciate your response. Mr. Chairman, my time has ended. But I would hope that, at some point, we could—he is not paying attention to me, so I'm going to keep talking. No, I hope that we have an opportunity to further explore that very issue.

You will remember back—President Bush said to people of color, "I am going to help you get Social Security, because you die early." We kept saying, "Don't tell us—help us get Social Security, stop—help us not die early, you know, stop us—the death decline of minority populations." So, I thank you for your——

Mr. ORSZAG. Well, while the Chairman is distracted, maybe we should say there should be a hearing on the topic, or——

Ms. TUBBS JONES. I think there should be a hearing. All in favor, say——

[Laughter.]

Chairman STARK. We had a hearing in June.

Mr. KIND. You just lost control of the Committee.

Chairman STARK. I think so, yes.

Ms. TUBBS JONES. I yield back the balance of my time.

Chairman STARK. Yes, your time just expired.

[Laughter.]

Chairman STARK. Mr. Kind, would you——

Mr. KIND. Thank you, Mr. Chairman. I want to thank our panel of witnesses today. I think this is an incredibly important topic,

and we really do need to wade into the weeds a little bit more on this.

The reason I think it's important is I think it's imperative that we do strive to reach a both public and private reimbursement system, based on outcomes in performance, value of care, health care. The only way we're going to be able to do that is if we can establish the standards of what that outcome in performance should be. The only way we can do that is collect the comparative analysis and the data. The only way we can get there is with an effective, fully interoperable HIT system, one that deals with the privacy and the security issues and that, but one that is completely interoperable.

Now, the details get difficult and tricky, and that's where you all are supposed to be helping us with type of incentives, disincentives that we can create in order to get this build-out and this infrastructure done sooner, rather than later.

I am proud to hail from a state that seems to be at the forefront of this movement in Wisconsin, with their quality health care collaborative initiative that they have, where all the providers have voluntarily agreed to come together to develop the comparative standards of care that we should be striving for. It is unfortunate that Mr. Reding wasn't able to make it here from Marshfield Clinic, because they have been doing some very interesting and exciting cutting edge things involving all this.

But, Dr. Orszag, let me start with you. We hear this $700 billion figure mentioned about potential savings in the Medicare system. Now, is that assuming that we get to this outcome, or performance-based reimbursement system with HIT in there and all these difficulties that have been discussed today resolved? Or does that involve other factors?

Mr. ORSZAG. Two things. First, that's for overall health spending, it's not just Medicare. Second, it is in—it's kind of scoping out what the potential is, and it would require the type of health IT system that we were discussing, it would require an aggressive comparative effectiveness research effort, it would require a substantial change in payment methodology, but under Medicare and the rest of the health system, in order to capture even a significant portion of it, and there would be lots of sort of political economy difficulties in doing that.

It is intended just to say, "What's the potential," while recognizing the massive constraints we face in trying to capture that.

Mr. KIND. My sense, too—as you said, 15 to 20 percent are already doing it, they've already made the investment and gone to HIT, you know, the various systems out there—but my sense is that this is also a generational thing. You've got some older practitioners out there that might be a little more loathe to make the conversation.

My sense, too, is it's kind of a difference between established hospitals with huge paper records already in existence, versus newer provider networks that are just getting up and going, and are willing to make that initial up-front investment.

But one of the areas—and I want to kind of wade into some sensitive area here, too—is we all realize there are substantial costs, as far as end-of-life care. I am just wondering what difference a performance or outcomes-based standardized system would make,

when it comes to medical decisions involving the final 6 weeks or 6 months of life, because it seems inherently subjective and so much depends on the attitude of the consumer, the patient, at that point, what their expectations of care really are.

I think one of the problems that we have in health care is we're not listening to the patients well enough when it comes to end-of-life care. Because I think, if we did, there would be an inherent more conservative attitude from most folks that what they really want is a chance to be at home, surrounded by their family and loved ones with pain medication to deal with it, but a chance to be in that type of setting, as opposed to multiple tests and prolonged ICU stays, and things of that nature. We really haven't touched about end-of-life care, and it is a big chunk of what we're dealing with here.

Mr. ORSZAG. Let me come back and say, again, if you look at the last six months of life, even at our leading medical centers, you see dramatic differences in the intensity of services, how many of those tests are being done, how many specialists you're seeing and what have you, which to me suggests, I mean, even at those places where, basically, the best medical care in the world is delivered, we are delivering it in different ways across different parts of the United States, and we don't know what we're getting in exchange for the more intense approaches.

Health IT and comparative effectiveness—the things we are discussing, would let you drill down in why—what are we getting, in exchange for that additional test, that additional procedure, that additional day in the hospital, which we can't answer now, and which many people express a lot of skepticism, in terms of whether there is any additional benefit.

I would also say there is evidence suggesting that when people are confronted with the types of choices that you are discussing, they do often choose the less expensive, less intensive approach.

Mr. KIND. All right. Thank you. Thank you, Mr. Chairman. I appreciate the hearing today.

Chairman STARK. Thank you. Ms. Schwartz, would you like to inquire?

Ms. SCHWARTZ. Thank you very much, Mr. Chairman. Again, thank you for your courtesy that you have extended to me. I really appreciate it, as—I don't know what to call myself—an adjunct visitor here.

But I wanted to—I think that I am here because I am very keenly interested in health IT, and some of you certainly know that we had, I thought, a very significant victory last week, with including e-prescribing—I pushed pretty hard for that—in the Medicare bill, with tremendous support, of course, from the Committee chair and the Committee, more broadly.

I have actually seen a great deal of interest expressed to me about the fact that we did get e-prescribing done. I think almost—now there are other members coming to me and saying, "Wow, I think we just did something really important, and we ought to do more of it."

So, I think it's creating an enormous opportunity for us to proceed with incentivizing. As you know, under e-prescribing, we used both carrots and sticks, as Dr. Orszag pointed out, to use that

model, moving forward. Now, of course, this is much more complex, to use electronic medical records more broadly. You raised a lot of the issues we have to deal with.

As I understand it—and there are many places for me to go, actually, in terms of my questions, but I wondered if you could give us some help on one aspect that we understand, which is just moving from paper to electronic records is simply not good enough. It might make it easier, but it isn't going to achieve the savings or the improved quality, unless it's really a comprehensive medical record, and it really changes behavior by the providers, and hopefully by the patients, as well.

We are looking at protocols, you know, different kinds of information that might be available not only between providers, but even for an individual medical practice or an individual provider.

So, instead of my giving the list of possibilities of evidence-based clinical protocols and things that might be added to this, could you better define what kind of conditions, or could we articulate what we would say if we were going to provide incentives for use of electronic medical records, what conditions, what the definition of those electronic medical records would contain?

You know, what would the expectation be that, again, this isn't just going to—going from paper to electronics, but what kinds of actions, what kinds of conditions, in addition to the privacy ones, in terms of patient practice, I think is—you know, I mean physician practice and hospital practice—that we might want to outline, define? Do you think we could do that?

We haven't heard much of anything—start with you.

Dr. EJNES. Yes, I think, you know, you're absolutely correct. Just going to collection of word processing documents that are legible is not an electronic record that is going to make a difference.

But certainly you spent a lot of time discussing what we refer to as decision support. That is something that we think a full-bodied EHR should have: decision support in terms of providing guidance on how to treat a condition; what types of evidence there are; reminders on monitoring, if someone is on a certain medication, what needs to be checked; the ability to check allergies, look at drug interactions; the ability to keep track of patients, the registry functions, if you will, so that, you know, we can get reports on how we're doing with our diabetics in the practice, or our hypertensives; and the interoperability, the ability to capture the information that the other doctors taking care of the patients can provide.

So, I think you are correct. The EHR has to be able to do more than just digitize what's in the charts in the record room.

Ms. SCHWARTZ. Two quick questions to follow up on this one. Is—do you think those are well defined enough for us to be able to articulate them and require them?

Do you think that we can create a system—and do you have suggestions for how to make sure that that is dynamic enough so that we don't set it in place?

We always have to be concerned about that here, that we set it in place so that it doesn't—it's got to change very frequently, it's got to be very dynamic, in order to—medical science changes all the time. You want to be able to say, "Okay, it wasn't last year's protocol. We want it to be today's protocol," and we have to make sure

that that's dynamic. Would you suggest how we actually make sure that happens?

Dr. EJNES. Yes, I think we can define what it is. In fact, a lot of the surveys that look at EHR uptake distinguish the full-fledged ones from the others. I think the certification commission has played a major role in defining the various functionalities that an EHR should have. So, I think we're on our way there.

Ms. SCHWARTZ. Maybe Dr. Orszag wants to answer this if anyone else does—so how much savings could we reap, if we actually do do it right? I do understand that that is a big question. But, assuming we do do it right, we want to incentivize this behavior, I am willing to see a stick at the end of the day.

How long will it take—maybe this is a question for anyone else, too—but how long will it take for us to reap a significant return on our investment and savings in the system?

Mr. ORSZAG. I think, again, it comes down to what do you mean by "doing it right." If doing it right means just health IT, I——

Ms. SCHWARTZ. No, no, no. I have already expressed the fact that this is——

Mr. ORSZAG. You've got the whole thing. Okay.

Ms. SCHWARTZ. Right.

Mr. ORSZAG. You've got the whole package. You are doing——

Ms. SCHWARTZ. It is interoperable, it has protocols that we're going to define quality, we're going to——

Mr. ORSZAG. Yes, but I am also going to layer on you're doing an aggressive comparative effectiveness effort, so that——

Ms. SCHWARTZ. Okay.

Mr. ORSZAG [continuing]. You are using the data that are coming out of that, and then you are actually then tying financial incentives for providers to the evidence that is coming out of that, despite all of the backlash that would then ensue.

Ms. SCHWARTZ. Right.

Mr. ORSZAG. You do all of that, and you do it very aggressively, I think that is the best hope for capturing a large share of that $700 billion. I can't quantify exactly how much, but it is—the more aggressive you do it, the more likely it is you're going to capture more of that efficiency.

Ms. SCHWARTZ. Okay. Thank you, Mr. Chairman.

Chairman STARK. Thank you. Mr. McDermott, would you like to inquire?

Dr. MCDERMOTT. Thank you, Mr. Chairman. I would like to follow a little bit of the Chairman's line of questioning, because a couple of people reacted negatively to one of his suggestions—that is, that we have one system, or can we get it down to one system.

When I was a medical student, I did research. You could find 2 left-handed plumbers living in a town of under 40,000 people in the Danish health records with no problem at all, and you still can't do that in the United States.

So, it strikes me that before we spend a time on incentives, there has to be a set of standards that are acceptable—the government puts out 65 percent of the health care money in this country already, with Medicare and Medicaid and Indian health and veterans health, and the DoD. So, we should set a standard at the Federal level. I will tell you why I feel this way.

I spent 5 years trying to get the veterans system and the Department of Defense to talk to each other. Much of that Veterans Administration stuff was done in Seattle. I have seen doctors sit there with two screens—one, the VA screen, and one, the DoD screen—some guy in Iraq comes back all beat up. He is discharged from the military. He goes into the Veterans' system. His military records are still at DoD. The two systems won't talk to each other.

I talked to admirals and generals and everybody up and down the medical line, and what I found was that there was a proprietary system developed by the military. God knows we can't touch a proprietary system. When we have this VA system which is a much better system, much more applicable, much more widely—it's now used in hospitals in Seattle, where people from the community can check into the Veterans' system if a veteran appears at the Swedish hospital, or at the university hospital, or whatever.

I reacted when I heard a couple of you—I think it was one of the doctors said, "We don't want a single standard." I understand that the free enterprise system wants to let a thousand flowers bloom. But explain to me how is a physician—if the point of the system is research, that is, we can compare across the country, and it is to give better health care, that is, since your patient appears in my hospital I can go in and find the information, why you wouldn't want one interactive system that would be—I mean, I have the problem with two computers, one in here in Washington, DC, and one in Seattle, and they can't seem to get the same thing on the screen when I open it up.

Dr. EJNES. Yes, yes. Just so that I am—you know, we're clear, this is—it's confusing, because we talk about system. I think I misunderstood the Chairman's question, initially. I thought he was asking about the software application that sits on the physician's desk.

I mean, I think we are all in agreement that there should be a system, there should be a common language that allows the information to be exchanged. My point was that, given that every physician's office differs in one way, shape, or form from another, to require a single software program that would be the EMR for all physicians would not be successful, because the needs of a large 50-physician group are different from those of a 2-physician group.

But in terms of the ability to take whatever sits on that desktop in that office, and exchange the information in the way that you describe, I think we're all on the same page, and we do support standards, we do support a system of health information exchange that allows different entities with different systems—either proprietary or open source—to exchange patient information. But when you get down to the institution level, to the practice level, there may be specific needs that may not be met by a one-size-fits-all application.

Dr. MCDERMOTT. But then—and here is the problem, it seems to me. We pass an incentive out of here, we put billions of dollars out there and we say, "Okay, guys, everybody in the medical profession should now be a part of the system," and they all plug into what?

What is incentivizing them to become a part of? Just to have hand-held devices, or are we a system, or what? What is it we're incentivizing? I would like to hear what——

Mr. WHITLINGER. Perhaps the analogy could come from the financial sector. I mean, there are hundreds——

Dr. MCDERMOTT. No, this is medicine. Talk about how it works in a hospital.

Mr. WHITLINGER. But if you think of the banking center, where there are thousands of banks, and each of those banks has its own data center and its own ability to store its data, keep it private, keep it secure, and give its own members the quality and the services of banking that they would like to provide, yet all those banks are interoperable, all those banks can exchange data, with regards to funds.

Dr. MCDERMOTT. So, is it——

Mr. WHITLINGER. Perhaps that is the analogy——

Dr. MCDERMOTT. The reason you need the different systems is because you want to protect the privacy of patients? Is that what you're talking about?

Mr. WHITLINGER. Well, you could——

Dr. MCDERMOTT. Why not have a system that I, as a doctor, could get in and read?

Mr. WHITLINGER. So, you could look at it from a couple of different perspectives. But one is that, perhaps, different medical practices would be offering different services. Another is that they could be competitive by offering different services of a data nature, as well.

Now, the fact that they can interoperate allows the system that we would all like to have, where you have transportability and importability of the data and the patients——

Dr. KING. My feeling is that Vista was paid for by taxpayers, and it should be available to taxpayers. It is a great system that evidence in the literature has literally hundreds of citations to support how good that it operates. It's the most interoperable system that exists in the United States right now, between specialists and everyone in the VA.

I think my personal feeling is that if we were going to sit down and design a system, we wouldn't be having—a health care system—if we started from scratch with a blank piece of paper, we wouldn't be asking this question. We would have one system, because that's what makes sense. The reason we are asking the question is because nobody designed the health care system, and it is a mess.

I personally believe we should have one system, and we should have competition at the vendor level. That would keep the health care costs in the health information technology arena down, because then you would have vendors that are competing against each other. Once you go proprietary, then you have to keep with what their support costs are, and you're locked in.

Dr. MCDERMOTT. So, you're saying you want something like what's happened with the tanker issue in the Air Force. You want to have two vendors compete for who can build the best tanker. Is that the——

Dr. KING. I'm not really familiar with that. I am not sure that's what I am advocating.

Dr. MCDERMOTT. Who could pay off the auditors, is what I——

Dr. KING. Did the tankers sink?

[Laughter.]

Dr. MCDERMOTT. The problem with that is that—I was a state legislator, and I bought the first computers for the Department of Health and Human Services in the state of Washington. I spent millions of dollars on them, and we threw out system after system after system that one vendor came in and sold us, and that one didn't work, or they couldn't make it work, so we threw out a—we came—I don't know how much money we have wasted in this country on buying systems.

I want something like Vista to——

Dr. KING. Right. But if you have one system, then what you can have is many vendors supporting that system. So, then you have the competition at the vendor level, instead of at the system level. I think that could save a lot of costs.

Mr. JONES. If I might point out, though, there are multiple kinds of systems that are involved. So, electronic health record is one thing that you may use in a physician office, but it needs to get information from a lab information system that a reference lab uses.

There is also a hospital information system which is different than an electronic health record system. There are systems that hold images. So, all of these different kinds of systems need to speak with one another. So, specifying one electronic health record system is sort of the camel's nose in a tent, because then you have to specify one lab information system, and one—you know, you ultimately would have to specify everything not only that exists, but that could be imagined.

So, we would have to—it is better to say, "Let's specify the way that they would speak to each other," and mandate whoever has a system does it that way.

Ms. MCGRAW. One of the—I know we're over, but one of the things that nobody has mentioned yet is the certification commission for health IT. The standards bodies that have been—the standards body that Lee has referenced, again, they are bringing the stakeholders together to come to agreement on what the common standards should be, so that these systems—which may themselves, in the software, have differences—at the level of creating a national health IT network will be able to talk to one another.

The certification commission, which is a contractor to the Federal Government, is being paid to come up with standards for certifying products that meet those standards, so that people buying the system that meets the CCHIT criteria know that they have bought a system that has the standards that essentially have been adopted or endorsed through this process. So,——

Chairman STARK. Would you yield?

Ms. MCGRAW. Yes, Sir.

Chairman STARK. I am informed that they are certifying systems that can't talk to each other.

Ms. MCGRAW. Well, that would be quite unfortunate. I——

Chairman STARK. That's my understanding of——

Ms. MCGRAW. But I think it is worth looking into, so that we get some clear information here.

Chairman STARK. Yes. Yes, it is.

Ms. MCGRAW. Because, from a consumer standpoint, I do worry about blessing one system that everyone has to buy, from a sort of innovation standpoint. Stifling that——

Chairman STARK. What about if it's one system that we give them free?

Ms. MCGRAW. Well, somebody has got to pay for that.

Chairman STARK. We already have, haven't we, Dr. Pete? It's Vista. We can continue this informally, if we like. We can give our clerk a reprieve and call the formal session to an end. Hopefully, some of you would like to stay and discuss this.

Thank you. I want to thank the panel. Thank you very much, Dr. Orszag, who normally would go off first by himself and get out of here a lot sooner, thanks for sticking around, Peter, and thank you all for taking the time. It has been very helpful.

We are going to call you back. I know we're going to need more information. Be well.

[Whereupon, at 12:10 p.m., the hearing was adjourned.]

[Questions for the Record follow:]

Congress of the United States
U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

August 6, 2008

Douglas J. Reding, MD, MPH, FACP
Oncologist/Hematologist
Vice President, Marshfield Clinic
1000 North Oak Ave
Marshfield, WI 54449-5777

Dear Dr. Reding:

As a follow up to the Health Subcommittee hearing on promoting the adoption and use of health information technology on July, 24th 2008; please respond to the following questions for the record.

Questions from Ranking Member Camp:

1. I understand that you have had a chance to review the health IT bill I introduced last month.

   Are there provisions in my bill that you believe should become law?

2. I understand that the Marshfield Clinic is just one of many hospital, clinic, and physician groups that have expressed their concerns about the privacy language in H.R. 6357.

   What impact do you feel this language would have on your clinic's ability to implement care and quality improvement programs as well as to monitor and prevent fraud?

3. Do you feel the current HIPAA protections sufficiently guard patient privacy as it relates to electronic records?

   What steps does the Marshfield Clinic take to ensure that information found patient's electronic records are kept private and used appropriately?

   How does the Marshfield Clinic deal with employees who improperly access medical records?

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MARSHFIELD CLINIC

August 19, 2008

Carrie Breidenbach
Hearing Clerk
Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

Dear Ms. Breidenbach:

On behalf of the Executive Committee and the Board of Directors of Marshfield Clinic, I am writing to respond to questions from Ranking Member Camp in follow-up to the hearing on promoting the adoption and use of health technology, which took place on July 24, 2008.

We appreciate the opportunity to provide our testimony and the following responses to the questions posed by Representative Camp.

Sincerely,

DOUGLAS J. REDING, M.D.
Vice President, Marshfield Clinic
Chairperson Government Relations

1. I understand that you have had a chance to review the health IT bill I introduced last month. Are there provisions in my bill that you believe should become law?

We have reviewed legislation introduced by Rep. Camp, HR 6179. There are several provisions of this legislation that we believe are important:

Section 101 would codify the Office of the National Coordinator for Health Information Technology, we believe this is essential to maintain the continuity of operations begun by Dr. David Brailer and now directed by Dr. Robert Kolodner. In particular, as a vendor of CattailsMD, the CCHIT certified proprietary electronic medical record developed by Marshfield Clinic, we believe that certification is an essential guarantee in an uncertain market that electronic medical records can be relied upon by providers and their patients.

Section 302 eliminates the Sunset applicable to the Stark exception for electronic health records. As we noted in our testimony submitted for the record, Marshfield Clinic is very closely associated with the Ministry Health System as well as other providers serving patients in our service areas. The exception provides some comfort to providers who are wary of any implication of improper referral influences.

Section 303 promotes the expansion of telehealth services. Marshfield Clinic is one of the largest telehealth providers in the country, serving a largely rural population with needs that stretch across state borders. We appreciate the reciprocity provisions and the expansion of telehealth sites of origin, which have been shown to add very minimal expense, and substantially improved access.

Finally, in Section 304 HR 6179 establishes an electronic health demonstration in Federally Qualified Health Centers. Marshfield Clinic is the sponsor of an FQHC known as the Family Health Center in Marshfield, which is nationally distinguished because it provides dental services to the indigent throughout the State of Wisconsin and incorporates periodontal records with the Marshfield Clinic electronic medical record. FQHCs should be supported because they bring us one step closer to the universal health coverage that we believe is necessary, at a reasonable cost.

2. I understand that the Marshfield Clinic is just one of many hospital, clinic, and physician groups that have expressed their concerns about the privacy language in H.R. 6357. What impact do you feel this language would have on your clinic's ability to implement care and quality improvement programs as well as to monitor and prevent fraud?

We are concerned that HR 6357, the "Protecting Records, Optimizing Treatment and Easing Communications through Health Care Technology Act of 2008" will increase the costs of providing health care and the cost of implementing electronic medical records without any measurement of the problem it is trying to solve. Provisions of HR 6357 may interfere with activities defined as "operations" under HIPAA that are essential to effective care management.

As we stated in our testimony, to improve quality performance, the Clinic developed software systems to care for chronically ill patients, to identify improvement opportunities, collect needed information at the point of care, and report performance back to physicians.

For example, our PreServ (Preventive Services) System is able to alert physicians when preventative services are due for a patient during a visit with a primary care manager.

Our EMR also includes a system for flagging high-priority patients. A "hierarchical defect recovery list," which acts as a safety net, includes high-risk patients with multiple chronic conditions that are in need of immediate attention.

We have also implemented an anticoagulation care management system for patients on Warfarin.

The Clinic has also implemented electronic prescribing to enhance safety.

We have implemented a 24-hour nurse line, with an automated e-mail system that notifies physicians whose patients have called.

We have developed a software tool called "iList" (Intervention List), which is used in primary care. iList generates a list of patients who have one of three chronic illnesses – diabetes, heart failure or hypertension – and who do not meet all of their recommended health goals.

The PROTECHT Act requires covered entities to make a reasonable effort to restrict the use, disclosure, or request of PHI to a "*limited data set*" of information as defined in regulation. The PROTECHT Act also includes a new consent provision that requires additional patient consent if the PHI is utilized in operations, such as peer review, quality review, standard of care review, malpractice review, or best practices analysis. We believe that most of our care management processes fall within the definition of the term operations. These activities are the substance of care management, and interference with them interferes with the practice of evidence-based medicine.

In addition, requiring an accounting of disclosures for all disclosures of PHI, including for treatment, payment, and healthcare operations will be difficult. These disclosures are not logged or accounted for - as the law does not currently require this. A requirement to log all these disclosures could add 10 – 30% to the cost of implementing a robust EMR.

How these provisions relate to our effort to prevent fraud.

The Marshfield Clinic electronic medical record includes features that enable us to require authentication for electronic signature of documents and prescriptions. We also use our electronic medical records to facility chart review for coding and other compliance issues.
The electronic medical record includes information about all of the treatments, procedures, diagnostics and therapies provided to any patient. At Marshfield Clinic we utilize the record to assure that patients receive the care that they need when they need it. CMS has shown that this pattern of practice may lead to improved quality of care and substantial savings for the Medicare program.

We refer you to the most recent results of the Physician Group Practice Demonstration, released by CMS August 14, 2008. As a result of improved quality and efficiency made possible through the use of our HIT system in this demonstration Marshfield Clinic will receive a payment from CMS of $5.78 million as a result of saving the Medicare Trust Funds $7,226,966 as measured by CMS, under the terms and conditions of the project.

Just as the EMR can be a tool for increasing efficiency, it might also serve as a tool for identifying inefficiencies or intentional over-utilization of services. The EMR also has the potential to serve as an audit tool that could throw light on the diminishing utility of unnecessary, redundant or equivocal services. The problem that Congress must grapple with is that these features of an efficient HIT system may scare some providers away from implementing HIT operational care infrastructure that could retain evidence of wrongdoing. HR 6357 doesn't solve this problem – it makes it less likely that providers could perform operations related to their treatment of patients that would leave an audit trail. We believe that the audit trail and the resulting accountability are in the public interest.

3. **Do you feel the current HIPAA protections sufficiently guard patient privacy as it relates to electronic records?**

Congress will have to decide where it places its priority. HIPAA is not a perfect law, but it does protect patient privacy. We might also add that electronic medical records are far more secure than paper records or any other alternative. Individual privacy, however, has been utterly compromised because marketing organizations now have many sophisticated tools to track consumer behavior. This information is valuable for marketing goods and services to targeted individuals and populations. To address and deter this invasion into the privacy of individuals, we recommend that congress strengthen enforcement of privacy violations.

What steps does the Marshfield Clinic take to ensure that information found patient's electronic records are kept private and used appropriately?

Marshfield Clinic has put in place the position of Data Security Officer. This is a general manager high-level position reporting directly to the Chief Information Officer of the corporation.

Marshfield Clinic audits all transmissions. For all access we know who accessed data, when and from what device. These audit files are kept indefinitely and can be scrutinized either for random check or for specific cause.

Access to the electronic health record is established within a role-based hierarchy. All employees are assigned a role. Based on the role the employee is only granted access to information necessary to complete their job's functions.

All information is maintained centrally. Information is only delivered to the workstation as a transient "screen shot". No patient data is ever stored remotely on the user workstations.

Education on the importance of security and confidentiality is continuous. All employees are required to annually sign a corporate confidentiality agreement as a term for continuing employment.

The following features complement the security of the Marshfield Clinic EMR:

- Required complexity standards for password authentication.
- Assignment of a primary device, typically a tablet computer for the vast majority of users.
- Security warning to users when they log into a device that is different from the previous device they logged into.
- Role-based security for access to applications.
- Screen designs that avoid casual exposure to patient health data.
- Device locking after a maximum 15 minutes of inactivity on a portable device, and after a maximum of 30 minutes on a tower workstation.
- Document-level audit trails of all user accesses to medical records.
- Review of users' accesses of medical documents for both cause and for sampling of selected users' accesses based on association profile with patients, e.g. co-workers, relatives, or neighbors.
- Routine suppression of health protected on data warehouse reports.
- End user access agreements including our policy on patient privacy that must be reviewed and affirmed yearly.
- Encrypted transmission of wireless data (AES 128 bit)
- Encryption of down-time data base.
- Minimal storage of patient information on end user devices.
- Physical security of main computer rooms.
- Restricted access of programmers to patient data.
- Anti-tamper hardware features of tablet computers.
- Secure disposal of printed reports.
- All computers have centrally managed virus/malware protection per industry best practice standards.

How does the Marshfield Clinic deal with employees who improperly access medical records?

All suspected breeches are investigated by the corporate data security officer and a senior staff attorney from corporate legal services. Marshfield Clinic handles improper employee access through the Clinic's progressive discipline policy, which may include termination. Discipline appropriate for the investigated findings is rendered. Flagrant and malicious breeches usually result in the termination of the offending employee.

[Submissions for the Record follow:]

Alex Hill, Statement

Clinical patient data is stored in a variety of electronic systems. These systems use a variety of programming languages and database systems to store and maintain the patient data. These systems encompass a mix of proprietary systems from commercial vendors, open source systems and systems developed at taxpayer expense by government agencies. However, combining data from different systems (a) to obtain a comprehensive view of an individual patient, or (b) to analyze large volumes of data for public health purposes, is a major IT problem. This problem is particularly acute in U.S. Healthcare since the majority of computer systems used in U.S. hospitals are based on legacy technologies, the most prominent of which is MUMPS. This is particularly true in the case of the hospital networks of the Veterans Administration (VistA) and the DOD's Military Health System (AHLTA/CHCS). However, it is also true of the systems offered by most of the leading commercial vendors of hospital systems.

The above problems are not unique to Healthcare. The same challenges are faced across all industry sectors whose systems are based on legacy technologies. Recently, an Israeli software company, CAV Systems Ltd, developed a set of solutions that address these challenges and the solutions are already being successfully deployed there.

Since these solutions are not industry-specific, they can be equally well applied to the challenge of legacy data and software in the U.S. Healthcare Industry. The potential benefits include billions of dollars in savings and accelerated progress towards the goal of a fully interconnected health IT infrastructure years ahead of present estimates.

The Problem of Legacy Systems and Data

(1) MUMPS is used by ~~over~~ ~~90%~~ *a majority* of hospital EHR applications and information systems *in the U.S*.

1. What is MUMPS?

It is a programming and database system developed 4 decades ago at Massachusetts General Hospital. It was subsequently adopted by many in the Healthcare community but is also used in other industry sectors.

2. The "pros"

At the time that MUMPS was conceived, the prevailing computer hardware, software, and programming staff were oriented towards the needs and economics of business rather than the needs of clinicians. MUMPS addressed the needs and economics of the clinical side of hospitals—and did so successfully.

3. The "cons"

Computer Science has advanced considerably since MUMPS was conceived. Several of its features that were viewed at that time as powerful, productive and beneficial are today no longer viewed as "good practice" for designing and programming complex systems such as Healthcare. Indeed it is the use of these features that is the source of many of the challenges facing the U.S. Healthcare industry at the present time. That is why they are today viewed as "bad practice".

(2) Many hospital systems in use in the U.S. today are effectively "abandoned" either because the vendors have gone out of business or have been acquired by competitors whose interests are to "sunset" these legacy systems (because they are based on MUMPS) and push new expensive systems that many hospitals—particularly those serving rural and smaller communities—simply cannot afford. The result is that "patient data is trapped" inside these legacy systems and cannot be accessed in any convenient, timely and affordable manner by other clinicians outside of the legacy system. This negatively impacts patient care.

(3) The cost of new Hospital Information Systems is staggering.

The power of computers has grown by orders of magnitude during the past two decades and the relative cost has decreased. The sophistication and usability of software has likewise advanced enormously during the same period and the relative cost has decreased.

One would therefore expect the cost of Hospital Systems would reflect these trends. However, with rare exceptions, the opposite has been the case. The costs of

upgrading hospital systems, including new EHR technology, are running into the tens of millions of dollars per hospital, and in some cases exceed a hundred million dollars. Most hospitals cannot make this kind of investment in their systems.

(4) The short-to-medium term solution is a way to extract the data from these legacy systems at an affordable cost:

1. **M2R—Replicator (MUMPS to Relational)***:*

The concept is simple: migrate the data from a legacy Mumps database to a more modern relational database format (*Oracle is one example of such a database*). ~~such as Oracle~~. The legacy application would continue to run and perform all of its tasks, while the data is now available in a usable database format. The process can be set up so that the data is automatically and continuously updated in the new relational database. Once in the relational database, then all kinds of tools can be used to sort, manage and analyze the data. This would be a way of extracting quality data for Medicaid/Medicare, for example.

A detailed outline of this process was submitted by CAV Systems to TRICARE Management Activity in December 2007 in response to "Joint DOD–VA Inpatient EHR RFI: W81XWH–08–RFI–EHR".

(5) The medium-to-long term solution is converting the legacy systems—the programs as well as the data—to prevailing technologies:

1. **JUMPS (Java from MUMPS)***:*

The concept is simple: create Java programs that are functionally identical to the MUMPS programs—and do so with a very high level of automated procedures and minimal manual intervention of IT professionals.

A detailed outline of this alternative approach was submitted by CAV Systems Ltd to TRICARE Management Activity in December 2007 in response to "Joint DOD–VA Inpatient EHR RFI: W81XWH–08–RFI–EHR".

(6) The viability and effectiveness of the CAV Systems' solutions has been demonstrated to work in the U.S. in one of the most intractable systems to work with—the Military Health System's legacy CHCS system.

1. Proof of Concept (PoC)Project

The Department of Defense's medical research arm, **Telemedicine and Advanced Technology Research Center (TATRC), U.S. Army Medical Research and Materiel Command**, located at Fort Detrick, Maryland, recently funded a Proof-of-Concept (PoC) project to validate the JUMPS technology [note: the M2R—Replicator technology is a subset of JUMPS so the PoC project was effectively validating both]. The Report of the results of the project was delivered to TATRC at the end of April 2008. Following are several quotes from the report:

- "The JUMPS technology works as claimed by CAV Systems. The JUMPS technology is scalable and can handle very large M/Caché systems whose scope and complexity are similar to those of CHCS."
- "The JUMPS migration process itself is straightforward and the skills required to effectively use JUMPS are easily acquired by IT professionals familiar with the M/Caché environment and the Java/Oracle environment."
- "—JUMPS is the only technology and process presently known to both parties that offers an automated methodology for the delivery of functionally identical systems from M/Caché to Java/Oracle, and to do so in relatively short timeframes—months rather than years."

2. **How can this new technology help VA/DoD interoperability/data-sharing issues?**

The most widely used database systems in today's world in almost all industries and all geographies are Oracle (from Oracle Corporation) and SQLServer (from Microsoft) in the commercial proprietary area, and MySQL and PostgreSQL in the Open Source sector.

CAV Systems' solutions—M2R—Replicator and JUMPS—are designed to work with any of these databases. This enables data that is trapped in legacy MUMPS systems to be "set free" since the vast majority of modern software products are already designed to be used with these leading databases.

The Military Health System presently encompasses two different systems—AHLTA with Oracle as its database technology and CHCS with MUMPS (or its proprietary version named Caché from InterSystems Corporation) as its database technology.

The Veterans Administration likewise encompasses two different systems—VistA with MUMPS (or Caché) as its database technology and MyHealtheVet with Oracle as its database technology.

Through the use of CAV Systems' solutions, all patient data will be in Oracle. This drastically simplifies the interoperability/data-sharing issues.

3. **How this can be used as a national model?**

The pilot project conducted by TATRC shows that these technologies can be used to extract the data locked into the CHCS systems as well as to migrate the entire program to a modern language, JAVA. This same model can be used for Mumps systems across the country. A Successful implementation by VA and DoD of interoperability/data-sharing that combines legacy data (from MUMPS systems) with data from modern systems such as Oracle would demonstrate the capability to the medical community at large. It would demonstrate several factors, including the value to patients and doctors alike, short time frames to a functional data exchange, as well as the savings compared to alternative approaches.

Since most commercial health information systems are still based on legacy MUMPS technology, the CAV Systems' set of solutions can bring similar benefits to the non-government sector of the healthcare community.

These technologies can save taxpayers billions of dollars and years of work in building the national health infrastructure network.

CAV Systems Ltd is an independent software house with 3 decades of experience and expertise in MUMPS. The aggregate MUMPS experience of the professional staff exceeds 250 man-years. It also has extensive experience and expertise in bridging the legacy world of MUMPS with the modern world of web-based systems and prevailing technologies such as Java and Relational Databases.

CAV Systems Ltd is the ***only*** company offering an approach ("process") and accompanying technology that automates the migration of very large legacy MUMPS systems to functionally identical Java/Oracle systems that can be deployed on commodity yet powerful platforms based on prevailing systems such as Linux—and can do so in highly compressed timeframes (i.e. months, not years).

Beverly Miner, Statement

My name is Beverly Miner, Vice President and Executive Director of the National E-Prescribing Patient Safety Initiative (NEPSI) for All scripts. All scripts is the leading provider of clinical software, connectivity and information solutions that physicians use to improve healthcare. The company's unique solutions inform, connect and transform healthcare, delivering improved care at lower cost. More than 40,000 physicians and thousands of other healthcare professionals in clinics, hospitals and extended care facilities nationwide utilize All scripts to automate everyday tasks such as writing prescriptions, documenting patient care, managing billing and scheduling, and safely discharging patients, as well as to obtain key information and connect with important stakeholders in the healthcare system.

The Committee is considering a bill which could bring healthcare into the modern age by encouraging the broad adoption and use of health information technology. The electronic prescribing program in the recently-passed Medicare bill—which encourages the use of e-prescribing when a physician is providing services to a Medicare patient—is a great first step toward this same goal because e-prescribing will introduce physicians and others to the benefits of all electronic health records (EHRs). However, more needs to be done on the e-prescribing front. *Congress needs to make sure that healthcare providers who do not serve the Medicare population—those who serve Medicaid patients, children, and adults under 65—are e-prescribing.* We must first jump this e-prescribing hurdle together before moving on to the other more complicated obstacles in our path to a comprehensive, fully interoperable Health IT system.

Most importantly, we need to make sure that we are addressing the underserved market by providing federal funds for e-prescribing to our safety net providers. If the safety net is not e-prescribing, the patients it serves will not be able to receive the increased quality of care that comes with e-prescribing. The Health IT bill that is under consideration must include significant funding to help these healthcare providers get started e-prescribing.

The benefits of e-prescribing are well recognized. E-prescribing ensures that crucial clinical information on patients and medications are delivered at the point-of-care, enabling physicians (and their staff) to make informed decisions regarding the

treatment for their patients and automating workflow that increases efficiency and reduces errors.

The Centers for Medicare and Medicaid Services (CMS) reported in November 2007 that a shift to e-prescribing "could avoid more than two million adverse drug events annually, of which 130,000 are life threatening" and "has enormous potential to create savings in health care costs, through reduction of adverse drug events and in improved workflows. One recent study estimated the potential savings at $27 billion per year in the United States."

The Congressional Budget office estimated that the Medicare e-prescribing provisions, alone, would save the Federal Government $2.1 billion over ten years. Imagine the savings if e-prescribing were adopted by the healthcare providers that are serving the rest of the nation.

Yet, only about 2% of the estimated 1.47 billion prescription transactions in 2007 were transmitted electronically. And only about 6% of office-based physicians are e-prescribing. This presents a serious problem. In order to reduce avoidable medication errors—care providers need access to information from all physicians who are prescribing for that patient. E-Prescribing benefits will not be fully realized until it is adopted and utilized on a widespread basis.

Therefore, in 2007 All scripts partnered with a number of key stakeholders—such as WellPoint, Aetna, Dell, Microsoft, Google, Sprint, and Cisco—to launch a nationwide initiative to provide an easy-to-use and secure internet-enabled e-prescribing solution free of charge to all healthcare professionals across the nation who are eligible to prescribe. This initiative, called the National E-Prescribing Patient Safety Initiative (NEPSI), provides the software application, hosting, a drug interaction database and a medication database.

Nevertheless, many physicians are not taking advantage of this free service. That is because the necessary investment in e-prescribing goes beyond the cost of software. Physicians face the likelihood of spending thousands of dollars on hardware, infrastructure, training, and practice management. They will need to invest a great deal of time and money to change their workflows to incorporate e-prescribing into their practices and convert their paper records.

All scripts recommends that Congress provide federal funding through a demonstration program or targeted grant program that will provide funds to healthcare providers for hardware, infrastructure, training, and practice management. We recommend that those funds be targeted at healthcare providers who face the biggest financial challenge and who otherwise might be unwilling to adopt e-prescribing—safety net and primary care providers. At a minimum, these funds should be distributed in the same years that federal funding is distributed under the Medicare e-prescribing program. Furthermore, in order to leverage the federal investment, Congress may want to consider providing additional funding to physicians who are willing to obtain their software for free from the private sector.

Thank you for considering my testimony.

Deborah C. Peel, Statement

Thank you for the opportunity to submit written testimony to the U.S. House of Representatives Committee on Ways and Means regarding health information technology legislation and the importance of privacy. We commend the hard work of this Committee and its staff.

The testimony being submitted here is on behalf of Patient Privacy Rights (PPR), a national organization that educates consumers about the importance of health privacy, champions smart policies and technologies, and holds industry accountable to protect what's most valuable—our health, our families and our reputations. Patient Privacy Rights has members in every state in the nation. While PPR prefers to work collaboratively with providers and industry we are beholden only to consumers and patients. PPR also leads the bipartisan Coalition for Patient Privacy, representing over seven million Americans, who want their rights to control personal health information to be restored.

As founder of PPR, I learned about the importance of privacy directly from my patients. A practicing physician in the field of psychiatry, I know effective treatment depends upon the trust established and maintained between doctor and patient. When I first entered private practice, people came and paid me cash on the barrelhead because they had lost jobs or their reputations were ruined when someone saw their health records that should not have.

Sitting face to face with patients for over thirty years and hearing how their privacy has been violated made me much more attuned to protecting their privacy. It

is that long-term, human contact that has made me so passionate about restoring privacy. Frankly, it is heart breaking to see the destruction caused when private, intimate information gets in the wrong hands. PPR, in operation for just a few years, hears *daily* from patients from every state in this nation, desperate for help and looking for justice.

In this submitted testimony, we will reiterate why privacy is the lifeblood of effective healthcare and successful adoption of health IT. Additionally, we will suggest ways to ensure both progress with health IT and privacy for all Americans. Finally, we will focus some comments on H.R. 6357, the bill recently reported by the Energy and Commerce Committee.

The importance of privacy

Privacy is about much more than minding one's own business. We believe that "who" can see, share or buy our most sensitive health information is a policy issue that deserves extensive public debate and a roll call vote. Our personal health information is worth billions of dollars. Continued open and easy access to that information is the **goal of** the insurance industry, large employers, data mining industry, drug companies, the for-profit research industry and others.

The lack of privacy is harmful and can be deadly. Millions of Americans avoid doctors and delay medical care for fear their employers will find out, their insurers will drop them or a vast world of strangers will know their most intimate mental, physical, or genetic details.

- According to HHS, **two million** Americans with mental illness do not seek treatment due to privacy concerns.[1]
- **600,000** cancer victims do not seek early diagnosis and treatment.[2]
- Millions of young Americans suffering from sexually transmitted diseases do not seek diagnosis and treatment (1 in 4 teen girls are now infected with a STD).[3]
- The California Health Care Foundation found that **1 in 8** Americans have put their health at risk by engaging in privacy-protective behavior: *Avoiding their regular doctor—Asking a doctor to alter a diagnosis—Paying privately for a test—Avoiding tests altogether.*[4]
- The Rand Corporation found that **150,000 soldiers** suffering from Post-Traumatic Stress Disorder (PTSD) do not seek treatment because of privacy concerns.[5]

Avoidance and delay in seeking health care costs society in real dollars, quality of care and life. Sadly, we have reached a point where some physicians find themselves having to choose between providing thorough, complete medical diagnosis and treatment and putting their patients' insurance coverage or even employment at risk if sensitive information is shared.

HIPAA

Before proceeding with our recommendations for health IT legislation, we want to reiterate the need to reduce the deficiencies and close the loopholes in the Health Insurance Portability and Accountability Act (HIPAA). First, despite the fact that HIPAA requires more stringent privacy-protective state laws and medical ethics to prevail over the privacy 'floor' in HIPAA, the opposite has occurred. This is all the more reason for federal law to ensure that what Americans say in the doctor's office, stays in the doctor's office. This expectation that the Hippocratic Oath means doctors will keep records private no longer holds true.

Second, HIPAA regulations allowing broad access to personal health information for the purposes of treatment, payment and health care operations without consent have created not only a radical shift in the traditional relationship we have had with our trusted doctors, but created a vast, unregulated market that treats our most personal information as a commodity. Data mining and sale of health information is rampant. This was not the intent of Congress. In fact, clearly members of the Energy and Commerce committee intended to stop this practice with the inclusion of SEC. 312(d) in H.R. 6357. An excellent and timely example of this practice specific to prescription records was highlighted just last week by journalists at *Busi-*

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[1] 65 Fed. Reg. at 82,779
[2] 65 Fed. Reg. at 82,777
[3] 65 Fed. Reg. at 82,778
[4] CHCH Consumer Health Privacy Survey, June 2005
[5] "Invisible Wounds of War", The RAND Corporation, p. 436 (2008)

ness Week and the *Washington Post* (See "They know what's in your medicine cabinet: how insurance companies dig up applicant's prescriptions and use them to deny coverage," *Business Week* by Chad Terhune, July 23, 2008 and "Prescription data used to assess consumers: records aid insurers but prompt privacy concerns," *Washington Post* by Ellen Nakashima, August 4, 2008).

Third, until the HIPAA loopholes are closed we are strongly opposed to extending HIPAA to cover personal health records (PHRs) and other non-HIPAA covered entities. While legislated policy is certainly needed to ensure privacy and security of PHRs and the other advances in technology, requiring these entities to comply with HIPAA would simply grant even more corporations the right to use protected health information without consent, facilitating even more data mining and sale of Americans' sensitive health records.

Congress has an opportunity to correct the above mentioned deficiencies. We caution that any efforts to promote health IT without addressing the weaknesses in HIPAA will compromise the success of any the health IT system. A system without privacy will never produce the trust necessary to get the data needed for research, for quality improvement, for comparative effectiveness, to lower costs, and to save lives. Our mutual goal of progress and privacy is not only possible, it is the only way Americans will fully participate in health IT and share personal information. To achieve this goal we recommend the following specific measures for the committee's consideration.

Recommendations

First, in H. R. 6357 the provisions in Sec 3002(b)(2)(B)(i) need to be strengthened in order to ensure individuals can segment sensitive or erroneous information in their electronic health records.

For example, a radiologist does not need to see psychiatric records, nor does a podiatrist need to know about a pap smear. Moreover, if a patient's information is mistakenly entered in another patient's electronic medical record as a result of medical identity theft, that patient should be able to suppress that information by segmenting from the rest of their medical records, to avoid potentially catastrophic errors. As currently drafted, the reported version of PRO(TECH)T only requires that the Health IT Policy Committee consider and make recommendations on technologies that ensure segmentation. In the current bill, it is up to the Secretary to determine if a recommendation for segmentation shall in fact be adopted.

Segmentation is already required for psychotherapy notes under HIPAA. The states require that several categories of information not be disclosed with the rest of general medical records without additional authorization, and federal law requires addiction treatment information to be disclosed only with specific authorization. Truly, any health IT system that fails to build segmentation into its design is outdated. Systems capable of segmenting sensitive information, offer Americans far greater privacy protections than those that do not. Technologies encouraged, supported and required by the Federal Government should promote and ensure innovation. Functionality to enable consumers to segment sensitive health information should be a policy required by Congress; the Secretary should be held accountable to implement policies—not make them.

Second, strengthen the provisions in H. R. 6357 Sec 312(d) to ensure entities cannot share, sell, re-sell, or disclose electronic health information in any format without consent. The requirement to obtain consent before protected health information is used for health care operations is a welcome step forward. However, this provision has two serious limitations.

(1) The definition of "Electronic Medical Record" is very limited. For example, it excludes prescriptions and laboratory data that are not created by doctors or staff at single institutions. Tying the consent requirement to this very limited definition of an EMR, will not prevent the use of the majority of protected health information for health care operations, which was PPR's understanding of the stated intent and purpose for adding this section to the bill.

(2) The restriction on disclosures without consent should apply to *every* entity that may use protected health information, not just providers. In fact, providers are the least likely to use protected health information for healthcare operations. Other covered entities and business associates, including insurers, data miners, researchers, corporations and others are the primary ones that exploit this loophole in HIPAA.

Third, we recommend including the NCVHS definition of privacy in the bill, *"health information privacy" means an individual's right to control the acquisition, uses, or disclosures of his or her identifiable health data.* The "P" in HIPAA does not stand for privacy. It is important for all stakeholders to speak the same lan-

guage. The definition of privacy is just as essential as any of the other terms defined in this bill

Fourth, we recommend the committee first establish a solid understanding of the actual uses of our personal health information in the marketplace. The health and health IT industry is a world clearly developing far faster than government regulations and standards. An essential part of this process should include investigations and documentation of the actual uses of our health information and the various markets that are sharing and selling our information today. With the exception of recent reports highlighting alarming rates of breaches, and dismal privacy and security within federal agencies, the public and Congress is frankly in the dark about the widespread under-the-radar use of personal health information. Patient Privacy Rights urges the committee to include provisions requiring a GAO (or similar body) study on the following:

- The extent that Federal Government databases are shared with other federal, state and local agencies.
- An accounting of all uses of personal health information for treatment, payment and operations by entities with federal health contracts.

In addition, we recommend Sec 303(b) of H.R. 6357 be revised so that reports covering reported HIPAA violations and the outcomes of those investigations are submitted quarterly versus only once/year. Furthermore, a report of all breaches of PHI, the notification of the breach, corrective action and any history of repeat offenders should be delivered to Congress quarterly. An investigatory hearing into the health data mining industry and the sale of personal health information would also be a very worthy exercise, bringing to light the massive secret misuse of the nation's sensitive personal health information.

Furthermore, clearly for privacy protections to be meaningful, they must be enforceable and enforced. We recommend that the RICO statute apply to entities that violate the law and improperly use, sell or share personal health information. Such entities should also be prohibited from winning any future federal contracts. Inclusion of a qui tam like provision, which authorizes private citizens to assist government prosecutors in enforcing the law, is also a proven mechanism to help accomplish the essential task of effective enforcement. Without it, prosecution of privacy law violations will rarely be a high priority.

Thank you for the opportunity to present our concerns and recommendations to the committee on this critical issue. We strongly believe that if we "build it right, they will come." If the electronic health information systems meet our citizens' privacy needs, all Americans, not just early adapters, will utilize such progressive tools and reap the potential rewards of health IT. We can and must ensure both progress and privacy. Americans need Congress to ensure that consent for treatment protects us as we come through the front door and laws preventing further disclosure and onward transfer protects our sensitive information from flowing out the back door. This is reasonable, achievable and will do worlds of good in this electronic health IT arena.

Jeffrey Kendal, Statement

Thank you for the opportunity to submit this testimony on the vital topic of health information technology. Expanding the use of information technology in the health care sector has great potential to reduce costs and improve quality of care. We commend the Subcommittee for focusing its attention on this critical area.

We have seen interoperable information technology systems drive tremendous improvements in customer service and cost containment in several industries over the last couple of decades. The banking industry and the travel industry are two good examples. They have utilized interoperable customer records and self-service technologies to dramatically improve the customer experience. The health care sector has been slower to adopt these technologies, but we are now seeing technology adoption start to pick up steam.

The reason health IT is gaining momentum is because of its well-established benefits:

- Reducing medical errors;
- Expanding care to hard-to-serve areas through telemedicine;
- Restraining the growth in health care costs;
- Reducing wait times and unnecessary delays;
- Empowering patients and their physicians.

All of these benefits are achievable for health care organizations, ranging from major medical centers to small town clinics. However, to maximize these benefits, it is critical that we make more progress on creating broadly accepted standards for interoperable electronic health records. Standardized EHRs are the key to unlocking the most significant benefits of health IT.

A strong partnership between private industry and the Federal Government is necessary to create these standards. That is why we support the work of the National Coordinator for Health IT. We also support legislation being considered in both the House and the Senate to strengthen the role of the Coordinator. These bipartisan bills would also solidify the role of the IT and health care industries as partners in standards development, and provide funding for pilot projects in underserved areas.

We hope that Congress will redouble its effort between now and adjournment to pass this legislation this year. We also hope that Congress will resist the temptation to add costly mandates that might have the unintended consequence of discouraging private sector investment in health IT systems. If Congress passes a balanced, technology-neutral bill this year, it will help kick-start the drive toward a standardized electronic health record.

While the path to nationwide health IT adoption has been somewhat slow, a number of hospitals, clinics and private practices around the country have been early adopters, and they have found the benefits to be substantial. I will give you a brief example with which we are familiar.

Empowering Patients—Reducing Wait Times:

The Medical Center of Central Georgia (MCCG) is a 600-bed acute care hospital that serves a 30-county area. MCCG is home to the Georgia Heart Center, which performs more than 1,100 heart surgeries each year. The hospital faced serious challenges in its patient intake and registration process. Registration bottlenecks led to some patients having to wait 20 to 25 minutes to see a registration clerk. Doctors' time was wasted because they had to wait while patients cleared the registration process. The process created stress for the staff and resulted in staff turnover.

In 2007, the hospital began piloting information technology tools designed to create an electronic registration process. The system was built around electronic health records and self-service kiosks. The results have been eye-opening. Patient wait times have been reduced by about 20 minutes; doctors' time is better utilized; staff morale has improved; and patient satisfaction scores are higher.

In addition, the hospital has been able to reduce costs by eliminating repetitive re-keying of information and scanning of paper documents. They have dramatically improved efficiency by streamlining processes for capturing patient information, submitting claims and managing medical records. At a time when declining reimbursements are pressuring hospitals to operate more efficiently, health IT systems are helping to reduce costs and free up staff to focus on patient care.

As a result of this well-designed use of health IT, service to the patient has been improved and the hospital's resources are being better utilized—a win-win for everyone.

Conclusion:

This example illustrates the benefits of one type of health IT—self-service technologies. These technologies empower patients, reduce errors, shorten wait times, and eliminate repetitive data entry requirements. Demand for, and acceptance of, time-saving self-service technologies is growing rapidly. Our annual survey conducted this spring found that 89% of health-care customers are willing and able to take advantage of self-service systems. It also found that 46% of respondents considered increased privacy a key benefit of self-service technologies.

This is just one type of health IT. There are many other beneficial health IT systems, including e-prescribing to reduce dangerous medication errors, and tele-medicine to expand health care access.

The benefits and savings associated with health IT investments are compelling. Electronic health records and the health IT systems that they empower will help to improve patient safety and rein in the high cost of health care. Congress can help foster continued adoption of health IT by:

- Passing Health IT legislation this year;
- Avoiding technology mandates that discourage investment in new technologies;

- Avoiding other types of mandates that may discourage investment in health IT systems; and
- Conducting regular oversight of the process of establishing health IT standards.

Thank you again for the opportunity to submit this testimony, and thank you for the constructive role you are playing in helping to promote the benefits of health IT. I would be happy to provide any additional information that would be helpful.

John J. Castellani, Statement

Business Roundtable is an association of 160 chief executive officers of leading U.S. companies with $4.5 trillion in annual revenues and more than 10 million employees. Member companies comprise nearly a third of the total value of the U.S. stock markets and represent over 40 percent of all corporate income taxes paid to the Federal Government. Collectively, Business Roundtable companies returned one hundred fourteen billion dollars in dividends to shareholders and the economy in 2006. The goal of Business Roundtable's public policy priorities is to ensure a vibrant economy and a competitive workforce. High health care costs are inhibiting job creation, hurting our ability to compete in global markets and straining the household incomes of many Americans. For Business Roundtable CEOs, health care costs are the number one cost pressure they face.

Business Roundtable companies provide health care coverage to more than 35 million Americans. We believe an affordable, accessible, high-quality health care system is of critical importance not only to Roundtable companies but to all Americans. Health information technology (HIT) is an essential component of a high quality 21st century health care system that would promote efficiencies, reduce errors and provide the technological platform to assess the quality and value of health care.

To advance our health system, the health care industry needs to invest in and deploy HIT. In order for this to happen the industry needs to know the rules will not change and that is why Congress must act. Four things must be done at the federal level:

- Establish federal leadership for a public-private process to set standards;
- Offer financial incentives to encourage the adoption of HIT;
- Educate Americans on the value of electronic health records and information on the quality of providers; and
- Address privacy and security questions as the system is deployed.

Our health care system is one of the few segments of the American economy that has not been transformed by modern, efficient information technology. This is not just inconvenient—it's costly and, in some cases, even lethal. An estimated 98,000 people die each year from medical errors, many of which might have been prevented with accurate and up-to-date electronic records. According to the RAND Corporation, widespread adoption of health IT has the potential to save as much as $165 billion a year from efficiencies and improved health outcomes.

When widely implemented, information technology will deliver a whole new dimension of choice, convenience and control to America's health care consumer. Patients will be able to access their medical histories, underserved communities in rural areas and inner cities will enjoy greater access to health care, adult children will be better able to care for their aging parents from far away, and doctors will be able to better monitor their patients.

We encourage the Committee to allow the adoption of HIT in the Medicare program. In June 2007, Business Roundtable released "Principles for Reform," which includes the principle that our health care system should promote and reward quality performance and the use of HIT. We recognize that payers in our health care system may need some incentives, either increased reimbursement or grants and loans, to encourage the adoption of health information technology.

We also applaud the introduction of HIT legislation by several leaders in Congress including: Energy & Commerce Chairman John Dingell (D–MI) and Ranking Member Joe Barton (R–TX) for their introduction of H.R. 6357, the bipartisan "Protecting Records, Optimizing Treatment, and Easing Communication through Health Care Technology Act," or "PRO(TECH)T Act;" Congresswoman Anna Eshoo (D–CA) and Congressman Michael Rogers (R–MI), for the introduction of H.R. 3800, the bipartisan "Promoting Health Information Technology Act;" and the Senate's bipartisan S. 1693 "Wired for Health Care Quality Act."

These bills would establish the foundation in law that is required for the widespread deployment of health IT. With this foundation, the adoption of health information technology would be accelerated and our U.S. health care system would become more efficient and effective which would benefit all Americans.

Business Roundtable CEOs have joined in a "Call to Action" (Divided We Fail) with AARP, the Service Employees International Union (SEIU) and the National Federation of Independent Business (NFIB) to engage the American people, businesses, non-profit organizations and elected officials in finding bipartisan solutions like health IT to ensure affordable, quality health care for all. Congress, the Administration, the health care industry and the public are united behind HIT, and *the Roundtable has made HIT legislation our number-one health care reform priority for 2008*.

Congress has the opportunity to take a big first step toward the goal of an affordable, accessible, high-quality 21st century health care system. We urge all members of Congress to pass legislation similar to the bills cited above that can be signed into law by the President during this Congress.

The Computing Technology Industry Association, Statement

Introduction

Chairman Stark, Ranking Member Camp, and Members of the Subcommittee, thank you for holding this important hearing to explore options of promoting of health information technology (HIT). **My name is** Roger J. Cochetti **and I am submitting testimony on behalf of the Computing Technology Industry Association (CompTIA) representing our 20,000 member companies.**

While nearly every industry has digitized records and communications, the health care industry remains in the analog, pen-and-paper world. Daily, there are new breakthroughs in medical imaging technology, yet the orders for such exams remain hand-written. The current regime of paper records is costly, inefficient, unsecure, and frequently impedes patients from receiving best care possible.

This is a real issue affecting the cost and quality of health care in America, and this issue is in urgent need of an immediate response. We believe your efforts to focus both congressional and public attention on this issue are most important.

CompTIA Overview

The Computing Technology Industry Association represents the business interests of the information technology industry. For over 25 years, CompTIA has provided research, networking, and partnering opportunities to its over 10,000, mostly-American, member companies. Nearly 75% of our membership is comprised of American Value Added Resellers, or VARs. These small, system integrators set up and maintain computer systems and networks for small businesses—including medical practices. An estimated 32,000 American VARs sell some $43 billion dollars worth of computer hardware, software, and services—mostly to the small businesses that drive the American economy. This means that around one-third of the computer hardware and software sold in the U.S. today is sold by VARs.

As further background, in addition to representing the interests of VARs, CompTIA also works to provide global policy leadership for the IT industry through our headquarters in Chicago and our public policy offices in Washington, Brussels, Hong Kong, and Sao Paulo.

Finally Mr. Chairman, for most people who work with computer technology, CompTIA is probably best known for the non-policy-related services that it provides to advance industry growth through standards, professional certifications, industry education, and business solutions. In order to most effectively serve the industry and our members, CompTIA has developed specialized initiatives and programs dedicated to major areas within the IT industry.

Today, over one million IT professionals—mostly American technology workers—possess one or more CompTIA certifications; and each month between 10,000 and 15,000 American IT workers take one or more of the CompTIA certification exams.

The Issue: Cost vs. Benefit

As the Committee is well aware, the benefits of HIT—ranging from e-prescribing to portable, interoperable electronic health records—are far reaching. A RAND study in 2005 estimated that HIT could yield an annual net savings to the health care sector of about $80 billion per year if all providers and hospitals adopted health

information technology and used it appropriately.[1] With total spending for health care at about $2 trillion per year, this represents a 4% savings. These savings would be the result of better administration of scheduling, coordination, and billing, better utilization of nurses—who could increase the portion of their time with patients as opposed to administrative work, increased safety, reduced hospital stays, and more efficient drug treatments. All of these benefits lead to the most important benefit of HIT, improved patient care. Portable, interoperable electronic health records (EHRs) will reduce medical errors, increase collaboration amongst physicians, and improve disease prevention and management.

Unfortunately, approximately only 4 percent of physicians have fully functional EHR systems and only **13 percent have even basic EHR systems**.[2] **It is significant to note that** physicians who practiced in groups of at least 50 were three times more likely as those in very small practices (three doctors or less) to have a basic EHR system.[3] Clearly, practice size impacts HIT uptake and should be addressed in any legislative solution.

Other impediments to uptake include cost in time and money, concerns about liability, lack of trained personnel, hesitance to change, concern about standards, and the fact that doctors bear the brunt of the cost but patients and payors receive most of the benefit. Purchasing and installing an electronic prescribing system costs a practice several thousand dollars and implementing a full EHR system costs tens of thousands of dollars. Additionally, a practice must bear the cost of downtime required to install the system and train employees, as well as annual maintenance and any new liabilities. While a practice can be back online at full capacity in a short time-period, the initial estimates can be daunting. In addition to being hesitant to change, the possibilities of transitioning to a new system before all technical standards have been established or creating a new area of liability gives physicians further pause. Finally, if a practice makes it to the point of full implementation, the cost savings highlighted above are not captured by the physicians, but rather the payors. As such there is little motivation for individual doctors and smaller medical practices to implement HIT that could have a transformative impact on health care.

Solutions

CompTIA was glad to see positive first steps in promoting HIT when Congress included e-prescribing provisions in the recently passed "Medicare Improvements for Patients and Providers Act of 2008" (P.L. 110–275). Both lives and money will be saved as medication errors from incorrect dosages, allergies, and negative interactions are decreased. However, this was only the first of many necessary steps to promote broad implementation of HIT.

In order to succeed in establishing broad, portable, interoperable HIT, medical care providers—particularly small providers—must be encouraged to implement and maintain HIT systems in their practices. HIT will not be universally successful unless it is adopted by the broadest health care provider group—the small health care practitioner. Clearly, the predominant obstacle for this group will be the costs of purchase, installation, and maintenance of a HIT system for their practice. In this regard, CompTIA continues to call for incentives that will enable small health care providers to join in the HIT evolution.

In his testimony, Dr. Orszag explained that "carrots" only benefit those already on the verge of implementing HIT, whereas sticks will influence behavior throughout the medical industry. While this may be true, it does not address the fact that smaller practices face ever-tightening profit margins and cannot rationalize such a large investment with such a little return. It is imperative that the Committee consider who pays the cost and who bears the benefit of implementing HIT. Doctors and practices cannot bear the cost of "sticks" without the benefit of "carrots" as well. CompTIA has long supported tax credits for physicians that implement HIT. As the Committee develops draft legislation, they must consider the cost to physicians, address the concerns of both large and small practices, and consider other impediments, such as liability.

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[1] Hillestad R, Bigelow J, Bower A, Girosi F, Meili R, Scoville R, and Taylor R, "Can Electronic Medical Record Systems Transform Healthcare? An Assessment of Potential Health Benefits, Savings, and Costs," *Health Affairs*, Vol. 24, No. 5, September 14, 2005.

[2] "Physician Adoption of Electronic Health Records Still Extremely Low, but Medicine May Be At a Tipping Point," Health Information Technology Adoption Initiative press release, June 18, 2008. http://hitadoption.org/index.php?module=News&id=cntnt01&cntnt01action=detail&cntnt01articleid=4&cntnt01returnid=30

[3] *Ibid.*

Conclusion

The cost of health care is growing astronomically. HIT could be a valuable tool in curbing some of the costs, while improving health care quality and security but broad implementation will remain a pipe dream until there are financial incentives in place for doctors and small practices to implement systems and the standards for definitions, interoperability, and privacy are addressed. As the Committee develops legislation, we encourage you to include financial incentives for uptake—especially for small practices—and further the standards discussions.

CompTIA is hopeful that technology will revolutionize health care through HIT in the same way technology and digitization has revolutionized other industries. We are confident that robust, interoperable HIT systems will lead to better patient care and cost savings. We thank you for the opportunity to voice our concerns and recommendations, and look forward to reading draft legislation as soon as it is available.