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USING INFORMATION TECHNOLOGY: FOR THE HEALTH OF IT

HEARING

BEFORE THE

SUBCOMMITTEE ON THE FEDERAL WORKFORCE AND AGENCY ORGANIZATION

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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USING INFORMATION TECHNOLOGY: FOR THE HEALTH OF IT

FRIDAY, SEPTEMBER 1, 2006

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON FEDERAL WORKFORCE AND AGENCY ORGANIZATION,
COMMITTEE ON GOVERNMENT REFORM,
St. Louis, MO.

The subcommittee met, pursuant to notice, at 1 p.m., in the Main Auditorium, Eric P. Newman Education Center, Washington University Medical Center, St. Louis, MO, Hon. Jon C. Porter (chairman of the subcommittee) presiding.

Present: Representatives Porter and Clay.

Staff present: Ronald Martinson, staff director; B. Chad Bungard, deputy staff director, chief counsel; Chad Christofferson, legislative assistant; and Adam C. Bordes, minority professional staff member.

Mr. PORTER. Good afternoon. I would like to bring the meeting to order. I appreciate you all being here today. Can you hear me OK? I guess that's a yes. Thank you very much.

Today I'd first like to acknowledge our committee and staff that are with us. As subcommittee chairman, it's an honor for me to have some great folks that work for me that helped put today's meeting together. We are the Subcommittee on the Federal Workforce and Agency Organization, where we have jurisdiction over all Federal employees, and jurisdiction over all Federal agencies. Plus we have oversight on many, many other issues that are impacting our communities across the country.

I am a Member of Congress from the State of Las Vegas. I used to tell folks that I represent Nevada and people would say, Well, that's nice. And one time I was at a—actually I was at Bethesda Naval Hospital and one of the folks that had been serving in Iraq had been in the hospital and I introduced myself as coming from Nevada, and he looked up to me and said, Have you ever been to Las Vegas? And I smiled, and he smiled, and I said, Yeah, I represent Las Vegas. The young man next to him in the hospital bed said, Yeah, I want to go to Las Vegas when I get out of the hospital. So I find that if I say I'm from Las Vegas, I seem to get a twinkle, and many times a story. Just know that what happens in Las Vegas stays in Las Vegas.

But I am honored to be here today with my committee and staff—I was asked to be here by Lacy Clay, also a very good friend of mine, and a good friend I know to St. Louis and the State and the country. I want you all to know that it is Lacy that has brought the subcommittee here on a very important topic that I know is

going to impact every man, woman and child in the country, and it has to do with technology and information and healthcare and what we can do to help improve healthcare.

Lacy and I worked on numerous pieces of legislation to try to help our families with the healthcare and have some ownership of healthcare. And today we had a chance to have lunch and have a meeting next door to the hospital at the Barnes-Jewish Center. And I tell you, again, great folks. We met with Michael Behaven, Senior Vice President, General Counsel; Lee Fetter, President of the Children's Hospital; David Weiss, Dr. Andy Ziskin, LeeAnn Chilton. I don't think I have missed anyone, but to our friends at BJC, thank you very much for your hospitality and sharing with us some of the state-of-the-art equipment, technology and means of taking care of your patients. So to those folks at BJC, thank you.

Truly, we have had numerous hearings on this around the country, and BJC has some of the finest. So it is a credit to you, Lacy, and your community.

Before I give my formal opening comments, I would like to turn it over to Lacy Clay for his opening statement.

[The prepared statement of Hon. Jon C. Porter follows:]

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Opening Statement of Chairman Jon Porter

Hearing of the House Government Reform
Subcommittee on the Federal Workforce and Agency Organization

"Using Information Technology: For the Health of It"

September 1, 2006

I would like to welcome everyone here today. I would first like to thank Representative Lacy Clay for suggesting we hold a hearing in his home town of St. Louis. We are privileged to meet in this exceptional auditorium here on the Washington University campus. I would like to thank all those at the University who have helped make this possible. I would also like to thank the Clay staff who have contributed in working with the University and with my staff to make our stay exceptional and inviting.

The issue before us today is one that has been gathering momentum and is of exceptional importance to every single American. It is an issue in which every single American can relate to. Nearly every one of us will need some sort of healthcare in his or her life. As a world leader in healthcare science, the United States is still deficient in healthcare information management and exchange. Today we still have people dying because non existent or incorrect information is being presented to the caring physician who then passes that information, or the lack thereof, on to the patient in the form of wrong treatment. People are being injured and even killed by incorrect prescription drugs or drug dosages. Healthcare costs are increasing at an alarming rate due to malpractice insurance costs and rising patient premiums.

With the implementation of health IT we can significantly reduce the number of medical errors and patient costs. This has been studied and proven in the many demonstration projects across this country and even the globe. We are here today to discuss what we can do and what is being done to help further the progress of America as we move out of a paper based healthcare system into an electronic one. I don't think I can reiterate enough a statement made by former Speaker of the House Newt Gingrich, "Paper kills…Instead of saving lives, our current paper-based health system is taking them."

Over the past year and a half as chairman of this subcommittee I have met with numerous groups and individuals regarding the use of health IT and the more I learn the more I realize how important it is for us to get health IT in place. It is very unfortunate that senseless deaths are occurring every day simply because a pharmacist could not read a doctor's handwriting, or because a patient was admitted to the hospital unconscious and doctors treated him for a stroke when he was having an insulin shock reaction. It is unfortunate that people like my mother need entire filing cabinets dedicated to all the paperwork doctors give them with regards to their treatment. It is time for us to move forward.

I realize change is difficult. With technology continually growing, improving, and changing at incredible rates, it can be difficult to change ourselves. Culturally speaking, technology can be somewhat of a shock to our systems, but if you look around, none of us are still using telegraph machines to transmit messages. We have cell phones, blackberries, email, and much more. It is absurd for healthcare information exchange to remain frozen in time while everything else continues to move forward. Think if the rest of healthcare had done the same. Would we have modern medicines that kill harmful bacteria? Would we have cancer treatments, would we even have something as simple and common place as the x-ray machine? If all these were created to improve the quality and delivery of healthcare, why are we now stumbling and waiting while innocent people are harmed or killed by paperwork?

I for one do not want to stand by as senseless deaths occur each year. That is why I have introduced legislation along with my colleague here, Mr. Clay, that would provide health IT to every Federal employee. It is my hope that this will eventually provide a way for health IT to reach everyone. The President stated that he wanted the Federal Government to become a leader in the health information technology movement. I believe that my legislation helps us do that. This legislation would require insurance carriers that provide health insurance to Federal employees to create carrier-based electronic health records and eventually personal electronic health records. I believe that information about your health should be shared with you and should be shared in a format you can understand.

Mr. Clay has also introduced legislation of which I am an original cosponsor that would make it easier for doctors to begin using health IT by offering grant and loan programs as well as creating exceptions to certain STARK and anti-kickback laws. It would also codify the office of the National Coordinator for Health Information Technology allowing this office to receive proper Federal funding. Together, we are trying to make a difference in modern health care.

On August 22 the President signed an Executive Order that I believe will move the Federal Government towards better healthcare. It is something that will compliment H.R. 4859 very nicely. The Executive Order will require insurance carriers that do business with the Federal Government to provide price transparency to their consumers. It will also require these carriers to adopt certain quality standards which will be monitored and published by the Office of Personnel Management. The Executive Order will require the carriers to adopt HIT interoperability standards that will be recognized by the Federal Government and will also require plans to develop more consumer driven health options.

Our government witnesses today will hopefully touch upon this new Executive Order and what they feel its outcome will be. They will also tell us how the Federal Government is progressing in the realms of HIT along with what we need to do to improve and what we can expect in the coming months and years as health information technology continues to progress. It is my hope that the private and education witnesses will tell us how the private sector is working to make health IT a national reality, and whether or not health IT issues are being taught at the very basic level of medical education and training. In order for us to change the paper mindset, new doctors and nurses are going to have to be trained and educated before they enter the medical field, otherwise we will be in a continual uphill battle for full HIT implementation.

I welcome our witnesses here today, and I welcome those in the audience, many of whom, I understand, are students and faculty. I hope today's hearing will be both interesting and educational.

Mr. CLAY. Thank you, Mr. Chairman. Let me begin by welcoming you and our committee staff to St. Louis, my hometown. It's been a real pleasure working with you on health IT issues, and I look forward to continuing that.

We are especially lucky today to be hosted by our friends at Washington University Medical Center, whose leadership is firmly committed to utilizing and pioneering the latest in medical treatments and technological advances on a daily basis.

I look forward to hearing the testimony of our distinguished panels. The benefits of utilizing health IT in our healthcare system will result in shorter hospital stays, improved management of chronic disease, and a reduction in the number of needless tests and examinations administered by physicians.

Although it is not a silver bullet for our Nation's healthcare deficiencies, health IT is a tool that will allow us to reduce medical errors, improve the quality of care provided, and strengthen our health-related research capacities in the future.

According to 2004 data, our national healthcare expenditures make up approximately $1.9 trillion of our gross domestic product. That represents 16 percent of our entire economy. Nevertheless, the institute of medicine estimates that medication errors alone result in approximately 1.5 million unnecessary injuries annually. These errors often lead to significant injuries, or in some cases death. Thus, it seems only appropriate to embrace health IT as a tool, not only to improve our healthcare outcomes, but to also receive a better return on our critical healthcare dollars.

Therefore, I believe it is time for the Federal Government to lead in the development and adaptation of a nationwide health information network for electronic records that is more efficient than current paper-based record systems, which will pave the way for improved-quality measures to track patient outcomes.

We are not alone as advocates for health IT. In fact, Health and Human Services Secretary Leavitt recently stated that the implementation of electronic health records is the most important thing happening in healthcare today.

According to the Center for Studying Health System Change, the use of HIT for clinical activities such as electronic health records has nearly doubled since 2001 to about 20 percent of all providers nationally. Local examples, whom I am very pleased to represent, include physicians here at Washington University Medical Center, and also providers within Missouri's Medicaid program. These programs are now able to measure patient outcomes and the effectiveness of treatment regimens in order to improve future care.

Furthermore, electronically stored information can serve as a basis for broad-based medical research as patient identities are removed and records are studied to determine the outcome of past therapies and treatments. As we pursue treatments and cures for genetically based disorders, such as some cancers and Parkinson's disease, having identifiable clinical information readily available to the research community will be invaluable.

I readily agree with my friends who believe that stronger security and privacy protection for a person's medical information are desperately needed, and these protections should be integral to the establishment of a nationwide health IT network.

However, I do not agree with critics who state that health IT platforms used for the preservation or transmission of identifiable patient information are any more vulnerable to security breaches than and current paper-based record systems.

In fact, many (inaudible) in accordance with HIPAA have already transitioned from paper-based records to electronic health records for exchanging patient financial and clinical information. What we need now is Federal leadership to define the roles and responsibilities of a nationwide health IT infrastructure. Appropriate standards should include: Requirements for protecting patient information, system interoperability standards, vendor software and hardware requirements and auditing processes to ensure institutional and vendor compliance with all laws and regulations.

In addition, we must explicitly give patients control over their health information for third-party disclosure or research purposes. As long as patients can be assured that they have ultimate control over the sharing of their personal information, then I believe that most will embrace the benefits and efficiencies of E-Health solutions in the future.

It is in this vein that Chairman Porter and I have authored and cosponsored innovative legislation to bring the benefits of E-health to everyone.

Chairman Porter's bill, H.R. 4859, the Federal Family and Health Information Technology Act of 2006, and that's a mouthful, would establish a program for Federal health benefit carriers to provide electronic health records among all Federal employees.

I've also introduced H.R. 4832, the Electronic Health and Information Technology Act of 2006, along with Chairman Porter, and in summary, my bill would strengthen the role of HHS, as our Nation's HIT standard (inaudible) authority provide (inaudible) to healthcare providers who want to transition to E-Health systems, and strengthen our patient privacy laws by establishing a uniform standard for all citizens.

Once again, thank you, Chairman, for your indulgence, and I welcome our panelists and guests. Thank you very much for being here.

Mr. PORTER. Also let the record reflect that this is a bipartisan panel. Contrary to what you read many times, from our friends around the country in media, and we have some good friends, this is a very important part of what we do, to work together. As a Republican from the State of Nevada, and I know Mr. Clay is a Democrat, we see what happens across the country and we see what happens in Washington, but this is an example of an issue that has no partisan boundaries. This is an issue that is about our families and our communities, and we agree that this should not be a partisan issue, which is why we are here together today, and I am honored to be here with my friend, Congressman Clay. And to his staff, I appreciate their hospitality. It has been a pleasure working with everyone in your office. And, of course, to Washington University, to the campus, what a great place to be. It's a phenomenal facility, and your reputation is absolutely one of the best, and I think very germane and I think the point is well-taken, that we are talking about a key issue in the halls of Washington University where the university is on the cutting edge of healthcare and education.

But also, I gotta tell you, I get nervous when I come to the university. I didn't do real well myself. Maybe there is still hope because I probably would have been sitting in the room sleeping in the back, 30 years ago.

But again, it is outstanding, so thank you.

Now, I have to give these formal remarks so bear with me for a moment. It's part of being chairman.

The issue before us today is one that has been gathering momentum and is of exceptional importance to every single American. It is an issue to which every single American can relate. Nearly every one of us will need some sort of healthcare in his or her life.

As a world leader in healthcare science, the United States is still deficient in healthcare information management and exchange. Today we still have people dying because nonexistent or incorrect information is being presented to the caring physician who then passes that information, or a lack thereof, onto the patient in the form of wrong treatment. People are being injured and even killed by incorrect prescription drugs or drug dosages. Healthcare costs are increasing at an alarming rate due to the malpractice insurance costs and rising patient premiums. With the implementation of health IT, we can significantly reduce the number of medical errors in patient costs. This has been studied and proven in many demonstration projects across this country, and even the globe. We are here today to discuss what we can do and what is being done to help further the progress of America as we move out of the paper-based healthcare system into an electronic one. I don't think I can reiterate enough a statement made by former Speaker of the House, Newt Gingrich, "Paper kills. Instead of saving lives, our current paper-based health system is taking over."

Over the past year and a half as chairman of the subcommittee, I met with numerous groups and individuals regarding the use of health IT, and the more I learned, the more I realized how important it is for us to get health IT in place. It is very unfortunate that senseless deaths are occurring every day simply because a pharmacist could not read a doctor's handwriting, or because a patient was admitted to the hospital unconscious and the doctors treated him for a stroke when he was having an insulin shock reaction. It is unfortunate, people, like my mother, who is 85, need to fill an entire cabinet full of information and paperwork that she must haul to doctors regarding her own treatment, and I think it is time that we moved forward.

I realize change is difficult, and with technology continuing to grow, improving and changing at an incredible rate, it can be difficult to change ourselves. Culturally speaking, technology can be somewhat of a shock to our systems. But if you look around, none of us are still using telegraph machines to transmit messages. We have cell phones, Blackberrys, e-mail and much more. It is observed—absurd for the healthcare information exchange to remain frozen in time while everything else continues to move fast-forward. Think if the rest of healthcare had done the same. Would we have modern medicines that kill harmful bacteria? Would we have cancer treatments? Would we even have something as simple and as commonplace today as the x-ray machine? If all these were created to improve the quality and delivery of healthcare, why are we

now stumbling and waiting while innocent people are harmed or killed by paperwork? I for one do not want to stand by while senseless deaths occur each year. That's why I have introduced legislation, along with my colleague, Mr. Clay, that would provide health information technology to every Federal employee, and there are close to 9 million, with their families in the Federal healthcare system.

It is my hope that this will eventually provide a way for health IT to reach everyone across the country, not just Federal employees.

The President stated that he wanted the Federal Government to become a leader in the health information technology movement. I believe that my legislation helps us do that. This legislation would require insurance carriers that provide health insurance to Federal employees to create carrier-based electronic health records, and eventually personal electronic health records. I believe the information about your health should be shared with you and should be shared in the format that you understand.

Unfortunately, today, in healthcare, the patient really is the last one to see his own information. Everyone else has it but him or her.

Mr. Clay introduced legislation, of which I am an original cosponsor, that makes it easier for doctors to begin using health IT, by offering grant and loan programs as well as creating exceptions to certain (inaudible) and anti-kickback laws, but also codify the office of the national coordinator for health information technology along with this office to receive proper Federal funding. Together, we are trying to make a difference in modern healthcare.

On August 22nd, the president signed an executive order that I believe will move the Federal Government's plans toward better healthcare. It is something that will be a complement to H.R. 4859 very nicely. The executive order will require insurance carriers that do business with the Federal Government to provide price transparency to their consumers. It also will require these carriers to adopt certain quality standards which will be monitored and published by the Office of Personnel Management. The executive order will require the carriers to adopt HIT interoperability standards. To be recognized by the Federal Government, it will also require plans to develop more consumer-driven health options.

Our government witnesses today will hopefully touch upon this new executive order and what they feel its outcome will be. They will also tell how the Federal Government's progress is, in the realms of HIT, along with what we need to do to improve, we can expect in the coming months and years as health information technology continues to prosper. It is my hope that the private and education witnesses will tell us how the private sector is working to make health IT a national reality, whether or not health IT issues are being taught at very basic levels of medicine and where it is today in our education and training field. In order for us to change the paper mindset, new doctors and nurses are going to have to be trained and educated before they enter the medical field. Otherwise, it will be a continual uphill battle for full HIT implementation.

I welcome our witnesses today, and welcome those in the audience, many of whom I understand are students and faculty, and I hope today's hearing will be interesting and educational.

I would like to note that we will be concluding the hearing at approximately 2:30, that we will be calling on each of our visitors today to keep their comments to approximately 5 minutes.

But first, we need to do a few procedural matters. I'll ask unanimous consent that all members have 5 legislative days to submit written statements, and questions for the hearing record, the answers to written questions to be provided by the witnesses also be included in the record. Without objection, so ordered.

Also ask unanimous consent that all exhibits, documents and other materials referred to by members and the witnesses may be included in the hearing record, that all members be permitted to revise and extend their remarks. Without objection, so ordered.

It is also the practice of this committee to administer the oath to all witnesses, so if you would now please stand and raise your right hands.

[Witnesses sworn.]

Mr. PORTER. Let the record reflect that the witnesses have answered in the affirmative. Please be seated.

As I mentioned, each witness will have approximately 5 minutes, and any further statements can and will be entered into the record. Of course, the full committee is not here today. As I mentioned, the full committee will have the ability to enter information in the record also.

First I would like to introduce the members of the panel. We will be hearing from Mr. Daniel Green, the Associate Director of Employee and Family Support Policy at the U.S. Office of Personnel Management, we will then hear from Mr. David Powner, the Director of IT Management Issues with the U.S. Government Accountability Office.

We will then be hearing from Mr. George Paz, the president and CEO of Express Scripts, Inc., Dr. James P. Crane, the associate vice chancellor for clinical affairs, School of Medicine at Washington University, and Mr. Mark A. Rothstein, director of institute for bioethics health policy and law at the University of Louisville, School of Medicine. Welcome. We appreciate you being here. Mr. Green.

STATEMENT OF DANIEL A. GREEN, DEPUTY ASSOCIATE DIRECTOR, CENTER FOR EMPLOYEE AND FAMILY SUPPORT POLICY, OFFICE OF PERSONNEL MANAGEMENT

Mr. GREEN. Mr. Chairman and members of the subcommittee, Representative Clay: Thank you for inviting OPM here today to discuss the benefits of using health information technology to improve the quality and delivery of healthcare. The Office of Personnel Management administers the Federal Employees Health Benefits Program which covers more than 8 million Federal employees, retirees and their dependents. OPM offers competitive health benefits products for Federal workers, like other large-employer purchasers, by contracting with private sector health plans. OPM has encouraged participating health plans to be responsive to consumer interests by emphasizing flexibility and consumer choice as key fea-

tures of the program. Adoption of health information technology is an important healthcare improvement that is being implemented by many of our health plans on behalf of their customers.

In our efforts to ensure healthcare rates are competitive and consumer choice is maximized, we are encouraging the use of health information technology for medical recordkeeping purposes and for many provider-to-consumer processes.

As the administrator of the countrys largest employee health insurance program, OPM plays a key role in fulfilling President Bush's vision of making medical records easily accessible to consumers through the adoption of advanced technologies.

Ten days ago, the President signed the Executive order, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs. The order firmly underscores the President's continued commitment to the promotion of quality and efficient delivery of health care. With the order, the President is greatly expanding the information that will be made available and he is committing the Federal Government to transparency in pricing and quality, adopting health IT standards, and providing insurance options that reward cost-conscious consumers.

OPM is strongly committed to working with FEHB carriers on carrying out the Presidents goals and objectives. In fact, we have already begun taking steps in this direction.

To ensure the electronic availability of quality and price information, OPM is working with carriers to encourage them to make their health IT systems interoperable. OPM is also continuing to work with carriers to ensure that FEHB enrollees have access to innovative health insurance options that allow consumers to select health plans with lower premiums as well as allow them to share in the savings that may result from efficiencies gained with the implementation of health information technology.

Our work with FEHB carriers and the work we are engaged in with HHS and others have helped us focus our near-term efforts to further the Presidents initiatives. Some carriers are offering personal health records to enrollees based on the claims, medications and medical history information already available in their healthcare systems. Some are also working with their pharmacy benefit managers to encourage ePrescribing, to link their disease management programs to health IT, and to ensure compliance with Federal requirements that protect the privacy of individually identifiable health information.

We plan to expand our Web site information to highlight the health IT capabilities of plans so that prospective enrollees can view this information in reviewing their health plan choices for 2007.

We are committed to confronting the rising cost of healthcare to help members of the Federal family afford the insurance coverage they need. This is reflected in our commitment to the Presidents Executive order and in our goals to strengthen the patient-physician relationship through price and quality transparency. We believe greater transparency in healthcare prices and quality can help patients better control their medical expenses. Therefore, we have taken steps in the FEHB Program to raise the level of trans-

parency that is available to enrollees for both provider prices and health-plan quality by the end of this year. We will highlight the plans that have demonstrated their commitment to OPMs healthcare cost transparency standards in our annual Guide to FEHB Plans and on our Web site.

Our commitment to transparency aligns with our efforts to promote wider use of health information technology. Each initiative supports the other, as articulated in the Executive order. Information technology will provide for standardized interoperable medical, pharmaceutical, and laboratory cost and utilization information. Making this information more transparent to consumers will help them to understand the value of personal health records in managing their own health needs and their healthcare expenses.

Together, we believe health IT and transparency can drive better-informed and more rational medical care decisions, resulting in increased efficiency and better quality care.

We appreciate this opportunity to testify before the subcommittee and look forward to working with you on furthering health information technology initiatives. I will be glad to answer any questions you may have.

[The prepared statement of Mr. Green follows:]

STATEMENT OF
DANIEL A. GREEN
DEPUTY ASSOCIATE DIRECTOR
CENTER FOR EMPLOYEE AND FAMILY SUPPORT POLICY
OFFICE OF PERSONNEL MANAGEMENT

before the

SUBCOMMITTEE ON THE FEDERAL WORKFORCE
AND AGENCY ORGANIZATION
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

on

Using Health Information Technology: For the Health of It

September 1, 2006

Mr. Chairman and Members of the Subcommittee:

Thank you for inviting OPM here today to discuss H.R. 4859 and the benefits of using health information technology (HIT) to improve the quality and delivery of healthcare.

The Office of Personnel Management (OPM) administers the Federal Employees Health Benefits (FEHB) Program which covers approximately 8 million Federal employees, retirees and their dependents. OPM offers competitive

health benefits products for Federal workers, like other large employer purchasers, by contracting with private sector health plans. OPM has encouraged participating health plans to be responsive to consumer interests by emphasizing flexibility and consumer choice as key features of the program. Adoption of health information technology is an important healthcare improvement that is being implemented by many of our health plans on behalf of their consumers.

In our efforts to ensure healthcare rates are competitive and consumer choice is maximized, we are encouraging the use of information technology for medical record keeping purposes and for many provider-to-consumer processes. While there are wide variations in the scope and extent of information technology currently being used by FEHB carriers, most are focusing their efforts on providing claims-based information to consumers through their web sites, linking disease management programs to health IT, and encouraging e-Prescribing.

As the administrator of the country's largest employee health insurance program, OPM plays a key role in fulfilling President Bush's vision of making medical records easily accessible to consumers through the adoption of advanced technologies. OPM is a member of two distinguished Federal organizations: the American Health Information Community, a Federal Advisory Committee charged

with developing recommendations to the Secretary of the Department of Health and Human Services (HHS) on how to facilitate the adoption of electronic health records (EHRs), and the Federal Interagency Health IT Policy Council, which coordinates Federal health information technology policy decisions across Federal departments and agencies that will drive Federal action necessary to realize the President's goals of widespread health IT adoption.

Ten days ago the President signed the Executive Order, *Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs*. The Order firmly underscores the President's continued commitment to the promotion of quality and efficient delivery of health care. With the Order, the President is greatly expanding the information that will be made available and he is committing the Federal Government to transparency in pricing and quality, adopting health IT standards, and providing insurance options that reward cost-conscious consumers.

Achieving transparent health care requires the commitment and collaboration of everyone in our health care system. Federal employees, Medicare beneficiaries and health insurance beneficiaries at the Department of Defense and the Department of Veterans Affairs represent about one quarter of Americans

covered by health insurance. Therefore, to help our Nation seize the opportunity to modernize the healthcare system, the federal government is leading by example.

OPM is strongly committed to working with FEHB carriers on carrying out the President's goals and objectives. In fact, we have already begun taking steps in this direction, some of which I will speak about today.

To ensure the electronic availability of quality and price information, OPM is working with carriers to encourage them to make their health IT systems interoperable—to have the capacity for sharing essential information with others in the health care system. OPM is also continuing to work with carriers to ensure that FEHB enrollees have access to innovative health insurance options that allow consumers to select health plans with lower premiums as well as allow them to share in the savings that may result from efficiencies gained with the implementation of health information technology throughout this market sector.

Our work with FEHB carriers and the work we are engaged in with HHS and others have helped us focus our near-term efforts to further the President's initiatives. OPM is encouraging FEHB plans to enhance their consumer education efforts to make enrollees more aware of how health IT can help to achieve improvement in healthcare quality and increase health care efficiency. Some

carriers are offering personal health records to enrollees based on the claims, medications and medical history information already available in their healthcare systems. Some are also working with their pharmacy benefit managers to encourage ePrescribing, to link their disease management programs to health IT, and to ensure compliance with Federal requirements that protect the privacy of individually identifiable health information.

Earlier this year, we asked carriers to develop business plans with action items and milestones for accelerating health IT for the remainder of CY 2006 and for CY 2007. We plan to expand our web site information to highlight the health IT capabilities of plans so that prospective enrollees can view this information in reviewing their health plan choices for 2007.

Comment [OU1]: We did not ask them to adopt hit standards because our carrier letter was issued way before the standards were raised as a potential EO requirement. This is an historical statement

We are committed to confronting the rising cost of healthcare to help members of the Federal family afford the insurance coverage they need. This is reflected in our commitment to the President's Executive Order and in our goals to strengthen the patient-physician relationship through price and quality transparency. We believe greater transparency in healthcare prices and quality can help patients better control their medical expenses. Therefore, we have taken steps in the FEHB Program to raise the level of transparency that is available to

enrollees for both provider prices and health plan quality by the end of this year. We will highlight the plans that have demonstrated their commitment to OPM's healthcare cost transparency standards in our annual Guide to FEHB Plans and on our web site. We have also encouraged FEHB carriers to enhance their web sites by adding more online decision tools with cost estimators related to both diagnoses and drugs, to group costs for common illnesses and conditions by geographic area, and to ensure that they describe the sources, limitations and currency of the data clearly and prominently on their web sites.

Our commitment to transparency aligns with our efforts to promote wider use of health information technology. Each initiative supports the other, as articulated in the Executive Order. Information technology will provide for standardized interoperable medical, pharmaceutical, and laboratory cost and utilization information. Making this information more transparent to consumers will help them to understand the value of personal health records in managing their own health needs and their healthcare expenses.

Comment [OU2]: Suggested change does not make sense as EO because eo includes both IT and transparency

Together, we believe health IT and transparency can drive better informed and more rational medical care decisions, resulting in increased efficiency and better quality care. We are very excited about the possibilities inherent in these efforts and are seeking plans willing to partner with us to conduct a use-case

demonstration in 2007. Our focus for this pilot program will be on ePrescribing. We believe this technology can provide efficiencies in the healthcare system with an early return on investment and can also assist in improving patient safety.

Medication errors can and do occur in a variety of ways. Dosage amounts and incorrect choice of the prescribed medication are probably the most notable. Some of the contributing causes for these errors are illegible handwriting, missing information, unknown patient history and others. The eHealth Initiative, in an April 2004 report, indicated that ePrescribing could reduce the Nation's healthcare costs by $2.9 billion per year. The Journal of Managed Care Pharmacy reported in 2003 on a study of one national mail-order pharmacy that found about 8.7 percent of new prescriptions "had incomplete, unclear, or missing information related to elements that are essential to accurate medication dispensing." These numbers demonstrate potential gains for all individuals in the healthcare system through ePrescribing.

Technologies are already in place that could allow this to happen in the near-term. This is why we think the time is ripe for such a pilot within the FEHB Program.

Promoting the Use of Health Information Technology

As I indicated in my June testimony to this subcommittee, OPM shares your interest in promoting the availability of electronic health records in the FEHB Program. Mr. Chairman, OPM agrees in principle with the legislation you drafted on this issue, H.R. 4859, and, although we have concerns with some of its provisions, we look forward to working with the Subcommittee to further health IT implementation.

We appreciate this opportunity to testify before the Subcommittee and look forward to working with you on furthering health information technology initiatives. I will be glad to answer any questions you may have.

Mr. PORTER. Thank you, Mr. Green. Mr. Powner, we welcome you again, and you are the Director of IT Management Issues at the GAO.

STATEMENT OF DAVID POWNER, DIRECTOR, IT MANAGEMENT ISSUES, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. POWNER. Chairman Porter, Representative Clay, we appreciate the opportunity to testify on healthcare information technology. As we have highlighted in several recent reports and testimonies for you, Mr. Chairman, as well as for Chairman Davis at the full committee, significant opportunities exist to use technology to improve the delivery of care, reduce administrative costs and to improve our Nation's ability to respond to public health emergencies.

Mr. Chairman and Representative Clay, I would like to commend both of you for introducing key legislation intended to further the adoption of health IT. Leveraging the Federal Government as a purchaser and provider of healthcare is critical. Mr. Chairman, your legislation calling for OPM to advance the creation of health records does just that. The Federal Employee Health Benefits Program has over 8 million beneficiaries, and advancing electronic health records to this critical mass would be significant.

Representative Clay, I first would like to thank you for your many years of overseeing key technology issues as the ranking member of the technology subcommittee. Your oversight of the Federal Government's annual $60 billion investment in IT has been essential and appropriately focused on improving the government's information security posture. Your health IT legislation highlighting the need for standards, privacy and security practices and a strategic plan are essential building blocks to accomplish the president's goal of a nationwide implementation of interoperable health IT.

This afternoon I will briefly describe the importance of information technology to the healthcare industry, progress to date and additional actions needed to put in place a detailed game plan for meeting the president's goals. Information technology can lead to many benefits in the healthcare industry that we have reported on for the past several years. For example, using bar code technologies and wireless scanners to verify the identities of patients and their correct medications can and has reduced medical errors.

In addition, surveillance systems can facilitate the timely collection and analysis of the disease-related information to better respond to public health emergencies. Standards-driven electronic health records have the potential to provide complete and consistent medical information necessary for optimal care. Electronic health records are critical since they are the central component of an integrated health information system, have the potential to reduce duplicative tests and treatments and can lead to reduction in medical errors.

Several major Federal healthcare programs including Medicare, Medicaid and OPM's Federal Employee Health Benefits Program provide healthcare services to over 100 million Americans. Given the Federal Government's influence over this industry, Federal leadership can lead to significant change associated with the adop-

tion of IT. Given this in April 2004, President Bush called for the widespread adoption of interoperable healthcare records within 10 years, and established a position of the national coordinator for health IT.

The national coordinator's office has issued a framework to guide the Nation's efforts, establish working groups of industry experts, and awarded contracts to define future direction. Through these efforts my written statement describes progress that has been made in five key areas.

First, certification criteria for ambulatory or electronic health records has been defined and 22 health record vendors have achieved certification.

Second, interoperability standards have been identified.

Third, prototypes for a national health information network are currently being pursued.

Fourth, privacy and security issues are being studied through contractual means in a newly formed American Health Information Community Work Group.

Fifth, the integration of public health data into these many efforts continues to be a focus area.

HHS through its contracts in the American health information community has made tangible progress to date, but significant challenges and efforts remain, including, further refinement of an accepted interoperability standards and insured widespread and consistent implementation, agreeing to an approach and deploying a secure national health information network, addressing privacy concerns so that these do not impede technological progress, fully leveraging the government as a purchaser and provider of healthcare and providing incentives for the private sector to partner and participate.

As we have previously recommended, these challenges and remaining efforts could benefit from a national strategy that includes detailed plans, milestones and mechanisms to monitor progress. Until these plans and milestones and performance measures are completed, it remains unclear specifically how the President's goal will be met and what the interim expectations are for achieving widespread adoption of interoperable electronic health records.

Mr. Chairman and Representative Clay, thank you for your leadership in pushing IT to this critical industry.

[The prepared statement of Mr. Powner follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Federal Workforce and Agency Organization, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 1:00 p.m. CDT
Friday, September 1, 2006

HEALTH INFORMATION TECHNOLOGY

HHS is Continuing Efforts to Define Its National Strategy

Statement of David A. Powner
Director, Information Technology Management Issues

GAO-06-1071T

Abbreviations

HHS	Department of Health and Human Services
IT	information technology
NIST	National Institute for Standards and Technology

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Highlights

Highlights of GAO-06-1071T, a testimony before the Subcommittee on Federal Workforce and Agency Organization, Committee on Government Reform, House of Representatives

Why GAO Did This Study

As GAO and others have reported, the use of information technology (IT) has enormous potential to improve the quality of health care and is critical to improving the performance of the U.S. health care system. Given the federal government's role in providing health care in the U.S., it has been urged to take a leadership role in driving change to improve the quality and effectiveness of health care, including the adoption of IT. In April 2004, President Bush called for widespread adoption of interoperable electronic health records within 10 years and issued an executive order that established the position of the National Coordinator for Health Information Technology. A National Coordinator within the Department of Health and Human Services (HHS) was appointed in May 2004 and released a framework for strategic action two months later. In May 2005, GAO recommended that HHS establish detailed plans and milestones for each phase of the framework and take steps to ensure that its plans are followed and milestones are met.

GAO was asked to identify progress made by HHS toward the development and implementation of a national health IT strategy. To do this, GAO reviewed prior reports and agency documents on the current status of relevant HHS activities.

www.gao.gov/cgi-bin/getrpt?GAO-06-1071T.

To view the full product, including the scope And methodology, click on the link above. For more information, contact David A. Powner at (202) 512-9286 or pownerd@gao.gov.

September 1, 2006

HEALTH INFORMATION TECHNOLOGY

HHS is Continuing Efforts to Define Its National Strategy

What GAO Found

In late 2005, to help define the future direction of a national strategy, HHS awarded several health IT contracts and formed the American Health Information Community, a federal advisory committee made up of health care stakeholders from both the public and private sectors. Through the work of the these contracts and the community, HHS and its Office of the National Coordinator for Health IT have made progress in five major areas associated with the President's goal of nationwide implementation of health IT (see table).

Five Areas of Progress and Supporting Activities

Areas of progress	Activities
Advancing use of electronic health records	• Defined initial certification criteria for certain electronic health records and certified 22 vendors' products. • Presented functional requirements for inclusion of patient information into electronic health records. • Initiated work to advance the use of electronic health records to rebuild medical records following disasters.
Establishing interoperability standards for a health information exchange	• American National Standards Institute Health IT Standards Panel selected 90 interoperability standards for areas such as electronic health records and public health detection and reporting. • Coordinated with the National Institute for Standards and Technology to align federal and private sector standards for interoperable health IT.
Developing prototypes of a nationwide health information network	• Awarded contracts for developing prototypes for a national network to four contractors. • Proposed more than 1000 functional requirements. • Held the first nationwide health information forum.
Addressing privacy and security issues associated with the nationwide exchange of health information	• Contracted with 34 states and territories to perform assessments of the impact of policies and laws on security and privacy practices. • Selected standards to help ensure privacy and confidentiality. • Formed a new workgroup to specifically address privacy and security policy issues. • Made recommendations covering topics that are central to challenges for protecting health information privacy in a national health information exchange environment.
Integrating public health systems into a national network	• Made recommendations to help support sharing of clinical care data with local, state, and federal biosurveillance programs, including the development of materials for public education on benefits to public health and national security, and the protection of patient confidentiality. • Selected information exchange standards for sharing clinical health information with public health.

Source: GAO analysis of HHS data

These activities and others are being used by the Office of the National Coordinator for Health IT to continue its efforts to complete a national strategy to guide the nationwide implementation of interoperable health IT. Since the release of its initial framework in 2004, the office has defined objectives and high-level strategies for accomplishing its goals. Although HHS agreed with GAO's prior recommendations and has made progress in these areas, it still lacks detailed plans, milestones, and performance measures for meeting the President's goals.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to comment on federal efforts to advance the use of information technology (IT) for health care delivery and public health. As we and others have reported, the use of IT has enormous potential to improve the quality of health care and is critical to improving the performance of the U.S. health care system.

Recognizing the potential value of IT in public and private health care systems, the federal government has been working to promote the nationwide use of health IT.[1] In April 2004, President Bush called for widespread adoption of interoperable electronic health records within 10 years and issued an executive order[2] that established the position of the National Coordinator for Health Information Technology within the Department of Health and Human Services (HHS). The National Coordinator's responsibilities include the development and implementation of a strategic plan to guide the nationwide implementation of interoperable health IT in both the public and private sectors.

At your request, today we will discuss progress made by HHS and its Office of the National Coordinator for Health IT toward the development and implementation of a national health IT strategy. In preparing this statement, we reviewed agency documents on the current status of HHS's activities related to a national health IT strategy and supplemented our analysis with interviews of agency officials. We also summarized prior GAO reports. Our work was performed in accordance with generally accepted auditing standards.

[1] Health IT is the use of technology to electronically collect, store, retrieve, and transfer clinical, administrative, and financial health information.

[2] Executive Order 13335, *Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator* (Washington, D.C.: Apr. 27, 2004).

Results in Brief

HHS and its Office of the National Coordinator for Health IT have made progress through the work of the American Health Information Community[3] and several recently-awarded contracts[4] in five major areas: (1) defining certification criteria for and certifying electronic health records, (2) identifying interoperability standards to facilitate the exchange of patient data, (3) defining requirements for the development of prototypes for the Nationwide Health Information Network, (4) addressing privacy and security issues associated with the nationwide exchange of health information, and (5) taking steps to integrate public health into a nationwide health information exchange. Specifically, certification criteria for ambulatory electronic health records[5] have been defined and 22 electronic health records vendors have achieved certification for their products. Additionally, 90 interoperability standards have been selected for areas such as electronic health records and public health detection and reporting, and functional requirements for a nationwide health information network have been proposed. The American Health Information Community has also formed a workgroup to specifically address confidentiality and security issues relevant to a nationwide health information exchange.

These activities and others are being used by the Office of the National Coordinator for Health IT to continue its efforts to complete a national strategy to guide the nationwide implementation of interoperable health IT. Since the release of its initial framework in 2004, the office has defined objectives and high-level strategies for accomplishing its goals. However, while HHS has

[3] The American Health Information Community is a federally-chartered commission made up of representatives from both the public and private health care sectors.

[4] In late 2005, HHS awarded several contracts to address a range of issues important for developing a health IT infrastructure, such as advancing the use of electronic health records, selecting health IT standards, developing prototypes of a national network, and defining privacy and security policies.

[5] Ambulatory electronic health records are records of medical care that includes diagnosis, observation, treatment, and rehabilitation that is provided on an outpatient basis. Ambulatory care is given to persons who are able to ambulate, or walk about.

made progress in these areas, it still lacks detailed plans, milestones, and performance measures for meeting the President's goals.

Background

Studies published by the Institute of Medicine and others have indicated that fragmented, disorganized, and inaccessible clinical information adversely affects the quality of health care and compromises patient safety. In addition, long-standing problems with medical errors and inefficiencies increase costs for health care delivery in the United States. With health care spending in 2004 reaching almost $1.9 trillion, or 16 percent, of the gross domestic product, concerns about the costs of health care continue. As we reported last year, many policy makers, industry experts, and medical practitioners contend that the U.S. health care system is in a crisis.[6]

Health IT provides a promising solution to help improve patient safety and reduce inefficiencies. The expanded use of health IT has great potential to improve the quality of care, bolster the preparedness of our public health infrastructure, and save money on administrative costs. As we reported in 2003, technologies such as electronic health records and bar coding of certain human drug and biological product labels have been shown to save money and reduce medical errors.[7] For example, a 1,951-bed teaching hospital reported that it realized about $8.6 million in annual savings by replacing outpatient paper medical charts with electronic medical records. This hospital also reported saving more than $2.8 million annually by replacing its manual process for managing medical records with an electronic process to provide access to laboratory results and reports. Health care organizations also reported that IT contributed other benefits, such as shorter hospital stays, faster

[6] GAO, *21st Century Challenges: Reexamining the Base of the Federal Government*, GAO-05-325SP (Washington, D.C.: February 2005).

[7] GAO, *Information Technology: Benefits Realized for Selected Health Care Functions*, GAO-04-224 (Washington, D.C.: Oct. 31, 2003).

communication of test results, improved management of chronic diseases, and improved accuracy in capturing charges associated with diagnostic and procedure codes. However, according to HHS, only a small number of U.S. health care providers have fully adopted health IT due to significant financial, technical, cultural, and legal barriers such as a lack of access to capital, a lack of data standards, and resistance from health care providers.

Federal Government's Role in Health Care

According to the Institute of Medicine, the federal government has a central role in shaping nearly all aspects of the health care industry as a regulator, purchaser, health care provider, and sponsor of research, education, and training. Seven major federal health care programs, such as Medicare and Medicaid, provide health care services to approximately 115 million Americans. According to HHS, federal agencies fund more than a third of the nation's total health care costs. Table 1 summarizes the programs and number of citizens who receive health care services from the federal government and the cost of these services.

Table 1: Beneficiaries and Expenditures in Major Federal Health Care Programs for Fiscal Year 2004

Federal agency	Program	Beneficiaries	Expenditure (in billions)
HHS	Medicare	42 million elderly and disabled beneficiaries	$309
HHS	Medicaid	43.7 million low-income persons	276.8 (joint federal and state)
HHS	State Children's Health Insurance Program	5.8 million children[a]	6.6 (joint federal and state)
HHS	Indian Health Service	1.8 million Native Americans and Alaska Natives	3.7
Veterans Affairs	Veterans Health Administration	5.2 million veterans	26.8
Department of Defense	Tricare Program	8.3 million active-duty military personnel and their families, and military retirees	30.4
Office of Personnel Management	Federal Employees Health Benefit Program	8 million federal employees, retirees, and dependents	27

Source: HHS, VA, DOD, and OPM budget documents.

[a]Based on fiscal year 2003 data.

Given the level of the federal government's participation in providing health care, it has been urged to take a leadership role in driving change to improve the quality and effectiveness of medical care in the United States, including an expanded adoption of IT.

In April 2004, President Bush called for the widespread adoption of interoperable electronic health records within 10 years and issued an executive order[8] that established the position of the National Coordinator for Health Information Technology within HHS. The National Coordinator's responsibilities include the development and

[8] Executive Order 13335.

implementation of a strategic plan to guide the nationwide implementation of interoperable health IT in both the public and private sectors. The first National Coordinator was appointed in May 2004,[9] and two months later HHS released *The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care—Framework for Strategic Action*, the first step toward the development of a national strategy. The framework described goals for achieving nationwide interoperability of health IT and actions to be taken by both the public and private sectors to implement a strategy. Just last week, President Bush issued an executive order calling for federal health care programs and their providers, plans, and insurers to use IT interoperability standards recognized by HHS.[10]

Need for a National Strategy and Greater Interoperability

In the summer of 2004, we testified on the benefits that effective implementation of IT can bring to the health care industry and the need for HHS to provide continued leadership, clear direction, and mechanisms to monitor progress in order to bring about measurable improvements.[11] Last year, we reported that HHS, through the Office of the National Coordinator for Health IT, had taken a number of actions toward accelerating the use of IT to transform the health care industry. To further accelerate the adoption of interoperable health information systems, we recommended that HHS establish detailed plans and milestones for meeting the goals of its framework for strategic action and take steps to ensure that those plans are followed and milestones are met.[12] The department agreed with our recommendation.

[9] This position was vacated by the first national coordinator in May 2006. HHS is currently in the process of conducting a nationwide search for a new national coordinator and a deputy national coordinator.

[10] *Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs* (Washington, D.C.: Aug. 22, 2006).

[11] GAO, *Health Care: National Strategy Needed to Accelerate the Implementation of Information Technology*, GAO-04-947T (Washington, D.C.: July 14, 2004).

[12] GAO, *Health Information Technology: HHS is Taking Steps to Develop a National Strategy*, GAO-05-628 (Washington, D.C.: May 27, 2005).

We also reported in June 2005 that challenges associated with major public health IT initiatives still need to be overcome to strengthen the IT that supports the public health infrastructure.[13] Federal agencies face many challenges in their efforts to improve the public health infrastructure, including (1) the integration of current initiatives into a national health IT strategy and federal architecture to reduce the risk of duplicative efforts, (2) development and adoption of consistent standards to encourage interoperability, (3) coordination of initiatives with state and local agencies to improve the public health infrastructure, and (4) overcoming federal IT management weaknesses to improve progress on IT initiatives. To address these challenges, we recommended that HHS align federal public health initiatives with the national health IT strategy and federal health architecture, coordinate with state and local public health agencies, and continue federal actions to encourage the development and adoption of data standards.

Last September, we testified about the importance of defining and implementing data and communication standards to speed the adoption of interoperable IT in the health care industry.[14] Hurricane Katrina highlighted the need for interoperable electronic health records as thousands of people were separated from their health care providers and their paper medical records were lost. As we have noted, standards are critical to enabling this interoperability. Although federal leadership has been established to accelerate the use of IT in health care, we testified that several actions[15] were still needed to position HHS to further define and implement relevant standards. Otherwise, the health care industry will continue to be plagued with incompatible systems that are incapable of exchanging

[13] GAO, *Bioterrorism: Information Technology Strategy Could Strengthen Federal Agencies' Abilities to Respond to Public Health Emergencies*, GAO-03-139 (Washington, D.C.: May 30, 2003); GAO, *Information Technology: Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Infrastructure*, (GAO-05-308) Washington, D.C.: June 10, 2005).

[14] GAO, *Health Care: Continued Leadership Needed to Define and Implement Information Technology Standards*, GAO-05-1054T (Washington, D.C.: Sept. 29, 2005).

[15] These actions included the lack of mechanisms for better agency coordination of the various standards efforts, incomplete milestones associated with these efforts, and no mechanism to monitor the implementation of standards across the health care industry.

medical information that is critical to delivering care and responding to public health emergencies.

In March 2006, we testified before this subcommittee[16] on HHS's continued efforts to move forward with its mission to guide the nationwide implementation of interoperable health IT in the public and private health care sectors. We identified several steps taken by the department, such as the establishment of the organizational structure and management team for the Office of the National Coordinator for Health IT under the Office of the Secretary and the formation of a public-private advisory body—the American Health Information Community—to advise HHS on achieving interoperability for health information exchange. The community, which is co-chaired by the Secretary of HHS and the former National Coordinator for Health IT, identified four breakthrough areas[17] — consumer empowerment, chronic care, biosurveillance, and electronic health records—and formed workgroups intended to make recommendations for actions in these areas that will produce tangible results within a one-year period. Subsequently, in May 2006 the workgroups presented 28 recommendations to the American Health Information Community that address standards, privacy and security, and data-sharing issues.

We also reported in March 2006[18] that HHS—through the Office of the National Coordinator for Health IT— awarded $42 million in contracts that address a range of issues important for developing a robust health IT infrastructure, such as an increasing number of health care providers adopting electronic health records, definitions of health information standards being developed, architectural definitions for a national network, and the development and implementation of privacy and security policies. HHS intends to use the results of the contracts and recommendations from the

[16] GAO, *Health Information Technology: HHS is Continuing Efforts to Define a National Strategy*, GAO-06-346T (Washington, D.C.: Mar. 15, 2006).

[17] Breakthrough areas are components of health care and public health that can potentially achieve measurable results in 2 to 3 years.

[18] GAO-06-346T.

American Health Information Community proceedings to define the future direction of a national strategy. In March, the National Coordinator told us that he intended to release a strategic plan with detailed plans and milestones later this year. The contracts are described in table 2.

Table 2: Health IT Contracts Awarded by HHS's Office of the National Coordinator

Contract	Date awarded	Duration	Cost (in millions)	Description
American Health Information Community Program Support	September 2005	1 year	$0.8	To provide assistance to the National Coordinator in convening and managing the meetings and activities of the community to ensure that the health IT plan is seamlessly coordinated.
Standards Harmonization Process for Health IT	September 2005	1 year	3.2	To develop and test a process for identifying, assessing, endorsing, and maintaining a set of standards required for interoperable health information exchange.
Compliance Certification Process for Health IT	September 2005	1 year	2.7	To develop and evaluate a compliance certification process for health IT, including the infrastructure components through which these systems interoperate.
Privacy and Security[a]	September 2005	1½ years	17.5 (Increased by $6 million in August 2006 to include additional studies)	To assess and develop plans to address variations in organization-level business policies and state laws that affect privacy and security practices that may pose challenges to an interoperable health information exchange.
Nationwide Health Information Network Prototypes	November 2005	1 year	18.6 (4 contracts)	To develop and evaluate prototypes for a nationwide health information network architecture to maximize the use of existing resources such as the Internet to achieve widespread interoperability among software applications, particularly electronic health records. These contracts are also intended to spur technical innovation for nationwide electronic sharing of health information in patient care and public health settings.
Measuring the Adoption of Electronic Health Records	September 2005	2 years	1.8	To develop a methodology to better characterize and measure the state of electronic health records adoption and determine the effectiveness of policies aimed at accelerating adoption of electronic health records and interoperability.
Gulf Coast Electronic Digital Health Recovery	September 2005	1 year	3.7	To plan and promote the widespread use of electronic health records and digital health information recovery in the Gulf Coast regions affected by hurricanes last year.

Source: HHS Office of the National Coordinator for Health Information Technology.

[a]Jointly managed by the Agency for Healthcare Research and Quality and the Office of the National Coordinator.

HHS Is Continuing Efforts to Advance the Nationwide Implementation of Health IT and Complete a National Strategy

HHS and its Office of the National Coordinator for Health IT have made progress through the work of the American Health Information Community and several contracts in five major areas: (1) advancing the use of electronic health records, (2) establishing standards to facilitate the exchange of patient data, (3) defining requirements for the development of prototypes of the Nationwide Health Information Network, (4) incorporating privacy and security policy, practices, and standards into the national strategy, and (5) integrating public health into nationwide health information exchange.

These activities and others are being used by the Office of the National Coordinator for Health IT to continue its efforts to complete a national strategy to guide the nationwide implementation of interoperable health IT. Since the release of its initial framework in 2004, the office has taken additional steps to define a complete national strategy, building on its earlier work. However, while HHS has made progress in these areas, it still lacks detailed plans, milestones, and performance measures for meeting the President's goals.

HHS Is Advancing the Use of Electronic Health Records

HHS has made progress toward advancing the adoption of electronic health records by defining initial certification criteria for ambulatory electronic health records. The Certification Committee for Health IT,[19] which was awarded the Compliance Certification Process for Health IT contract, finalized functionality, security, and reliability certification criteria for ambulatory electronic health records in May 2006 and described interoperability criteria for

[19] The Certification Committee for Health IT is a voluntary, private sector organization that is working to certify health IT products in three areas: ambulatory electronic health records for the office-based physician or provider, inpatient electronic health records for hospitals and health systems, and the network components through which the electronic health records operate and share information.

future certification requirements. The committee subsequently certified 22 vendors' electronic health records products in July. Its next phase is to define and recommend certification criteria for inpatient electronic health records. The committee plans to publish these criteria for public comment during the last quarter of 2006, with certification beginning in the second quarter of 2007.

Additionally, the Nationwide Health Information Network contracts have thus far resulted in the identification of draft functional requirements for incorporating lab results and patient information, such as medical history and insurance information, into electronic health records. The requirements were presented to the Secretary of HHS in June 2006, and an initial set of requirements for the Nationwide Health Information Network are expected to be issued in September 2006.

In our March 2006 testimony, we described the Gulf Coast Electronic Digital Health Recovery contract, which was awarded by HHS to promote the use of electronic health records to rebuild medical records for patients in the Gulf Coast region affected by hurricanes last year. The outcomes of the contract are expected to coordinate planning for the recovery of digital health information in cases of emergencies or disasters and to develop a prototype of health information sharing and electronic health records support. The contract established a task force of local and national experts to help area providers turn to electronic medical records as they rebuild medical records for their patients.

HHS Has Initiated Steps to Establish Health IT Standards

HHS awarded its Standards Harmonization Process for Health IT contract to ANSI.[29] The contract is supported by ANSI's Health IT Standards Panel, a collaborative partnership between the public and private sector. This effort integrates standards previously identified

[29] The American National Standards Institute is a private, nonprofit membership organization that coordinates the development and use of voluntary standards in the United States.

by the Consolidated Health Informatics[21] and other federal initiatives. To date, the panel has selected 90 interoperability standards for areas such as electronic health records and public health detection and reporting. The selected standards specifically address components of the breakthrough areas defined by the American Health Information Community and were produced by accepted standards organizations. The Nationwide Health Information Network functional requirements also incorporate standards defined through the work of the Standards Harmonization Process for Health IT contract. The selected standards are currently being reviewed for acceptance by the Secretary.

HHS has also involved the Department of Commerce's National Institute for Standards and Technology (NIST) with HHS's work to implement health IT standards through its standards harmonization contract. HHS's standards harmonization contractor is required to maximize the use of existing processes and collaborate with NIST where appropriate, including consideration of outputs from the standards harmonization process as Federal Information Processing Standards[22] relevant to federal agencies. NIST's issuance of Federal Information Processing Standards for health IT is to be aligned with recommendations from public and private sector coordination efforts through the American Health Information Community, as accepted by the Secretary of HHS. The Federal Information Processing Standards are to be consistent with the standards adopted by the harmonization contract to enable the alignment of federal and private sector standards and widespread interoperability among health IT systems, particularly electronic health records systems.

[21] Consolidated Health Informatics was initiated in December 2001 as an Office of Management and Budget e-government project to establish federal health information standards to enable federal agencies to build interoperable health data systems. The project was incorporated into the Federal Health Architecture in September 2004.

[22] Federal Information Processing Standards are developed by NIST in collaboration with national and international standards committees, users, industry groups, consortia, and research and trade organizations when there are no existing voluntary industry standards to address federal requirements for the interoperability of different systems, for the portability of data and software, and for computer security.

HHS Has Begun to Define Requirements for the Development of Prototypes for the Nationwide Health Information Network

HHS's Nationwide Health Information Network contracts are intended to provide architectures and prototypes of national networks based on the breakthrough areas defined by the American Health Information Community. HHS awarded contracts for developing these architectures and prototypes to four contractors. The contractors are to deliver final operating plans and prototypes of a national network that demonstrates health information exchange across multiple markets in November 2006.

In late June 2006, HHS held its first Nationwide Health Information Network forum. More than 1000 functional requirements for a Nationwide Health Information Network were presented for discussion and public input. The requirements addressed general Nationwide Health Information Network infrastructure needs and the breakthrough areas defined by the American Health Information Community. The requirements are being reviewed by the National Committee for Vital and Health Statistics,[23] which is expected to release its approved requirements by September 2006.

HHS Is Taking Steps to Incorporate Privacy and Security Policies, Practices, and Standards into Its National Strategy

HHS, through its contracts and recommendations from the American Health Information Community and the National Committee for Vital and Health Statistics, has initiated several actions to address privacy and security issues associated with the nationwide exchange of health information. In May 2006, 22 states subcontracted under HHS's privacy and security contract to perform assessments of the impact of organization-level business policies and state laws on security and privacy practices and the degree to which they pose challenges to interoperable health information exchange. In August 2006, 11 more states and Puerto Rico were

[23] The National Committee on Vital and Health Statistics was established in 1949 as a public advisory committee that is statutorily authorized to advise the Secretary of HHS on health data, statistics, and national health information policy, including the implementation of health IT standards.

added to the scope of the contract. The outcomes of the contract are to provide a nationwide synthesis of information to inform privacy and security policy making at federal, state, and local levels.

In addition, the standards selected through the standards harmonization contract include those that are applicable to the consumer empowerment breakthrough area, specifically privacy and confidentiality. Its initial standards are intended to allow consumers the ability to establish and manage permissions and access rights, along with informed consent for authorized and secure exchange, viewing, and querying of their medical information between designated caregivers and other health professionals. Additionally, the proposed functional requirements for the Nationwide Health Information Network include security requirements that are needed for ensuring the privacy and confidentiality of health information.

In May 2006, several of the American Health Information Community workgroups recommended the formation of an additional workgroup comprised of privacy, security, clinical, and technology experts from each of the other American Health Information Community workgroups. The Confidentiality, Privacy, and Security Workgroup was formed in July to frame the privacy and security policy issues relevant to all breakthrough areas and solicit broad public input to identify viable options or processes to address these issues. The recommendations developed by this workgroup are intended to establish an initial policy framework and address issues including methods of patient identification, methods of authentication, mechanisms to ensure data integrity, methods for controlling access to personal health information, policies for breaches of personal health information confidentiality, guidelines and processes to determine appropriate secondary uses of data, and a scope of work for a long-term independent advisory body on privacy and security policies. The workgroup convened last month.

In June 2006, the National Committee on Vital and Health Statistics presented to the Secretary of HHS a report recommending actions regarding privacy and confidentiality in the Nationwide Health Information Network. The recommendations cover topics that are, according to the committee, central to challenges for protecting

health information privacy in a national health information exchange environment. Specifically, they address (1) the role of individuals in making decisions about the use of their personal health information, (2) policies for controlling disclosures across a national health information network, (3) regulatory issues such as jurisdiction and enforcement, (4) use of information by non-health care entities, and (5) establishing and maintaining the public trust that is needed to ensure the success of a national health information network. The recommendations are being evaluated by the American Health Information Community workgroups, the Certification Commission for Health IT, Health Information Technology Standards Panel, and other HHS partners. The committee intends to continue to update and refine its recommendations as the architecture and requirements of the network advance.

HHS Is Continuing to Address Public Health Integration

To help promote the integration of public health data into a nationwide health information exchange, the American Health Information Community's biosurveillance workgroup made recommendations in May 2006 intended to help the simultaneous flow of clinical care data to and among local, state, and federal biosurveillance programs. The community recommended that HHS develop sample data-use agreements and implementation guidance to facilitate the sharing of data from health care providers to public health agencies. The workgroup also recommended that HHS, in collaboration with privacy experts, state and local governmental public health agencies, and clinical care partners, develop materials to educate the public about the information that is used for biosurveillance including the benefits to the public's health, improved national security, and the protection of patient confidentiality by September 30, 2006.

Information exchange standards for sharing clinical health information (e.g., emergency department visit data and lab results) with public health are included in the 90 standards recently recommended as a result of HHS's standards harmonization contract. The standards are intended to enable the transmission of essential ambulatory care and emergency department visit,

utilization, and lab result data from electronic health care delivery and public health systems in standardized and anonymized[24] format to authorized public health agencies within less than one day. In addition to advancing the use of electronic health records, the Gulf Coast contract is intended to help support public health emergency response by fostering the availability of field-level electronic health records to clinicians responding to disasters.

HHS Is Continuing Efforts to Complete and Implement a National Strategy for Health IT

As called for by the President's executive order in April 2004, the national coordinator's office is continuing its efforts to complete a national strategy for health IT. Since we testified in March 2006, the office has worked to evolve the initial framework and, with guidance from the American Health Information Community, has revised and refined the goals and strategies identified in the initial framework. The new draft framework—*The Office of the National Coordinator: Goals, Objectives, and Strategies*—provides high-level strategies for meeting the President's goal for the adoption of interoperable health IT and is to be used to develop internal performance measures for the office's activities.

The framework identifies objectives for accomplishing each of four goals, along with 32 high-level strategies for meeting the objectives. The Office of the National Coordinator has identified and prioritized the 32 strategies for accomplishing the framework's goals and has initiated 10 of them, which are supported by the contracts that HHS awarded in fall 2005. Table 3 illustrates the framework's goals, objectives, and strategies and identifies the 10 strategies that have been initiated.

The Office of the National Coordinator has prioritized the remaining 22 strategies defined in its framework. Six strategies are under active consideration, and the remaining 16 require future discussion. According to officials with the office, the strategies were prioritized based on guidance and direction from the American Health Information Community. The Office of the National Coordinator

[24] Anonymized data are data that have had personally identifying information removed.

expects the framework to continue to evolve through collaboration among the Office of the National Coordinator and its partners, such as other federal agencies and the American Health Information Community, and as additional activities are completed through the contracts.

Table 3: Office of the National Coordinator's Goals and Initial Objectives and Strategies

Goals	Objectives	High-level strategies
Goal 1: Inform health care professionals	High-value electronic health records	Simplify health information access and communication among clinicians[a]
		Increase incentives for clinicians to use electronic health records[c]
	Low-cost and low-risk electronic health records	Foster economic collaboration for electronic health records adoption[b]
		Lower total cost of electronic health records purchase and implementation[b]
		Lower risk of electronic health records adoption[a]
	Current clinical knowledge	Increase investment in sources of evidence-based knowledge[c]
		Increase investment in tools that can access and integrate evidence based knowledge in the clinical setting[c]
		Establish mechanisms which will allow clinicians to empirically access information and other patient characteristics that can better inform their clinical decisions[c]
	Equitable adoption of electronic health records	Ensure low-cost electronic health records for clinicians in underserved areas[c]
		Support adoption and implementation by disadvantaged providers[c]
Goal 2: Interconnect health care	Widespread adoption of standards	Establish well-defined health information standards[a]
		Ensure federal agency compliance with health information standards[a]
		Exercise federal leadership in health information standards adoption[a]
	Sustainable electronic health information exchange	Stimulate private investment to develop the capability for efficient sharing of health information[b]
		Use government payers and purchasers to foster interoperable electronic health information exchange[a]
		Adapt federal agency health data collection and delivery to NHIN solutions[c]
		Support state and local governments and organizations to foster electronic health information exchange[a]
	Consumer privacy and risk protections	Support the development and implementation of appropriate privacy and security policies, practices, and standards for electronic health information exchange[a]
		Develop and support policies to protect against discrimination from health information[c]
Goal 3: Personalize health management	Consumer use of personal health information	Establish value of personal health records, including consumer trust[b]
		Expand access to personal health management information and tools[a]
	Remote monitoring and communications	Promote adoption of remote monitoring technology for communication between providers and patients[a]
	Care based on culture and traits	Promote consumer understanding and provider use of personal genomics for prevention and treatment of hereditary conditions[c]

Goals	Objectives	High-level strategies
		Promote multi-cultural information support[c]
Goal 4: Improve population health	Automated public health and safety monitoring and management	Enable simultaneous flow of clinical care data to and among local, state, and federal biosurveillance programs[b]
		Ensure that the nationwide health information network supports population health reporting and management[c]
	Efficient collection of quality information	Develop patient-centric quality measures based on clinically relevant information available from interoperable longitudinal electronic health records[b]
		Ensure adoption of uniform performance measures by health care stakeholders[c]
		Establish standardized approach to centralized electronic data capture and reporting of performance information[c]
	Transformation of clinical research	
	Health information support in disasters and crises	Foster the availability of field electronic health records to clinicians responding to disasters[b]
		Improve coordination of health information flow during disasters and crises[c]
		Support management of health emergencies[c]

Source: HHS Office of the National Coordinator for Health IT

[a] Strategy has been initiated

[b] Strategy is under active consideration

[c] Strategy requires future discussion

While HHS has taken additional steps toward completing a national strategy and has initiated specific activities defined by its strategic framework, it still lacks the detailed plans, milestones, and performance measures needed to ensure that its goals are met. While the National Coordinator acknowledged the need for more detailed plans for its various initiatives and told us in March that HHS intended to release a strategic plan with detailed plans and milestones later this year, current officials with the office could not tell us when detailed plans and milestones would be defined. Given the complexity of the tasks at hand and the many activities to be completed, a national strategy that defines detailed plans, milestones, and performance measures is essential. Without it, HHS risks not meeting the President's goal for health IT.

In summary, Mr. Chairman, our work shows that HHS is continuing its efforts to help transform the use of IT in the health care industry. However, much work remains. While HHS, through the Office of the National Coordinator for Health IT and the American Health Information Community, has initiated specific actions for

supporting the goals of a national strategy, detailed plans and milestones for completing the various initiatives and performance measures for tracking progress have not been developed. Until these plans, milestones, and performance measures are completed, it remains unclear specifically how the President's goal will be met and what the interim expectations are for achieving widespread adoption of interoperable electronic health records by 2014.

Mr. Chairman, this concludes my statement. I would be pleased to answer any questions that you or other Members of the Subcommittee may have at this time.

Contacts and Acknowledgments

If you should have any questions about this statement, please contact me at (202) 512-9286 or by e-mail at pownerd@gao.gov. Other individuals who made key contributions to this statement are Amanda C. Gill, Nancy E. Glover, M. Saad Khan, and Teresa F. Tucker.

Mr. PORTER. Thank you very much for your testimony. We will go off the script for a moment and summarize what we've heard so far. We feel a responsibility as a Federal Government to set the standard. There are a lot of different programs, different approaches to health IT and we are happy that's happening. But as Mr. Clay and I looked at the issues specific to Federal employees, we felt that if we can set the standard with 8 million or more participants, that will incur the balance of the private sector across this country to step up to the plate. That's the insurance carriers, providers, all gamuts of the healthcare delivery system.

So not only are we talking about Federal employees, we realize that if we can set the standards, we will save lives across the country. So we appreciate the government's perspective, the experts that we have here today.

Next we would like to hear from the private sector and from the university system and get their perspective on what's happening.

I know that we have with us Mr. Paz who is the president and CEO of Express Scripts, Inc. I understand that you are one of the largest providers in the country and a major employer here in the St. Louis area and in the State. Mr. Clay and others in the community have spoken highly of what you are doing for the community and for healthcare, so we appreciate you being here. Mr. Paz, if you would give us your testimony, please.

STATEMENT OF GEORGE PAZ, CHAIRMAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, EXPRESS SCRIPTS, INC.

Mr. PAZ. Good afternoon, Chairman Porter and Congressman Clay. My name is George Paz, and I am chairman, president and CEO of Express Scripts, Inc., a Fortune 150 company based here in St. Louis.

Express Scripts provides pharmacy benefit management services to tens of millions of Americans throughout its relationships with employers, managed care plans, unions and governmental entities. We employ over 13,000 people across the country and in Canada. Last year we processed more than 475 million prescription claims, and in the last quarter we reported an industry-leading generic fill rate of 56.3 percent.

I am here today to talk about our experiences in electronic healthcare, and to offer our recommendations for you to consider in your efforts to spur further adoption and utilization of these exciting technologies. I have prepared additional materials which I would like to submit for the record.

Before I begin, let me first congratulate the Congress on your efforts to date. Congressional efforts toward the encouragement of electronic healthcare solutions have created great momentum in both the public and private sectors. Provisions in the Medicare Modernization Act relating to electronic prescribing standards have led to positive dialog toward standards in both government and the private sector. Inclusion of the directive in the MMA relating to the creation of exceptions to the Stark law and safe harbors under the Medicare fraud and abuse laws, have led to positive developments on both fronts which may help to spur adoption.

Also before I begin, let me just clarify that when we talk about electronic prescribing, it is important to note that what we mean

is a process by which a prescribing physician, at the point of prescribing, has access to current eligibility, formulary, medication history and other relevant information, in order to inform the prescribing decision and facilitate a discussion with the patient about the costs and benefits of differing treatment options. We are not simply referring to an electronic process to move a prescription from point A to point B.

From the early days of the Internet boom, Express Scripts has been working with technology vendors in their pursuit of solutions that would allow physicians to prescribe medications more safely, more efficiently, and more affordably for their patients. Early on, we formed relationships with many of these companies to provide formulary information for our members so that it could be made available to physicians at the point of prescribing. However, as the industry grew, we came to realize that working with each of these companies individually did not maximize efficiency, nor did it allow the industry to maximize the potential of these new technologies. At about the same time, our chief competitors were coming to the same conclusions.

In February 2001, we formed RxHub with Medco Health Solutions and a company that is now Caremark. The purpose of RxHub was three-fold. First, we wanted to create a common infrastructure to connect many payors and prescription benefit managers to many electronic prescribing vendors. Second, we wanted to create transaction standards so that we could conduct electronic prescribing transactions in a standard format across all connected participants. Finally, we sought to create a critical mass of information so that physicians who adopted electronic prescribing technologies could get access to relevant prescribing information for a sizable portion of their patients.

I am proud to say that our vision for RxHub has been achieved. In fact, RxHub now connects six data sources to over 30 technology vendors, and the numbers continue to grow. RxHub led a comprehensive industry-based consensus process that led to the creation of transaction standards for electronic prescribing, and those standards have become the de facto industry standard. A number of them are currently being pilot-tested in conjunction with the CMS pilots for recognition of e-Prescribing standards for the Medicare program. By adopting electronic prescribing solutions connected to RxHub, physicians today can access information to create safer, more affordable prescriptions for over 150 million Americans.

Nonetheless, our overall vision for electronic prescribing has yet to be fully realized. The industry remains hampered by a patchwork of State laws and regulations that create conflicting demands on prescribers and electronic prescribing vendors. The standards for electronic prescribing envisioned under the Medicare Modernization Act thus far only apply to Medicare, and don't address all of the issues germane to electronic prescribing. Whereas, we believe, the MMA envisioned a comprehensive national set of standards for electronic prescribing that would promote broad adoption. The legislative language has been interpreted as essentially creating a 51st standard of requirements for Medicare patients as an overlay to the 50 existing State regulatory schemes applicable to electronic prescribing. Because these State laws are not preempted,

the Medicare scheme cannot drive the market as is sometimes the case. This needs to be fixed.

Another remaining issue, perhaps related, is that electronic prescribing cannot reach its full potential until all physicians adopt it. Getting physicians to adopt the technology has remained more challenging than we had hoped, and the reasons for that are varied. I'll offer here just a few.

First, and perhaps foremost, physicians have generally not been given incentives to transform their paper-prescribing to electronic. Adoption has been most successful where payors and/or employers have joined together to help physicians purchase the technology, or offered financial incentives tied to adoption and the use of it. In most markets, however, no one employer or payor has a significantly large portion of the market to justify paying for technology initiatives that will serve to benefit all patients.

Moreover, in order to make a meaningful impact on overall utilization, adoption initiatives often would need to reach thousands of physicians. While stand alone electronic prescribing solutions are relatively inexpensive, in the vicinity of $2,000 per physician for the first year, the cost of providing technology to thousands of physicians is often daunting.

Consequently, physicians must make the decision to adopt, and fund it on their own. But many physicians believe they should not be required to fund the technologies themselves, since most of the financial benefit from enhanced prescribing accrues to the payors, employers, and patients. These issues could be solved, either through a funded mandate, or better-aligned incentives for physicians. Given the new Medicare drug benefit, the Federal Government has as much at stake as anyone.

Another issue facing physicians is what to adopt. The significant and growing interest in Health IT by the Federal Government over the past few years has drawn great attention, and has spurred the industry to further develop technologies and pursue interoperable solutions. At the same time, the sheer volume of activity in the industry and in Washington have left many wondering what the outcome would be. The push toward electronic personal health records, interoperable electronic medical records and regional health information organizations, combined with Federal initiatives like the pursuit of a National Health Information Infrastructure, the American Health Information Community, and various legislative proposals, have left some physicians afraid to adopt any technology for fear of it becoming obsolete in the near future.

This is unfortunate. Workable solutions exist today, and should not wait. Perfection in the form of interoperable health records for every American, should not become the enemy of good. Good can be achieved today, by improving quality and reducing costs in connection with prescription medications, through electronic prescribing. What's more, in addition to the immediate benefits that are achievable through broad adoption of electronic prescribing, it is also a good first step for clinicians toward more sophisticated solutions.

The adoption of electronic prescribing is relatively simple. The technology generally is compatible with existing office systems used by physicians, installation is relatively easy, and the learning curve

for using the technology is quick. At most, physicians need a little extra time to get used to using a stylus and a handheld computer, rather than paper and a pen. More importantly, adoption of the technology does not disrupt other physician-office systems. Existing records remain, but are augmented by electronic prescribing solutions.

In contrast, for a physician to adopt a full electronic medical record system, the entire office needs to be transformed. While the transformation is clearly achievable, and solutions are becoming increasingly sophisticated, it is often daunting for physicians. Entire rooms of paper records need to be digitized for future access, or a hybrid system would need to be adopted to accommodate the physicians need to see the historical record in order to make current treatment decisions. In that instance, physicians would need to access both a paper and an electronic medical record. Many physicians simply cannot face the expense or the disruption of such a major paradigm shift. This has major implications for the ability of our healthcare system to tackle the problem. Today, physicians trained using electronic records often have had to learn to use a paper system when they joined an existing practice. It is not a simple problem, and a subset of patients with electronic personal health records wont be enough to push a physician to make the transition.

Until electronic medical records are widespread in physician offices, we believe the push toward electronic personal health records may be misplaced. While greater patient involvement in their own healthcare is a laudable goal, without an interoperable system through which physicians can easily interact with such records, they aren't likely to succeed in enhancing efficiency and safety in the delivery of care. Ultimately, it will only re-create the current system in which it is incumbent upon patients to inform their physicians of existing medical conditions and prior history. Having a new system to achieve that, whether through printouts or Web access, may not add much. Patients who utilize them may be better equipped to be advocates for their own better care, though many may elect not to use them given that their physicians wont be able to do much with them.

In contrast, getting physicians to prescribe electronically will create great impact for our entire healthcare system. Internal unpublished research at Express Scripts has estimated that just a single percentage point increase in generic utilization creates approximately a 1 percent savings in overall drug spend. Electronic prescribing has been shown in a number of published studies to help physicians increase generic utilization by multiple percentage points.

As important, the recent Institute of Medicine report, Preventing Medication Errors, estimates that there are at least 1.5 million preventable adverse drug events per year, creating cost in excess of $3.5 billion. That report lists a number of potential solutions which may help bring this problem under control. Among the offered solutions are the adoption of electronic solutions by prescribers, and greater patient involvement in their own care. These are achievable goals. Many electronic prescribing solutions integrate solutions which allow patients to provide inputs as to their own medications,

including over-the-counter medications, which are then readily accessible to physicians using the system. These solutions are available today. They are affordable, and they have great potential for transforming the cost and quality of care. We urge you to look closely at these solutions as you deliberate about how programs for Federal employees can spur change in our entire healthcare system.

In closing, let me reiterate our principal recommendations: First, we believe it is imperative to clearly establish a comprehensive, Federal preemptive set of standards for electronic prescribing, leveraging industry experience and the workable processes adopted by standards development organizations.

Second, we urge you to help find ways to either assist physicians with the cost of adoption of electronic prescribing, or implement appropriate incentive arrangements for them to adopt on their own, and help push physicians toward adoption of electronic prescribing as a logical first step toward capturing the advantages of e-health.

Finally, we recommend that any Federal efforts toward the encouragement of other e-health solutions such as personal health records or electronic medical records, make explicitly clear that all solutions must be developed to be compatible with the e-prescribing standards, so that physicians will be confident when adopting electronic prescribing that other developing technologies will be compatible. Thank you for having me here today.

[The prepared statement of Mr. Paz follows:]

House Government Reform Committee
Field Hearing
September 1, 2006
St. Louis, Missouri

Testimony of George Paz
Chairman, President and Chief Executive Officer
Express Scripts, Inc.

Good afternoon Chairman Porter and Congressman Clay. My name is George Paz, and I am Chairman, President and CEO of Express Scripts, Inc., a Fortune 150 company based here in St. Louis.

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I am here today to talk about our experiences in electronic health care, and to offer our recommendations for you to consider in your efforts to spur further adoption and utilization of these exciting technologies. I have prepared additional materials which I would like to submit for the record.

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Also before I begin, let me just clarify that when we talk about electronic prescribing, it is important to note that what we mean is a process by which a prescribing physician, *at the point of prescribing*, has access to current eligibility, formulary, medication history, and other relevant information, in order to inform the prescribing decision and facilitate a discussion with the patient about the costs and benefits of differing treatment options. We are not simply referring to an electronic process to move a prescription from point A to point B.

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become the defacto industry standards. A number of them are currently being pilot-tested in connection with the CMS pilots for recognition of e-prescribing standards for the Medicare program. By adopting electronic prescribing solutions connected to RxHub, physicians today can access information to create safer, more affordable prescriptions for over 150 million Americans.

Nonetheless, our overall vision for electronic prescribing has yet to be fully realized. The industry remains hampered by a patchwork of state laws and regulations that create conflicting demands on prescribers and electronic prescribing vendors. The standards for electronic prescribing envisioned under the Medicare Modernization Act thus far only apply to Medicare, and don't address all of the issues germane to electronic prescribing. Whereas, *we believe*, the MMA envisioned a comprehensive national set of standards for electronic prescribing that would promote broad adoption, the legislative language has been interpreted as essentially creating a 51st set of requirements for Medicare patients as an overlay to the 50 existing state regulatory schemes applicable to electronic prescribing. Because these state laws are not preempted, the Medicare scheme *cannot* drive the market as is sometimes the case. This needs to be fixed.

Another remaining issue, perhaps related, is that electronic prescribing cannot reach its full potential until all physicians adopt it. Getting physicians to adopt the technology has remained more challenging than we had hoped, and the reasons for that are varied. I'll offer just a few here.

First, and perhaps foremost, physicians have generally not been given incentives to transform their paper prescribing to electronic. Adoption has been most successful where payors and/or employers have joined together to help physicians purchase the technology, or offered financial incentives tied to adoption and use of it. In most markets however, no one employer or payor has a significantly large portion of the market to justify paying for technology initiatives that will serve to benefit all patients.

Moreover, in order to make a meaningful impact on overall utilization, adoption initiatives often would need to reach thousands of physicians. While standalone electronic prescribing solutions are relatively inexpensive (in the vicinity of $2,000 per physician for the first year), the cost of providing technology to thousands of physicians is often daunting.

Consequently, physicians must make the decision to adopt, and fund it on their own. But many physicians believe they should not be required to fund the technologies themselves, since most of the financial benefit from enhanced prescribing accrues to payors, employers, and patients. These issues could be solved, either through a funded mandate, or better-aligned incentives for physicians. Given the new Medicare drug benefit, the federal government has as much at stake as anyone.

Another issue facing physicians is what to adopt. The significant and growing interest in Health IT by the federal government over the past few years has drawn great attention – and has spurred the industry to further develop technologies and pursue interoperable solutions. At the same time, the sheer volume of activity in the industry and in Washington have left many wondering what the outcome would be. The push toward electronic personal health records, interoperable electronic medical records and regional health information organizations, combined with federal initiatives like the pursuit of a National Health Information Infrastructure, the American Health Information Community, and various legislative proposals, have left some physicians afraid to adopt any technology for fear of it becoming obsolete in the near future.

This is unfortunate. Workable solutions exist today, and should not wait. Perfect, in the form of interoperable health records for every American, should not become the enemy of good. Good can be achieved today, by improving quality and reducing costs in connection with prescription medications, through electronic prescribing. What's more, in addition to the immediate benefits that are achievable through broad adoption of electronic prescribing, it is also a good first step for clinicians toward more sophisticated solutions.

The adoption of electronic prescribing is relatively simple. The technology generally is compatible with existing office systems used by physicians, installation is relatively easy, and the learning curve for using the solutions is quick. At most, physicians need a little extra time to get used to using a stylus and a handheld computer, rather than paper and a pen. More importantly, adoption of the technology does not disrupt other physician office systems. Existing records remain, but are augmented by electronic prescribing solutions.

In contrast, for a physician to adopt a full electronic medical record system, the entire office needs to be transformed. While the transformation is certainly achievable, and solutions are becoming increasingly sophisticated, it is often daunting for physicians. Entire rooms of paper records need to be digitized for future access, or a hybrid system would need to be adopted to accommodate the physician's need to see the historical record in order to make current treatment decisions. In that instance, physicians would need to access *both* a paper and an electronic medical record. Many physicians simply cannot face the expense or the disruption of such a major paradigm shift. This has major implications for the ability of our health care system to tackle the problem. Today, physicians trained using electronic records often have had to learn to use a paper system when they joined an existing practice. It is not a simple problem, and a subset of patients with electronic personal health records won't be enough to push a physician to make the transition.

Until electronic medical records are widespread in physician offices, we believe the push toward electronic personal health records may be misplaced. While greater patient involvement in their own health care is a laudable goal, without an interoperable system through which physicians can easily interact with such records, they aren't likely to succeed in enhancing efficiency and safety in the delivery of care. Ultimately, it will only recreate the current system in which it is incumbent on patients to inform their physicians of existing medical conditions and prior history. Having a new system to achieve that, whether through printouts or web access, may not add much. Patients who

utilize them may be better equipped to be advocates for their own better care, though many may elect not to use them given that their physicians won't be able to do much with them.

In contrast, getting physicians to prescribe electronically will create great impact for our entire health care system. Internal unpublished research at Express Scripts has estimated that just a single percentage point increase in generic utilization creates approximately a one percent savings in overall drug spend. Electronic prescribing has been shown in a number of published studies to help physician increase generic utilization by multiple percentage points.

As important, the recent Institute of Medicine Report, *Preventing Medication Errors* (IOM, 2006), estimates that there are *at least* 1.5 million preventable adverse drug events per year, creating cost in excess of $3.5 billion. That report lists a number of potential solutions which may help bring this problem under control. Among the offered solutions are the adoption of electronic solutions by prescribers, and greater patient involvement in their own care. These are achievable goals. Many electronic prescribing solutions integrate solutions which allow patients to provide inputs as to their own medications, including over-the-counter medications, which are then readily accessible to physicians using the system. These solutions are available today. They are affordable, and they have great potential for transforming the cost and quality of care.

We urge you to look closely at these solutions as you deliberate about how programs for federal employees can spur change in our entire health care system.

In closing, let me reiterate our principal recommendations:

First, we believe it is imperative to clearly establish a comprehensive, federal *preemptive* set of standards for electronic prescribing, leveraging industry experience and the workable processes adopted by standards development organizations.

Second, we urge you to help find ways to either assist physicians with the cost of adoption of electronic prescribing, or implement appropriate incentive arrangements for them to adopt on their own, and help push physicians toward adoption of electronic prescribing as a logical first step toward capturing the advantages of e-health.

Finally, we recommend that any federal efforts toward the encouragement of other e-health solutions such as personal health records or electronic medical records, make explicitly clear that all solutions must be developed to be compatible with the e-prescribing standards, so that physicians will be confident when adopting electronic prescribing that other developing technologies will be compatible.

Thank you for having me here today.

Mr. PORTER. Thank you, Mr. Paz. I appreciate your testimony. Next we have Dr. James Crane, associate vice chancellor for clinical affairs, Washington University.

STATEMENT OF JAMES P. CRANE, M.D., ASSOCIATE VICE CHANCELLOR FOR CLINICAL AFFAIRS, CEO WASHINGTON UNIV. PHYSICIANS FACULTY GROUP PRACTICE, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

Dr. CRANE. Thank you, Mr. Chairman and Congressman Clay. We appreciate you coming to Washington University Medical Center today to hold this hearing, as well as the opportunity to discuss the benefits and challenges of utilizing health information technology to improve both the quality and delivery of healthcare.

My name is James Crane. I am an actively practicing physician and also serve as CEO of Washington University's faculty group practice. By way of background, our group practice is composed of 980 faculty physicians, or roughly one in every 10 physicians practicing in the State of Missouri. We are the third-largest academic group practice in the Nation and we encompass 53 different medical and surgical subspecialties. Each year we care for nearly 300,000 patients annually, with 75 percent of our clinical activity occurring here on the Medical Center campus and the remaining 25 percent distributed across 49 locations in suburban St. Louis and rural Missouri and Illinois. We are the largest Medicaid physician provider in the State of Missouri and a critical provider of specialty care for the uninsured in our community.

I am here today to share with you our progress in implementing an electronic health record for our patients, the benefits we hope to achieve and the hurdles we face.

Many of our patients have chronic and complex medical problems and require highly coordinated care involving multiple subspecialties. This, along with the geographically distributed nature of our clinical practice, were major catalysts in our decision to move to develop an electronic health record for our patients.

As you've heard, EHRs offer many advantages for both patients and providers. My comments today will focus on four specific ways in which the quality and efficiency of patient care can be enhanced by health information technology.

The first specific way is the ability to have a single integrated patient chart. Historically, each of our 53 subspecialties here on the campus have maintained their own paper medical records which are stored in different locations. As you can imagine, managing paper records for 300,000 patients seeking the care of 53 different subspecialties across a 130-acre campus, not to mention our dozens of off-campus clinics, is an enormous and highly complex undertaking. Our EHR initiative allows us to integrate these separate paper charts into a single integrated health record for each patient. This insures that all of the physicians involved in a patient's care have full access to the information they need to make informed medical decisions and deliver the best possible care.

The second benefit is the ability to have real-time access to a patient's chart after-hours. Patients commonly present at nights or on weekends with emergent and sometimes life-threatening situations. An integrated EHR provides the treating physician with instant ac-

cess to a complete list of the patients medical problems, their medications, and other information regarding their past medical history that can eliminate the need for redundant testing, expedite care and prove critical in guiding management and influencing clinical outcomes. We have designed our EHR's so the patients medical record can be immediately accessed via a HIPAA-compliant secure network from virtually any location, including a hospital environment, the emergency room, the clinic, a physicians academic office, their home or even from out of town.

A third major benefit from my perspective is the opportunity to enhance patient safety. As has been mentioned, the Institute of Medicine estimates that 1.5 million Americans are injured annually by preventable medication errors. Our EHR solution includes an e-prescribing component that guards against medication errors via built-in logic that automatically checks for proper dosage, drug allergies and potential adverse interactions with other medications the patient may be taking.

Another way to enhance patient safety is via the task management functionality built into our EHR solution. As an example, the system automatically alerts the ordering physicians of any abnormal lab results. This ensures that abnormal lab findings are acted upon promptly and not inadvertently lost or filed without proper physician review.

The fourth benefit I'll mention is the ability to advance medical discovery and define best clinical practice via clinical outcomes research. As a research institution, Washington University is focused not only on providing the best care possible, but also in finding ways to make care even better. Properly designed EHRs create a searchable data base that can be used to answer important clinical questions about the efficacy and the safety of new therapies and procedures. We are designing our EHR system in such a way that anonymous patient data can be mined, analyzed and utilized to advance the practice of medicine. Electronic retrieval of clinical data will become increasingly important in the future as advances in genomics allow us to tailor or personalize medical therapies to make them more effective and reduce unwanted side effects.

Let me move on now to two key challenges and lessons learned as we have deployed our enterprise-wide EHR at Washington University School of Medicine.

The first point I would like to make is the startup costs are substantial. Once fully implemented, EHRs can enhance physician and support staff productivity and reduce operating expenses associated with paper-record storage, dictation and transcription of physician notes and copying and faxing of paper records to referring physicians and other consultants involved in a patients care. To achieve these improvements, the Medical School is investing $10.5 million to implement our EHR solution across the faculty practice, an average cost of $12,445 per faculty physician. Our experience suggests that while these gains will be sufficient to offset the ongoing maintenance costs for our EHR system, we will not recover the startup and development costs. This is a significant challenge for us to fund internally and is the major reason we are phasing in our EHR over a 4-year period.

The pace of EHR adoption on a national basis would be greatly accelerated if external public or private-sector funding were made available to help providers defray the cost of migrating from paper record systems to electronic format. This would also be a sound investment for governmental and private payors. For example, the Center for Health Information Technology has estimated that universal adoption of e-prescribing across the Nation would save payors $29 billion annually thanks to systems that automatically alert physicians to formulary coverage and generic drug options. While payors would be the primary beneficiary of universal e-prescribing, physicians must bear the implementation and ongoing maintenance cost for e-prescribing systems.

One of the merits of H.R. 4832 is the creation of statutory safe harbors that would allow hospitals and payors to donate health IT software and hardware to physicians, thereby helping to mitigate the substantial financial costs associated with EHR adoption. As the door is opened for the donation of technology, we believe steps should be taken to ensure that such assistance is motivated by the goals of improved patient care and quality and not for purposes of competitive advantage.

Direct Federal funding to help providers implement EHRs would serve as an even greater catalyst to facilitate the widespread physician adoption of health information technology and should be given serious consideration.

The second point I would like to make has to deal with the complexity of designing an integrated EHR. A key challenge in getting physicians to migrate to electronic health records is demonstrating their value. Busy clinicians must feel confident that an EHR will enhance their ability to deliver better care and to enhance patient safety. Physicians also need assurances that any EHR solution will improve, not impede, physician and staff productivity. To provide these assurances, we have taken great care to design our EHR to meet the unique needs of each subspecialty in terms of what information is captured and how that information is organized in an electronic format to streamline work flow and efficiency.

We have developed a process for engaging the physician and support staff stakeholders within each subspecialty to customize the design of our EHR to meet their particular needs. This process takes, on average, 6 months to complete the design, train the physicians and staff and then "go live."

We have also had to invest significant time and resources in building interfaces with other clinical information systems to provide our clinicians with the ability to review radiology studies online and to review lab results and inpatient hospital data within a single integrated electronic record.

The take-home lesson here is that designing and building a robust EHR requires careful thought, meaningful stakeholder engagement and most importantly, time. The complexity of EHR development and implementation needs to be appreciated by Federal leaders as they craft legislation defining timelines and standards for electronic health records.

We recognize that legislation such as H.R. 4832 is intended to foster the growth of interoperable health information systems. I am

encouraged by such efforts, especially those to assist healthcare providers in making this paradigm change.

Thank you, again, for the opportunity to share our experience and our perspective as providers and for your understanding of these complex and important issues.

[The prepared statement of Dr. Crane follows:]

1) **The ability to have a single integrated patient chart**

Historically, each of our 53 subspecialties has maintained their own paper medical record system. As you can imagine, managing paper records for 300,000 patients seeking the care of 53 different subspecialties across a 130 acre campus, not to mention our dozens of off-campus clinics, is an enormous and highly complicated undertaking. Our EHR initiative allows us to integrate these separate paper charts into a single electronic health record for each patient. This gives all of the physicians involved in a patient's care instant access to all relevant medical information and eliminates the need to request paper records from multiple caregivers. Having immediate access to comprehensive patient information improves both the quality and efficiency of medical care.

2) **The ability to have real-time access to a patient's chart after-hours**

Patients commonly present at nights or on weekends with emergent and sometimes life-threatening situations, creating a challenge for physicians and nurses if a medical record is not immediately available. An integrated EHR provides the treating physician with instant access to a complete list of the patient's medical problems, their medications, and other information regarding their past medical history that can eliminate the need for redundant testing, expedite care and prove critical in guiding management and influencing clinical outcomes. In addition, the patient's medical record can be accessed via a HIPAA-compliant secure network from virtually any location, including a physician's academic office, their home or even from out-of-town.

3) **The opportunity to enhance patient safety**

The *Institute of Medicine* estimates that 1.5 million Americans are injured annually by preventable medication errors. Our EHR solution includes an e-prescribing component that guards against medication errors via built-in logic that automatically checks for proper dosage, drug allergies and potential adverse interactions with other medications the patient may be taking.

Another way to enhance patient safety is via the "task management" functionality built into our EHR solution. As an example, the system automatically alerts the ordering physician of

any abnormal lab results. This ensures that abnormal findings are acted upon promptly and not inadvertently lost or filed without physician review.

4) **The ability to advance medical discovery and define "best clinical practice" via clinical outcomes research**

As a research institution, Washington University is focused not only on providing the best clinical care possible, but also in finding ways to make care even better. Properly designed EHR's create a searchable database that can be used to answer important clinical questions about the efficacy and safety of new therapies and procedures. We are designing our EHR system in such a way that de-identified patient data can be mined, analyzed and utilized to advance the practice of medicine. Electronic retrieval of clinical data will become increasingly important in the future as advances in genomics allow us to tailor or personalize medical therapies to make them more effective and reduce unwanted side effects.

Let me move on now to two key challenges and "lessons learned" as we have deployed our enterprise-wide EHR at Washington University School of Medicine:

1) **The start-up costs are substantial!**

Once fully implemented, EHR's can enhance physician and support staff productivity and reduce operating expenses associated with paper record storage, dictation and transcription of physician notes and copying and faxing of paper records to referring physicians and other consultants involved in a patient's care. To achieve these improvements, the Medical School is investing $10.5 million to implement our EHR solution across the faculty practice, an average cost of $12,445 per faculty physician. Our experience suggests that while these gains will be sufficient to offset the ongoing maintenance costs for our EHR system, we will not recover the start-up and development costs. This is a significant challenge for us to fund internally and is the major reason we are phasing-in our EHR over a 4-year period.

The pace of EHR adoption on a national basis would be greatly accelerated if external public or private sector funding were made available to help providers defray the cost of migrating from paper record systems to electronic format. This would also be a sound investment for governmental and private payors. For example, the *Center for Health Information*

Technology has estimated that universal adoption of e-prescribing across the nation would save payors $29 billion annually thanks to systems that automatically alert physicians to formulary coverage and generic drug options. While payors would be the primary beneficiary of universal e-prescribing, physicians must bear the implementation and ongoing maintenance costs for e-prescribing systems.

One of the merits of HR 4832 is the creation of statutory safe harbors that would allow hospitals and payors to donate health IT software and hardware to physicians, thereby helping to mitigate the substantial financial costs associated with EHR adoption. As the door is opened for the donation of technology, we believe steps should be taken to ensure such assistance is motivated by the goals of improved patient care and quality and not for purposes of competitive advantage.

Direct federal funding to help providers implement EHR's would serve as an even greater catalyst to facilitate widespread physician adoption of health information technology and should be given serious consideration.

2) **The complexity of designing an integrated EHR is significant!**

A second key challenge in getting physicians to migrate to electronic health records is demonstrating their value. Busy clinicians must feel confident that an EHR will enhance their ability to deliver better care and enhance patient safety. Physicians also need assurances that any EHR solution will improve, not impede, physician and staff productivity. To provide these assurances, we have taken great care to design our EHR to meet the unique needs of each subspecialty in terms of what information is captured and how that information is organized in an electronic format to streamline work flow and efficiency.

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We have also invested significant time and resources to building interfaces with other clinical information systems to provide our clinicians with the ability to review radiology studies, lab results and inpatient hospital data within a single integrated electronic record.

The "take home" lesson here is that designing and building a robust EHR requires careful thought, meaningful stakeholder engagement and most importantly, time. The complexity of EHR development and implementation needs to be appreciated by federal leaders as they craft legislation defining timelines and standards for electronic health records.

We recognize that legislation such as HR 4832 is intended to augment federal initiatives underway to foster the growth of interoperable health information systems. I am encouraged by such efforts, especially those to assist health care providers making this paradigm change.

Thank you again for the opportunity to share our experience and perspective for your understanding of these complex and important issues. I would be happy to entertain any questions you may have.

Mr. PORTER. Thank you, Dr. Crane. I appreciate it. Next is Mark Rothstein, director, Institute for Bioethics Health Policy. Welcome.

STATEMENT OF MARK A. ROTHSTEIN INSTITUTE FOR BIOETHICS, HEALTH POLICY, AND LAW UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE

Mr. ROTHSTEIN. Thank you very much. Good afternoon, Chairman Porter, Representative Clay. My name is Mark Rothstein. I am the Director of the Institute for Bioethics Health Policy and Law at the University of Louisville School of Medicine. I am also Chair of the Subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics, which is the statutory public advisory committee to the Secretary of Health and Human Services on health information policy. I am testifying today in my individual capacity.

I am pleased to testify about the significant privacy and confidentiality issues surrounding the conversion of our health records system from paper to electronic form and the linking of electronic health record systems through an interoperable network to create the Nationwide Health Information Network.

Many individuals are concerned about the potential for sensitive information to be divulged through negligent or intentional acts of snoops, hackers, rogue employees, or—as we've seen recently—the careless storage of sensitive information. Although these concerns are valid and demand strong security measures, I want to focus on more fundamental questions of privacy and confidentiality. In short, as we move from paper to electronic records, its not just the form of the records that will change, its the magnitude and nature of the contents.

Today, the No. 1 protection for privacy and confidentiality of individual health information is the fragmentation of the health records system. It would be practically impossible to aggregate all of the paper health records for the typical adult who has lived in several places and who has seen numerous healthcare providers for a myriad of conditions over many years. In an electronic health records system, however, the fragmentation will be gone. That's a good thing for a variety of individual and public health reasons that you heard discussed previously. But, it will mean that with a few key strokes, healthcare providers will be able to obtain all of an individual's health records. In many cases, the old records will have no medical relevance or clinical utility to the reason the person is currently being treated. Furthermore, the old records may contain extremely sensitive information related to domestic violence reports, drug and alcohol treatment, reproductive health, sexually transmitted diseases, mental health, and all sorts of other things.

An even more troubling implication is the fact that individual health records are frequently used in nonhealthcare settings. It is common for employers, life insurers, and other third parties to condition a job or an insurance policy on an individual signing an authorization for the release of his or her health records. Such practices are legal. According to my research, there are approximately 25 million compelled authorizations in the United States each year. Today, sensitive health information is disclosed to numerous enti-

ties, many of which are not covered under the HIPAA Privacy Rule. In the future, the volume and detail of these records will increase greatly.

In designing the NHIN, individuals need to be given a meaningful say in how their records are linked and disclosed. To date, however, there has been inadequate consideration of the specific rights of individuals to, for example, opt in or out of the NHIN or to control what records are disclosed and to whom. There also has been little effort in researching the feasibility of privacy-enhancing technologies that could be incorporated into the NHIN. If such measures are not included within the NHIN architecture, it may be too late or prohibitively expensive to add these features in the future.

Mr. Chairman and Representative Clay, our health records system and our healthcare system in general are based on the trust that individuals have in their physicians, nurses, and other professionals to safeguard their confidential information. If we develop an interoperable, comprehensive health records system that undermines patient trust, then the political support for the NHIN will be destroyed, and substantial numbers of individuals are likely to engage in defensive practices to protect their privacy that could jeopardize their own health and also the health of the public. I thank the members of the subcommittee, and I look forward to your questions.

[The prepared statement of Mr. Rothstein follows:]

TESTIMONY OF MARK A. ROTHSTEIN
INSTITUTE FOR BIOETHICS, HEALTH POLICY, AND LAW
UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE

before the

SUBCOMMITTEE ON THE FEDERAL WORKFORCE
AND AGENCY ORGANIZATION

HOUSE COMMITTEE ON GOVERNMENT REFORM

Using Information Technology: For the Health of It

St. Louis, Missouri
September 1, 2006

MR. CHAIRMAN and members of the Subcommittee. My name is Mark Rothstein. I am the Herbert F. Boehl Chair of Law and Medicine and Director of the Institute for Bioethics, Health Policy and Law at the University of Louisville School of Medicine. I am also Chair of the Subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics, the statutory public advisory committee to the Secretary of Health and Human Services on health information policy. I am testifying today in my individual capacity.

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Many individuals are concerned about the potential for sensitive information to be divulged through negligent or intentional acts of snoops, hackers, rogue employees, or – as we've seen recently in other contexts – the careless storage of sensitive information. Although these concerns are valid and demand strong security measures, I want to focus on more fundamental questions of privacy and confidentiality. In short, as we move from paper to electronic records, it's not just the form of the records that will change – it's the magnitude and nature of the contents.

Today, the number one protection for privacy and confidentiality of individual health information is the fragmentation of the health records system. It would be practically impossible to aggregate all of the paper health records for the typical adult who has lived in several places and who has seen numerous health care providers for a myriad of conditions over many years. In an electronic health records system, however, the

fragmentation will be gone. That's a good thing for a variety of individual and public health reasons. But, it will mean that with a few key strokes, health care providers will be able to obtain all of an individual's health records. In many cases, the old records will have no medical relevance or clinical utility to the reason the person is currently being treated. Furthermore, the old records may contain extremely sensitive information related to domestic violence reports, drug and alcohol treatment, reproductive health, sexually transmitted diseases, mental health, and other matters.

An even more troubling implication is the fact that individual health records are frequently used in non-health care settings. It is common for employers, life insurers, and other third parties to condition a job or an insurance policy on an individual signing an authorization for the release of his or her health records. Such practices are legal. According to my research, there are approximately 25 million compelled authorizations in the U.S. each year. Today, sensitive health information is disclosed to numerous entities, many of which are not covered under the HIPAA Privacy Rule. In the future, the volume and detail of these records will increase greatly.

In designing the NHIN, individuals need to be given a meaningful say in how their records are linked and disclosed. To date, however, there has been inadequate consideration of the specific rights of individuals to, for example, opt in or out of the NHIN or to control what records are disclosed and to whom. There also has been little effort in researching the feasibility of privacy-enhancing technologies that could be incorporated into the NHIN. If such measures are not included within the NHIN architecture, it may be too late or prohibitively expensive to add these features in the future.

Mr. Chairman, our health records system and our health care system in general are based on the trust that individuals have in their physicians, nurses, and other professionals to safeguard their confidential information. If we develop an interoperable, comprehensive health records system that undermines patient trust, then the political support for the NHIN will be destroyed and substantial numbers of individuals are likely to engage in defensive practices to protect their privacy that could jeopardize their own health and the health of the public.

I thank the members of the Subcommittee, and I look forward to your questions.

Compelled Disclosure of Health Information

Protecting Against the Greatest Potential Threat to Privacy

Mark A. Rothstein, JD
Meghan K. Talbott, JD

IN 2004, PRESIDENT BUSH CALLED FOR WIDESPREAD ADOPtion of interconnected electronic health records (EHRs) within 10 years.[1] The US Department of Health and Human Services (HHS) has been charged with leading these efforts, including developing the Nationwide Health Information Network (NHIN). Although the specifics of the NHIN and its component organizations are still being developed, it is envisioned as a public-private partnership of health information organizations using common electronic formats, thereby enabling ease of access to EHRs through any secure portal. The NHIN will link health records maintained in hospitals, physicians' offices, clinics, and other locations.

In concept, an interconnected system of EHRs will benefit patients, clinicians, and the public. For patients, EHRs will provide ready access to personal health information, facilitate active management of care, enable use of telehealth services, permit better disease management, and allow for greater choice in health care. For clinicians, EHRs will save time in obtaining patient histories, permit writing of prescriptions electronically with greater accuracy, help reduce medical errors, and ease coordination of care. For the public, EHRs will permit real-time public health surveillance, allow for distribution of evidence-based standards of care tailored to each patient, and facilitate outcomes research.

However, the potentially easy access to large volumes of identifiable health information through interconnected EHRs also raises serious concerns about privacy and confidentiality. Most officials[2] and commentators[3,4] recognize the importance of ensuring health privacy in the NHIN, but privacy analyses have centered on computer security issues[5] and whether to provide individuals with some level of control of the content of their health records.[6] Little or no attention has been given to mechanisms to prevent the disclosure of sensitive health information with no current clinical usefulness when third parties compel individuals to disclose their health information.[6] Although compelled disclosures have been largely unexamined, they must be controlled to protect health privacy and confidentiality.

Legal Framework

In the United States, laws to protect health information privacy and confidentiality are largely designed to protect against unauthorized access to, use of, and disclosure of personal health information. A variety of state and federal laws attempt to make health information secure from snoops, hackers, and rogue health care employees.[7] Some laws specify the form in which health records may be stored or transmitted; other laws attempt to punish unauthorized access through civil or criminal sanctions.[8] Although these laws are valuable, they fail to address the compelled, authorized disclosure of personal health information.

As a condition of applying for employment, various types of insurance, and certain benefit programs such as Social Security Disability Insurance or workers' compensation, millions of Americans each year sign authorizations for the release of vast amounts of personal health information maintained in files at physicians' offices, hospitals, and other health care settings. There can be no effective protection of health privacy and confidentiality unless compelled, authorized disclosures of health information are regulated. Yet legally and practically, this will be difficult to accomplish.

Few current laws place any restrictions on the scope or level of detail of information that third parties may require individuals to release pursuant to an authorization. Even if there were legal restrictions, it would be practically impossible in most instances for the custodians of health records to limit the disclosure. Typical paper-based health records, such as most hospital and physician office records, are often a montage of disparate reports and clinical encounters involving wide-ranging conditions over a prolonged period of time. The records may intermingle routine clinical data with sensitive information such as mental health, genetic test results, sexually transmitted diseases, human immunodeficiency virus (HIV) antibody status, sexual history, history of abortions and other reproductive matters, domestic violence, and drug and alcohol abuse. The disclosure of such sensitive health information to entities without a treatment relationship, without a need to know, and for nonmedical purposes may lead to embarrassment

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and stigma. The mere possibility of such a disclosure also may lead individuals to forgo some potentially beneficial medical tests and procedures or even medical care altogether.[9]

Health Insurance Portability and Accountability Act. Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[10] the HHS promulgated Standards for Privacy of Individually Identifiable Health Information (Privacy Rule).[11] The Privacy Rule applies only to 3 classes of "covered entities" (health providers, health plans, and health clearinghouses [which standardize the format of health claims information]).[12] With a few exceptions, the Privacy Rule does not limit who may request or require an authorization. Although covered entities generally may not condition the provision of health care on the signing of an authorization,[13] the Privacy Rule permits health plans to condition enrollment on the provision of an authorization. It also does not prohibit noncovered entities, such as employers and life insurers, from making execution of an authorization a condition of commencing employment or applying for insurance.

Americans with Disabilities Act. The employment provisions of the Americans with Disabilities Act of 1990 (ADA)[14] attempt to regulate the flow of health information to employers so that individuals with disabilities may be considered for employment based on their abilities before an employer may consider an individual's actual or perceived limitations. Under the ADA, an employer's access to an individual's health information depends on the time at which the information is sought. After a conditional offer of employment, an employer is permitted to inquire into the health status of the individual and may require the individual to submit to a medical examination performed by a clinician of the employer's choosing.[15] The ADA also does not prohibit employers from requiring that the individual sign an authorization to disclose to the employer or its designee *all* of the individual's health records maintained by any past or current clinician. It is unlawful for an employer to withdraw a conditional offer of employment for a health-related reason unless the individual, even with reasonable accommodation, is unable to perform the essential functions of the job.[16] Consequently, an employer is entitled to receive health information of a broader scope than it is permitted to use. State disability discrimination laws generally follow the same framework as the ADA.

Other Laws. Most states have laws restricting the disclosure of HIV/AIDS information without individual consent.[17] Federal regulations also prohibit the unauthorized disclosure of substance abuse treatment information.[18] Laws regulating insurance do not restrict the scope of health information insurers may obtain in applications or claims processing.[19] Even when there are legal restrictions, such as many workers' compensation laws,[20] it is usually not feasible for a clinician or health record custodian to isolate the claims-related information in a large medical record.

Compelled Authorizations

It is impossible to calculate the precise number of compelled authorizations for disclosure of health records in the United States each year, but the figure is likely in the millions. Compelled authorizations are required for many purposes, including employment entrance examinations, individual health insurance applications, individual life insurance applications, individual long-term care insurance applications, individual disability insurance applications, individual and group disability insurance claims, automobile insurance personal injury claims, Social Security Disability Insurance applications, workers' compensation claims, veterans' disability claims, and personal injury lawsuits.

Effects of Compelled Disclosures

Disclosure of sensitive health information may result in the inability to obtain insurance or employment. In addition, individuals may experience embarrassment, humiliation, shame, anxiety, and depression if their health secrets are revealed. That is why many individuals withhold some sensitive health information from their loved ones, closest friends, and even their physicians. Yet these individuals may not be able to withhold sensitive health information from other unknown third parties if they want to be considered for employment, other essential life activities, or insurance.

Assuming that the non–health care entities to which the disclosures are made are diligent in limiting access to individuals with a need to know, there is still cause for concern about disclosure. For example, in small towns the insurance agent or the human resources manager at a prospective employer may also be the individual's neighbor or friend. At small companies, even in large cities, most or all of the employees know each other. Furthermore, once disclosure of health information is made to an entity not covered by HIPAA pursuant to an authorization, HIPAA does not prohibit the redisclosure of the information.

Confidentiality is a foundational principle of medical ethics. Modern health care would be exceedingly difficult if patients were not willing to disclose sensitive information to their physicians, but patient disclosure is founded on the belief that the physician will not wrongfully disclose the information. In the Oath of Hippocrates, physicians pledge that they will never reveal the secrets of their patients. A similar provision appeared in the American Medical Association's first Code of Ethics in 1847,[21] and comparable statements have been included in the codes of ethics of physicians, nurses, dentists, and other health professionals ever since.[22]

There is ample evidence that concern about confidentiality adversely affects health care. According to a 1999 California Health Care Foundation study,[23] 1 in 6 Americans reported that they had taken some sort of evasive action to avoid the inappropriate use of their health information by providing inaccurate information to a physician, changing

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physicians, or avoiding care altogether. A follow-up study in 2005 by the foundation found that, despite the intervening enactment of the HIPAA Privacy Rule, 1 in 8 Americans still engaged in evasive action to protect health privacy, even though doing so may present a risk to their health.[24] Vulnerable patients (eg, minors) and individuals with potentially stigmatizing medical conditions (eg, HIV infection, substance abuse, and mental illness) may be even more likely to forgo care that is essential for their own health and the health of the public.

Contextual Access Criteria

By aggregating and disseminating comprehensive health information, EHRs and the NHIN present challenges to health privacy and confidentiality. The development of new health information technology, however, also creates a unique opportunity to enhance privacy and confidentiality by designing ways to limit the scope of disclosures for nonmedical purposes.

Contextual access criteria enable holders of individual health information to limit the scope of disclosures for nonmedical purposes based on the type of information needed by the third party. For example, contextual access criteria would enable disclosures to life insurers to include only health information relevant to mortality risk. Similarly, employers would be able to access only health information relevant to an individual's ability to perform specific job-related functions.

Contextual access criteria is a concept, not an available technology. Although there is reason to believe contextual access criteria could be successfully developed, experts in health information systems design must conduct research and undertake pilot testing before possibly incorporating this technology into the NHIN. Unfortunately, no such initiatives are being pursued in the public or private sectors.[25]

Should such initiatives develop, systems design experts, third-party users of health information (eg, employers, insurers), clinicians, health care organizations (eg, hospitals, health systems), consumer and privacy representatives, and government officials need to collaborate in developing standards for each application of contextual access criteria. The applications will vary in difficulty of design and implementation. For example, life insurance may be one of the easiest applications because life insurers are interested in a single medical determination (mortality risk). By contrast, employment is likely to be the most complicated application because there are thousands of different job classifications with different physical and mental demands.

Undoubtedly, there will be political concerns to address. Some current recipients of complete health records are likely to oppose any limitations on their prerogatives. On the other hand, contextual access criteria may be welcomed by some third-party users of health information for legal and practical reasons. For example, employers often receive more personal health information pursuant to an authorization than they can legally use. If an HIV-positive individual applies for a typical job, state and federal law would preclude the employer from using the individual's HIV status in deciding employability. Any adverse action against the individual could result in a lawsuit because the individual might assume that the basis for the employer's action was his or her HIV status. With contextual access criteria, however, employers could avoid potential liability by receiving only job-related health information.

The use of contextual access criteria also promotes individual and population health. Limiting the disclosure of sensitive health information to third parties will reduce the incentive for patients to engage in defensive practices by withholding information from their treating physicians. Furthermore, there are significant intangible benefits to core health care values, such as justice and respect for persons, when a society not only espouses a commitment to privacy and confidentiality, but actually takes the steps to implement a system to ensure that the rhetoric becomes a reality. Ultimately, protecting privacy and confidentiality through contextual access criteria will be complicated and depend on developing the health information technology, enacting legal provisions to restrict the scope of permissible disclosures of health information to third parties for nonmedical uses, and applying more specific medical evaluation criteria by third-party users.

Conclusions

Currently, the leading protection for privacy and confidentiality of personal health information is the fragmentation of paper-based health records. It is virtually impossible to locate and collect all of an individual's medical records stored by different clinicians and health care organizations (eg, hospitals, health systems) in different geographical areas. The older the records, the more difficult they would be to access. Thus, most individuals generally can be confident that years- or decades-old, sensitive health information that may have no current clinical usefulness is unlikely to be disclosed when they authorize release of their medical records for employment or insurance purposes.

However, the world of health information technology is rapidly changing. Interconnected networks will soon have the capacity to link easily and instantly EHRs from numerous locations kept by diverse clinicians and health care entities. Privacy and confidentiality protection through fragmentation will no longer exist. One possible replacement will be a system in which disclosures to third parties for purposes unrelated to health care will be comprehensive and longitudinal, with all requestors receiving the complete health records of the individual. Another possibility is that contextual access criteria will enable the disclosure only of relevant health information, granting authorized third parties access to necessary health information but keeping other information confidential.

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The decision about which vision to embrace must be made over the next several months. Contractors selected by the HHS already have begun work on initial system design proposals for the NHIN. If privacy and confidentiality protections are not part of the architecture of the NHIN, it will be very difficult, and perhaps cost-prohibitive, to add privacy-enhancing features to the system in the future. Furthermore, without a mechanism to limit the scope of disclosures to third parties pursuant to an authorization, the creation of the NHIN has the potential to result in a major loss of privacy and confidentiality.

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Subcommittee on Federal Workforce and Agency Organization
Committee on Government Reform

September 1, 2006

Using Information Technology: For the Health of It

Testimony by James P. Crane, M.D.
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CEO, Washington University Physicians Faculty Group Practice
Washington University School of Medicine

Mr. Chairman and Congressman Clay, thank you for the opportunity to appear before you to discuss the benefits and challenges of utilizing health information technology (HIT) to improve the quality and delivery of health care.

My name is James Crane. I am an actively practicing physician and also serve as CEO of Washington University's faculty group practice. Our group practice is composed of 980 faculty physicians or roughly one in every 10 physicians practicing in the State of Missouri. We are the third-largest academic group practice in the nation and we encompass 53 different medical and surgical subspecialties. We care for nearly 300,000 patients annually with 75% of our clinical activity occurring here on the Medical Center campus and the remaining 25% distributed across 49 locations in suburban St. Louis and rural Missouri and Illinois. We are the largest Medicaid physician provider in the State of Missouri and a critical provider of specialty care for the uninsured.

I am here today to share with you our progress in implementing an electronic health record (EHR) for our patients, the benefits we hope to achieve and the hurdles we face.

Many of our patients have chronic and complex medical problems and require highly coordinated care involving several of our physicians. This, along with the geographically distributed nature of our clinical practice, were major catalysts for implementing an electronic health record.

EHR's offer many advantages for both patients and providers. My comments today will focus on four specific ways in which the quality and efficiency of patient care can be enhanced by HIT:

Mr. PORTER. Thank you very much. We appreciate your testimony. I will open up the questions from the panel. And due to time, we will be submitting additional questions for you to respond to after today's meeting.

Mr. Clay, would you have any questions?.

Mr. CLAY. I would like to start with Mr. Paz. Your testimony was pretty compelling, and I know that a major concern within your industry is that many States have different E-prescribing standards that are not uniform with Federal standards authorized for Medicare. Please explain to us how this impacts your business and services provided. Is legislation required to harmonize Federal and State standards as some have proposed, or are current HHS E-prescribed standards adequate to meet the needs of our——

Mr. PAZ. Yes, Congressman Clay. In response to your question, I would say that there are several limiters for physician adoption of electronic prescribing. One that is often cited is that of trying to get a universal standard, because the concern is that to the extent that the one that exists in the Medicare Modernization Act doesn't necessarily comport with all State laws. It has to be—it has to fit both of those two different standards. As you know, the State pharmacy boards often regulate those type areas and impact on the legislation that's ultimately passed.

And when we look at that, we see that many different physicians are more reluctant to adopt the technology because, again, they don't want to go through the cost and the hassle of implementing if in fact they don't know for sure what the ultimate end game is going to be. I think if we could standardize the end game, we have a much better chance of getting adoption by the physicians.

Mr. CLAY. How about in your business, the interoperability between you and your competitors? Is that easy for you-all to communicate, to do comparison of E-script, I guess, with your patients and maybe you-all have common patients, share patients, can you all communicate now?

Mr. PAZ. Yes, us and our two largest competitors. There are three large prescription benefit managers in the United States: Express Scripts, Medco Health Solutions and Caremark. The three of us have come together and standardized the process through an entity call RxHub which we each have funded in order for it to help identify a standard process in this vein. So to the extent that you are a member or your prescription is managed by any one of the three of us, that data is there. It is on the standardized format. Any type of device that accesses that data can go into the RxHub and find out which of our different plans actually exist, and from that we can gain eligibility data, prescribing information on that individual, a whole wealth of data that can really have a very positive outcome on that member's—that patient's ultimate health outcome.

Mr. CLAY. Thank you for the response.

Dr. Crane, we have just passed the first anniversary of Hurricane Katrina, and in a few days we will mark the fifth anniversary of the 9/11 attacks. One of the lessons that we learned from these national tragedies is that in case of a terrorist attack or a major national disaster, emergency responders are hampered by a lack of information and inability to communicate with each other quickly.

From the homeland security perspective, in a national emergency, how valuable would a secure national electronic health records network be for emergency room physicians and other medical providers?

Dr. CRANE. I would think again, it would be extremely valuable, Congressman Clay, to be able to access patient information like that in such situations. I would say that I think the issue of disaster preparedness is more complicated than that. We had the experience here in St. Louis after Katrina. While we weren't directly affected, we mobilized and staffed a command center out at the airport, and that was a demonstration to me, again, of perhaps there were opportunities to improve our preparedness just to be able to manage and staff a facility such as that, mobilize the manpower, for example, to be able to staff such a facility. And recently we had a severe heat wave and power outage in the St. Louis area and I think we did a little better that time around. There were some of the emergency rooms in the area that stopped accepting new patients, some hospitals that had to stop admitting new patients, and we learned some lessons from Katrina. But I believe there is still opportunity to improve.

To answer your question, I think, again, it could be extremely valuable. We have to make sure that the system not only exists but they can be operated in emergency situations. You have to have redundant facilities. And one of the concerns in this area would be an earthquake. So wherever that information is housed is impacted, again, having a system in and of itself is not very helpful.

Mr. CLAY. I am sure your experience with the Katrina evacuees was very difficult to piece together their medical history once they arrived here.

Dr. CRANE. Absolutely.

Mr. CLAY. Thank you very much.

Mr. PORTER. I want to talk about one of the success stories for the moment of Katrina, and in the hours before Rita, Blue Cross Blue Shield transferred about 800,000 of their insurer's files from manual to electronic data form literally in 4 days. That's true of the success of the industry, 800,000 in 4 days. I know that concern about losing files in that natural disaster. And I know you mentioned Homeland Security and how critical that is.

We experience a challenge in our community of Nevada with 40 million visitors a year in a State of about 2.2 million people. Of course, a lot of folks who travel aren't sure about all their health information. And I've had a number of meetings and hearings in Nevada, and if I could mention Colorado, but probably 10 to 12 percent of the visitors to our emergency rooms in Nevada are visitors for different reasons. Unfortunately a lot of folks don't know what their information is. And as I mentioned in my opening statement, may not even be conscious for some health related reasons. So it is difficult.

What I saw today at Barnes-Jewish Hospital is really an example of where we need to be around the country. I know that a lot of companies don't have the ability—or healthcare providers don't have the ability to do what the hospital has done here, but it truly is an example. If more of those in the private sector would do what

the hospital is doing here, we wouldn't need to be having hearings by the way because they have done a tremendous job.

But a concern that I have is privacy. I hear all the time, especially as we are looking at the Federal employees, with the employee labor organizations, and they are very concerned. I know that we trust our banks and our financial institutions and our ATM machines and maybe we shouldn't but we do. We trust that information when we enter—when I check on my mortgage or check on other financial tools that I have, I go to the Web. I am wondering in healthcare, probably one of the bigger areas of concern is if you are in a hospital bed and there is a chart sitting outside your door, there really is access to information, and I think what we learned at least this morning, a Xerox machine can copy a lot of papers in a hurry so there is not a whole lot of privacy, even though they try in a hospital setting. But I guess my question has to do with how we can eliminate some of these fears on the security side. Can we trust our financial institutions? It seems to me the only one that has all of our health information—or the only one that doesn't have the health information is the individual. Everybody else has it. But what can we do to provide more security? I know this is your area. Could you help us a little bit, Mr. Rothstein?

Mr. ROTHSTEIN. Yes. I would be happy to try. I think security is a major concern of the public. And actually if you see polls or do them yourselves as I have done of the public and you ask them are you concerned about health privacy, they tell you, yes, I'm worried about somebody hacking into my records. So what they associate as privacy really is, as you mentioned, security.

There are all sorts of technological proposals and possible solutions to make them more secure. But you raised, I think, a very good point relative to, how do you build the public's confidence that whatever measures we would come up with really do work. That I think takes a major effort that we have not yet been willing to undertake.

For example, when we enacted HIPAA and put the privacy rule into place, there was very little in the way of public and professional education. If we don't do a better job with the NHIN, then I'm afraid we'll have all these doubts that you suggested might occur. And so the public really needs to have a degree of confidence that their records will not be wrongfully disclosed. The only way we can do this is to make sure that people have a role in formulating what the rules are and also that they get good information about what the protections are that are in place.

Mr. PORTER. I guess what concerns me is that, again, my information is available to the world right now. I can't get it as an insurer or a patient, but everyone else can get my information. It seems to me that we can put in technology safeguards where actually I could see the information for once, and not unlike Barnes-Jewish where there is a log of anyone that checks in, any information there is a log, and anyone that checks in has to have the proper credentials, it seems to me that we can provide that protection, but why is it that we trust our banks but we would not trust our healthcare?

Mr. ROTHSTEIN. Well, I think for many people healthcare information is conceived of being even more sensitive than financial information. You have some kinds of illnesses that are tremendously stigmatized and that, for example, could result in someone losing their ability to get health insurance or life insurance or employment or all sorts of other things. Or they fear this, whether it will actually happen or not. So I think health information is sort of in a special category that people are more worried about. And also, it is much more complicated and complex than financial information. It goes over a long period of years and it has many different dimensions than most people's financial information. And I think what happens to that, people don't really understand.

Mr. PORTER. With our financial records, if the credit reporting is wrong, we fix it. With healthcare, we have no idea what information they have and they could be providing improper information now because we don't know what it is.

Mr. ROTHSTEIN. That's right, and under the privacy rule you have a right to suggest corrections, but you don't have a right to make those corrections. And, in fact, many healthcare providers have informally or formally adopted the policy of never making corrections to records because they think it is going to be a bad precedent. So they will take you—if you want to put something in your file, fine, but we are not changing what's already in our file, even if it misidentifies a person or has somebody else's lab results, they tend to stay in there and you can object and suggest a correction.

My main concern about privacy is the scope of the information and who gets it. There are lots of people who have, that is third party entities, not healthcare people, who have a legitimate interest in individual's health information, but not the comprehensive cradle to grave healthcare information. We currently have no way of restricting the amount of information that is disclosed. So as a practical matter, even if I have an enlightened employer or an enlightened insurance company and they say send me Mark's healthcare information that's related only to this topic, don't send me the rest, there is no way to do that. I am concerned that we are putting into effect an electronic system that doesn't have that capacity either. The amount of information that will be disclosed is going to be much more great.

Mr. PORTER. I think there is presumption and reality and I think they are two different issues, but do you think there is the ability to protect this information if done properly.

Mr. ROTHSTEIN. I think there is. Unfortunately, we haven't spent any money in the private or public sectors researching and trying to develop the technology that would allow us, for example, to develop what's called contextual access criteria. This was one of the recommendations of the National Committee on Vital Health Statistics, the secretary in our June letter, and what this would do, this would be a way of designing information to segregate it into various categories, and so that when someone says I have a Workers' Compensation claim that was filed, then the orthopedic information and so forth would go and other kinds—I'm told in a hearing from the designers of the NHIR, this could be done, but there is no push to do that.

We also think that there should be in the healthcare uses role-based access criteria. Now, most of the integrated healthcare systems such as Wash U, and I assume this is the case and I am assure Dr. Crane will correct me, even though the people at Wash U Medical Center, if their healthcare providers have a right to see patient's records, they don't have the same right of access depending on what their job category is. So, in other words the food service workers don't get to see the full records. The billing clerks don't get to see the full records but the physicians do. What we've suggested is that when records are transported via the NHIN downstream to somebody else, that those protections go with them. So that records that are discovered or obtained through the NHIN also come with a capacity and the restrictions of these role-based limitations. Unless we built that into the system, we're going to have a system that provides less privacy protection than the individual healthcare systems that we have.

Mr. CLAY. Thank you, Mr. Chairman. Mr. Powner, we know that at least 50,000 Americans die needlessly each year because of medical errors due to incomplete or inaccurate medical records, lack of coordination of care between providers and unforeseen drug interactions. Any estimate on how many lives you think could be saved if we have any national health IT?

Mr. POWNER. I think when you look at the national statistics, it is in the tens of thousands of people that die annually due to medical errors. It is clear, we don't have exact numbers, but clearly you are talking tens of thousands that could clearly be affected due to the current errors that exist.

Mr. CLAY. Let me ask you about the NHIN that Mr. Rothstein just mentioned it. Can you identify the flaws in the NHIN planning efforts concerning issues of security, reliability and long-term integrity, and would you agree that the NHIN, once created, should be considered a component of our Nation's critical infrastructure, isn't it no different in concept than an electric grid serving a region.

Mr. POWNER. Representative Clay, first of all, when you look at the NHIN it is currently in a prototype phase, so it is unclear exactly what the security measures will be. I know that's being looked at and I know Mr. Rothstein referred to that.

It is important, though, when we look at the NHIN that we build security in. We focused on security standards. We engineered in up front many years of looking at information security at the Federal agencies. That's one of the big problems, we don't engineer it up front and then we pay 10 times later down the road after we found out about the security vulnerabilities. So that will be key going forward when we look at our approach for the NHIN.

Now, your question in regards to critical infrastructure protection: Public health in the healthcare industry since the mid 1990's has been considered critical infrastructure along with the electric power grid, with our transportation systems, with chemical infrastructure. That's been called for in Presidential directives and Executive orders as well as laws that currently exist with Homeland Security.

The healthcare industry, similar to what we are discussing here, is behind the curve when it comes to securing our critical infrastructures. Public health, clearly when you look at public health

perspectives, that's critical infrastructure. Those of us who work in the critical infrastructure arena are very concerned about—when it is not a natural disaster but if it is a terrorist activity and you have a physical attack and then you attack the response mechanisms. So we talked about the benefits with Katrina where we have electronic health records that are now automated. If you actually had some cyber disruption, that could really wreak havoc. So clearly it should be considered critical infrastructure, but clearly the industry needs to move forward as our electric industry, the chemical industry and some of the others in advancing security in terms of critical infrastructure protection.

Mr. CLAY. Thank you. Mr. Green, a question. As a member of the AHIC panel, and since HHS declined to provide a witness today, I thought I might ask you a question about the panel activities. The AHIC (inaudible) for HHS to review and accept. These include standards for secure messaging, lab information transactions and certification of vendor products. As an AHIC participant, can you update us on the status of the recommendations and if the final standards have been developed.

Mr. GREEN. Representative Clay, I will sort of point out, I am not the best person to speak to this. But I can say that we, as members of the work group on consumer empowerment and being involved in the program that the standards—all of the recommendations that came from the work group require that standards be in place in order for many of the initiatives to be underway. It is my understanding that the first set of standards are scheduled to be issued this month.

Mr. CLAY. Thank you for that response.

Mr. PORTER. I have one additional question. What do you think—from the Federal side, what do you think we need to do to help expedite the implementation of the HIT across the country? What else can we do?

Mr. POWNER. Mr. Chairman, I think a couple things here. First of all, we need a clear strategy, a game plan going forward. We need a clear strategy going forward. Your focus is on leveraging, the Federal Government, we clearly need to do that. We need to create incentives for the private sector to participate and partner. I think it was mentioned by several of our panelists here, your legislation looking at grants and loan programs, that's a good one. It has been suggested that we offer tax incentives for providers who are implementing IT. If got serious about the incentives, we could help move the marketplace. If we got serious about leveraging the Federal Government as a purchaser and provider—I mean, we have 100 million people who are provided services through Federal healthcare programs. That would do a lot. Those would be the key items.

Mr. PORTER. What do you think, Mr. Green?

Mr. GREEN. Well, of course, my view is pretty parochial. I'm more interested and have responsibility for Federal employees and retirees and their families and their healthcare. But I do support the idea that the government should lead by example, and the Executive order that the president signed, the legislation that you each have proposed would help forward that. We are very large purchasers. My understanding is that one-quarter of all U.S. citizens

have health insurance through the Federal Government, so that can drive the marketplace. And of course, the reason that we are interested and we are doing this, is because it is—makes good sense for our program and for our enrollees. So hopefully if that can also further the overall effort, that's even better.

Mr. PORTER. Thank you.

Mr. CLAY. Thank you, Mr. Chairman. Mr. Paz, just kind of a final question that may help summarize some of what we heard today, we are hopeful that this national health IT system could save at least $80 billion per year in precious healthcare dollars. What impact would that money have if applied to closing the healthcare disparities gap among minorities and low-income Americans, and could be savings that also provide a way to help cover the 46 million Americans who don't have any health insurance. I don't know if you have given that any thought, but if you have, could you shed some light on it for folks.

Mr. PAZ. Absolutely, Congressman Clay. A couple things. First of all, to digress just slightly, since we are on the anniversary of the hurricane last year, I think it is important to note the value of electronic data and what exists today. When we look at what happened in New Orleans and the surrounding areas, many of the people were displaced. Many diabetics without insulin, many people in need of their heart medications. We at Express Scripts worked through the Labor Day weekend and worked with many of the boards of pharmacies. The States did a fabulous job, in my opinion, and also working together in order to relax those standards which require before a prescription can be dispensed that they could go back and look at our prescription drug data. So as an example, an individual who might be in Oklahoma City or here in St. Louis or in Minneapolis or anywhere else in the country, if we could show that person had an insulin prescription delivered within the last 6, 8 months, same thing with different medications, that the boards of pharmacy waive those rights so they didn't have to find a local doctor to write a prescription. I think that's a small testament to what actually—both the States working together with the private sector in order to develop solutions for people that were in great need. But it did take—it did utilize the electronic information that exists today. Now, to the extent that we can make that even more robust and get it in the hands of the prescribing physician, I think there is a tremendous opportunity here.

With respect to saving money, at Express Scripts, some of the studies that we have done, we believe that there could be a generic fill rate in excess of 70 percent in the marketplace today. On average, that number is running slightly north of 50 percent. For every 1 percent reduction means about a 1 percent reduction over all drug trends. Many physicians are influenced by the pharmaceutical manufacturers and the very expensive branded products coming to market. Sometimes those are required, but often the generic solutions are quite—are quite sufficient.

I think to the extent that we can utilize that information that exist today to inform the physician of the opportunities that exist out in the marketplace, it could free up significant—millions and millions of millions of dollars to then further help with those areas that you referenced, such as the needs of the uninsured. We still

have multiple, multiple layers of uninsured that exist today. And again, through the use of generics and other medication and access opportunities, I think it will go a long way to improving the health of millions of Americans today.

Mr. CLAY. Thank you for that response. And my time is up. I want to thank the entire panel for your testimony today. You have certainly shed some light on this important subject.

I want to also thank my constituents and those in the audience. I would love to hear from all of you here by e-mail, telephone, letter, and even verbally on your thoughts on health IT so that we can address it in a very adequate way that may relieve some of your fears, if you have fears, about the subject. And again, I want to also thank the chairman, Jon Porter, for being here and the entire staff of the government. Thank you very much.

Mr. PORTER. Thank you. And I think your last question summarized it really quite well. No. 1, we want to save money. Healthcare—we want to continue to have the best in the world, but we also want every man, woman and child to have access so it is not a have-and-have-nots issue. And that's why we are also working on some technology for Medicaid recipients. That's critical with some projects. We have $150 million I think we approved this year to help in Medicaid so everyone can have access to health technology. And I think some of the Medicaid recipients probably need as much as anyone because of the moving around and different communities. We want to make sure that information is available. As we want to save money, we also want to make sure that people have ownership over their healthcare. I think with ownership we are going to have far fewer health problems. We are going to be more proactive. And I think it is important to mention, it will save lives. 700,000 injuries related to healthcare accidents from improper prescription to information and close to 80 or 90,000 lives.

So we know what the problem is. I think what we have to find is a solution to the privacy issue, has to be done sooner, it has to be done fast. Delivery, we have so many test projects around the country, I think it is a time that we can stop testing things, stop talking about things and that's part of the reason that Lacy and I are here today. We want to take action, find solutions. Again, there is the Katrina example, Blue Cross/Blue Shield, there is insurance carriers and there is Barnes-Jewish and there is HCA in Nevada. So I think really, Mr. Powner, you said it well, we need a very defined mission and goal and we need to get the job done; a clear vision. That's why we are here today. So I thank again, Mr. Clay, you and your staff for your hospitality. I think that this is a first-class facility here at the university. Thank you to the folks at Washington University. To the witnesses, thank you for traveling, those that did. And to students that are here today, we need your help as we move forward. And one other individual I want to thank, Frank Taylor, where did he go? Frank, thanks.

So with that, the meeting is adjourned and the members of the committee will have additional time to submit their questions and we will be forwarding some to you as witnesses. Thank you all very much for being here. The meeting is adjourned.

[Whereupon, at 2:38 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

Testimony
Before the
Subcommittee on Federal Workforce and Agency Organization
Committee on Government Reform
House of Representatives

Accelerating the Adoption of Health Information Technology

Statement of

Jodi G. Daniel, J.D., M.P.H.

Director, Policy and Research
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services

STATEMENT FOR THE RECORD

September 1, 2006

St. Louis, Missouri

Thank you for inviting me to testify today on some of the health information technology activities underway in the Department of Health and Human Services. I regret that I am unable to appear in person, but am pleased to submit the following statement for the hearing record.

Setting the Context

On April 27, 2004, the President signed Executive Order 13335 announcing his commitment to the promotion of health information technology (IT) to improve efficiency, reduce medical errors, improve quality of care, and provide better information for patients and physicians. In particular, the President called for widespread adoption of electronic health records (EHRs) within 10 years so that health information will follow patients throughout their care in a seamless and secure manner. Reaching this ambitious goal requires cooperation among Federal agencies and Departments that play a role in advancing our understanding and use of health information technology: coordination across all Federal HIT programs; and coordination with the private sector. Toward those ends, the Secretary of Health and Human Services established within his office the position of National Coordinator for Health Information Technology on May 6, 2004 to advance the President's vision.

As my testimony will demonstrate, this approach is working. The Office of the National Coordinator works closely with the Centers for Medicare and Medicaid Services (CMS), the Department of Defense, the Department of Veterans Affairs, the Office of Personnel Management (OPM), and multiple other agencies and departments to ensure synergy in our efforts and avoid unnecessary duplication.

On August 22, 2006, the President issued the Executive Order entitled "Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs." This order will ensure that health care programs administered or sponsored by the Federal Government promote quality and efficient delivery of health care through the use of health information technology, transparency regarding health care quality and price, and better incentives for program beneficiaries, enrollees, and providers. It further advances the movement towards a modern health information system by directing that "As each agency implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards."

On July 21, 2004, the Department published the "Strategic Framework: The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care." The Framework outlined an approach toward nationwide implementation of interoperable EHRs and identified four major goals. These goals are: 1) inform clinical practice by accelerating the use of EHRs, 2) interconnect clinicians so that they can exchange health information using advanced and secure electronic communication, 3) personalize care with consumer-based health records and better information for consumers, and 4) improve public health through advanced bio-surveillance methods and streamlined collection of data for quality measurement and research. Since that time, the Department has been further refining health IT objectives and strategies while focusing on these goals and the clinical business, and technical foundations.

The Clinical Foundation: Evidence of the Benefits of Health IT

We believe that health IT can save lives, improve care, and improve efficiency in our health system. For example, five years ago, the Institute of Medicine (IOM) estimated that as many as 44,000 to 98,000 deaths occur each year as the result of medical errors. Health IT can help contribute to reduced medical errors and improved quality.

Every primary care physician knows what a recent study in the Journal of the American Medical Association (JAMA, February 2, 2005 –Vol. 293, No. 5) showed: that clinical information is frequently missing at the point of care, and that this missing information can be harmful to patients. That study also showed that clinical information was less likely to be missing in practices that had full electronic records systems. Patients know this too and are taking matters into their own hands. A recent survey by AHRQ with the Kaiser Family Foundation and the Harvard School of Public Health found that nearly 1 in 3 people say that they or a family member have created their own set of medical records to ensure that their health care providers have all of their medical information.

Business Foundation: The Health IT Leadership Panel Report

Recognizing that the healthcare sector lags behind most other industries in its investment in IT, HHS employed a contractor, the Lewin Group, to convene a Health IT Leadership Panel to help understand how IT has transformed other industries and how, based upon their experiences, it can transform the health care industry. The 9 CEO's comprising the Leadership Panel came to the conclusion that the Federal government should act as leader, catalyst, and convener of the nation's health information technology effort. Private sector purchasers and health care

organizations can and should collaborate alongside the Federal government to drive adoption of health IT. In addition, the Leadership Panel members recognized that widespread health IT adoption may not succeed without buy-in from the public as health care consumer. In response to the Leadership Panel report, and in an effort to proactively build support for HHS initiatives, the Secretary has been meeting with major employers throughout the country. To date the Secretary has met with 21 of the top 100 employers in the nation and is obtaining their support to join the Federal government in promoting health IT, especially through the highlighted activities outlined in the President's recent Executive Order 13410.

The Technical Foundation: Public Input Solicited on Nationwide Network

HHS published a Request for Information (RFI) in November 2004 that solicited public input about whether and how a Nationwide Health Information Network (NHIN) could be developed. This RFI asked key questions to guide our understanding around the organization and business framework, legal and regulatory issues, management and operational considerations, standards and policies for interoperability, and other considerations.

Over 500 responses to the RFI were received. These responses yielded rich insights on how a National Health Information Network based on interoperability of health information exchange could be developed to realize our goal of improving the safety, quality and efficiency of care. Clear themes that emerged from this wide group of stakeholders include:

- A NHIN should be a decentralized architecture built using the Internet, linked by uniform communications and a software framework of open standards and policies.

- A NHIN should reflect the interests of all stakeholders with a governance entity composed of public and private stakeholders to oversee the determination of standards and policies.
- A key challenge will be the provision of sufficient safeguards to protect the privacy of personal health information. Others include the need for additional and better refined standards; accurately verifying patients' identity; and addressing discordant inter- and intra-state laws regarding health information exchange.
- Incentives may be needed to accelerate the deployment and adoption of a NHIN.
- Existing technologies, federal leadership, and certification of EHRs will be the critical enablers of a NHIN.

Departmental Action

Two critical challenges to realizing the President's vision for health IT are now being addressed: a) interoperability and electronic portability of health information using information technology and b) electronic health record adoption. Further, the gap in EHR adoption between large hospitals and small hospitals, between large and small physician practices, and among other healthcare providers must also be addressed. This adoption gap has the potential to shift the market in favor of large players who can afford these technologies, and can create differential health treatments and quality, resulting in a quality gap.

These challenges are being met by key actions currently underway in the ONC: harmonizing health information technology standards; promoting the certification of health IT products to assure consistency with standards; addressing variations in privacy and security policies that can pose challenges to interoperability; and developing a prototype, nationwide, Internet-based

architecture for sharing of electronic health information. These efforts are inter-related, and Secretary Leavitt's Federal advisory committee, the American Health Information Community, is charged with making recommendations on actions necessary to accelerate Health IT adoption and interoperability.

American Health Information Community

On July 14, 2005, Secretary Leavitt announced the formation of the American Health Information Community (the Community), a national public-private collaboration formed pursuant to the Federal Advisory Committee Act. The Community has been formed to facilitate the transition to interoperable electronic health systems through a market-based approach. The Community is providing input and recommendations to the Secretary on use of common standards and how interoperability among Health IT systems can be achieved while assuring that the privacy and security of health information is protected. On September 13, 2005, Secretary Leavitt named the Community's 17 members, including nine members from the public sector and eight members from the private sector.

At its November 29, 2005 meeting, the Community formed workgroups that were charged to make recommendations for specific achievable near-term results in the following "breakthrough" areas:

- Consumer Empowerment - Make available a consumer-directed and secure electronic record of health care registration information and a medication history for patients.
- Chronic Care - Allow the widespread use of secure messaging, as appropriate, as a means of communication between doctors and patients about care delivery.

- Electronic Health Records - Create an electronic health record that includes laboratory results and interpretations, that is standardized, widely available and secure.
- Biosurveillance - Enable the transfer of standardized and anonymized health data from the point of health care delivery to authorized public health agencies within 24 hours of its collection.

During the August AHIC meeting, a new workgroup was formed. The first meeting of the Confidentiality, Privacy, and Security workgroup was on August 21, 2006. This workgroup will make recommendations on confidentiality, privacy, and security issues related to the other workgroups' activities. The first issues that will be discussed are identity proofing and user authentication.

Health Information Technology Processes

In addition to the formation of the Community, HHS through ONC has issued contracts for key processes, the outputs of which may serve as inputs for the Community's consideration. Specifically, these contracts focus on the following major areas:

Standards Harmonization. HHS awarded a contract to the American National Standards Institute, a non-profit organization that administers and coordinates the U.S. voluntary standardization activities, to convene the Health Information Technology Standards Panel (HITSP). The HITSP brings together U.S. standards development organizations and other stakeholders. The HITSP is developing and implementing a harmonization process for achieving a widely accepted and useful set of health IT standards that will support interoperability among health care software applications, particularly EHRs.

To improve coordination and specificity in setting standards, a process was implemented where standards are identified and developed specific to real-world scenarios, or "use cases." As of March 2006, we have three common use cases for the standards harmonization process, which will also be used in the other contracts discussed below. In May 2006, the HITSP proposed "named standards" for the three use cases and is now developing interoperability specifications for each.

Compliance Certification. HHS awarded a contract to the Certification Commission for Health Information Technology (CCHIT) to develop criteria and evaluation processes for certifying EHRs and the infrastructure or network components through which they interoperate. CCHIT is a private, non-profit organization established to develop an efficient, credible, and sustainable mechanism for certifying commercial health care information technology products. The contract, currently scheduled for a three-year period, will address three areas of certification: ambulatory electronic health records, inpatient electronic health records, and the infrastructure components through which they could interoperate

The CCHIT has made significant progress regarding the certification of commercial ambulatory electronic health records. In February 2006, CCHIT began using its final criteria to conduct ambulatory electronic health record certification pilot tests and has been accepting applications for operational certification as of March 2006. At this point there are more than twenty-two ambulatory EHR products that are CCHIT certified based on testing against CCHIT's published criteria. Now that this first successful phase of certification is complete, CCHIT is shifting into a

quarterly application/certification process. Certification will help buyers of health IT determine whether products meet minimum requirements.

NHIN Architecture. HHS has awarded contracts totaling $18.6 million to four consortia of health care and health information technology organizations to develop prototype architectures for the Nationwide Health Information Network (NHIN). The four consortia will move the nation toward the President's goal of personal electronic health records by creating a usable architecture for health care information. The NHIN architecture will be coordinated with the work of the Federal Health Architecture and other interrelated infrastructure projects. The goal is to develop real solutions for nationwide health information exchange by stimulating the market through a collaborative process and the development of network functions. In June 2006, the contractors submitted over 1200 proposed functional requirements for the NHIN to HHS. There was a public forum to discuss these functional requirements and receive broad public input. The National Committee on Vital and Health Statistics is working to develop an initial set of minimal functional requirements for the NHIN activity based on this input.

Security and Privacy. HHS awarded a contract to RTI International working with the National Governors Association Center for Best Practices to form the Health Information Security and Privacy Collaboration (HISPC). Through this contract, healthcare stakeholders, including consumers, within and across 34 states and territories will assess variations in organization-level business policies and State laws that affect electronic health information exchange; identify and propose practical solutions for addressing such variation that will comply with privacy and

security requirements in applicable Federal and State laws; and develop detailed plans to implement identified solutions.

All State and territory governors were invited to submit, or have a designee submit, a proposal for participation. States and territories that participate in the HISPC will be required to undertake certain activities that include: examining privacy and security policies and business practices regarding electronic health information exchange; convening and working closely with a wide range of stakeholders in the State, including consumers, to identify best practices, barriers and solutions; and developing an implementation plan for solutions to address organization-level business practices and State laws that affect privacy and security practices for interoperable health information exchange.

In the next six months, state consortia will produce an interim assessment of current privacy and security variations. To do this, state subcontractors will form collaborative workgroups to define this preliminary landscape. State solutions and implementation plans under this contract will be finalized in early 2007.

EHR Adoption Study

To assess progress toward the President's goal for EHR adoption, we must be able to measure the rate of adoption across relevant care settings. To date, several health care surveys have queried health care providers such as individual physicians, physician group practices, community health centers, and hospitals on their use of EHRs in an effort to estimate an overall "EHR adoption rate." These surveys indicate an adoption gap; however, the surveys and what

they have measured have varied. These variations occur from survey factors such as the type of entity, geography, provider size, type of health information technology deployed, how an EHR is defined, the survey sampling frame methodology (e.g., the source list of physicians), and survey data collection method (i.e., phone interview, mail questionnaire, internet questionnaire, etc.).

Due to the variations in the purpose and approach, these surveys have yielded varying methods of EHR adoption measurement. In particular, no single approach yields a reliable and robust long-term indicator of the adoption of interoperable EHRs that could be used for (1) bench marking progress towards meeting the President's EHR goal and (2) informing Federal policy decisions that would catalyze progress towards reaching this goal. Therefore, HHS awarded a contract to the George Washington University and Massachusetts General Hospital Harvard Institute for Health Policy to support the Health IT Adoption Initiative. The new initiative is aimed at better characterizing and measuring the state of EHR adoption and determining the effectiveness of policies to accelerate adoption of EHRs and interoperability.

Federal Health Architecture

Now that HHS has established an infrastructure to address standards harmonization, compliance certification, nationwide health information network architecture, security and privacy, and EHR adoption measurement through its contracts, there is a need to gain the Federal perspective in these and other Federal health information technology areas. To accomplish this, we are looking to the Federal Health Architecture (FHA), an HHS managed initiative, established on March 22, 2004 as a Federal line of business. As of March 2006, FHA has been realigned to ensure that the initiative is consistent with the President's Health IT initiative, and so that interoperability can

exist within and between the public and private sector. FHA will achieve this refined vision by providing input into the established infrastructure, guidance for implementation within the Federal agencies, and mechanisms for accountability.

Stark and Anti-Kickback

Regulations that support adoption of e-prescribing and electronic health records were proposed last October. CMS proposed to create exceptions to the "physician self-referral" law to allow hospitals and certain health care organizations to furnish hardware, software, and related training services to physicians for e-prescribing and software and related training services for electronic health records, particularly when the support involves systems that are "interoperable" and thus can exchange information effectively and securely among health care providers.

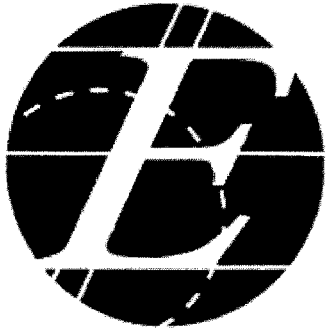
In a parallel action, the OIG announced proposed safe harbors for arrangements involving the donation of technology for e-prescribing and electronic health records. Arrangements for the provision of items and services that meet the requirements of the safe harbors would be exempt from enforcement action under the Federal anti-kickback statute. In August 2006, HHS released final rules for both exceptions and safe harbors. Accompanying these rules were two guidance documents, both posted on the ONC website at www.hhs.gov/healthit. The first identifies Secretarially recognized criteria for ambulatory EHRs and second serves as interim guidance regarding the process an organization can follow in order to apply to be considered a recognized certification body in accordance with two final rules.

Interoperable HIT as a Foundation for other Initiatives

The Department recognizes that interoperable health IT is critical in not only transforming how care may be delivered, but also in informing patients and other consumers about costs of care, and some aspects of its quality. Innovative incentive programs such as value-based purchasing could benefit from high fidelity reliable, information being available.

Conclusion

Thank you for the opportunity to update you on the progress we are making in the area of health information technology. HHS, under Secretary Leavitt's leadership, is giving the highest priority to fulfilling the President's commitment to promote widespread adoption of interoperable electronic health records, and it is a privilege to be a part of this transformation.



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Charting the Future of Pharmacy

House Government Reform Committee

Field Hearing, St. Louis, Missouri
September 1, 2006

Express Scripts – Who We Are

Express Scripts, Inc. is one of America's largest pharmacy benefit managers, providing the pharmacy benefit for millions of people nationwide through employers, managed-care plans, unions and governmental entities.

Overview

- Headquarters in St. Louis, Missouri
- Major administrative offices in multiple states, including Minnesota, Pennsylvania, Arizona, New Jersey and Florida
- Pharmacy and customer service operations in 10 states
- Canadian operations in Quebec and Ontario
- Employs a work force of more than 13,000 people

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Why Electronic Prescribing?

- ***Improved Quality and Safety*** – Decision support; prevention of medication errors through medication history, prevention of handwriting errors, etc.
- ***Efficiency*** – physician, patient and pharmacy (fewer calls, less rework)
- ***Cost Savings*** – generic utilization, formulary compliance; information re: lower-cost distribution channels
- ***Information at the point of care***

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Why Electronic Prescribing?

- Potential savings from enhanced generic utilization, formulary compliance and reduced adverse drug events
  - 2005 potential savings from maximizing generic utilization estimated at $21.7 billion (Express Scripts, 2006) (for commercially insured population in 48 states for six therapy classes)
  - Additional savings from enhanced generic utilization in Medicare population
- Enhanced efficiency in pharmacy operations, physician offices and payor operations
- Improved patient experience with manage benefits

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Dot.com Electronic Prescribing: The Beginning

- What it had:
  - Entrepreneurs/venture investors
  - Broad market focus - heavy pharma focus
  - Huge green field - success measured by deployments rather than actual use
  - Acceptable premise - dot.com fever/ momentum
- What was missing:
  - Physician value proposition – no critical mass of information
  - Network effect – spotty participation from physicians, PBMs and pharmacies
  - Common infrastructure
  - Industry standards
  - Governmental support

Bottom Line: RxHub model offered eRx its best value proposition – strengthening the model by bringing critical mass of robust information to the point of prescribing

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PBM Industry and eRx

- 3 largest national PBM's shared vision for industry utility to help facilitate electronic prescribing through:
  - transaction standards
  - common infrastructure to carry transactions
  - critical mass of information for vendors/physicians
  - single point-of-contact for vendors
- Founded RxHub in February, 2001
- Continues to add additional PBM/Payors as participants
- Connected or connecting to nearly all players in electronic prescribing today

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Why Payors and PBMs?

- eRx is key to value proposition
  - Basics: eligibility, formulary, Rx history
  - Ability to deliver programs to plan sponsors
- eRx drives industry efficiencies
  - Fewer pharmacy rejects
  - Fewer provider and member inquiries
  - Enhanced pharmacy efficiency – lower cost-to-fill

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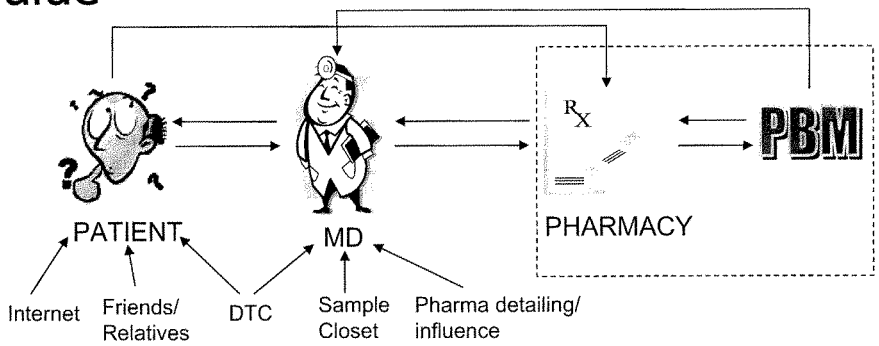
Adding Value

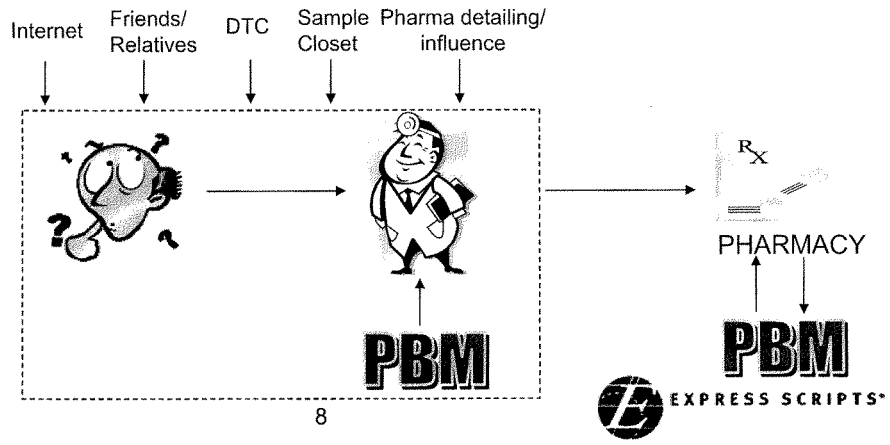
Before RxHub:

Information used to attempt to change decisions *after the fact*



After RxHub:

Information applied *at point of prescribing* – allows informed dialogue



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RxHub: Underpinnings

- Payors/PBMs can only succeed in eRx *together*
- Need to get behind a common model to achieve critical mass
- Utility model facilitates *all players* equally
- eRx *adds* value to managing pharmacy benefit – POS functionality essentially maximized

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Currently Available ePrescribing Functionality

- ***Master Patient Index:*** Contains over 180 million members that can be uniquely identified using 5 demographic elements (First Name, Last Name, DOB, Gender, Zip).
- ***Eligibility:*** Enables prescribers to access patient eligibility, formulary, benefit, and medication history information.
- ***Formulary & Benefits:*** Provides patient specific formulary and benefit coverage information to physicians to prescribe the most therapeutic and cost effective treatment for the patient.
- ***Medication History:*** Provides up to 2 years of PBM drug history for all coverages and includes original prescription and refills. Information can be used to indicate patient compliance, therapeutic interventions, drug-drug and drug-allergy interactions, adverse drug reactions, duplicate therapy and over prescribing.
- ***Prescription Routing:*** Facilitates electronic prescribing between physicians and retail/mail order pharmacies.

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e-Health Momentum

- Medicare Drug Improvement and Modernization Act of 2003 (MMA)
  - eRx recognized as key to managing program expense
  - Inclusion of eRx has increased awareness
  - eRx further accelerated by process to create standards and funding of pilot projects

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e-Health Momentum

- Significant push by HHS
- New stark and anti-kickback exemptions should help promote adoption
- Growing federal and state legislative activity on health information technology
- Statewide and community efforts
- JCAHO Medication Reconciliation Requirement

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Broad Range of Stakeholders will Benefit from Greater Adoption

- Consumers/Patients
- Physicians/Providers
  - Technology Vendors
  - Network Providers
- Payors/PBMs
- Pharmacies
- Hospitals/ER/LTC…
- Public Sector
  - Federal
  - State
  - Regional

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e-Health Momentum Growing, But…

Key Issue: National efforts toward e-health, while driving visibility of the overall topic, may actually slow the adoption of electronic prescribing

Bottom Line: eRx is easier and brings more immediate value than a full-blown interoperable health record, and is achievable now

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EHR vs. eRx

EHR	eRx
•High adoption cost	•Low adoption cost
•Total practice transformation	•Minor process changes
•Financial benefits rely largely on interoperability	•Financial benefits linear –Each physician contributes to system enhancement
•Some products "connected" to provide accurate prescription eligibility, formulary and medication history – many are not yet	• Most existing stand alone products connected for real time prescription eligibility, formulary and medication history

Bottom Line: eRx can provide immediate benefits and is much easier and less expensive to adopt – any mandate should start with eRx

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Preemption Still an Issue: Current State Laws and Regulations

- States have not taken a consistent approach on electronic prescribing. Today there are:
  - States that prohibit or place severe restrictions on electronic prescribing;
  - States that do not address electronic prescribing; and
  - States that set their own standards for electronic prescribing
- Specific state laws and regulations that have hindered the adoption of electronic prescribing include:
  - Requirements of special patient consent to the use of electronic prescribing.
  - Prohibitions on intermediaries facilitating transmission of prescription information (e.g., anti-depot rules)
  - Restrictions on prescription content and format, especially those drafted with only paper prescriptions in mind
  - Absence of a standard on which pharmacists can rely for authenticating the source of electronic prescriptions
  - Varying state privacy laws and restrictions (e.g., requirements that certain drugs be filtered out of medication histories unless the source of the medication history obtains the patient's consent)
  - Rules that require vendors to seek approval of their applications before operating in a state

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Benefits of Federal Preemption to Electronic Prescribing

- States that have not addressed electronic prescribing often have laws and regulations drafted for paper prescriptions that are ill-suited for application to electronic prescriptions. Preempting these laws and regulations with respect to electronic prescribing systems will help reduce costs of interpretation and help drive adoption.
- States that have set standards for electronic prescribing have not done so in a uniform way among states. Preempting these laws and regulations with *comprehensive* uniform standards will help drive nationwide adoption of electronic prescribing.

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Recommendations

- Continue push for comprehensive standards covering all aspects of electronic prescribing – preemptive of conflicting state laws, regulations, pharmacy board rules, etc. (current standards are cursory and apply only to Medicare)
- Leverage standards development organizations (SDO's) for creation AND updating of standards to allow industry to progress without burden of outdated regulations
- Push for adoption of technologies by physicians, with electronic prescribing as logical first step

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