THE LAST FRONTIER: BRINGING THE IT REVOLUTION TO HEALTHCARE

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM HOUSE OF REPRESENTATIVES

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THE LAST FRONTIER: BRINGING THE IT REVOLUTION TO HEALTHCARE

THURSDAY, SEPTEMBER 29, 2005

HOUSE OF REPRESENTATIVES, COMMITTEE ON GOVERNMENT REFORM, Washington, DC.

The committee met, pursuant to notice, at 10:08 a.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis (chairman of the committee) presiding.

Present: Representatives Tom Davis, Mica, Gutknecht, Porter, Schmidt, Waxman, Maloney, Cummings, Kucinich, Davis of Illi-

nois, Clay, Watson, Ruppersberger, and Norton.

Staff present: Melissa Wojciak, staff director; Chas Phillips, policy counsel; Rob White, press secretary; Drew Crockett, deputy director of communications; Victoria Proctor, senior professional staff member; Susie Schulte, professional staff member; Teresa Austin, chief clerk; Sarah D'Orsie, deputy clerk; Phil Barnett, minority staff director/chief counsel; Kristin Amerling, minority general counsel; Sarah Despres, minority counsel; Earley Green, minority chief clerk; Jean Gosa; minority assistant clerk; and Cecelia Morton, minority office manager.

Chairman Tom Davis. The meeting will come to order.

Millions of Americans are nearing retirement and will become greater consumers of healthcare over the coming years. Innovations are helping people live longer and healthier lives. In recent years, information technology has brought great advances in quality, efficiency, and cost savings to almost all sectors of our economy. It has been the driver of the American economy.

The Government Reform Committee has worked to ensure that the Federal Government has access to the latest technology at the lowest possible cost to bring the innovations of the private sector to the public sector. We have witnessed the improvements in Government services that come from harnessing the power of information technology. Until now, however, the healthcare industry has failed to embrace technology. Technology that could dramatically improve the quality of healthcare and reduce cost.

We live in a world of IT systems that handle millions of transactions daily in real time. We interface with them quickly, and they process our requests efficiently and accurately. We do this when we

transfer money, buy gas, or shop online. It is routine.

But the routine in healthcare is different. It is primarily a paperbased system of disconnected records and files in multiple locations. Doctors continue to write billions of handwritten prescriptions every year, a significant portion of which are illegible, or involve incorrect or incompatible drugs.

According to one survey, only 15 percent of physicians are using electronic prescribing systems, and only 3 percent of prescriptions are processed electronically. Computerized order entry systems coupled with electronic health records offer enormous potential.

A more troubling routine is a healthcare system in which the Institute of Medicine reports that around 50,000 to 100,000 Americans die every year due to medical errors. A modern IT-based system could cut errors dramatically. One can argue that hospitals, doctors, insurance companies, and the Government are endangering lives by moving too slowly in adopting electronic health records. There is a direct link, in my view, between health IT and healthcare quality and safety.

As we have seen recently with Hurricane Katrina, physicians are often our second responders. They should have the support of the same sophisticated IT systems as our first responders, enabling them to respond to a crisis quickly, to retrieve and share the critical records of information that they need to save lives.

I hope we can bring a sense of urgency to this issue. The recent events surrounding Hurricane Katrina highlight the need for accessible, accurate medical records and medical information. I am particularly interested in VHA's experience during this period.

I hope the system that we create will help us share information quickly, effectively, and securely, which is something we have been pushing the Federal Government to do in all aspects of its operations. I believe we can enhance patient care by providing every medical professional with instant access to life-saving information. With the information technology available to us today, we can no longer accept injury or death because of preventable errors.

Efforts to convert to electronic health records have met some resistance, however. Many stakeholders have been slow to see the long term benefits that upfront investments in new technology can bring. Small providers could be asked to bear burdens that benefit others initially. Fewer than one in four doctors currently enter information into an electronic health record.

There will be other challenges as we move from a paper-based system. Many hospitals and doctors' offices are still lacking in information security, physical security, and privacy protection practices that will be needed with electronic health records, but we have faced these challenges before.

In this committee, we work constantly to bring the best private sector practices and procedures to the Federal Government to encourage information sharing, information security, and encourage the efficient use of the latest information technology. Each of these priorities is relevant to the health IT debate.

The healthcare industry is a fragmented and complicated marketplace. We need to exercise caution when we are asked to step in with regulations and mandates. I am interested in learning what level of governmental, including congressional, action is warranted.

We have seen a lot of action recently on health IT legislation, and we have a unique opportunity. Many issues on Capitol Hill can be divisive, but there appears to be broad bipartisan support for health technology. Of course, anytime you propose dramatic

changes that affect such a broad community, challenges will arise. I hope we can continue to work together to solve them and move toward the ambitious goals we have set.

The purpose of today's hearing is to highlight the challenges and opportunities that will come with the widespread adoption of health information technology. The principles driving health IT are the same principles the committee pushes Government-wide, bringing the best information technology, policies, and practices to the Government at the lowest possible cost. It is a goal we will continue to support tinue to support.
[The prepared statement of Chairman Tom Davis follows:]

Opening Statement of Chairman Tom Davis Committee on Government Reform "The Last Frontier: Bringing the Information Technology Revolution to Healthcare" September 29, 2005

Millions of Americans are nearing retirement and will become greater consumers of health care over the coming years. Innovations are helping people live longer and healthier lives.

In recent years, information technology has brought great advances in quality, efficiency and cost savings to almost all sectors of our economy. It has been the driver of the American economy.

The Government Reform Committee has worked to ensure that the Federal Government has access to the latest technology at the lowest possible cost, to bring the innovations of the private sector to the public sector. We have witnessed the improvements in government services that come from harnessing the power of information technology. Until now, however, the health-care industry has failed to embrace technology -- technology that could dramatically improve the quality of health care and reduce cost.

We live in a world of IT systems that handle millions of transactions daily in realtime. We interface with them quickly and they process our requests efficiently and accurately. We do this when we transfer money, buy gas, or shop online. It is routine.

But the routine in healthcare is different. It is primarily a paper-based system of disconnected records and files in multiple locations.

Doctors continue to write billions of handwritten prescriptions every year, a significant portion of which are illegible, or involve incorrect or incompatible drugs. According to one survey, only 15 percent of physicians are using electronic prescribing systems, and only 3 percent of prescriptions are processed electronically. Computerized order-entry systems coupled with electronic health records offer enormous potential.

A more troubling routine is a health-care system in which the Institute of Medicine reports that around 50,000 to 100,000 Americans die every year due to medical errors. A modern IT based system could cut errors dramatically. One can argue that hospitals, doctors, insurance companies and the government are endangering lives by moving too slowly in adopting electronic health records. There is a direct link, in my view, between health IT and health care quality and safety.

As we have seen recently with Hurricane Katrina, physicians are often our "second" responders. They should have the support of the same sophisticated IT systems

as our first responders, enabling them to respond to a crisis quickly, to retrieve and share the critical records and information that they need to save lives.

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Efforts to convert to electronic health records have met some resistance, however. Many stakeholders have been slow to see the long-term benefits that upfront investments in new technology could bring. Small providers could be asked to bear burdens that benefit others initially. Fewer than one in four doctors currently enter information into an electronic health record.

There will be other challenges as we move from a paper-based system. Many hospitals and doctor's offices are still lacking in information security, physical security and privacy protection practices that will be needed with electronic health records. But we have faced these challenges before.

On this committee, we work constantly to bring the best private sector practices and procedures to the federal government, to encourage information sharing, to ensure information security, and encourage the efficient use of the latest information technology. Each of these priorities is relevant to the health IT debate.

The health care industry is a fragmented and complicated marketplace. We need to exercise caution when we are asked to step in with regulations and mandates. I am interested in learning what level of governmental -- including Congressional -- action is warranted.

We have seen a lot of action recently on health IT legislation, and we have a unique opportunity. Many issues on Capitol Hill can be divisive, but there appears to be broad bipartisan support for health technology. Of course, anytime you propose dramatic changes that affect such a broad community, challenges will arise. I hope we can continue to work together to solve them and move toward the ambitious goals we have set.

The purpose of this hearing is to the highlight the challenges and opportunities that will come with the widespread adoption of health information technology. The principles driving health IT are the same principles the Committee pushes government-

wide: bringing the best information technology, policies, and practices to the government at the lowest possible cost. It is a goal I will continue to support.

Chairman Tom Davis. Now I will recognize our distinguished ranking member who has been very active, not just in the IT field but the health field as well, Mr. Waxman, for his opening statement.

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

It is entirely appropriate for this committee to be holding an oversight hearing related to the U.S. healthcare system, a system in need of major improvement. There are more than 45 million Americans without health insurance, and that number keeps rising each year. Millions of Americans forego needed treatment or declare bankruptcy because of the cost of healthcare. Unjust disparities in access and outcomes are common across a wide range of conditions

Today's hearing addresses a small but important part of the solution to the healthcare system's problems, the need for better information technology. A network of electronic medical records may allow treating physicians to share information about a patient's condition quickly and efficiently, preventing redundant treatment. Computerized warnings could stop medical errors. Access to key patient data in an emergency can literally be lifesaving.

While improvements in health information technology may bring many benefits, it will also bring new challenges. Privacy is a major issue. There must be safeguards in place to ensure that patients' health information is secure, and that the information will not be

misused.

Then there is the question of who pays. Creating an interoperable network of standardized electronic medical records is going to be expensive. While many are convinced that these costs will be more than offset by the savings these systems may offer, others are not so sure.

Some experts have raised the concern that the projections of cost savings are based on rosy assumptions. If the American taxpayer is footing the bill, we need to ensure that we have a realistic understanding of what health information technology can actually deliver.

I look forward to learning about the promise of health information technology today, and I thank the witnesses for coming. And I hope the testimony we receive today will form part of a broader examination by Congress of problems facing our healthcare system.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Henry A. Waxman follows:]

OPENING STATEMENT BY REP. HENRY A. WAXMAN, RANKING MINORITY MEMBER COMMITTEE ON GOVERNMENT REFORM HEARING ON "THE LAST FRONTIER: BRINGING THE IT REVOLUTION TO HEALTHCARE"

September 29, 2005

Thank you, Mr. Chairman. It is entirely appropriate for this committee to be holding an oversight hearing related to the U.S. healthcare system – a system in need of major improvement.

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Chairman Tom Davis. Mr. Waxman, thank you.

Jean Schmidt was appointed to the committee on September 15, 2005. She is a lifelong resident of Clermont County. She is the first woman ever elected to represent southern Ohio in Congress. She served for two terms in the Ohio State House. According to the Cincinnati Enquirer, she proved effective in passing legislation to address her district's concern.

While serving in the State legislature, she enacted legislation to create jobs, protect Ohio's children, and ensure access to quality healthcare. And prior to her election to the Ohio State House, she

served 10 years as a Miami Township Trustee.

She resides in Miami Township with her husband, Peter, and her daughter, Emily. She holds a degree in Political Science from the University of Cincinnati. And her other interests include auto racing and long distance running. Jean, how many marathons have you done?

Mrs. Schmidt. Fifty-six.

Chairman Tom Davis. Fifty-six, so she will be well-suited to our

hearings. [Laughter.]

Fifty-six marathons and still counting, that is 53 more than the chairman. I just want to say, welcome to the committee. We are very pleased to have you here. And if you want to make an opening statement here or not—

Mr. WAXMAN. Before you recognize her as a new member, I also want to extend my welcome to her on behalf of the Democratic side of the aisle to join our committee. You have run 56 marathons more than I have run. [Laughter.]

Mrs. Schmidt. Well, in 2 weeks, it will be my 57th, hopefully. Thank you so much, Chairman Davis and fellow members of this wonderful Government Reform Committee. It is my honor to serve with your

with you.

I am very excited about the fact that our first topic is healthcare because, in the Ohio Legislature, that was one of the chief concerns that I had, that we have quality healthcare access to all individuals in all walks of life. As an elected official, my top priority is to make sure that our precious tax dollars are spent correctly and used efficiently.

My seat on this committee will allow me to work with all of you to cut waste, streamline bureaucracy, and to ensure that we American citizens get the most from our Government. I am very excited to work with you in the coming months. There is a lot of work to do, so I am going to be quiet and let us get started. Thank you.

Chairman Tom Davis. Thank you very much. Any other Members wish to make opening statements?

Ms. Norton.

Ms. NORTON. I particularly appreciate this hearing. I am going to be in and out because there are two other hearings at the same time. I believe that one of the most important questions we could answer is why the healthcare industry lags behind other industries so substantially in IT.

It seems to be there is a very deep conundrum here. First of all, you can call this an industry if you want to, but essentially a bunch of people who deliver healthcare is what we are talking about. We are talking about healthcare. We are talking about hospitals. We

are talking about HMOs. We are talking about individual practitioners.

And to bring IT to such an important sector, scattered among the neighborhoods, if you will, scattered in every part of our country, would itself be a feat, especially if you want the system to be able to talk to wherever patients go.

I see an up front problem, and that is the cost of healthcare itself. Here we have hospitals, and HMOs, and those who provide Medicare hardly able to keep up with the most inflationary part of the economy.

So, in essence, if we are talking IT, especially IT beyond what my doctor has, and she has it fine. It is in her office, but she isn't hooked up to every hospital in the District of Columbia. She isn't hooked up to where I might go somewhere in the country, if that is what you are talking about.

If that is not what you are talking about, then I am not sure why we are here. If that is what you are talking about, there has to be some incentive for an industry that can hardly keep up with its basic mission, which is providing healthcare for the American people, to in fact come forward with the up front costs that IT would involve. What is the incentive for them to do that, to hook themselves up, or to put in systems that would allow themselves to hook themselves up with whomever?

The beneficiary, it seems to me, in all of this would really be the American people; it would be individuals, far more than providers. Until we figure out who would benefit and who would pay the cost, then the wonderful talk about IT is going to be just that. We are not talking about putting in computers, I do not believe. We are not talking about being as computer savvy as my doctor is. We are talking about having your records, so that they would be accessible wherever you go.

We are talking about the kind of use of IT that would mean doctors would be less often the objects of malpractice suits because they know everything about a patient because they would be able to find that through IT, in a way now it is even more difficult to do.

So we kind of started with the back end of how great it would be to hook us all up. Somebody has to tackle the hard question, cost in an industry where cost is the primary question and cost in a industry where 43 million Americans don't have access to a doctor and could care less about IT.

Who would benefit? Would it really be the HMO? Would it really be the hospital? Why should they do it if, in fact, the benefit would be to you and me? Then it seems to me the Government of the United States has to face that it is the American people who would benefit, and somehow or the other the incentives have to be there for that cost to be provided for us to benefit.

Thank you very much, Mr. Chairman.

Chairman Tom Davis. Thank you very much. Any other Members wish to make opening statements?

Mr. Porter.

Mr. PORTER. Thank you, Mr. Chairman. I appreciate the opportunity to speak on this important issue today.

The subject of this hearing touches every single one of us in some shape or form. Everyone here has gone to the doctor, some more than others, but we understand what it is like to have to visit a doctor or visit a hospital. Quality healthcare is of great importance to everyone. However, notwithstanding the fact that the United States is a world leader in healthcare science, its delivery and management of healthcare is often outmoded and very inefficient.

Over 90 percent of the activities that go into the delivery of healthcare are centered information and information exchange. If this component is flawed in any way, the optimal delivery of care will not be achieved. On July 27th the Subcommittee on Federal Workforce and Agency Organization, which I chair, explored this

very issue.

During this hearing, we explored the potential of deploying health information technology, its implications, and its potential for success. At this hearing, we heard testimony from the Federal Government, medical experts, and others who are very interested in

deploying HIT for 8 million of our Federal employees.

Hurricane Katrina and Rita shed limelight over this issue. With millions of Americans scattering from the Gulf Coast Region all over the country, we soon realized that many of the hurricane victims would require adequate healthcare from many different doctors and many different hospitals. Many medical records were not immediately available for patients, potentially putting some patients at even greater risk. We must make sure that situations like this are avoided in the future. By deploying HIT, it would be a step in the right direction.

One insurer, however, stands out as a stark example of HIT excellence. Blue Cross Blue Shield of Texas extracted data on its members who lived in the areas that were evacuated before Rita hit. To help physicians care for Hurricane Rita evacuees, Blue Cross of Texas is making its members' clinical summaries electroni-

cally available to physicians.

The summaries contain historical and current data such as lab results, pharmacy information, basic medical history. Some of those members won't return home for several weeks, maybe even months or years, because of the hurricane. Blue Cross took its payer-based data for 830,000 members, and converted it into electronic health records available to any treating provider for hurricane-affected States, and did it for 4 days.

The benefits of computerizing health records are simply substantial. Health information technology will improve the quality of care, reduce the redundancy of testing and paperwork, and virtually eliminate prescription errors, prevent adverse effects from conflicting courses of treatment, and significantly reduce medical errors,

and reduce administrative costs.

The President, in announcing his 10 year goal, admonished the Federal Government has to take the lead. The FEHB Program is no exception and should leverage as buying power about $8\frac{1}{2}$ million participants to support President Bush's goal and lead by example.

That is why in the next 2 weeks, I will be introducing legislation called the Federal Family Health Information Technology Act. This bill will provide every Federal employee and participant of the Federal employee.

eral Employees Health Benefits Program with an electronic healthcare record and will effectively serve as the largest HIT dem-

onstration project in the country.

No one can claim that moving information technology into the healthcare industry is going to be easy; it is going to be difficult. However, as the Blue Cross Blue Shield of Texas case demonstrates with payer-based data, there is no reason not to get started with the data that currently is available to the Federal Government. The HIT bill I will be introducing recognizes that there are three components of electronic health record, and each component will be phased in accordingly.

The first component is the payer-based record which will use claims data and other information readily available to carriers. The other components, a personal health record and provider-based record will be phased in accordingly. The bill also requires carriers in the program to provide each program participant with a wallet-size electronic health record identification card within 5 years of

passage of this act.

As chairman of the subcommittee, I am committed to supporting the President's goal and this committee, full committee's goal. Mr. Chairman, I appreciate this opportunity. I look forward as the hearing unfolds. But realize that we are so far behind in our technology, that many American lives are at stake. I look forward to moving forward with my bill, which we will be introducing, and others that have come before us.

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

STATEMENT FOR THE RECORD

Congressman Jon Porter (NV-3)
Government Reform Committee
"The Last Frontier: Bringing the IT Revolution to Healthcare"
September 29, 2005

Mr. Chairman, I appreciate the opportunity to speak on this important issue today.

The subject of this hearing touches each and every single one of us. Everyone here has either gone to the doctor's office or the hospital or knows someone who has.

Quality healthcare is of great importance to everyone; however, notwithstanding the fact that the United States is a world leader in health-care science, its delivery and management of healthcare is often outmoded and inefficient.

Over 90% of the activities that go into the delivery of healthcare are centered on information and information exchange. If this component in flawed in any way, the optimal delivery of care will not be achieved.

On July 27th, the Subcommittee on Federal Workforce and Agency Organization, in which I chair, explored this very issue. During this hearing, we explored the potential of deploying health information technology (HIT), its implications, and its potential for success. At this hearing, we heard testimony from the federal government, medical experts, and others who were very interested in deploying HIT for our 8 million federal employees.

Hurricanes Katrina and Rita shed limelight over this issue. With millions of Americans scattering from the Gulf Coast region, we soon realized that many of the hurricane victims would require adequate health care from doctors. Many medical records were not immediately available for patients, potentially putting some patients at even greater risk. We must make sure that situations like this are avoided in the future, and deploying HIT would be a step in the right direction.

One insurer, however, stands out as a stark example of HIT excellence. Blue Cross Blue Shield of Texas extracted data on its members who lived in areas that were evacuated before Rita hit. To help physicians care for Hurricane Rita evacuees, Blue Cross of Texas is making its members' clinical summaries electronically available to physicians. The summaries contain historical and current data, such as lab results, pharmacy information and basic medical history. Some of those members won't return home for several weeks because of the hurricane. Blue Cross took its payor based data for 830,000 members and converted it into an electronic health record available to any treating provider for a hurricane affected state, and did it in four days.

The benefits of computerizing health records are simply substantial. Health information technology will improve the quality of care, reduce the redundancy of testing and paperwork, virtually eliminate prescription errors, prevent adverse effects from

conflicting courses of treatment, and significantly reduce medical errors and reduce administrative costs.

In announcing his ten-year goal, the President admonished, "The Federal Government has got to take the lead." The FEHB Program is no exception and should leverage its buying power of about eight and a half million participants to support President's Bush's goal and lead by example.

That is why within the next two weeks, I will be introducing the Federal Family Health Information Technology Act. This bill will provide every Federal employee (and participant of the Federal Employees Health Benefits Program) with an electronic health care record and will effectively serve as the largest HIT demonstration project in the country.

No one can claim that moving information technology into the health care industry is going to be easy. However, as the Blue Cross/Blue Shield of Texas case demonstrates with payor based data, there is no reason not to get started with the data that is currently available.

The HIT bill that I will be introducing recognizes that there are three components of an electronic health record and each component will be phased in accordingly. The first component is the payor based record, which will use claims data and other information readily available to carriers. The other components, a personal health record and a provider based record, will be phased in accordingly. The bill also requires carriers in the Program to provide each Program participant with a wallet-sized electronic health record identification card within five years of the passage of this Act.

As Chairman of the Subcommittee, I am committed to supporting the President's goal and guiding the implementation of health information technology in both the FEHB Program and throughout the nation. Again, Mr. Chairman, thank you for holding this important hearing today. I look forward to hearing the testimony from our witnesses and working with you to further the Committee's goals to better protect the American public.

* * *

Chairman Tom Davis. Thank you.

Ms. Watson.

Ms. WATSON. I want to thank you, Mr. Chairman, for having this

hearing this morning.

In reading over the analysis of this meeting, it says health IT may be especially beneficial for inner city and rural populations and other medically under-served areas. We all witnessed a month ago how the under-served were those who were very, very ill or be-

came very, very ill.

What I find our problem is, it is two-fold. No. 1, we don't have a national health insurance program, and we need to focus on that. And No. 2, we don't have the outreach. We all assume that communities are on the Internet. And so, as we go through these discussions around legislation, I would hope that our panels would address how we outreach in communities that are under-served. That is our biggest problem.

I represent a city in California called Los Angeles, and it is spread out. We don't access; we don't have IT; and we don't have outreach. People suffer from lack of information, and they suffer from inaccessibility. So as we discuss IT, I hope we will broaden out that discussion, so we can be sure the under-served is indeed

served through this new technology.

Thank you, Mr. Chairman.

Chairman Tom Davis. Thank you very much. Members will have 7 days to submit statements for the record. We are going to now recognize our first panel.

I am sorry, Mr. Clay, do you want to say something?

Mr. CLAY. Thank you, Mr. Chairman.

Chairman Tom Davis. You are recognized.

Mr. CLAY. Just very quickly, thank you for calling today's hearing on ways we can improve the use of information technology in our healthcare delivery system. I welcome our witnesses today and hope to partner with them in the future on transforming our healthcare system into an electronically based model for medical efficiency.

In the coming weeks, like the other gentleman stated, I plan to introduce a bill that will strengthen the Federal Government's role in developing and strengthening electronic health record standards while allowing private sector stakeholders to remain innovative in their own EHR implementation efforts. My legislation seeks to ac-

complish two major endeavors.

First, it would codify the office of Dr. Brailer and strengthen his role as the leading health information standard setting organization in the Federal Government by establishing stringent milestones and compliance requirements for all Federal health agencies. We will reduce barriers to sharing health information between agencies while providing the marketplace a model for efficient and secure health information exchange.

Second, the bill will establish a loan program modeled after the William D. Ford Direct Loan Program for Students for providing financing options among providers and organizations in the process of establishing EHR systems. A major barrier to developing a nationwide health information network is the capital costs involved with the design and implementation of the system, particularly

among small providers lacking access to capital markets or specialized financial instruments.

I believe the Federal Government ought to foster its economic resources in a responsible manner to provide such capital where necessary, and our Direct Loan Program provides for us a model to do

Mr. Chairman, this concludes my remarks, and I ask that they be included in the record.

[The prepared statement of Hon. Wm. Lacy Clay follows:]

STATEMENT OF THE HONORABLE WM. LACY CLAY HEALTH CARE INFOMATICS SEPTEMBER 29, 2005

Thank you, Mr. Chairman, for calling today's hearing on ways we can improve the use of information technology in our health care delivery system. I welcome our witnesses today and hope to partner with them in the future on transforming our health care system into an electronically based model for medical efficiency.

A recent study undertaken by the RAND Corporation estimated that the implementation of a nationwide health care information network that is utilized by 90% of providers would produce an annual savings of approximately \$80 billion, while reducing the number of adverse patient drug reactions in hospitals by 200,000 and over 2 million in outpatient settings. Thus, I believe it is imperative that the federal government lead in the establishment of a blueprint for interoperable data, coding, and transaction standards for all federal agency health care systems, while providing additional financing options for the development and implementation of electronic health record systems among private sector health care providers.

In the coming weeks, I plan to introduce a bill that will strengthen the federal government's role in developing and strengthening electronic health records standards, while allowing private sector stakeholders to remain innovative in their own E-H-R implementation efforts. My legislation seeks to accomplish two major endeavors. First, it would

codify the Office of Dr. Brailer and strengthen its role as the leading health information standard setting organization in the federal government. By establishing stringent milestones and compliance requirements for all federal health agencies, we will reduce barriers to sharing health information between agencies while providing the marketplace a model for efficient and secure health information exchange.

By achieving this goal, we will have established a federal health architecture that is open to new technological developments and ready to incorporate new IT advances in the future. The new Office will seek to partner with the private sector through an expanded grant and demonstration program effort that will become a key economic resource. In addition, this new Office will institute research endeavors and provide seed funding for implementation costs among institutions seeking to expand their E-H-R capabilities.

Second, my bill will establish a loan program, modeled after the William D. Ford Direct Loan Program for students, for providing financing options among providers and organizations in the process of establishing E-H-R systems. A major barrier to developing a nationwide health information network is the capital costs involved with the design and implementation of the system, particularly among small providers lacking access to capital markets or specialized financial instruments. I believe the federal government ought to foster its economic resources in a responsible manner to provide such capital where

necessary, and our Direct Loan program provides for us a model to do so.

If we continue in our pursuit of utilizing IT throughout our health care delivery system, we are sure to experience shorter hospital stays, improved management of chronic disease, and a reduction in the number of needless tests and examinations administered over time. While it is not a panacea, I believe the pursuit of such a network will prove far more efficient in both economic and human terms than its costs, while improving our utilization of cutting edge technology for the betterment of society.

This concludes my remarks, Mr. Chairman, and I ask that they be included in the record.

Chairman Tom Davis. Without objection.

Do any other Members wish to make opening statements? Then we will proceed to our first panel. We have Dr. David Brailer, who is an M.D. and a Ph.D. He is the National Coordinator for Health Information Technology at the U.S. Department of Health and Human Services.

And Mr. Robert Kolodner, M.D., who is the Chief Health Informatics Officer at the Veterans Health Administration. First, let me thank you both for your service. It is our policy that we swear you in before you testify, so if you would rise and please raise your right hands.

[Witnesses sworn.]

Chairman Tom Davis. Thank you. We have a light in front of you that will turn green when you start; it will turn orange or yellow after 4 minutes, red after 5. Your entire statement is part of the record, and our questions are based on the entire statement.

So if we can keep within time, it helps. I won't gavel if you feel you need an extra minute or so because we want to make sure you get your points across. This is important testimony. Dr. Brailer, we will start with you and then go to Dr. Kolodner. Thank you very much for being with us.

STATEMENTS OF DAVID J. BRAILER, M.D., PH.D., NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ROBERT M. KOLODNER, M.D., CHIEF HEALTH INFORMATICS OFFICER, VETERANS HEALTH ADMINISTRATION

STATEMENT OF DAVID J. BRAILER

Dr. Brailer. Thank you, Mr. Chairman and members of the committee. I appreciate the opportunity to speak with you today and to continue our discussions about health information technology.

We are far along in our efforts to begin understanding what the Nation's work will be like to bring health information tools to our doctors, hospitals, and consumers. There are three foundations that have been strongly set. The first and most important is a clinical foundation that essentially says that the use of health information tools appropriately set up and appropriately trained for clinicians save lives.

The second is a technical foundation that asks: Do we have the components, and the pieces, and the know-how to do this? And we believe that we have, if not all of it, most of it because of the opportunities already underway in many healthcare organizations as well as other industries. The question of an economic foundation which is, how does this get paid for and how does it generate economic value, is something that has been explored at length and will continue to be as well.

We view there being two fundamental challenges around health information technology, and they work together. The first is how to get these important tools into the hands of doctors, and not just a few but all, into the hands of other clinicians, into the hands of professionals, and consumers, institutions, clinics, and other settings. This adoption challenge has many pieces that include financing, culture, training, legal issues.

And second is the question of portability of information, or its interoperability which involves a separate set of issues about how organizations and healthcare relate to each other and ultimately how they can come together to deliver seamless care for each patient.

We are now ready to begin full scale implementation of the administration's agenda, and I would like to summarize some of the key steps that are underway in the next few weeks. The first is the American Health Information Community which is a group comprised of 17 members, 8 of which are from the Federal Government, 8 from the private sector, and 1 from a State government.

This American Health Information Community will be the main steering group for the health information technology agenda in the administration. It will prioritize breakthroughs, a breakthrough being some specific way that health information technology can be useful to the American public. It will balance the short term goals against long term issues as we buildup an infrastructure and a capacity in the United States to bring this across to all forms of healthcare and to all the different constituents. It will ensure that various voices are heard including those of key Federal agencies like Medicare and the Office of Personnel Management in terms of how they can participate and bring their Federal tools to this agenda.

Second, from that we will be setting up work groups to oversee these breakthroughs. If, for example, a breakthrough is a personal health record, or tools for chronic care disease management, or eprescribing, or bioterrorism surveillance just to name a few, each of these will have a work group constituted of Federal, State, and private leaders to ensure that we can move these agendas forward, and address barriers, and work against a very specific timetable.

The American Health Information Community has its first meeting on Friday, October 7th. And we expect by the end of the year to have the breakthroughs chartered, and charged, and working against a timetable. At the same time next week, we will be announcing the Federal Government's partner for standards harmonization.

We do have a significant number of different, somewhat overlapping, and ambiguous standards in the United States, and the standard harmonization partner will help us align those into one single fabric, one set of tools that can ensure that information can be exchanged and shared seamlessly.

We will also be identifying our conformance certification partner, which is another way of saying the entity that will help us determine what are the characteristics of an electronic health record that is used by doctors and hospitals. We will be establishing a consortium of State leaders together to identify security and privacy advances that are needed to protect information the coming Information Age and address the question of portability in the context of that security.

And finally, later in October, we will be identifying the groups of entities that will develop models, or architectures, or plans for what the Nation's capacity to share information looks like. There are many technical components of these, and we are asking for six

different groups to work, so we can extract from that and combine the very best ideas of any of those groups.

My office has had the privilege of working with the private sector recently in the health information response to Hurricanes Katrina and Rita. I am happy to tell you that this was a remarkable experience by which many groups came together and operated well within the bounds of law to produce for up to 80 percent of the evacuees a prescription data base in a secure, non-centralized data tool that was available to physicians and shelters within 7 days. This remarkable experience will redefine what urgency is in health information and what it means to really break through and to address real problems.

These actions that are underway will be supplemented by other policies and other changes over the course of the next few months that are needed to continue to drive both portability and adoption. We have many things to do, but at this point we are underway, and we expect to see significant progress over the course of the

next several months.

I welcome your interest in this topic, and I certainly look forward to further discussion about it. Thank you.

[The prepared statement of Dr. Brailer follows:]



Testimony Before the Government Reform Committee U.S. House of Representatives

Activities of the Office of the National Coordinator for Health Information Technology

Statement of

David J. Brailer, M.D., Ph.D.

National Coordinator for Health Information Technology

U.S. Department of Health and Human Services

For Release on Delivery Expected at 10:00 a.m. Thursday, September 29, 2005 Chairman Davis and Members of the Committee, I am Dr. David Brailer, the National Coordinator for Health Information Technology. The Office of the National Coordinator for Health Information Technology is a component of the Department of Health and Human Services (HHS). Thank you for inviting me to testify today on health information technology activities underway in the Department.

Setting the Context

On April 27, 2004, the President signed Executive Order 13335 (EO) announcing his commitment to the promotion of health information technology (IT) to lower costs, 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. Toward that vision, the EO directed the Secretary of the Department Health and Human Services (HHS) to establish within the Office of the Secretary the position of National Coordinator for Health Information Technology (National Coordinator), with responsibilities for coordinating Federal health information technology (health IT) programs with those of relevant executive branch agencies, as well as coordinating with the private sector on their health IT efforts. On May 6, 2004, Secretary Tommy G. Thompson appointed me to serve in this position.

On July 21, 2004, during the Department's Health IT Summit, we published the "Strategic Framework: The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care," (The Framework). The Framework outlined an approach toward nationwide implementation of interoperable EHRs and in it we 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. The Framework has allowed many industry segments, sectors, interest groups, and individuals to review how health IT could transform their activity or experience, consider how to take advantage of this change,

and to participate in ongoing dialogue about forthcoming efforts. My office has obtained significant additional input concerning how these four goals can best be met.

- We have consulted with, and actively partnered with, numerous federal agencies in the
 U.S. Government including the Departments of Veterans Affairs, Defense, Commerce, and
 Homeland Security.
- We have met with many organizations and individuals representing stakeholders of the healthcare system to obtain their individual views.
- We have reached out to states and regions through site visits and town hall meetings to
 understand the health IT challenges experienced at the local level as well as best practices
 for the use of, and collaboration regarding, health IT.
- We have regularly testified before, and been informed by, the National Committee on Vital and Health Statistics (NCVHS) on issues critical to the nation's health IT goals.
- We have monitored, and coordinated with, the efforts of the Commission for Systemic Interoperability. (The Medicare Modernization Act called for the Secretary to establish the Commission to develop a comprehensive strategy for the adoption and implementation of health care information technology standards that includes a timeline and prioritization for such adoption and implementation.) and
- We have met with delegations involved with health IT from other countries, including Canada, Netherlands, Japan, Australia, Great Britain, and France to learn from their individual country experiences.

Building on the EO, The Framework, and this input, we have developed the clinical, business, and technical foundations for the HHS health IT strategy. Let me turn to some of those now.

The Clinical Foundation: Evidence of the Benefits of Health IT

We believe that health IT can save lives, improve care, and reduce costs in our health system. 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, through applications such as computerized physician order entry can help reduce medical errors and improve quality. For example, studies have shown that adverse drug events have been reduced by as much as 70 to

80% by targeted programs, with a significant portion of the improvement stemming from the use of health IT.

Every primary care physician knows what a recent study in the Journal of the American Medical Association (JAMA) 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 the Agency for Healthcare Research and Quality (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.

There are mixed signals about the potential of health IT to reduce costs. Some researchers estimate that potential savings from the implementation of health IT and corresponding changes in care processes could range anywhere from 7.5 percent of health care costs (Johnston et al., 2003; Pan et al, 2004) to 30 percent (Wennberg et al., 2002; Wennberg et al., 2004; Fisher et al., 2003; Fisher et al., 2003). These estimates are based in part on the reduction of obvious errors. For example, a medical error is estimated to cost, in 2003 dollars, about \$3,700 (Bates et al, 1997). But, these savings are not guaranteed through the simple acquisition of health IT: If poorly designed or implemented, health IT will not bring these benefits, and in some cases may even result in new medical errors and potential costs (Koppel et al.2005).

Therefore, achieving cost savings requires a much more substantial transformation of care delivery that goes beyond simple error reduction. Health IT must be combined with real process change in order to see meaningful improvements in our delivery system. It requires the industry to follow the best diagnostic and treatment practices everywhere in the nation. For example, cholesterol screenings can lead to early treatment, which in turn can reduce the risk for heart disease. Where that has been done, there have been substantial savings on cardiac expenditures.

So, this is the clinical foundation for our work, which demonstrates that health IT can save lives, improve care, and improve efficiency in our health system; now let me turn to the economic foundation.

The Economic Foundation- The Leadership Panel

Recognizing that the healthcare sector lags behind most other industries in its investment in IT, an HHS contractor convened a Health IT Leadership Panel for the purpose of understanding how IT has transformed other industries and how, based upon their experiences, it can transform the health care industry.

The Leadership Panel was comprised of nine CEOs from leading companies that purchase large quantities of healthcare services for their employees and dependents and that do not operate in the healthcare business. The Leadership Panel included CEOs from FedEx Corporation, General Motors, International Paper, Johnson Controls, Target Corporation, Pepsico, Procter & Gamble, Wells Fargo, and Wal-Mart Stores. The business leaders were called upon to evaluate the need for investment in health information technology and the major roles for both the government and the private sector in achieving widespread adoption and implementation. Based upon their own experiences using IT to reengineer their individual business – and by extension, their industries – the Leadership Panel concluded that investment in interoperable health IT is urgent and vital to the broader U.S. economy due to rising health care demands and business interests.

As identified by the Lewin Group, the Leadership Panel unanimously agreed that the federal government must begin to drive change before the private sector would become fully engaged. Specifically, the Leadership Panel concluded:

- Potential benefits of health IT far outweigh manageable costs.
- Health IT needs a clear, broadly motivating vision and practical adoption strategy.
- The federal government should provide leadership, and industry will engage and follow.
- Lessons of adoption and success of IT in other industries should inform and enhance adoption of health IT.

- Among its multiple stakeholders, the consumer—including individual beneficiaries, patients, family members, and the public at large—is key to adoption of health IT and realizing its benefits.
- Stakeholder incentives must be aligned to foster health IT adoption.

The Leadership Panel identified as a key imperative that the Federal government should act as leader, catalyst, and convener of the nation's health information technology effort. The Leadership Panel stated that federal leverage as purchaser and provider would be needed—and welcomed by the private sector. 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. Panelists suggested that the national health IT vision must be communicated clearly and directly to enlist consumer support for the widespread adoption of health IT.

These findings and recommendations from the Leadership Panel were published in a report released in May 2005 and laid the business foundation for the HHS health IT strategy. Now, let me turn to the technical foundation.

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.

We received over 500 responses to the RFI, which were reviewed by a government-wide RFI Review Task Force. This Task Force was comprised of over 100 Federal employees from 17 agencies, including the Departments of Homeland Security, Defense, Veterans Affairs, Treasury, Commerce, and Health and Human Services, as well as multiple agencies within the

departments. The resulting public summary document has begun to inform policy discussions inside and outside the government.

We know that the RFI stimulated substantial and unprecedented discussions within and across organizations about how interoperability can really work, and we have continued to build on this. These responses have yielded one of the richest and most descriptive collections of thoughts on interoperability and health information exchange that has likely ever been assembled in the U.S. As such, it has set the foundation for actionable steps designed to meet the President's goal.

While the RFI report is an illustrative summary of the RFI responses and does not attempt to evaluate or discuss the relative merits of any one individual response over another, it does provide some key findings. Among the many opinions expressed by those supporting the development of a NHIN, the following concepts emerged:

- 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 and be a joint public/private effort.
- A governance entity composed of public and private stakeholders should oversee the determination of standards and policies.
- A NHIN should provide sufficient safeguards to protect the privacy of personal health information.
- Incentives may be needed to accelerate the deployment and adoption of a NHIN.
- Existing technologies, federal leadership, prototype localized or regional exchange efforts, and certification of EHRs will be the critical enablers of a NHIN.
- Key challenges to developing and adopting a NHIN were listed as: the need for additional and better refined standards; addressing privacy concerns; paying for the development and operation of, and access to the NHIN; accurately verifying patients' identity; and addressing discordant inter- and intra-state laws regarding health information exchange.

Key Actions

Building on these steps, two critical challenges to realizing the President's vision for health IT are being addressed: a) interoperability and the secure portability of health information, and b)

electronic health record (EHR) adoption. Interoperability and portability of health information using information technology are essential to achieve the industry transformation goals sought by the President. Further, the gap in EHR adoption between large hospitals and small hospitals, between large and small physician practices, and between other healthcare providers must 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.

To address these challenges, HHS is focusing on several key actions: harmonizing health information standards; certifying health IT products to assure consistency with standards; addressing variations in privacy and security policies that can pose challenges to interoperability; and, developing an architecture for nationwide sharing of electronic health information. HHS has allocated \$86.5 million to achieve these and other goals in FY 2005 and has requested \$125 million in FY 2006. These efforts are inter-related, and they will be coordinated through the formation of a new collaborative known as the American Health Information Community.

American Health Information Community (the Community)

On July 14, 2005, Secretary Mike Leavitt formally announced the formation of a national collaboration, the American Health Information Community (the Community), a public-private body formed pursuant to the Federal Advisory Committee Act. The Community has been formed for the purposes of helping transition the nation to electronic health records in a smooth, market-led way. The Community will provide input and recommendations to the Secretary on use of common standards and how interoperability among EHRs can be achieved while assuring that the privacy and security of those records are protected. And, it has been designed as an open, transparent and inclusive collaboration.

On September 13, 2005, Secretary Mike Leavitt announced the membership for the American Health Information Community (the Community). The Community has 17 commission members, including Secretary Leavitt, who serves as chairperson. It consists of nine members from the public sector and eight members from the private sector:

• Scott P. Serota, President and CEO, Blue Cross Blue Shield Association

- Douglas E. Henley, M.D., Executive Vice President, American Academy of Family Physicians
- Lillee Smith Gelinas, R.N., Chief Nursing Officer, VHA Inc.
- Charles N. Kahn III, President, Federation of American Hospitals
- Nancy Davenport-Ennis, CEO, National Patient Advocate Foundation
- Steven S Reinemund, CEO and Chairman, PepsiCo
- Kevin D. Hutchinson, CEO, SureScripts
- Craig R. Barrett, Chairman, Intel Corporation
- E. Mitchell Roob, Secretary, Indiana Family and Social Services Administration
- Mark B. McClellan, M.D., Administrator, Centers for Medicare and Medicaid Services
- Julie Louise Gerberding, M.D., Director, Centers for Disease Control and Prevention
- Jonathan B. Perlin, M.D., Under Secretary for Health, Department of Veterans Affairs
- William Winkenwerder Jr., M.D., Assistant Secretary of Defense, Department of Defense
- Mark J. Warshawsky, Assistant Secretary for Economic Policy, Department of Treasury
- Linda M. Springer, Director, Office of Personnel Management
- Michelle O'Neill, Acting Under Secretary for Technology, Department of Commerce

The Community will start by building on the vast amount of standardization already achieved inside and outside the healthcare industry. Specifically, the Community will:

- Make recommendations on how to maintain appropriate and effective privacy and security protections.
- Identify and make recommendations for prioritizing health information technology
 achievements that will provide immediate benefits to consumers of health care (e.g., drug
 safety, lab results, bio-terrorism surveillance, etc.).
- Make recommendations regarding the ongoing harmonization of industry-wide health IT standards and a separate product certification and inspection process.
- Make recommendations for a nationwide architecture that uses the Internet to share health information in a secure and timely manner.
- Make recommendations on how the Community can be succeeded by a private-sector health information community initiative within five years.

The Community has been chartered for two years, with the option to renew and duration of no more than five years. The Department intends for the Community to be succeeded by a private-sector health information community initiative that, among other things, would set additional needed standards, certify new health information technology, and provide long-term governance for health care transformation.

In addition to the formation of the Community, the Office of the National Coordinator issued four requests for proposals (RFPs). The outputs of the contracts stemming from these RFPs will, in part, serve as inputs for the Community's consideration. We are in the process of awarding contracts for these RFPs in September and October 2005. Specifically, these contracts will focus on the following major areas:

Standards harmonization

We are in the process of awarding a contract to develop, prototype and evaluate a process to harmonize industry-wide standards development, and also unify and streamline maintenance of and refinements to existing standards over time. Today, the standards-setting process is fragmented and lacks coordination, resulting in overlapping standards and gaps in standards that need to be filled. We envision a process where standards are identified and developed around real scenarios – i.e., around use cases or breakthroughs. A "use case" is a technology term to describe how actors interact in specific value-added scenarios – for example, rapidly assembling complete patient information in an emergency room; we also call them "breakthroughs".

Compliance certification

We are in the process of awarding a contract to develop, prototype and evaluate a process to specify criteria for the functional requirements for health IT products – beginning with ambulatory EHRs, then inpatient EHRs, and then the infrastructure components through which EHRs interoperate (e.g., NHIN architecture). The output of this contract will also evaluate a process for inspection based on conformance with these criteria.

NHIN Architecture

We are in the process of awarding a set of contracts to develop models and prototypes for a NHIN for widespread health information exchange that can be used to test specialized network

functions, security protections and monitoring, and demonstrate feasibility of scalable models across market settings. The NHIN architecture will be coordinated with the work of the Federal Health Architecture and other interrelated RFPs. The goal is to develop real solutions for nationwide health information exchange and ultimately develop a market – particularly the supply side – for health information exchange, which does not exist today. These contracts will fund up to 6 architectures and operational prototypes that will maximize the use of existing resources such as the Internet, and will be tested simultaneously in three markets with a diversity of providers in each market. HHS intends to make these prototype architectures available in the public domain to prevent control of ideas and design.

Security and privacy

HHS is in the process of awarding a contract to assess variations in state laws and organization-level business policies around privacy and security practices, including variations in implementations of HIPAA privacy and security requirements, that may pose challenges to automated health information exchange and interoperability. This contract, administered by AHRQ, will seek to define workable mechanisms and policies to address these variations, while maintaining the levels of security and privacy that consumers expect.

Fraud and Abuse Study

HHS has a 6-month project underway to determine how automated coding software and a nationwide interoperable health information technology infrastructure can address healthcare fraud issues. The project is being conducted through a contract with the Foundation of Research and Education (FORE) of the American Health Information Management Association (AHIMA)

While only a small percentage of the estimated 4 billion healthcare claims submitted each year are fraudulent, the total dollars in fraudulent or improper claims is substantial. The National Health Care Anti-Fraud Association (NHCAA) estimates that healthcare fraud accounts for 3 percent of U.S. health expenditures each year, or an estimated \$56.7 billion. They cite other estimates, which may include improper but not fraudulent claims, as high as 10 percent of U.S. health expenditures or \$170 billion annually.

At present, the contractor is completing two main tasks. One task is a descriptive study of the issues and the steps in the development and use of automated coding software that enhance healthcare anti-fraud activities. The second task is identifying best practices to enhance the capabilities of a nationwide interoperable health information technology infrastructure to assist in prevention, detection and prosecution, as appropriate, in cases of healthcare fraud or improper claims and billing. An expert cross-industry committee composed of senior level executives from both the private and public sectors has guided this second task.

The project's final report is on schedule for completion in September 2005.

EHR Adoption Study

To realize 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 arrive at an "EHR adoption rate." These surveys have revealed an adoption gap exists; 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, the National Coordinator is issuing a contract for an EHR measurement initiative to more accurately and consistently measure EHR adoption and thus progress toward meeting President's goal of wide spread adoption of EHRs in 10 years.

Conclusion

Thank you for the opportunity to present this summary of the activities of the Office of the National Coordinator for Health Information Technology. A year ago, the President created this position by Executive Order. In that time, we have established the clinical, business and technical foundations for the HHS health IT strategy. Now, we have begun to execute key actions that will give us real, tangible progress toward that goal.

HHS, under Secretary Michael 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.

Chairman, this concludes my prepared statement. I would be delighted to answer any questions that you or the Members of the Committee may have.

Chairman Tom DAVIS. Thank you very much. Dr. Kolodner.

STATEMENT OF ROBERT KOLODNER

Dr. KOLODNER. Good morning, Mr. Chairman and members of the committee. I am Dr. Robert Kolodner, the Chief Health Informatics Officer in the Department of Veterans Affairs. Thank you for inviting me here today to discuss our work in the field of health information technology.

Seventeen months ago President Bush outlined an ambitious plan to ensure that most Americans have electronic health records within 10 years. The President made his announcement during a visit to the Baltimore VA Medical Center where patients have benefited from electronic health records for years.

Four months ago, HHS Secretary Leavitt issued a report which concluded that the widespread adoption of IT should be a top priority for the American healthcare system and the U.S. economy. Collaboration between private sector organizations, and public sector health entities such as VA, and activities like Connecting for Health, and the eHealth Initiative were cited as a key factor in the advancement of health IT.

One month ago Hurricane Katrina struck, and in minutes the IT innovations we have been pursuing for years suddenly went from esoteric to essential. My written testimony describes VA's health IT activities in greater detail, but I want to highlight in my oral testimony the benefits of these activities during this recent crisis.

VA's Electronic Health Record, known as VistA, is recognized as one of the most comprehensive and sophisticated electronic health records in use today. As a doctor and as a patient, I am passionate about the use of this technology and the very real effect it can have on patients' lives. It can mean the difference between life and death.

How many of the Katrina evacuees with chronic medical conditions would have been spared additional suffering if their treatments and medications had continued without disruption because their new physicians and access to their previous medical records? What would have been the value to the millions of Katrina evacuees of we had a National Health Information Network in place to support access to their complete health information regardless of where the evacuees sought care?

For our patients, these capabilities are not the stuff of fantasy. Our VistA system supports secure nationwide access to our patients' health information and gives our providers a single place to review test results and drug prescriptions, place new orders, and update a patient's medical history. VistA is used routinely at all VA medical centers, outpatient clinics, and long term care facilities across the country. That is over 1,300 sites of care.

Of course, electronic systems of any sort are not impervious to natural disasters. In the aftermath of Hurricane Katrina, many of the IT systems VA relies on were interrupted, and a great deal of work was needed to restore network connectivity, email, Black-Berry service, and other telecommunications. While clinicians and emergency personnel focused on saving lives, IT staff worked

around the clock to restore access to critical patient care information.

Katrina had a significant impact on more than a dozen VA healthcare facilities in the Gulf Coast Region. When Katrina hit, the Gulfport VAMC was completely destroyed. New Orleans VA Medical Center was forced to shut down their VistA system and evacuate their patients when that city flooded. Although power and communications were lost at the Jackson and Biloxi VA Medical Centers, their VistA systems continued to operate within those facilities using emergency generator power.

Although medical records were temporarily unavailable for evacuated patients, within 1 day, we were able to provide access to pharmacy, laboratory, and radiology results for all of these patients using a regional data warehouse. With less than 100 hours of effort, we were able to bring the New Orleans VistA system back online.

And by the next week, when commercial telecommunications were restored to Biloxi, the complete electronic health records for all veterans were again available nationwide to help us serve these veteran evacuees. Many patients affected by Katrina, such as the 282 veterans from the Gulfport Armed Forces Retirement Home who were relocated to their sister campus less than 2 miles from the Capital had minimal disruption in their continuity of their healthcare.

The difference between the availability of electronic health records and paper medical records is striking. Many or most of the paper records in the affected areas may never be recovered. The result is that the majority of the 1 million people displaced by Hurricane Katrina have incomplete medical records or no medical records at all, a consequence that will affect families and communities across the Nation.

This single natural disaster has reinforced the Nation's need for a host of technical advances from electronic health records and personal health records to secure communications networks. The VA quick recovery of crucial health information after Hurricane Katrina simply would not have been possible without VistA. Our experience confirmed that VA's health IT strategy, including our new initiative to provide personal health records to veterans, has been a good one as we continue to invest in, refine, and improve our information technology solutions to support the future models of healthcare.

One of the most important vehicles for achieving the President's vision for health IT is the AHIC which was discussed by Dr. Brailer and convened by HHS. We are delighted that VA's Under Secretary for Health, Dr. Jonathan Perlin, will serve as one of the 17 AHIC Commissioners. I invite each of you to visit a VA medical center to see our systems firsthand. We look forward to sharing our systems, knowledge, and expertise with our partners through the healthcare community.

Mr. Chairman, this completes my statement. I will be happy to answer any questions that you or other members of the committee have.

[The prepared statement of Mr. Kolodner follows:]

Statement of
Robert M. Kolodner, MD
Chief Health Informatics Officer
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Department of Veterans Affairs

Before the U.S. House of Representatives Committee on Government Reform September 29, 2005

Good Morning, Mr. Chairman and Members of the Committee.

Thank you for inviting me here today to discuss our work in the field of health information technology.

In April of last year, Dr. Jonathan B. Perlin, MD, PhD, MSHA, FACP, Under Secretary for Health, Department of Veterans Affairs, appeared before the House Committee on Veterans' Affairs, Subcommittee on Oversight and Investigations to discuss the importance of electronic health records and the role of the Department of Veterans Affairs (VA) in the development, use, and sharing of this valuable technology. President Bush had just outlined an ambitious plan to ensure that most Americans have electronic health records within 10 years. The President noted a range of benefits possible with the expanded use of information technology, including reduced costs; improved health care quality; reduced frequency of medical errors; advancements in the delivery of appropriate, evidence-based medical care; greater coordination of care among different providers; and increased privacy and security protections for personal health information.

A lot has happened in the field of health information technology in the year since the President's call to action announced at the VA Maryland Health Care System in April 2004, and discussions about the potential of electronic health records have become part of the national conversation. I have included, for the record, a brochure that highlights President Bush's April visit to the Baltimore VA Medical Center.

One of the most important vehicles for achieving the President's vision for health IT is the American Health Information Community (AHIC), convened by the Department of Health and Human Services (HHS). AHIC will provide a valuable forum for us to work with our public- and private-sector partners on issues affecting veterans' health. VHA Under Secretary for Health Dr. Jonathan B. Perlin, will serve as one of 17 AHIC commissioners. AHIC will actively engage with the health community to provide input and recommendations to HHS on how to make health records digital and interoperable,

and ensure that the privacy and security of those records are protected, in a smooth, market-led way.

Today I'd like to talk about VA's leadership in the field of health information technology, and tell you about our next generation health information system, known as HealtheVet. I'd also like to highlight our work in three areas that I think are pivotal to the broader, successful adoption of electronic health records: data standardization, interoperability, and privacy.

A History of Innovation

With one of the most comprehensive electronic health record (EHR) systems in use today, VA is a recognized leader in the development and use of EHRs and other information technology tools. VA's work in health information technology goes back almost 30 years, when VA created the Decentralized Hospital Computer Program (DHCP), one of the first automated health information systems ever developed to support multiple sites and cover the full range of health care settings. VA has continued to lead the health care community in the development of new health IT tools, building on the foundation of DHCP to create the VistA system in use today – a suite of over 100 applications which support the day-to-day clinical, financial, and administrative functions of the Veterans Health Administration (VHA). These applications form the foundation of VistA – the Veterans Health Information Systems and Technology Architecture, the automated health information system used throughout VHA.

Many VistA enhancements were designed to support the transformation of the VA health system over the past decade, as VA shifted its emphasis from inpatient care to outpatient care, and introduced performance measures and performance-based accountability throughout its health care system. In the mid-1990's, VHA embarked on an ambitious effort to improve the coordination of care by providing integrated access to these applications through implementation of an electronic health record, known as the Computerized Patient Record System or CPRS.

With CPRS, providers can access patient information at the point of care – across multiple sites and clinical disciplines. CPRS provides a single easy to use graphical user interface through which providers can update a patient's medical history, place a variety of orders, and review test results and drug prescriptions. The system has been implemented at all VA medical centers and at VA outpatient clinics, long-term care facilities, and domiciliaries – 1,300 sites of care throughout VHA.

The Benefits of Electronic Health Records

Electronic health records, or EHRs, are appealing for a number of reasons, including convenience, availability, and portability. The most compelling reason to use information technology in health care is that it helps us provide better, safer, more consistent care to all patients. The President referred to an off-cited 1999 report in which the Institute of Medicine (IOM) estimated that between 44,000 and 98,000

Americans die each year due to medical errors. IOM's 1999 report further found that many more die or suffer permanent disabilities because of inappropriate or missed treatments in ambulatory care settings. IOM cited the development of an electronic health record as essential for reducing these numbers and improving the safety of health care. In its 2002 publication *Leadership by Example*, IOM noted that "[c]omputerized order entry and electronic medical records have been found to result in measurably improved health care and better outcomes for patients."

How do EHRs improve patient safety and quality of care? First, with an EHR, all relevant information is available to clinicians when they need it, where they need it – and it's legible. A provider can quickly review information from previous visits, have ready access to clinical guidelines, and survey research results to find the latest treatments and medications. All of this information is available wherever patients are seen – in acute settings, clinics, examining rooms, nursing stations, and offices.

Many of us see different doctors for different medical conditions. How many of these physicians have access to all of the information that has been collected over the course of these visits? In VHA, patient records from multiple sites and different providers can be viewed at the same time at the point of care. This is simply not possible with paper records.

In addition to making medical records more accessible, EHRs help clinicians better document the reasons a patient sought care and the treatment that was provided. Given the time constraints they face, many physicians resort to writing brief, sometimes cryptic notes in a patient's chart, and then write more complete documentation when they have time. EHRs enable clinicians to document care quickly and thoroughly, and can provide reminders based on the specific medical conditions and test results that have been documented.

CPRS, for example, allows clinicians to enter progress notes, diagnoses, and treatments for each encounter, as well as discharge summaries for hospitalizations. Clinicians can easily order lab tests, medications, diets, radiology tests, and procedures electronically; record a patient's allergies or adverse reactions to medications; or request and track consults with other providers.

Even if we could transfer paper records quickly and reliably from one provider to another, and make sure that the information in records was complete, many hard-copy patient records simply contain too much information for a clinician to sift through effectively. There is always the possibility that something crucial could be missed. When health information is stored electronically, however, we can make use of software tools to analyze that information in real-time. We can target relevant information quickly, compare results, and use built-in order checks and reminders to support clinical decision-making. These capabilities promote safer, more complete, more systematic

Consider the benefits we have seen in VHA in the area of medication ordering. When orders for medications are handwritten or given verbally, opportunities for errors are unacceptably high and occasional serious errors are inevitable. However, when physicians use computerized order-entry systems to enter medication orders electronically, errors caused by illegible handwriting or misinterpretation of dosages, strengths, or medication names are virtually eliminated. CPRS includes automated checks for drug-drug or drug-allergy interactions, alerting the prescribing physician when potentially dangerous combinations occur. Currently, 94% of all VHA medication orders are entered by the ordering provider directly into VistA using CPRS.

Information technology can also serve to reduce the number of errors that occur when medications are given to a patient. VHA's Bar Code Medication Administration system (BCMA) is designed to ensure that each patient receives the correct medication, in the correct dose, at the correct time. In addition, the system reduces reliance on human short-term memory by providing real-time access to medication order information at the patient's bedside.

BCMA provides visual alerts – prior to administration of a medication – if the correct conditions are not met. For example, alerts signal the nurse when the software detects a wrong patient, wrong time, wrong medication, wrong dose, or no active medication order. These alerts require the nurse to review and correct the reason for the alert before actually administering the drug to the patient. Changes in medication orders are communicated instantaneously to the nurse administering medications, eliminating the dependence on verbal or handwritten communication to convey these order changes. Time delays are avoided, and administration accuracy is improved.

BCMA also provides a system of reports to remind clinical staff when medications need to be administered or have been overlooked, or when the effectiveness of administered doses should be assessed. The system also alerts staff to potential allergies, adverse reactions, and special instructions concerning a medication order, and order changes that require action.

The VistA Imaging system is another application which has extended the capabilities of VistA and CPRS. VistA Imaging stores medical images such as x-rays, pathology slides, scanned documents, cardiology exam results, wound photos, and endoscopies directly into the patient record as soon as they become available, providing clinicians with additional information essential for diagnosis and treatment.

I have used VA's electronic health record system for years. As a doctor – and as a patient – I am very enthusiastic about the benefits of this technology.

The Importance of Standards

The richness of VA's EHR is evident, in terms of both clinical features and health data. Imagine the benefits of sharing this data – appropriately and securely – among VA's health delivery partners, so that relevant health information would be available

regardless of where a veteran sought care. As we move towards this goal, we need to make sure that we share not only *data*, but *meaning*. And to do this, we need health data standards.

Virtually all clinical documents created by VA providers are stored in the EHR, and data from commercial medical devices can be transmitted automatically directly into a patient's health record. To give you a sense of the magnitude of EHR use in VA, let me give you some round numbers: As of June 2005, VA's VistA systems contained 698 million progress notes, discharge summaries, and other clinical documents; 1.4 billion orders, and 338 million images. More than 567 thousand new clinical documents, 930 thousand orders, and 533 thousand images are added *each workday* – a wealth of information. As VA moves to a patient-centered health data repository, over 850 million vital sign recordings from sites throughout VA will also be available. And yet, with an electronic health record – as with a paper record – more information isn't always better if we can't use it. How can we be sure we can take full advantage of the voluminous information we collect in the EHR? The key is data standardization.

There's an old joke in the standards field: "The great thing about standards is that there are so many to choose from." For nearly every kind of clinical data – from diseases, procedures, and immunizations, to drugs, lab results, and digital images – there are multiple sets of standards to choose from. For example, there are at least 12 separate systems for naming medications, and the ingredients, dosages, and routes of administration associated with them.

It is often necessary to use a combination of data standards to transmit a single message from one system to another. Even health care organizations committed to using standards have a difficult time figuring out which standards to use.

Consolidated Health Informatics (CHI) is an eGov initiative involving Federal agencies with responsibility for health-related activities and information. CHI participants evaluate and choose health data and communication standards to be incorporated into their IT systems maintaining, processing, or transmitting this information. VA was instrumental in the formation of CHI, and works closely with the Department of Defense (DoD) and the Department of Health and Human Services (HHS), and other CHI partners, to help foster the federal adoption of the agreed-upon standards as part of a joint strategy for developing federal interoperability and sharing of electronic health information. To date, CHI has selected 20 communications and data standards in areas such as laboratory, radiology, pharmacy, encounters, diagnoses, nursing information, and drug information standards developed through collaboration between VA and HHS. We also work with external Standards Development Organizations (SDOs) to augment and refine available standards to ensure that they meet health care delivery needs in the VA.

Within VA, we have established a formal program across all sites of care, to coordinate the adoption, implementation, and verification of health data standards selected through the CHI process, and standards agreed upon through the AHIC process as they become available. The work involved in adopting and implementing data standards is

deliberative and difficult. It requires collaboration among clinicians, health information professionals, developers, and business process experts. Yet, the use of data standards can have a very real effect on a patient's care.

When VA developed its first EHR, the technological environment in VA hospitals – as in other hospitals at the time – was very different from the environment today. There was not a computer on every desk. There were no graphical user interfaces, only text-based displays on "dumb terminals." There were no multi-color screens, no Windows, no pull-down menus. No one had a mouse. When you wanted to enter data in an electronic health record, you didn't point-and-click to choose from a menu of options, you typed.

For example, when a clinician wanted to document a patient's allergy to penicillin, he typed the word "penicillin" in the allergy section of the patient's electronic health record. To save time, many clinicians entered "PCN", a common abbreviation for penicillin.

As part of our data standardization effort, we went back and looked at the allergy data that had been collected over the years. We found that "penicillin" and "PCN" had been typed in more than 75,000 times. We also found thousands of entries in which penicillin had been misspelled. Not only is it a waste of time to type the same information over and over, it introduces a potential patient-safety issue. Let me give you an example.

Suppose a veteran comes in for a check-up and tells the physician that he is allergic to sulfa drugs. The physician enters this information in the patient's record under allergies, but because he is typing quickly, he inadvertently misspells the word 'sulfa'. Suppose that on a subsequent visit, another clinician orders Sulfamethoprim, which is a type of sulfa drug. When a clinician orders a medication, CPRS checks the patient's record to see if the patient is allergic to the medication. Although the system checks for common misspellings, it can't predict every possible misspelling of every medication. In this case, CPRS might not alert the second physician that he had ordered a drug the patient was allergic to, simply because the word "sulfa" was misspelled when it was entered by the first physician. By eliminating misspellings and establishing a standard vocabulary across sites, we will ensure that medication order checks work as intended, and that the EHR supports patient safety and clinical decision-making to the fullest extent.

Data Standards and Interoperability

The use of electronic health records and other information technology tools in a single medical office can improve health care quality, reduce medical errors, improve efficiency, and reduce costs for the patients treated there. However, as the President noted a year ago, the full benefits of IT will be realized when we have a coordinated, national infrastructure to accelerate the broader adoption of health information technology.

The problems created by a lack of standardized data are magnified when interacting with other organizations. Even seemingly straightforward information can be misconstrued when it is interpreted by different organizations.

Consider two simple terms: yes and no. In many computer systems, the number '1' is used to indicate 'yes', and the number '2' is used to indicate 'no'. In some systems, it is reversed: '1' means 'no', and '2' means 'yes'. Some systems use '0' and '1', instead of '1' and '2'. In still other systems, 'Y' is used to indicate 'yes', and 'N' is used to indicate 'no'. Sometimes lower-case 'y' and 'n' are used. Sometimes, 'yes' is actually stored as 'y-e-s', and 'no as 'n-o'. In VA, we found 30 different combinations of codes for 'yes' and 'no', stored in nearly 4,000 different data fields. We can standardize our representation of 'yes' and 'no' within VA computer systems, but unless our healthcare partners employ the same standards to exchange data with us, we cannot be sure that we are conveying the intended meaning of the data we are exchanging. If standardizing on a simple "yes or no" is this complicated, just imagine the complexity of implementing standards across all areas of health information.

The Office of the National Coordinator for Health Information Technology (ONCHIT) recognizes the importance of data and communications standards in developing a comprehensive network of interoperable health information systems across the public and private sectors. Without data standards, we might be able to exchange health information, as we do now when we copy and send paper records, but we won't be able to use it as effectively to deliver safer, higher-quality care using clinical alerts and reminders. True interoperability between providers simply cannot be achieved without data standardization.

VHA has a long history of participation in standards development organizations. As a health care provider and early adopter of health IT on a large scale, VHA frequently identifies areas for standards development and works with other public- and private-sector organizations to develop consensus-based solutions. HHS Secretary Mike Leavitt recently announced the formation of the American Health Information Community. ONCHIT has released a Request for Proposal to develop, create prototypes for, and evaluate a process for standards harmonization. This effort will foster a more cohesive, integrated approach to standards development, replacing the existing fragmented, inefficient approach in which standards are developed topic-bytopic. VHA supports ONCHIT efforts and continues to participate in HHS-led activities with other Federal partners.

Our data standardization efforts at VA have already improved our ability to share information with other agencies. I'd like to highlight our work with the Department of Defense.

In April 2002, VA and DoD adopted a joint strategy to develop interoperable electronic health records by 2005. This cross-cutting initiative, known as the VA/DoD Joint Electronic Health Records Interoperability (JEHRI) Plan - Health People (Federal), is based on the common adoption of standards, the development of interoperable data repositories, and joint or collaborative development of software applications to build a replicable model of data exchange technologies. The progress made by VA and DoD has served as a catalyst to move the health care industry toward the use of interoperable health information technologies that have the potential to improve health

care delivery, increase patient safety, and support the provision of care in times of crisis.

Through collaborative efforts, VA and DoD will be better positioned to evaluate health problems among service members, veterans, and shared beneficiary patients; to address short- and long-term post-deployment health questions; and to document any changes in health status that may be relevant for determining disability.

VistA-Office EHR

As a physician, I have seen first-hand the benefits of electronic health records in VA: immediate access to information, elimination of duplicate orders, increased patient safety, improved information-sharing, more advanced tracking and reporting tools, and reduced costs. VHA is now working with the Centers for Medicare and Medicaid Services (CMS) to make the benefits of electronic health records available to private physician offices and clinics. CMS is contracting to adapt the VistA-Office EHR (VOE), an enhanced version of VA's VistA and CPRS designed specifically for use in non-VA clinics and physician offices. On September 19th, CMS released an evaluation version of VOE, and will be closely monitoring the impacts of this release.

The HealtheVet Program

The spirit of innovation that inspired the development of VistA, CPRS, BCMA, and VistA Imaging has led VA to the next step in the evolution of health care IT – HealtheVet. HealtheVet-VistA is VA's next-generation health information system, designed to support more personalized care for our veterans, more sophisticated clinical tools for our doctors and nurses, and more advanced communication with our health care partners. HealtheVet builds on decades of VA expertise in health care IT to support the strategic goals of the department, meet interagency obligations, take advantage of new developments in technology to address weaknesses in the current system, and most importantly, improve the safety and quality of health care for veterans.

VA has been recognized by IOM and the mainstream press as having one of the most sophisticated EHR systems in the world. VistA and CPRS are in the public domain and have served as models for healthcare organizations in the public and the private sectors alike. VistA has been adopted for use by the District of Columbia Department of Health, and state veterans homes in Oklahoma. A number of other countries have either implemented VistA or expressed an interest in acquiring the technology. VA's DHCP system was modified for use in DoD and DHCP, and VistA is used in modified form by the Indian Health Service. By the late-1990's, the three largest federal systems providing direct health care were using derivatives of VA's EHR, although only VA was using the current and more robust version including CPRS.

Under the HealtheVet-VistA program, VA will incrementally enhance and supplement the current functional capabilities of VistA and will provide increased flexibility, more sophisticated analytical tools, and support for seamless data sharing among providers

both within and outside VA. Like VistA, software developed under the HealtheVet program will be available in the public domain. Federal agencies, small medical practices, and EHR system vendors will all benefit from the advances made through HealtheVet-VistA.

Given the success of VistA, some people have asked why we are changing it. The short answer is "to benefit the veteran".

VA health IT systems have been forged and tested in the real world of health care. I can think of no other successful organization, with a history of innovation and a world-class system, that would simply rest on its laurels.

One reason there is so much interest in VistA is that it has never been a static system. The health care environment of today is not the health care environment of ten years ago. Nor is the VistA system today the VistA system of ten years ago — or even of one year ago. VA has continued to refine and enhance VistA since its introduction to reflect advances in clinical practice, the availability of new commercial products, the changing VA health care model, new Congressional mandates (such as those related to current combat engagements), and federal laws (such as the Health Insurance Portability and Accountability Act, the Federal Information Security Management Act, and the Privacy Act.

We have to make these types of changes all the time – that's the nature of health care. The current VistA system has served us well through decades of transformation in health care. But VA has outgrown its facility-centric architecture, and the system is simply becoming too expensive to maintain. HealtheVet-VistA will give us a more flexible architecture so that we can support integrated ambulatory care and home-base health care, maintain continuity of operations in the event of a disaster, and improve response time by increasing system capacity and communications speed.

Health<u>e</u>Vet-VistA will also allow us to strengthen privacy and security protections through use of features such as role-based access. We will be able to limit access to information based on the user's identity, location, job function, or legal authority, for example. We will strengthen our ability to track exactly who looks at the information, at what time, and for how long.

An estimated 40% of veterans we treat at VA each year also receive care from non-VA physicians. VA is working with DoD, ONCHIT, and other partner organizations to develop a longitudinal health record that will incorporate information from DoD, VA, and private-sector health providers from whom the veteran has sought care. Throughout these collaborative projects, safeguards have been implemented to ensure that the privacy of individuals is protected in accordance with the various confidentiality statutes and regulations governing health records, including the Privacy Act, the HIPAA Privacy Rule, and several agency-specific authorities. As we work toward greater data exchange and true interoperability with our health care partners, privacy and security of medical information will be a top priority.

Personal Health Records and My HealtheVet

I'd like to highlight another key component of the Health<u>e</u>Vet initiative: the My Health<u>e</u>Vet personal health record system, designed specifically to meet the needs of veterans

Personal health records are an adjunct to the electronic health records used in a clinical setting, providing patients a secure means of maintaining copies of their medical records and other personal health information they deem important. Information in a personal health record is the property of the patient; it is the patient who controls what information is stored and what information is accessible by others. Personal health records enable patients to consolidate information from multiple providers without having to track down, compile, and carry around copies of paper records. By simplifying the collection and maintenance of health information, personal health records encourage patients to become more involved in the health care decisions that affect them.

The VHA My HealtheVet project was conceived as a way to help veterans manage their personal health data. My HealtheVet is a secure, web-based personal health record system designed to provide veterans key parts of their VHA health record as well as enabling them to enter, view, and update additional personal health information. Patients who take over-the-counter medications or herbs, or who monitor their own blood pressure, blood glucose, or weight, for example, can enter this information in their personal health records. They can enter readings such as cholesterol and pain, and can track results over time. My HealtheVet includes a direct link to the Medlineplus.gov library of information on medical conditions, medications, health news, and preventive health from the National Institutes of Health and other authoritative sources. Veterans can use the system to explore health topics, research diseases and conditions, learn about veteran-specific conditions, understand medication and treatment options, assess and improve their wellness, view seasonal health reminders, and more.

The implications of My HealtheVet are far-reaching. Clinicians will be able to communicate and collaborate with veterans much more easily. With My HealtheVet, veterans are able to consolidate and monitor their own health records and share this information with non-VA clinicians and others involved in their care. Patients who take a more active role in their health care have been found to have improved clinical outcomes and treatment adherence, as well as increased satisfaction with their care.

The first version of My HealtheVet was released on Veterans Day 2003, and more than 50,000 veterans are now registered to use the system. The My HealtheVet user community is growing, with over 300 new registrants joining each day. By the end of this summer, veterans who receive their health care at VA will be able to use My HealtheVet to refill prescriptions online. By this time next year, veterans receiving care at VA medical centers will be able to request and maintain copies of key portions of their health records electronically through My HealtheVet and to grant authority to view that

information to family members, veterans' service officers, and VA and non-VA clinicians involved in their care. This would allow a relative to provide support and care – even at a distance – by being better informed about the veteran's health and medical status. Subsequent releases will provide additional capabilities, enabling veterans to view upcoming appointments and see co-payment balances.

Summarv

For decades, VA has developed innovative IT solutions to support health care for veterans. Over the past several years, VA has worked with federal, state, and industry partners to broaden the use of information technology in health care. We have continued to enhance the capabilities of the EHR while protecting the privacy of our veteran population and maintaining the integrity of our systems. These efforts have helped lay the groundwork for the President's health IT initiative.

The team of VHA developers, clinicians, and administrators who designed VistA changed the practice of medicine in VA by creating IT tools such as these to support the interaction between providers in VA and their patients, increase patient safety, and improve reporting and tracking of clinical and administrative data. VA is now involved with public- and private-sector partners in the development of a new national model for the use of IT in health care, featuring more sophisticated clinical decision support tools, increased data sharing among health care providers, and the availability of affordable EHR technology to providers large and small.

When he announced his plan to transform health care through the use of information technology, the President noted our country's long and distinguished history of innovation — as well as our failure to use health information technology consistently as an *integral* part of medical care in America.

We still have a long way to go in optimizing our use of information technology in health care; yet, we are not starting from scratch. Electronic health records, personal health records, data and communication standards, and sophisticated analytical tools – the building blocks of a comprehensive, national health information infrastructure – have already been implemented in some communities and settings and are maturing quickly. Our challenge is to create a technology infrastructure that will revolutionize health care without interfering with the human interaction between physicians and patients that is at the core of the art of medicine and without compromising the security and privacy of personal health information.

The President recognized America's medical professionals and the skill they have shown in providing high-quality health care despite our reliance on an outdated, paper-based system. At VA, we know that the support of clinicians is essential to the successful implementation of electronic health records and new IT tools. Clinicians, while often the greatest proponents of health information technology, can also be the greatest critics. At VA, physicians, nurses, and other providers are actively involved in defining requirements and business rules for systems, prioritizing enhancements, and

conducting end-user testing. This involvement improves system usability, increases user acceptance, minimizes disruption during upgrades, and most importantly, enables us to tailor systems to the needs of the health care community.

Throughout VA, the electronic health record is no longer a novelty – it is accepted as a standard tool in the provision of health care. For 20 years, VA has been an innovator in health care IT. We are now at the brink of a new era in health care, in which a new national model for the use of IT will support the development of more sophisticated clinical decision support tools, increased data sharing among health care providers, and the broader availability of affordable EHR technology to providers large and small. As VA refines and expands its use of information technology, we look forward to sharing our systems and expertise with our partners throughout the health care community to support the President's plan for transforming health care – and the health of our veterans.

Mr. Chairman, this completes my statement. I will now be happy to answer any questions that you or other members of the Subcommittee have.

Chairman Tom Davis. Well, thank you both.

Dr. Brailer, let me start with you. You mentioned the adoption gap in electronic health records between large and small hospitals, and you mentioned several areas you are focusing on to bridge that

gap. Ultimately, isn't this about money and resources?

Dr. Brailer. Money and resources are clearly one of the fundamental challenges, but there are also numerous other barriers as well. I will just identify a few. First, to the financial resources, we know that for many providers, they invest in health information technology and can't recover those investments. This is because either they are small or because of the way they are paid, but this is a challenge for some organizations.

But beyond that, there is a technical capacity and technical know-how. Many large organizations do have substantial resources of experts about information technology and small organizations don't have that. Large organizations also have the capacity to operate, if you would, strategically to be able to understand how they can get the benefits from these tools as they compete in the mar-

ket, and many small organizations cannot.

So the gap of adoption is multifaceted and can't be crossed only with money. And it means raising the know-how of these organizations, providing to them resources to help them implement these complicated systems, and re-engineer their workflows to change the way their business operates, and to have the kinds of benefits that other large organizations bring.

Chairman Tom Davis. Transforming the use of IT in healthcare delivery is a huge task. What kind of incentives does the Federal Government need to create to keep the private sector involved?

Dr. Brailer. Many payers have looked at this question. And the Federal Government is able to operate really in two ways with respect to this healthcare financing question. First, in CMS, and Medicare, and Medicaid, there is activity underway through demonstration projects and forthcoming through MMA implementation for CMS to provide incentives for health IT adoption through pay for performance programs, essentially allowing organizations that are paid somewhat of a differential for performance to be able to get a bonus for health IT.

And this is consistent with how the private sector has viewed the role of other payers providing ultimate payment for the value that health information technology brings. Second, through organizations like the Office of Personnel Management, many other purchasers of care, other large employers are looking at how to direct their health plans and other carriers to support health information technology adoption among providers. There are many ways, and this is consistent with how we view the Federal Government's role of being a catalyst and a purchasing promoter of good health IT. Chairman Tom Davis. Dr. Kolodner, has VA's VistA project been

able to demonstrate any improvements in quality of care?

Dr. KOLODNER. Yes, Mr. Chairman. The VA's VistA system is part of a suite of activities including performance measure that VA has used to improve its quality of care over the last 10 years, and we currently have quite a number of performance measures that are published in the literature that show that VA's quality of care meets or exceeds that quality of any other healthcare system in the

country. There have been reports by the Rand Corp. that have been published to that effect, and other measures that we have.

Chairman Tom Davis. Dr. Brailer, recent articles report that the State and public health officials, who have a lot to gain from the improved use of IT in healthcare, are feeling excluded from national strategy efforts. Are you working to better include health IT efforts? Do you think these are justified? Are we doing things like establishing regional health information organizations and national health information networks? Can you talk a little about that?

Dr. Brailer. Sure. I am unaware of those reports, and I am frankly surprised by them. I think one of the most interesting and useful aspects of health information technology is the grassroots

nature, both at the State and community level.

We have seen more than 200 regional areas come together and form regional health information organizations where a local group is able to begin understanding what they can do to bring these tools to their doctors, hospitals and consumers, to be able to address privacy concerns and other security issues, to support adoption financing and other things. It is a remarkable effort, and it is something that didn't happen at the behest of the Federal Government or at any other entity; it came together because of this broad grassroots interest.

Also, many States are involved and have activities underway. I have personally visited 20 States so far that have health information technology efforts underway, and we are working very closely with them. This one new collaborative relationship we are about to establish around security and privacy will be directly with States, working together to understand how we can advance security and

privacy rules.

So I think that there is a significant amount of activity underway, and we work very closely with them, and I certainly look forward to expanding that in the future.

Chairman Tom Davis. Thank you very much.

Mr. Clay.

Mr. CLAY. Thank you, Mr. Chairman, and I thank the witnesses

for being here.

Dr. Brailer, there is no questioning the leadership you have provided the Government in the area of electronic health records, but I am concerned that you do not have adequate resources or authority to bring all Federal agencies into compliance. What barriers do you see having an impact on getting the Federal agency community to adopt and implement health informatic standards developed through your office? Has there been agency resistance to particular initiatives begun by your office?

Dr. Brailer. First, thank you, sir. I appreciate the support for

what we are doing.

It is certainly the case that before this office was created, many different Federal agencies viewed them having a charge to support health information technology, or standards, or things related to this.

And as you might not be surprised to know, they worked somewhat independently, agencies in the Veterans Affairs Department, DOD, and HHS. I have been very well received by these agencies, in fact more than I expected, and beyond that we have had very

good working relationships with them address to these foundational questions on standards.

Let me give you two examples. We will announce this new partner for standards harmonization, and that entity will be an entity where all the Federal agencies come together, along with the private sector, to agree on a common set of standards. And this has

been done with and through the agencies.

Second, in our certification partner, it is the same thing, where many agencies are involved in this effort, and we will look and take their cues from that as well. We are doing other things internally to make sure we have alignment in our goals and alignment in our plans, but I would never characterize our relationships with the agencies as not cooperative and not focused on the same goal. There are certainly more things we can and will do, but I am very, very happy with the amount of progress that we have made to

Mr. Clay. That is good to hear. Perhaps this is somewhat forward thinking, but can you expand on the measures and outcomes you will be utilizing to demonstrate progress and efficiencies achieved through a nationwide health information infrastructure? Are there sufficient tools in place to measure the benefits of implementing an interoperable standard structure for electronic health records? And also, have you thought about how to protect the privacy rights of patients?

Dr. Brailer. Thank you. It is something that I am happy to speak about. We actually very soon will be announcing a contract with an independent third party that will perform an annual survey that looks at the adoption of electronic health records and the

electronic transactions that share clinical data.

And that gets to the very base level of: Are these tools being put in place? Are they being put in place across both urban and rural settings, across large providers and small, in different specialties or different other settings? We want to understand that, and we want it to be done objectively. So that will be underway starting this year.

There are two levels above that. One, given that these tools are adopted, the question becomes: Are they being used? And we have been working with a variety of organizations that already inspect or observe what clinicians do in their offices or what hospitals do. They are onsite, like NCQA and the Joint Commission, to understand what they can do to being looking not at adoption but are they being used.

And then the final question, and the one where we all want to be, is: What are the outcomes? I have been very encouraged by the studies that are done in some of the large pay for performance projects, where organizations that do have health information technology do substantially better in their performance than those that do not. So we want to look for the final value that is realized by

the American public.

And to your comment, there are negative outcomes, the potential for privacy breaches or new abuses that come from this data, and this is exactly what the Security and Privacy Consortium will speak to. What do we need to put in place at a business policy or a public policy to ensure that as we move into the Information Age that we have policies and tools to take us there as well? We will be watching for complaints, privacy breaches, things that are already being reported but asking an additional question about: Is

this related to an information tool, or is it paper?

Mr. CLAY. That is reassuring to know that you are sensitive to the privacy issues and how we protect the patients to the utmost. One last question, the Federal Government seems to be an appropriate vehicle to coordinate the development of a National EHR System but have State and local governments begun the widespread use and implementation of these systems?

Dr. Brailer. We have had, as I commented with the prior question, very encouraging relationships and progress with States, but it is variable. There are about 20 States that have been quite enthusiastic, that have come forward and are working with us, that are looking at how they can incorporate support for health IT in, for example, their Medicaid program, or in looking at their own State privacy laws, or at licensure issues, or at encouraging adoption in State funded or county-funded clinics and other settings.

And then other States are, I would call, neutral. We have none that have really been adverse or opposed to this, but there are some that I think see differential priorities, other things they have to do first. So we are working more with the willing today, but we want to create an imperative where all the States see this as something fundamental to what the State government does.

Mr. CLAY. Thank you for your response. Thank you, Mr. Chair-

man.

Chairman Tom Davis. Yes, ma'am, the gentlelady from Ohio, any questions?

Mrs. Schmidt. No, thank you, Mr. Chairman.

Chairman Tom Davis. Mr. Gutknecht.

Mr. GUTKNECHT. Mr. Chairman, I am not sure I have a question as much as a comment.

First of all, thank you for this hearing, and we really do appreciate it. I have a keen interest in this whole subject, and I think as we go forward, this is going to become more and more important. I am delighted that at least there are people inside our Government who do take it seriously.

Let me talk about this from a somewhat different perspective. I also chair a committee of the Rural Caucus that has been interested in telecommunications policy. Ultimately, this issue and telecommunications policy do meet, and they are inexorably intertwined.

One of the things that we learned, and I suspect that you have probably already bumped into this, and that is that an awful lot of the constituencies for the services we are talking about here today live in small towns. Many of those small towns do not have the same kind of broadband access that some of us in larger communities take for granted.

We had three separate hearings. What we learned in those hearings was that one of the things that is important, if we are going to continue to build out broadband services to small towns and rural parts of America, is that we have to have a Universal Service Fund. I don't know how familiar you are with that, but it is important to those small, rural providers. In Minnesota, all of the tele-

communications people want to serve Bloomington, MN; not many

want to serve Blooming Prairie, and that is a big problem.

That problem becomes worse because the telecommunications business is changing and evolving even as we speak. A year ago I didn't know what VOIP was, but it is a fact of life, and it is going to become more and more important. Voice Over Internet Protocol is going to become more and more important. What we have is more of these companies who want to use the network, so to speak, but they don't want to help pay for the network.

I think this is for the benefit of members of the committee as well. I understand that the Commerce Committee here in the House is working on a telecom bill, and we hope to have it out on

the floor. And it is going to have some good things in it.

I don't want to be critical, but one of the most important things, I think, is going to be ignored. That is: How are we going to deal with this Universal Service Fund in a telecommunications industry that is changing so fast? I am afraid that all of the good work that you are doing here on this area, well, not all, is going to be wasted, but some is going to be wasted because we don't have that last mile and we don't have an awful lot of our rural communities included.

If we don't come up with a reasonable solution to the Universal Service Fund issue, who pays and who gets to draw out, and for what services can it be used for? It strikes me that is going to be very, very important to your deliberations as you go forward.

Dr. Brailer. Perhaps just a comment on that, I certainly can't comment on the Universal Service Fund, but I think it is not coincidence that the President announced the health information technology agenda in the same speech where he announced the administration's broadband efforts. They are part and parcel.

We need that infrastructure to do the things that we are discussing, and the things that are happening here give value to why those broadband networks need to exist. I think this is particularly true in rural areas as you described because today we are talking about the sharing of labs, and prescriptions, and other things that are not very heavy in bandwidth.

But not too far out we are talking about telemedicine, and remote video, and monitoring live feed devices that are in people's homes or on their bodies for monitoring their physiological status, and those are bandwidth dependent. So I think this is moving very quickly where it will become something where we will say, here is a value that broadband will give us.

This is an issue that I am particularly sensitive to, being from a very small town in West Virginia that has an 18-bed hospital that I am proud to tell you my mother is on the board of. We look at this quite a lot and say: How do we make sure that we are rais-

ing the playing field for everyone?

Mr. GUTKNECHT. You say that you can help us by putting a little pressure both on the administration and some of our colleagues in Congress, but ultimately we have to resolve this issue of the Universal Service Fund because all the other efforts we have, I think, dwarf in terms of the relative importance to rural communities in building out that broadband service.

Because if we don't get that done, all of these magic things, and I have seen a lot of them, and I agree with you. The potential of this is enormous. But you can't do that if you don't have the wire or the cable to carry the information.

Dr. Brailer. I will make sure that message is conveyed.

Mr. GUTKNECHT. Thank you.

Dr. Brailer. Thank you.

Chairman Tom Davis. Ms. Watson.

Ms. Watson. From the outside looking in, what would you suggest we do here? Now we were just discussing the fund, and if this is going to work to service the entire Nation, and I would hope it would do that.

What do you see as the obstacles? How could we remove them and make it work in the small areas that most of this technology never reaches? And how do we get to the under-served? What would you suggest? I address that to both panelists.

Dr. Brailer. Thank you.

Ms. WATSON. And blue sky, you know. Don't worry about the budgetary restraints; let us worry about that. What would you suggest to make this an effective, operational system?

Dr. Brailer. Thank you. I don't get asked to do that very often.

[Laughter.]

Again, I think we need to recognize that if we look at, for example, an urban population or a population that is under-served, their healthcare system has numerous challenges around delivering basic services in addition to health information technology.

So if you look at, for example, many community clinics or countyfunded clinics, they have certainly financial challenges of being able to support the adoption and use of tools, but they also have a significant manpower issue in terms of just skill base, people that understand technology, being able to negotiate the contracts to procure the services, etc. I think it is a combination of support financially plus the kinds of know-how.

One of the things that, in the tool that has come out through CMS from VA, the VistA Office EHR, the one area where we think there is real opportunity is being able to make that tool available into those kinds of settings because it can give support, but it also involves not a lot of the legal issues around negotiating those con-

tracts and other things.

How the funding actually comes to be, I certainly couldn't comment, except to say that I have been impressed at the variability of Medicaid programs and the extent to which they either take a forward leaning posture on technology use in clinics and other set-

tings, or they don't.

I am encouraged to see some of the ones have been quite supportive, and I have visited a number of clinics that I think would by far exceed what many private sector providers have in terms of their technical capacity to really care for patients in a seamless way. So I think it can be done, but I would not say it is money alone. I am really worried about the Nation's overall manpower supply of experts in this field, particularly how it is distributed into those settings.

Ms. Watson. What resonated with me in the beginning of your statement was the fact of training. I ran a program back in the 1960's at UCLA and Allied Health. We said, 10 years from now, that was 1960, there will be 10,000 new jobs that we don't know

about today. Well, there must be 300,000 new jobs that correspond

to the developing technology.

So maybe there should be a training component. Whatever we do, we ought to have a training component so we will have personnel out in the field that can indeed utilize this new technology to its fullest extent. I appreciate your input, and I ask my staff to take notes because maybe we will come up with a piece of legislation in addition to what is already on the table.

Dr. KOLODNER. I think also the idea is the technology has to adapt to the individuals. All of us can use telephones right now; they are simple to use. Trying to program your VCR still is a chal-

lenge for many people.

I think that as those of us who are in the technology field look forward, particularly as we get into the personal health records which I think will, in fact, revolutionize the relationship between the providers and the patients—raising it up so that the provider, in fact, becomes the expert counsel to the patient instead of the caretaker for the patient and empowers people to take control of their health as they move forward. Things like the personal health record, or even the electronic health record for the providers, have to be simple to use; they have to be understandable; they have to be able to be tailored to the particular style, or reading level, or others of the person who is using it.

Ms. Watson. Thank you.

Chairman Tom Davis. I recognize Mr. Porter.

Mr. PORTER. Thank you, Mr. Chairman.

Dr. Brailer, are there still a lot of disincentives out there for the industry to get into technology, the providers? Are there some barriers that we should be breaking? It seems to me we do a lot of Government incentives, and there are grants, low loan rates, which are all good things. Assuming that there are some barriers, which I think there are, is there something we can do market-driven, to help jump start this?

Dr. KOLODNER. Let me start just by saying that one of the things, if you look at VA, Kaiser Permanente, DOD—where there have been advances for large systems in the use of the information technologies—they are systems where the systems are both the provider and the payer because it is really on the payer side that a lot of the benefits occur. Actually, it is at the level of beneficiary.

But in terms of the people who are making the decisions, the payer gets the benefit of not having duplicate tests and being able to operate more efficiently. Over the last 10 years, VA has doubled the number of patients that we have seen with only about a 15 percent increase in our budget at a time when healthcare has been double digit. Not all of it, but a good part of it, had to do with putting in the electronic health records, helping us to be more efficient.

Dr. Brailer. It is a great question. It is one that we obviously spend a lot of time with. It is no surprise that large physician groups or prepaid group practices are among the Nation's leaders in the use of advanced health information technology because they live in a world that has both clinical care and bottom line risk in the same organization, and they have few, if any, barriers to collaboration between doctors and institutions.

Mr. PORTER. Plus, they have the resources in many respects.

Dr. Brailer. Sure, they do. As we think about how do we extend that across the industry, I think the question is not how do we provide incentives per se, but how do we take away the perverse or the contrary incentives to not invest because it is against the financial interest of many providers to actually put in tools that improve quality or improve efficiency. That is because we pay for volume, and efficiency and quality by definition reduce volume.

So that is a real challenge I think that is across the industry. Many physicians and hospitals want to do the right thing if we could at least make the incentives neutral with respect to that.

Second, there are barriers to doctors and hospitals cooperating around the care of their patients in a way that can improve quality. Health information technology is just one, one very large but just one, of those areas.

Then third, as we move toward this concept of interoperability, most of the technical infrastructure is built with the concept of somewhat proprietary data, that the data is very difficult to move and that many of our technical companies make a lot of money in their revenue cycle from implementation of somewhat standardized tools. In a world that is highly interoperable, or plug and play, means a fundamentally different kind of value stream for them as well. So there are barriers up and down the supply chain of health IT, if you would, that need to be addressed.

Mr. Porter. Mr. Chairman, if I may continue. It was mentioned earlier there are those pockets in the country that are under-served by healthcare and technology. One of my goals in the legislation I am proposing is if you take a group the size of the Federal Government, 9½ million people, and by having the proper encouragements in place to have the providers, doctors, and the patients involved in the system, it hopefully will flow into the rest of the free market system because the systems will be in place.

But I know that there are small doctors that are piecemealing systems because they can't afford to get into it, like the clinics and the combinations. There are small doctors across the country that would like to, but then there are those that don't want to change. There is the culture of this is the way we have always done things.

It seems to me if we can help provide an incentive, a market-driven incentive to make sure that those doctors that use the latest, and providers throughout the system use the technology, there may be some incentive to reduce their medical liability insurance, and have medical liability carriers engaged in finding a way to provide assistance because it reduces, of course, the loss of life and injury, but on the dollar side reducing some costs. So part of the legislation I am working on will hopefully provide some incentives to reduce medical liability insurance costs because the losses are fewer, which in turn could be returned.

I understand there are lots of barriers. We have to come out of the Dark Ages as soon as possible. I appreciate what you are doing. You guys, you are on the cutting edge. I am not sure about the title of our hearing, the Last Frontier. I think this is the frontier; we are there. I appreciate what you are providing for us today, and I look forward to working with you.

Chairman Tom Davis. Thank you.

Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman.

I appreciate that you have talked about some of the barriers. They are pretty big barriers. I spoke about one barrier. Mr. Porter, who has just spoken, had a hearing in another of our subcommittees on which I serve on this issue. It is absolutely fascinating because of how hard it is to get a handle on it. It would be hard enough if, given the decentralized nature of the sector, if costs were the only barriers, but when you really get into interoperability and you get into other technical matters, you get into personal matters, and cultural matters, and professional ethics, and age, they are quite awesome.

I am interested in the VA. When we had our hearing in subcommittee, it was a subcommittee that deals with the Federal Government and Federal workers. I noticed, Dr. Kolodner, that on page 6 of your testimony, you say, you use an example which is the best

way to make people understand a subject like that.

You said, suppose a veteran comes in for a check-up and tells a physician he is allergic to drugs, etc. So the first thing I want to know is once a veteran is in the system in one part of the country, does that mean his records are accessible in every veterans' hospital throughout the country?

Dr. KOLODNER. Yes, it does, whether that is progress notes, whether that is lab results, radiology reports. Actually, starting this month, we started rolling out a new capability so that all of the images that exist at one hospital are available in any another.

Ms. NORTON. I just think this is very important. This isn't going to happen unless the Federal Government shows it can happen. And here we have closed system here. We are the Government. We can make things happen in our organization, the largest organization in the country in a way that even the largest HMOs would have more difficulty because we can appropriate money.

We can do it through pilot projects, or we can look at what the Veterans Administration is already doing, and remove some of these barriers simply by showing, in fact, what the benefits are. The benefits are to all involved, but that is certainly not immediately apparent to all involved in today's healthcare world.

You say, for example, on page 9 of your testimony that about 40 percent of veterans that come to one of your facilities each year receives care some place out from non-VA physicians, and you are now beginning to tackle that notion. I see you as a possible pilot here. When you go from your own system, which you appear now to have a hold of, you now have to deal with the fact, the kind of situation rather, that healthcare outside of the Government will face.

I would like you to discuss how you expect to be able to do for that 40 percent what you can do for those within your system and what you can do about keeping track within your system. It might not matter if, in fact, you get somebody seriously ill, for example, who normally does not come to your system—and perhaps you both have talked about Katrina and Rita—if, in fact, healthcare is normally received outside of your system. Will you speak to that, please?

Dr. Kolodner. Yes. The figure that you cited, the estimated 40 percent of veterans we treat each year getting care outside of VA, is one of the very reasons why VA has been very active both in the area of standards development that was mentioned earlier as well as the close working relationship we have with Dr. Brailer's office and our active participation in public/private initiatives such as those you will be hearing about on one of the subsequent panels with the eHealth Initiative and the Connecting for Health.

That allows us to work with others because we are not going to be able to solve this alone. We need electronic health records on the outside. We need those National health information networks that we can connect into. We can certainly contribute our experience, the things that we have learned along the way as we have brought up the systems and connected our hospitals, and as we have worked with the Department of Defense to connect these two large departments, and where we are moving information back and forth bi-directionally between the two departments in order to help our veterans, some of who are getting care at the Department and De-

But it is really in the public/private initiatives and with Dr. Brailer's office, where they have the charge for these broader community initiatives that we are really able to—

Ms. NORTON. So you are really not able. If this veteran who is not in your system comes in, and now you have a lot of information that you get from him, are you able to connect with his HMO, let us say, if in fact that HMO could speak to you through your system? Would some of the barriers that we have been discussing be such that you could feel that you could use IT to retrieve data about him rather than relying on the old-fashioned methods?

Dr. KOLODNER. We can't do that today. That is the goal, and that is to work with the regional health information organizations and with these other organizations in order to establish the standards, the protocols, and the rules of the road for accomplishing exactly what you are talking about.

Ms. NORTON. Dr. Brailer, I must say, I see what your doing. It is very complicated. I really think in the busy world of HMOs and physicians, it is so complicated that unless somebody can set up a pilot that somebody sees works, this is just not going to work. The best, it seems to me, possibility might be within the VA and some kind of pilot involving the VA and patients who are not regularly in VA or who are sometimes in VA and sometimes not in VA, because setting people down to even want to do this is a task unto itself.

The cost task is such that even in your testimony, Dr. Brailer, you are cautious, and I think that is being very responsible about whether anybody should be promised cost savings. Ultimately, as with almost everything in our country, if we see a system that works in this way, that has solved the considerable problems in your testimony, it seems to me that we will have a better chance of connecting our healthcare system than I see us having now.

I just think this is a show-me country and if we can't show the country a system that works, then I think we are not going to be able, in the context of costly healthcare today, to move ahead, particularly when it is normally provided by private parties.

Thank you, Mr. Chairman.

Mr. Gutknecht [presiding]. Mr. Ruppersberger.

Mr. RUPPERSBERGER. Sure. Excuse me if I duplicate some of

these questions, but I had to come late.

First, there are many issues involving a national health information system, but one of my major concerns is making sure that the various healthcare systems nationwide can talk to each other. It serves no one any good if we have a bunch of networks and data bases that can't talk to each other and that are not centralized. Now where are we as it relates to where you are and where we need to move forward as far as the systems talking to each other?

Dr. Brailer. We have what I would consider to be numerous pieces that are now coming together. We have, for example, in the regional and local areas these 200 or more projects that are trying to build the capacity to do what you described, to share information, to talk together, to make it seamless. And those organizations go from those that who do have actually very good demonstration sites of what has happened to those that are still moving forward, including one here in D.C.

At the same time at the Federal level, we are trying to make sure that there are a single set of standards and a capacity, this national health information network architecture that can tie these together. So we are trying to converge all of those pieces together to make sure that the easy thing for a doctor or a hospital to do is to be online and sharing their information with other doctors and hospitals as the patient permits.

Mr. Ruppersberger. Are there any lessons learned that you can pass onto the private sector in your efforts to create an electronic

health record system? Anyone?

Dr. KOLODNER. There are many lessons that would be something. Actually we have a report the GAO did where we talked about lessons learned between VA and DOD in terms of the information exchange. The ability to meet the needs of the provider, and make sure that the systems are fitting the workflow, and are not designed from the outside by non-clinicians but actually are shaped by the needs of clinicians, so that it fits into their clinical practice is an important way of succeeding with the electronic health record

But the focus really needs to remain on the fact that IT is an enabler. It is not an end itself; it is the means for delivering better

quality of care and safer care.

Mr. Ruppersberger. Let me talk about the issue of barriers. Sometimes we, in Congress, try to fix a problem and when we fix it, it sometimes makes the problem worse. Even though we need to deal with the issue of confidentiality, I think HIPAA is an exam-

It seems to me that people in the medical field, from either a hospital perspective or doctors, are involved in so much paperwork now, that even HIPAA has gotten to the point of maybe giving people excuses, some in the medical field: When you have a parent that has dementia, well, I can't talk to you because of HIPAA. It has also been said that HIPAA is great for the paper business because there is a lot of paper generated.

How would you look at the issue of HIPAA as it relates to what we are talking about here today, and how would you solve maybe some of the tremendous administrative wastes of time and personnel that are focusing more on HIPAA than actually treating patients?

Dr. Brailer. I think HIPAA is a good example of where the information age can be advantageous in many ways. For example, providers do have concerns about being burdened with the costs of accounting and disclosure. Information-based exchange is much less manually intensive. It is cheaper for them to keep track of who they gave data to and how to release that data.

So I think information tools are actually a positive thing in a HIPAA world. Second, with respect to consumers that want to get their data, electronic data is easier for them to get, and get access to, and give to third parties. The information age, I think, will let consumers be much more engaged in not just getting their informa-

tion but controlling who has access to it.

I think the one challenge, not really in HIPAA but across the States that have often superceded HIPAA with their specific State requirements, is the concept of flexibility. Flexibility here means that the way a hospital or a doctor implements their security and privacy regime varies from very small organizations to very large ones.

That flexibility is often at odds with data portability. It is not a security or privacy issue, per se; it is an issue about whether or not those create barriers to information exchange. That is exactly what this project is going to do, where we bring together all the State leaders and regional leaders to understand what they can do to have both flexibility and data portability at the same time. So I think it is a positive step, and we will be looking at that from the perspective of what are the protections or guidances needed to make sure that we can protect data yet have it be portable as the patient chooses.

Mr. Ruppersberger. OK, thank you.

Chairman Tom Davis [presiding]. Any other questions? If not, that is all I have for this panel. We appreciate it very much.

Just let me ask, in the interest of time, we are going to combine panels two and three. We appreciate this very much. We will take a 2-minute recess. And I want to thank Mr. Powner for his flexibility and assistance in letting us go to two panels, so we can try to get to a prospective noon vote.

On our second panel, we have Mr. David Powner, who is the Director of Information Technology Management Issues at the GAO; Carol Diamond, M.D., the managing director of the Markle Foundation; Janet Marchibroda, who is the CEO of eHealth Initiative and Foundation; Diane Carr, who is the associate executive director of Healthcare Information Systems, Queens Health Network; and Mr. Larry Blue, the vice president and general manager of Symbol Technologies.

[Recess.]

Chairman Tom Davis. As you know it is our policy that we swear everyone in. If you will rise with me and raise your right hands. [Witnesses sworn.]

Chairman Tom Davis. Thank you very much. We will start with you. I think everyone understands how we try to operate on time. With GAO, if you need a couple of extra minutes to do it, your whole report is in the record, and we have worked up questions based on the entire testimony, but take what you need to highlight what you need.

Thank you all for being with us.

STATEMENTS OF DAVID POWNER, DIRECTOR, INFORMATION TECHNOLOGY MANAGEMENT ISSUES, GOVERNMENT ACCOUNTABILITY OFFICE; CAROL DIAMOND, M.D., MANAGING DIRECTOR, MARKLE FOUNDATION; JANET M. MARCHIBRODA, CHIEF EXECUTIVE OFFICER, EHEALTH INITIATIVE AND FOUNDATION; DIANE M. CARR, ASSOCIATE EXECUTIVE DIRECTOR, HEALTHCARE INFORMATION SYSTEMS, QUEENS HEALTH NETWORK; AND LARRY BLUE, VICE PRESIDENT AND GENERAL MANAGER, SYMBOL TECHNOLOGIES

STATEMENT OF DAVID POWNER

Mr. Powner. Chairman Davis, Ranking Member Waxman, and members of the committee. We appreciate the opportunity to testify on healthcare information technology. As we have highlighted in several recent reports completed at your request, Mr. Chairman, significant opportunities exist to use IT to improve the delivery of care, reduce administrative costs, and to improve our Nation's ability to respond to public health emergencies.

This morning I will briefly describe the importance of defining and implementing standards to achieve the President's goal of nationwide implementation of interoperable healthcare systems. I will also summarize key administration efforts to further define standards and conclude by highlighting key items for consideration.

IT standards enable the interoperability of data and systems and defining such standards can help speed the adoption of IT for the healthcare industry. For example, standards are essential to provide greater consistency of patient medical records. Standards-driven electronic health records have the potential to give caregivers with complete and consistent medical histories necessary for optimal care. Standards are equally important as systems are pursued to detect and respond to public health emergencies including acts of bioterrorism.

This past summer, Mr. Chairman, we issued a report to you that highlighted the importance of developing and adopting consistent standards to enable interoperability of key surveillance systems like CDC's BioSense and Homeland Security's BioWatch. Despite this critical need, today's standards are uncoordinated and have resulted in conflicting and incomplete standards. We recommended several years ago that the Secretary of HHS reach consensus across the healthcare industry on the definition and use of standards and to create mechanisms to monitor the implementation of standards.

HHS has taken several actions that should help to define standards for the healthcare industry. First, the coordinator has assumed responsibility for the Federal Health Architecture which is expected to include standards for interoperability and communica-

tion. This architecture effort now also includes the Consolidated Health Informatics Initiative, one of the original OMB eGov initiatives to facilitate the adoption of Federal healthcare standards.

Second, HHS agencies continue to identify standards including those for clinical messaging, drugs, and biological products. Third, HHS plans to leverage private sector expertise by awarding a contract to develop and evaluate a process to further define industry-wide standards. In addition, HHS also formed a public/private committee to help transition the Nation to electronic health records

and to provide input and recommendations on standards.

The importance of a national health information network that integrates interoperable data bases was just recently highlighted on a smaller scale with the coordinator facilitated the development of a web-based portal to access prescription information for Katrina evacuees. This online service is to allow authorized health professionals to access medication and dosage information from anywhere in the country and was made possible when commercial pharmacies, health insurance programs, and others made accessible the

prescription data.

Although Federal leadership has been established, and plans and several actions have positioned HHS to further define and implement relevant standards, consensus on the definition and use of standards remains a work in progress. Key items to consider as the administration moves forward with this vital effort are completing detailed plans for defining standards that include private sector input, fully leveraging the Federal Government as a purchaser and provider of healthcare, enlisting consumer support to a point where patients demand electronic health records, and providing incentives for the private sector to participate and partner.

In summary, standards are essential to achieving interoperable data and systems, and are critical in the pursuit of electronic health records and public health systems. Clearly, vision and leadership are now present, but detailed plans associated with the National framework remain incomplete, and we are still quite far from sufficiently defining standards necessary to carry out this vi-

sion.

Once this occurs, the healthcare industry will confront the more difficult challenge of consistently implementing a comprehensive set of standards. Until these standards are implemented, the healthcare industry will not be able to effectively exchange data and, consequently, will not reap the costs, clinical care, and public health benefits associated with interoperability.

This concludes my statement. I would be pleased to respond to any questions that you have.

[The prepared statement of Mr. Powner follows:]

GAO

United States Government Accountability Office

Testimony

Before the Committee on Government Reform, House of Representatives

For Release on Delivery 10:00 a.m. EDT September 29, 2005

HEALTH CARE

Continued Leadership Needed to Define and Implement Information Technology Standards

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





before the Committee on Government Reform, House of Representatives

Why GAO Did This Study

Health care delivery in the United States has long-standing problems with medical errors and inefficiencies that increase costs. Hence, health information technology (T) has great potential to improve the quality of care, bolster preparedness of our public health infrastructure, and save money on administrative costs. The threats of natural disasters and terrorist attacks further underscore the need for interoperable information systems, and the critical importance of defining and implementing standards that would enable such interoperability.

GAO has reported on the quality of care benefits derived by using Tr, federal agencies' existing and planned information systems to support national preparedness for public health emergencies, and the status of health Tr standards settings initiatives.

The House Committee on Government Reform asked GAO to summarize (1) its previously issued reports and recommendations on health IT standards and (2) recent actions taken by HHS to facilitate the development of health IT standards.

www.gao.gov/cgi-bin/getrpt?GAO-05-1054

To view the full product, including the scope and methodology, click on the link above. For more information, portlast David Powner at (202) 512-9286 or pownert@gab.gov. September 29, 2005

HEALTH CARE

Continued Leadership Needed to Define and Implement Information Technology Standards

What GAO Found

As GAO reported in 2003, health care data, communications, and security standards are necessary to support interoperability between IT systems; however, the identification and implementation of such standards was incomplete across the health care industry. Further, while several standard setting initiatives were underway, GAO raised concerns about coordinating and implementing these initiatives. To address the challenges of coordinating and implementing a set of standards, GAO recommended that the Secretary of Health and Human Services (HFIS), among other things, reach further consensus across the health care industry on the definition and use of standards, establish milestones for defining and implementing standards, and create a mechanism to monitor the implementation of standards throughout the health care industry. Last summer, GAO testified before your technology subcommittee, highlighting progress made in announcing additional standards and plans to incorporate standard setting initiatives into the Federal Health Architecture. GAO reported that progress in assuming leadership had occurred with the President's establishment of the National Coordinator for Health IT to guide the nationwide implementation of a interoperable health information systems and stated that as health IT initiatives are pursued, it will be essential to have continued leadership, clear direction, measurable goals, and mechanisms to monitor progress.

In following up on our recommendations, GAO found that HHS has taken several actions that should help to further define standards for the health care industry. First, the coordinator has assumed responsibility for the Federal Health Architecture that is expected to establish standards for interoperability and communication throughout the federal health community. Second, several HHS agencies continue their efforts to define standards as part of the department's Framework for Strategic Action. For example, the Agency for Healthcare Research and Quality is working with the private sector to identify standards for clinical messaging, drugs, and biological products. Third, HHS expects to award a contract to develop and evaluate a process to unify and harmonize industry-wide information standards. Fourth, in July of this year, a public-private committee was formed to help transition the nation to electronic health records and to provide input and recommendations on the standards, among others. All of these are positive steps, and the Coordinator has provided needed leadership and direction, however, much works remains to reach further consensus across the health care sector on the definition and use of standards. Until this occurs, federal agencies and others throughout the health care industry will not be able ensure that their systems are capable of exchanging data when needed, and consequently will not be able to reap the cost, clinical care, and public health benefits associated with interoperability.

United States Government Accountability Office

Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss the importance of defining and implementing standards to speed the adoption of interoperable information technology (IT) in the health care industry. It has been widely recognized that the use of IT for delivering care, supporting the public health infrastructure, and performing administrative functions has great potential to improve care, bolster preparedness, and save money. Health and Human Service's Secretary Leavitt recently stated that Hurricane Katrina has underscored the need for interoperable electronic health records as thousands of people have been separated from their health care providers, and medical records have been lost. Standards are critical to enabling this interoperability.

At your request, today I will summarize (1) our previously issued reports and recommendations on health IT standards and (2) recent actions taken by the Department of Health and Human Services (HHS) to develop health IT standards. In preparing this testimony, we summarized our prior reports and updated progress toward implementing recommendations in accordance with generally accepted auditing standards.

Results in Brief

We reported in 2003 that the identification and implementation of health care data, communications, and security standards—which are necessary to support interoperability of IT systems—remained incomplete across the health care industry. Further, while several standards-setting initiatives were underway, we raised concerns about the coordination of these initiatives. To address the challenges of coordinating and implementing a set of standards, we recommended that the Secretary of HHS, among other things, reach further consensus on the definition and use of standards, establish milestones for their definition and implementation, and create a mechanism to monitor their implementation throughout the health care industry. Following up on our recommendations, last summer we testified before your technology subcommittee, highlighting progress made in announcing additional standards and plans to

incorporate standard setting initiatives into the federal health architecture. We also reported that progress in assuming leadership had occurred with the President's establishment of the National Coordinator for Health IT, but noted that it was essential to have continued leadership, clear direction, measurable goals, and mechanisms to monitor progress.

In following up on our recommendations, we determined that HHS has taken several actions that should help to further define standards for the health care industry. First, the Office of the National Coordinator for Health Information Technology has assumed responsibility for developing a federal health architecture that is expected to, among other things, establish standards for interoperability and communication throughout the federal health community. Second, several HHS agencies continue to further define standards as part of the Framework for Strategic Action. For example, the Agency for Healthcare Research and Quality is working with the private sector to identify standards for clinical messaging, drugs, and biological products. Third, HHS expects to award a contract to develop and evaluate a process to unify and harmonize industry-wide information standards. Fourth, in July of this year, a public-private committee was formed to help transition the nation to electronic health records and to provide input and recommendations on the standards and other issues.

Although the Coordinator has provided needed leadership and direction, much work remains to reach further consensus on the definition and use of standards. Until this successfully occurs and health IT standards are more fully implemented, federal agencies and others throughout the health care industry cannot ensure that their systems will be capable of exchanging data with other systems when needed, and consequently will not be able to reap the cost, clinical care, and public health benefits associated with interoperability.

Background

According to the Institute of Medicine, health care delivery in the United States has long-standing problems with medical errors and inefficiencies that increase health care costs. The U.S. health care delivery system is an information-intensive industry that is complex and highly fragmented, with estimated spending of \$1.7 trillion in 2003. Hence, the uses of IT—in delivering clinical care, performing administrative functions, and supporting the public health infrastructure—have the potential to yield both cost savings and improvements in the care itself. Information technologies such as electronic health records (EHR)' have been shown to save money and reduce medical errors.

Key Standards for Health Care

IT standards, including data standards, enable the interoperability and portability of systems within and across organizations. Many different standards are required to develop interoperable health information systems. This reflects the complex nature of health care delivery in the United States.

Vocabulary standards, which provide common definitions and codes for medical terms and determine how information will be documented for diagnoses and procedures, are an important type of data standard. These standards are intended to lead to consistent

¹There is a lack of consensus on what constitutes an EHR, and thus multiple definitions and names exist for EHRs, depending on the functions included. An EHR generally includes (1) a longitudinal collection of electronic health information about the health of an individual or the care provided, (2) immediate electronic access to patient- and population-level information by authorized users, (3) decision support to enhance the quality, safety, and efficiency of patient care, and (4) support of efficient processes for health care delivery.

² Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged. Portability is the degree to which a computer program can be transferred from one hardware configuration or software environment to another.

³ GAO, Automated Medical Records: Leadership Needed to Expedite Standards Development, GAO/IMTEC-93-17 (Washington, D.C.: April 30, 1993).

descriptions of a patient's medical condition by all practitioners. The use of common terminology helps in the clinical care delivery process, enables consistent data analysis from organization to organization, and facilitates transmission of information. Without such standards, the terms used to describe the same diagnoses and procedures sometimes vary. For example, the condition known as hepatitis may also be described as a liver inflammation. The use of different terms to indicate the same condition or treatment complicates retrieval and reduces the reliability and consistency of data.

In addition to vocabulary standards, messaging standards are important because they provide for the uniform and predictable electronic exchange of data by establishing the order and sequence of data during transmission. These standards dictate the segments in a specific medical transmission. For example, they might require the first segment to include the patient's name, hospital number, and birth date. A series of subsequent segments might transmit the results of a complete blood count, dictating one result (e.g., iron content) per segment. Messaging standards can be adopted to enable intelligible communication between organizations via the Internet or some other communications pathway. Without them, the interoperability of federal agencies' systems may be limited and may limit the exchange of data that are available for information sharing. In addition to vocabulary and messaging standards, there is also the need for a high degree of security and confidentiality to protect medical information from unauthorized disclosure.

Need for Standards Has Been Recognized

The need for heath care standards has been recognized for a number of years. The development, approval, and adoption of standards for health IT is an ongoing, long-term process and includes federally mandated standards requirements and a voluntary consensus process within a market-based health care industry. The use of some standards, such as those defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA)* and the Medicare

⁴ Public Law 104-191, sec 262 (1996).

Modernization Act, is mandated by the federal government, while others are defined by standards development organizations such as the American Association of Medical Instrumentation and the National Council for Prescription Drug Programs. HHS identifies and researches standards defined by the organizations that develop them, and determines which of the approved ones are appropriate for use in federal agencies' health IT systems.

In August 1996, Congress recognized the need for standards to improve the Medicare and Medicaid programs in particular and the efficiency and effectiveness of the health care system in general. It passed HIPAA, which calls for the industry to control the distribution and exchange of health care data and begin to adopt electronic data exchange standards to uniformly and securely exchange patient information. According to the National Committee on Vital and Health Statistics (NCVHS), significant progress has occurred on several HIPAA standards, however, the full economic benefits of administrative simplification will be realized only when all of them are in place.

In 2000 and 2001, the NCVHS reported on the need for standards, highlighting the need for uniform standards for patient medical record information, and outlining a strategy that included their development and use. The Institute of Medicine and others had also reported on the lack of national standards for the coding and classification of clinical and other health care data, and for the secure transmission and sharing of such data.

In 2001, the Office of Management and Budget created the Consolidated Health Informatics (CHI) initiative as one of its e-government projects to facilitate the adoption of data standards for, among others, health care systems within the federal government. The CHI initiative was an interagency work group led by HHS and composed of representatives from the Departments of Defense and Veterans Affairs, as well as other agencies. Recognizing the need to incorporate standards across federal health care systems, the group announced in March 2003 the adoption of 5, and in May 2004 the adoption of another 15. Once federal agencies adopted the recommended standards, they were expected to incorporate them into their architectures and build systems

accordingly. This expectation applied to all new systems acquisition and development projects.

In April 2004, the President issued an executive order that called for the establishment of a National Coordinator for Health IT and the issuance of a strategic plan to guide the nationwide implementation of interoperable health information systems. The National Coordinator for Health IT was appointed in May 2004; in July 2004, HHS released a framework for strategic action—the first step toward a national strategy. The framework defines goals and strategies that are to be implemented in three phases. Phase I focuses on the development of market institutions to lower the risk of health IT procurement, phase II involves investment in clinical management tools and capabilities, and phase III supports the transition of the market to robust quality and performance accountability. The framework includes a commitment to standards and reiterates that a key component of progress towards interoperable health information systems is the development of technically sound interoperability standards.

Actions Needed for Implementation of Health Information Technology Standards

In May 2003, we reported that federal agencies recognized the need for health care standards and were making efforts to strengthen and increase their use. However, while they had made progress in defining standards, the identification and implementation of data standards necessary to support interoperability were incomplete across the health care sector.

⁶ According to HHS, market institutions include certification organizations, group purchasing entities, and low-cost implementation support organizations that do not currently exist but are necessary to support clinicians as they procure and use IT.

⁶ 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).

First, agencies lacked mechanisms that could coordinate their various efforts so as to accelerate the completion of standards development and ensure consensus among stakeholders. The process of developing health care data standards involves many diverse entities, such as individual and group practices, software developers, domain-specific professional associations, and allied health services. This fragmentation slowed the dissemination and adoption of standards by making it difficult to convene all of the relevant stakeholders and subject matter experts in standards development meetings and to reach consensus within a reasonable period of time.

Second, not all of the federal government's standard setting initiatives had milestones associated with efforts to define and implement standards. For example, while the CHI initiative—the primary initiative to establish standards for federal health programs—had announced several standards and implementation requirements for health care information exchange, it had not yet established milestones for future announcements.

Finally, there was no mechanism to monitor the implementation of standards throughout the health care industry. NCVHS had reported on a need for a mechanism, such as compliance testing, to ensure that health care standards were uniformly adopted as part of a national strategy, but without an implementation mechanism and leadership at the national level, problems associated with systems' incompatibility and lack of interoperability would persist throughout the different levels of government and the private sector and, consequently, throughout the health care sector.

We stated that until these challenges were addressed, agencies risked promulgating piecemeal and disparate systems unable to exchange data with each other when needed, and that this could hinder the prompt and accurate detection of public health threats. We recommended that the Secretary of HHS define activities for ensuring that the various standards-setting organizations coordinate their efforts and reach further consensus on the definition and use of standards; establish milestones for defining and implementing standards; and create a mechanism to monitor the implementation of standards through the health care industry.

Following up on our recommendations, we testified in July 2004 on HHS's efforts to identify applicable standards throughout the health care industry and across federal health care programs. $\ensuremath{^{7}}$ Progress was continuing with the establishment of the National Coordinator for Health IT, who, among other things, assumed federal leadership to expedite the standards development process in order to accelerate the use of EHRs. The Coordinator also assumed responsibility for identifying standards for federal health programs as part of the CHI initiative. While plans for the CHI initiative called for it to be incorporated into HHS's Federal Health Architecture' by September 2004, many issues—such as coordination of the various standards-setting efforts and implementation of the standards that had been identified-were still works in progress. We reiterated our conclusions that unless these standards were more fully implemented, federal agencies and others throughout the health care industry could not ensure that their systems would be capable of exchanging data with other systems when needed. Further, we concluded that as federal health IT initiatives moved forward, it would be essential to have continued leadership, clear direction, measurable goals, and mechanisms to monitor progress.

In June of this year, we issued a report to this committee on the challenges faced by federal agencies in implementing the public health infrastructure. We reported that, among others, HHS's Centers for Disease Control and Prevention and the Department of Homeland Security faced challenges developing and adopting consistent standards to encourage interoperability of public health initiatives.

⁷ GAO, Health Care: National Strategy Needed to Accelerate the Implementation of Information Technology, GAO-04-947T (Washington, D.C.: July 14, 2004).

⁸ PHA was initiated in 2003 in HHS's Office of the Chief Information Officer. It is intended to provide a structure for bringing HHS's divisions and other federal departments together, initially targeting studards for enabling interoperability. The FHA program is supported by four advisory work groups.

⁹ GAO, Information Technology: Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Intrastructure, GAO-05-308 (Washington, D.C.: June 10, 2005).

Recent Actions Taken by HHS to Develop Health Information Technology Standards

Following up on our recommendations, we reported in May 2005 that HHS was working towards a national strategy for health IT that called for a sustained set of actions to help to further define standards for the health care industry. The Office of the National Coordinator for Health IT is now responsible for the FHA program, which is to provide the structure or "architecture" for collaboration and interoperability among federal health efforts. FHA partners are responsible for improving coordination and collaboration on federal health IT investments and improving efficiency, standardization, reliability, and availability of comprehensive health information solutions. This fall, HHS plans to produce the first release of an information architecture for the federal health enterprise. This release will contain foundational elements to support the development and evolution of the full architecture, which will occur over several years. In addition, the CHI activities are now moving forward under the FHA. HHS, through the CHI initiative, is encouraging the implementation of standards within the federal government to order to catalyze private sector action in this area. Progress towards achieving standards and policies is a key component of progress toward the implementation of a national strategy that provides interoperable health IT systems.

The framework also builds upon already existing work in HHS divisions and includes plans to identify and learn from agencies' experiences. HHS divisions have been and continue to be responsible for selecting and adopting standards. Among other activities:

- The Agency for Healthcare Research and Quality is working to identify and establish clinical standards and research to help accelerate the adoption of interoperable health IT systems, including industry clinical messaging and terminology standards, national standard nomenclature for drugs and biological products, and standards related to clinical terminology.
- The Centers for Medicare and Medicaid are responsible for identifying and adopting standards for e-prescribing and for

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implementing the administrative simplification provisions of HIPAA, including electronic transactions and code sets, security, and identifiers.

- The National Institutes of Health's National Library of Medicine is working on the implementation of standard clinical vocabularies, including support for and development of selected standard clinical vocabularies to enable ongoing maintenance and free use within the United States' health communities, both private and public. In 2003, the National Library of Medicine obtained a perpetual license for the Systematized Nomenclature of Medicine (SNOMED)® standard and ongoing updates, making SNOMED available to U.S. users. Other efforts at the National Library of Medicine include the uniform distribution and mapping of HIPAA code sets, standard vocabularies, and Health Level 7" code sets.
- The Centers for Disease Control and Prevention, through its Public Health Information Network initiative, is working on the development of shared data models, data standards, and controlled vocabularies for electronic laboratory reporting and public health information exchange that are compatible with federal standards activities such as CHI.
- The Food and Drug Administration and the National Institutes of Health, together with the Clinical Data Interchange Standards Consortium (a group of over 40 pharmaceutical companies and clinical research organizations), have developed a standard for representing observations made in clinical trials—the Study Data Tabulation Model.

HHS expects to award a contract to develop and evaluate a process to unify and harmonize industry-wide information standards. In June 2005, HHS issued four requests for proposals (RFPs). The

 $^{^{10}}$ SNOMED is a nomenclature classification for indexing medical vocabulary, including signs, symptoms, diagnoses, and procedures. It was adopted as a CHI standard in May 2004.

 $^{^{\}rm II}$ HL7 is a standards development organization that creates message format standards for electronic exchange of health information

 $^{^{\}rm 12}$ In November 2004, HHS issued a request for information seeking public input and ideas for developing a national health information network and received over 500 responses.

department also expects to award contracts based on these proposals by October 2005. The proposals focus on four areas, including the development of a process to unify and harmonize industry-wide health information standards development, maintenance and refinements over time. The standards-focused RFP states that the current landscape of standards does not ensure interoperability due to many factors such as conflicting and incomplete standards. The other RFPs include (1) the development of a certification process for health IT to assure consistency with standards, (2) the development of prototypes for a nationwide health information network architecture for widespread health information exchange, and (3) an assessment of variations in organization-level business policies and state laws that affect privacy and security practices.

In addition, in July of this year, HHS announced plans for a public-private committee—known as the American Health Information Community—to help transition the nation to electronic health records and to provide input and recommendations on standards. Chaired by the Secretary of HHS, it will provide input and recommendations on use of common standards and how interoperability among EHRs can be achieved while assuring that the privacy and security of those records are protected. HHS is also working with other private sector groups to develop standards and certification requirements for EHR functionality in order to reduce the risk of implementation failure.

The importance of a national health information network that integrates interoperable databases was just recently highlighted when the Office of the National Coordinator for Health IT facilitated the rapid development of a Web-base portal to access prescription information for Katrina evacuees. This online service is to allow authorized health professionals to access medication and dosage information from anywhere in the country. A broad group of commercial pharmacies, government health insurance programs such as Medicaid, private insurers, and others compiled and made accessible the prescription data. Although the scope of this effort is much smaller than the national network and comprehensive EHRs (which contain much more than prescription information)

envisioned, it demonstrates the need called for by the President.

In summary, identifying and implementing health IT standards is essential to achieving interoperable systems and data in the health care industry and is critical in the pursuit of effective EHRs and public health systems. Although federal leadership has been established and plans and several actions have positioned HHS to further define and implement relevant standards, consensus on the definition and use of standards still needs to occur. Otherwise, the health care industry will continue to be plagued with incompatible systems that are incapable of exchanging key data that is critical to delivering care and responding to public health emergencies. HHS needs to provide continued leadership, sustained focus and attention, and mechanisms to monitor progress in order to bring about measurable improvements and achieve the President's goals.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions that you or members of the committee may have at this time.

Contacts and Acknowledgements

If you should have any questions about this testimony, please contact me at (202) 512-9286 or by e-mail at powderd@gao.gov. Other individuals who made key contributions to this testimony are M. Yvonne Sanchez, Assistant Director, and Amos Tevelow.

Chairman Tom DAVIS. Thank you very much. Dr. Diamond.

STATEMENT OF CAROL DIAMOND

Dr. DIAMOND. Thank you, Mr. Chairman and other members of the committee. Thank you for having me here today.

In my role at the Markle Foundation, I chair an initiative called Connecting for Health which is a unique public/private sector initiative consisting of over 100 organizations who represent all the stakeholders in healthcare. Over the last few years we have participated in shaping the National drive toward interoperable health information by building broad consensus about a road map of immediate actions and priorities, and most recently by developing a working prototype of an electronic national health information exchange based on common open standards and policies. Our prototype, which includes the exchange of information both within and among local communities, is deployed in northern California, Indiana, and Massachusetts.

As this hearing demonstrates, the public and private sector recognition for the need for health information technology has increased dramatically over the last several years, but nothing could better highlight how far we still need to go than Hurricane Katrina. As was mentioned earlier, in response to the storm the Office of the National Coordinator, the Markle Foundation, and 150 other public and private organizations worked closely an intense crash effort to establish an online service for authorized professionals to gain access to prescription records for evacuees.

The medication history information came from a variety of public and private sources and covered the majority of the evacuees. This was a marvelous collaborative effort, but the challenge of creating it had little to do with technology. In truth, the technologies to move health information between facilities or communities are relatively well understood and operate today within many complex enterprises. Instead, katrinahealth.org came into being because of good faith commitment to overcome established business, legal, and policy challenges to information charges.

policy challenges to information sharing.

If there is any lesson that can be instructive going forward, it is that a narrow focus on technical aspects of creating an electronic health information environment will not produce a sustainable, effective network. Longstanding policy, legal, and business obstacles prevent our personal information from being brought together and

applied to our health needs.

To overcome these obstacles, Government leadership is needed in three areas: policy, uniformity, and a level of public participation that maintains focus on the needs of the American people. The policies that govern information access, acceptable uses, consent, privacy, and security must be crafted in parallel with the deployment of technology if we are to have a trusted and effective health information environment, and the technology choices themselves must incorporate policy objectives.

The ultimate success of efforts to promote widespread adoption of health information technology and electronic records will depend on the confidence and willingness of consumers to accept and use the technology. However, several studies note significant public concerns about the privacy of electronic personal health data, even when most people acknowledge the benefits.

The policies that establish who has access to health information, what uses of information are acceptable, the extent to which patients can give or withhold access to their information, and the design of privacy and security safeguards must be crafted in parallel with the deployment of technology, and the technology choices themselves must consciously incorporate policy objectives that protect patients.

The second area is uniformity through a common framework. To the opening remarks on achieving goals for a broad, nationwide health information network while making good use of the precious, private and public sector dollars that are invested, we must be dependent on a uniform set of standards and policies that allow all parties who participate to adopt and participate in information sharing.

In our work we call this a common framework, and it is based on a network of networks in which existing healthcare institutions agree to adhere to a small set of shared rules. This includes technical standards and explicit policies for information use and governance.

The key to this approach is the articulation of these uniform policies and technical standards, and this approach supports a complete diversity of technologies to coexist. Our experience teaches us that the Nation will need to have an entity to promulgate this common framework, containing both policy and technical standards that provide structure to our health information environment.

The AHIC recently defined by the Secretary may be the first institutional attempt to provide these functions, and we intend to work closely with it. The Markle Foundation is now working with over 30 national consumer groups who are aware of the importance of health information technology and want to help shape this agenda. The Federal Government and Congress should establish a meaningful process to address the issues and priorities of the public as the AHIC and other health information technology activities move forward.

As the AHIC and various Federal agencies begin to set national priorities for the pace and scope of health information adoption, they must give attention to the services that produce high value for individual Americans, particularly technologies that give people more access to their own information and more control over their healthcare.

It is not enough to connect healthcare enterprises to each other; we must also connect people to their doctors, to each other, and to innovative resources that provide new ways to deliver and improve health. Personal health records that can connect doctors and other health system networks may provide the foundation for Americans to improve the quality and safety of the care they receive, to communicate better with their doctors, to manage their own health, and take care of loved ones.

Thank you again for inviting me to speak. I look forward to responding to questions.

[The prepared statement of Dr. Diamond follows:]

PREPARED STATEMENT BY CAROL D. DIAMOND, MD, MPH MANAGING DIRECTOR, MARKLE FOUNDATION CHAIR, CONNECTING FOR HEALTH

Committee on Government Reform U.S. House of Representatives

Engaging Americans in their Health and their Health Care through Health IT

September 29, 2005

PREPARED STATEMENT BY CAROL D. DIAMOND, MD, MPH MANAGING DIRECTOR, MARKLE FOUNDATION CHAIR, CONNECTING FOR HEALTH

Committee on Government Reform U.S. House of Representatives

Engaging Americans in their Health and their Health Care through Health IT

September 29, 2005

Chairman Davis and distinguished members of the Committee on Government Reform, thank you for inviting me to meet with you today.

Attention Has Intensified

In the last few years, public and private sector awareness of the need for information technology in health care has intensified dramatically. Prominent government activities include the President's call for the creation of electronic health records for all Americans, numerous legislative bills, implementation of many agency pilots and programs, the activities of the Office of the National Coordinator for Health Information Technology, and, most recently, the establishment by Secretary Leavitt of the AHIC. These efforts represent a broad commitment to bring about change.

But all this is merely prelude. We continue to lack an information infrastructure that supports safe, efficient, evidence-based medical care. Even the best-trained, best-equipped, and best-intentioned American health professional cannot provide high quality care in an information vacuum. No research study or pilot program better highlights this point than the reality of Hurricane Katrina. As you know, hundreds of thousands of residents of areas hit by the hurricane were displaced from their homes and most are still living in shelters or temporary housing across the United States. Neither the evacuees nor their current health care providers have access to their paper medical records, many of which were destroyed by the hurricane. A survey by the Kaiser Family Foundation and the Washington Post estimated that 40 percent of evacuees were taking prescription medications before the storm hit, and many more need new or additional medications now. Many of their medical records can never be recovered and have literally been washed away by the total devastation of their usual sources of care. Piecing their medical histories together and figuring out what medications they were on is a daunting task for those providing their care now.

From the earliest experiences of the first responders providing medical care to the heart-wrenching stories that continue to emerge about the consequences of such a massive disruption in health care for these evacuees there was a clear message about what was needed—the ability to know at a minimum what prescription medications and

therapeutic regimens these evacuees were on before the disaster hit. Without access to their prescriptions and recent medication history, thousands of Americans with daily health care needs ranging from cancer to managing serious chronic conditions have been suddenly exposed to grave risks. Katrina underscores the critical need for real-time access to the most-up-to-date summary of medical history information at the point-of-care, regardless of where individuals are being treated.

In response to the storm, ONCHIT, the Markle Foundation, and 150 other public and private organizations worked closely in an intense crash effort to establish an online service for authorized health professionals to gain electronic access to prescription medication records for evacuees (www.katrinahealth.org). The medication history information from a variety of government and commercial sources has been indexed and made accessible through a single Internet portal. Sources include electronic databases from commercial pharmacies, government health insurance programs such as Medicaid and the Veteran's Health Administration, private insurers, and pharmacy benefits managers in the states affected by the storm. As a result of this effort, today most evacuees can approach any retail pharmacist or licensed physician in America and, with proper credentials, gain access to vital information about their recent medication history.

This was a marvelous collaborative effort – but it should not require weeks of 24/7 heroics by hundreds of good-hearted Americans responding to a tragedy to move a simple string of bytes across a wire into a health professional's hands. In truth, the technologies to move health information between facilities or communities are relatively well understood – and operate today within many complex enterprises. Instead, KatrinaHealth.org came into being because of a good-faith commitment to overcome established business, legal, and policy obstacles to information sharing. If there is any lesson in this that can be instructive going forward, it is that a narrow focus on the technical aspects of creating an electronic health information environment will not produce a sustainable, effective network. The policies that govern information access, acceptable uses, consent, privacy and security must be crafted in parallel with the deployment of technology if we are to have a trusted and effective health information environment. And the technology choices, themselves, must incorporate the policy objectives.

Today, if I were to need emergency care here in Washington, no information about me would be available to my providers, and my care would depend on my memory and good guesses by my doctors – just as over a million Katrina victims found themselves without their health information at a critical time. We must move quickly to create an information environment that can move a patient's critical health information where it's needed, when it's needed – while protecting the privacy and security of that information and providing the patient with the ability to access and control it.

About Connecting For Health

Many of us involved in the response to Katrina have been working together over the last few years as part of a broad collaboration focused on using information technology to provide the American people with electronic access to their medical records. Our history of collaboration and problem solving toward this goal enabled us to move quickly to meet the emergency needs caused by the hurricane.

For the last three years, I have had the privilege of chairing Connecting for Health (see www.connectingforhealth.org), an initiative established and operated by the Markle Foundation, with additional funding and support from the Robert Wood Johnson Foundation. Connecting for Health is committed to accelerating actions on a national basis to tackle the barriers that prevent us from bringing health care into the information age - to improve the quality of health care, reduce medical errors, lower costs and empower patients.

Today, Connecting for Health is a truly unique public-private sector initiative, consisting of over 100 stakeholders representing providers, patients, payers, accreditors, government agencies, researchers and health care information systems manufacturers and vendors (see the appendix for the list of current Steering Group members).

Connecting for Health has been actively participating in shaping the national drive toward interoperable health. In our 2004 Roadmap document, "Achieving Electronic Connectivity in Healthcare: A Preliminary Roadmap from the Nation's Public and Private-Sector Healthcare Leaders," we recommended a consensus set of immediate actions to be taken by all health care stakeholders to create a decentralized and standards-based information network of networks that is effective for health care and patients.

Based on the principles laid out in the Roadmap, Connecting for Health is now operating a novel prototype of an electronic national health information exchange based on common, open standards. This effort is the first step in enabling patients and authorized physicians in all 50 states and DC to share health information on a completely voluntary basis in a secure and private manner. The prototype, which includes the exchange of information both within and among local communities, is now being conducted in California, Indiana, and Massachusetts.

To be specific, the model of information exchange Connecting for Health envisions—based on a "Common Framework" of open, consensus-driven and non-proprietary standards, uniform policies that protect privacy, assure security, and support existing trust relationships, and a common technical approach to linking personal health information—can be the springboard to a generation of innovation and improvement in health care and in personal health. Clinical models, self-care and decision-support tools, application and communications software, and even redesigned care practices will emerge within this new environment. Research and innovative approaches to prevention and treatment can be strengthened and the results integrated more rapidly into health care and health-related decision making. The delivery of high quality care can become more likely, less expensive, and timelier—bringing the right skills and knowledge to the right person at the right time. We can put patients and families at the very center of the health care system, supported and surrounded by an information environment that they can use—

or allow others to use – to make decisions, monitor health, provide feedback, and support strategic analytic functions that produce measurable improvements in health.

The Connecting for Health Model

The basic idea underlying the Roadmap and now the prototype is that information exchange can take place among existing health care institutions over the Internet if all participants adhere to a small set of shared rules—a "Common Framework" of technical components, standardized methodologies, and explicit policies for information use and governance. We believe that general adoption of this small set of critical tools can permit rapid attainment of an interoperable information environment that supports modern health care practice.

The many Connecting for Health collaborators identified several features of the future health information environment. These provide the basis for the prototype information exchanges we are now operating. With contemporary technology – and to help protect patients' privacy – we do not advocate a system that requires taking personal health information out of the hands of those who collect it: doctors, patients, hospitals, pharmacies and others. There are many effective information networks already working in health care today – tying together large health systems like the Veterans Health Administration or Kaiser Permanente, community-wide networks such as the New England Health Exchange Network, and large business networks such as the prescription benefits management and laboratory companies. We can leverage the investment and sophistication of these existing networks, and tie them together in a distributed, federated "network of networks". By adopting common data standards, and common rules for handling the information and assuring patient privacy, any authorized party should be able to access and share appropriate information with another authorized party.

The key to this approach is the articulation of nationally uniform policies and technical standards – so that every entity that wishes to share information across the network knows the rules and can choose to conform to them. Every network participant – and every patient – needs to be confident that health information will be handled in a secure, reliable and trustworthy way. Patients must be afforded a means of controlling who accesses their personal health information and how it is used. And, as the Internet has taught us, we do not need to have a central administrator issuing permissions or charging a toll for every information exchange if the network has been properly designed.

Connecting for Health believes that there needs to be a single national entity to promulgate both the policy and technical standards that provide structure to our health information environment. The AHIC recently defined by Secretary Leavitt may be the first institutional attempt to provide these functions, and we intend to work closely with the AHIC and the contractors and partners that will be engaged. Our work highlights the importance of several elements of these national standards and policy bodies. They must represent the public interest – both through their governance and participatory processes - and not only the interests of any particular professional or stakeholder sector. They must maintain transparency and accountability to the public. Above all, the work of defining

policies and public priorities must be closely linked to the selection and implementation of the enabling technologies.

These design characteristics have been endorsed by a broad-cross section of public interest and private sector stakeholders, and are now being implemented in our prototype. We believe that they form the basis of a distinctively American solution to the challenges of 21st century health care. It is particularly important to note that this approach creates an information architecture that provides maximum protection to the privacy of personal health information while accommodating innovation in the management of information and, indeed, in the configuring of health care services.

Engaging Patients in the Process

The will to overcome the technical, financial, and other barriers to information exchange, and the ultimate success of efforts to promote widespread adoption of HIT and electronic health records will depend on the confidence and willingness of consumers to accept and use the technology.

Policymakers must take into account that the public has serious concerns about health information technology. Seventy percent of Americans believe that a system of electronic health records would result in exposure of private health information, and 69 percent worry that such a system would result in more sharing of personal health information without their knowledge, according to a recent Harris survey. The same survey found that almost half of Americans believe that the privacy risks outweigh any other benefits that health information technology has to offer.

Given the concerns expressed by the public, the federal government needs to establish a meaningful process to address the issues and priorities of consumers as it moves forward with AHIC and other activities spear-headed by ONCHIT to advance widespread adoption of HIT. We are working now with a network of over thirty national consumer groups who are aware of the importance of information technology in health care and want to help shape this agenda for the benefit of their constituents. These groups are ready to serve on appropriate boards and commissions, but the need to address consumer concerns goes beyond nominal participation in advisory bodies.

We must remember that Americans regard their personal health information as "sacred," and all of us share a public trust to treat their information with suitable care and not merely as a business commodity. Patients and consumers must be given the ability to control whether and how their information is used, and both technology and policy solutions must make every effort to assure the secure handling of patient information. As we design our health information environment – including the first projects prioritized by the AHIC and other federal investments, we must include the patient and family as essential users of the information network. We hear much talk about "patient-centered" and "consumer-driven" health care, but these objectives will not be reached if we fail to design our information network with the individual as the most important user.

Engaging Americans in their own Care

Personal Health Records (PHRs) can and should play an important role in helping bridge an information gap that exists too often today between people and the health professionals who serve them. Such PHRs would enable people to manage their health information and health care transactions electronically. By facilitating a host of health management activities, PHRs have the potential not only to improve personal and family health but also to support major national health objectives.

There is good reason to believe that general use of PHRs – leveraging an interoperable health IT environment - could improve health and trigger a restructuring of our health care system (see the Connecting for Health report "Connecting Americans to their Healthcare" at www.connectingforhealth.org). In early research studies, PHRs have been found to help people:

- Understand the health issues and decisions they face.
- Improve engagement with physician recommendations and disease management plans.
- Assume a greater responsibility for their care.
- Monitor important data about themselves on a regular basis.
- Verify the accuracy of the information in their medical records.
- Avoid bureaucracy in tracking down their information.
- Facilitate communication with family members and friends about health issues.
- Improve communication with physicians.
- Share in the decision making process with their provider.
- Require less physician time is spent tracking down medication information.
- Flag interactions, contraindications, side effects and allergies.
- Reduce the number and the associated costs of unnecessary and duplicative tests.
- Increase the efficiency of making and responding to requests for information from various providers.
- Improve the outcomes of care, and reduce the associated health care costs, for people with chronic conditions.
- Save professional, administrative and patient time.

But most of these gains cannot be achieved if personal health records remain isolated from the mainstream of medical care. The value of electronic health records will only be maximized when we have a health information environment that allows information to move freely from one professional component to another – and for it to move both to and from the patient.

Several federal agencies have begun to include PHRs in their programs and plans. This expanding federal activity is generating questions about how government can best support and serve the public interest as PHRs evolve. Awareness is growing within and

beyond government of the need for a more strategic and coordinated federal approach in this area. In addition, many governmental agencies have espoused the principles of patient-centered care, greater consumer control and empowerment, improved chronic care management and fuller translation of knowledge into practice with respect to both public health and health care. If PHRs are a means toward these important policy goals, as many believe, then government can be expected to help nurture their development in its own programs and in the country as a whole.

These dual goals – an interoperable environment and widespread distribution of personal health records that connect to that environment – will only be achieved by collaboration between the public and private sectors, and with federal leadership.

Congress and the Administration have begun to take the critical first steps. The creation of a single national entity to set standards and policies, development of personal health records by government agencies, funding of small demonstration projects – these are all worthwhile. But the images of Hurricane Katrina victims should remind us that we need to act quickly and creatively. Key elements of infrastructure must be created immediately, so that every bit of health information that is now stored in digital form can be made available to those who need it when authorized by the patient.

Conclusion

As the government continues to evaluate and coordinate national efforts, Connecting for Health will be ready to help in any appropriate way. We represent the widest diversity of our great health care system – patients, professionals, payers, researchers, technologists, regulators – and we want to see our national system fulfill its potential to help every American achieve the best possible health with the available resources. Our approach is above all pragmatic; it is based not on any particular ideology or economic interest, but on our shared sense of what practical actions will bring results. We can work together to achieve the national vision of an interconnected heath system by 2014. Thank you. I will be pleased to try to answer any questions members may wish to

Appendix: Connecting for Health, Steering Group Participants

Steering Group Leaders

Carol Diamond, MD, MPH, Managing Director, Health, Markle Foundation Daniel Garrett, Vice President and Managing Director of Computer Sciences Corporation's Global Health Solutions Practice

John R. Lumpkin, MD, MPH, Senior Vice President, Robert Wood Johnson Foundation and Chair, National Committee on Vital and

Health Statistics

Janet M. Marchibroda, Executive Officer of the eHealth Initiative and the Foundation for eHealth Initiative

Herbert Pardes, MD, President and CEO, New York-Presbyterian Hospital

Steering Group Members

Peter A. Andersen, MD, Senior Program Manager, Lockheed Martin Information Technology

William Braithwaite, MD, Senior Vice President and Chief Medical Officer, eHealth Initiative, Co-Chair Policy Sub Committee

Claire Broome, MD, Sr. Advisor to Director for Integrated Health Information Systems, Centers for Disease Control and Prevention

Gary Christopherson, Deputy Director, Quality Improvement Group Office of Clinical Standards and Quality, Centers For Medicare and Medicaid Services

Carolyn Clancy, MD, Director, Agency for Healthcare Research and Quality

Janet Corrigan, PhD, President and CEO, National Committee for Quality Health Care Mike Cummins, Chief Information Officer, VHA Inc.

Francois de Brantes, Program Leader, Health Care Initiatives, GE Corporate Headquarters

Mary Jo Deering, PhD, Director for Informatics Dissemination, National Cancer Institute/National Institutes of Health, USDHHS

Don Detmer, MD, FACMI. President, AMIA

Carol Diamond, MD, MPH, Managing Director of the Health Program, Markle Foundation

David Epstein, Director, Solution Development - Public Sector, IBM

Colin Evans, Director Policy & Standards, Digital Health Group, Intel Corporation Mark Frisse, M.D., MBA, MSc, Accenture Professor and Director, Tennessee Volunteer eHealth Initiative, Vanderbilt Center for Better Health, Co-Chair Policy Sub Committee Daniel T. Garrett, Vice President and Managing Partner, Computer Sciences Corporation Peter Geerlofs, MD, Chief Medical Officer, Allscripts Healthcare Solutions

John Glaser, PhD, Chief Information Officer, Partners HealthCare System John Halamka, MD, Chief Information Officer, CareGroup Healthcare System

W. Edward Hammond, PhD, Professor, Community and Family Medicine Duke University

Linda Harris, Ph.D., Senior Health Communication Scientist, National Cancer Institute Douglas Henley, MD, Executive Vice President, American Academy of Family

Physicians

Joseph Heyman, MD, Secretary, American Medical Association

Yin Ho, MD, Director eBusiness, Pfizer, Inc.

Kevin Hutchinson, Chief Executive Officer, SureScripts

Michael Jackman, Chief Technology Officer, Health Imaging Group, Eastman Kodak Company

Charles Jaffe, MD, PhD, Senior Global Strategist, Digital Health Group, Intel Corporation

William F. Jessee, MD, President and CEO, MGMA

Michael L. Kappel, Sr Vice-President, Government Strategy and Relations, McKesson Provider Technologies

Brian Keaton, MD, FACEP, Attending Physician/ EM Informatics Director and Board Member, ACEP Summa Health System

Linda Kloss, RHIA, CAE, Executive Vice President and CEO, AHIMA

Allan Korn, MD, FACP, SVP eClinical Affairs Blue Cross Blue Shield Association David Lansky, PhD, Senior Director, Markle Foundation

Gail Latimer, MSN, RN, Vice President, Chief Nursing Officer, Siemens Corporation Mark Leavitt, MD, PhD, FHIMSS, Medical Director / Director of Ambulatory Care HIMSS - The Source for Healthcare Information

Gary Levine, Senior Director, Business Planning & Development, Medco Health Solutions

Jack Lewin, MD, President, California Medical Association

Stephen Lieber, CAE, President, HIMSS

John R. Lumpkin, Senior Vice President Director, Health Care Group, Robert Wood Johnson Foundation

Patricia MacTaggart, Director, EDS Executive State and Local Government

Janet M. Marchibroda, Executive Director, eHealth Inititiative

Howard Messing, President, Meditech

Arnold Milstein, MD, MPH, Medical Director, Pacific Business Group on Health, The Leapfrog Group

Margaret O'Kane, President, National Committee for Quality Assurance

Dennis O'Leary, MD, President, Joint Commission on Accreditation of Healthcare Organizations

J. Marc Overhage, MD, President and Chief Executive Officer, Indiana Health

Information Exchange; Associate Professor of Medicine, Indinana University, School of Medicine Regenstrief Institute for Healthcare

Herbert Pardes, MD, Chief Executive Officer, New York-Presbyterian Hospitals, University Hospitals of Columbia and Cornell

Alison Rein, Assistant Director of Food and Health Policy, National Consumers League Russell J. Ricci, MD, Chief Medical and Strategic Officer, HealthSTAR Communications Craig Richardson, Vice President, Health Care Connectivity and Alliances, Johnson and Johnson Health Care Systems, Inc

Wes Rishel, Board Chair, Health Level Seven, Gartner

William Rollow, MD, Deputy Director, Quality Improvement Group Office of Clinical Standards and Quality Centers for Medicare and Medicaid Services

David Schulke, Executive Vice President, The American Health Quality Association

Steve Shihadeh, General Manager of the Healthcare Industry Solutions Group, Microsoft Clay Shirky, Adjunct Professor, New York University

Steve Sleigh, PhD, Director, Strategic Resources, International Association of Machine and Aerospace Workers

Michael Solomon, VP Strategic Planning & Initiatives, IDX Systems Corporation Ellen Stovall, President, National Coalition for Cancer Survivorship

Thomas Sullivan, MD, Past President, Massachusetts Medical Society Women's Health Center Cardiology

Paul Tang, MD, Chief Medical Information Officer, Palo Alto Medical Foundation Robin Thomashauer, Executive Director, Council for Affordable Quality Healthcare John Tooker, MD, MBA, FACP, Executive Vice President American College of Physicians

Micky Tripathi, Chief Executive Officer, Massachusetts eHealth Collaborative Charlene Underwood, Director/Government & Industry Affairs, Siemens Corporation Robert Wah, MD, Captain, MC, USN Director, Information Management, Department of Defense

Scott Wallace, President/Chief Executive Officer, The National Alliance for Health Information Technology

Andrew Wiesenthal, MD, Associate Executive Director, The Permanente Federation Robert B. Williams, MD, MIS Director, Healthcare Consulting Deloitte Chelle Woolley, Communications Officer, RxHub

William Yasnoff, MD, PhD, Managing Partner, NHII Advisors

Chairman Tom DAVIS. Thank you very much. Ms. Marchibroda, thank you for being here.

STATEMENT OF JANET MARCHIBRODA

Ms. Marchibroda. Thank you, Chairman Davis, distinguished members of the committee. I am honored to be here today to testify before you on the state of information technology, and health information sharing, and the progress and challenges related thereto.

My name is Janet Marchibroda. I am testifying today on behalf of the eHealth Initiative and its foundation. I service the CEO of both organizations which are independent, nonprofit, national organizations whose missions are the same, to improve the quality, safety, and efficiency of healthcare through information and information technology. Both convene multiple stakeholders, both within the private and public sector, to reach agreement on and stimulate the adoption of common principles and strategies for accelerating the use of information to support health and healthcare.

In addition, it is important to note that through EHI, the eHealth Initiative Foundation, we have built a coalition of almost 1,000 stakeholders in nearly 50 States across the country who are

now mobilizing information to support healthcare.

Despite the recent increase in interest in the use of IT to address quality, safety, and efficiency issues, current penetration rates continue to be low, particularly in the small physician practices where a majority of our healthcare is delivered. And it is also important to note while installing electronic health records can address some of our healthcare challenges, the real value in terms of improving quality and safety, saving lives, reducing costs comes from the mobilization of data across systems. You really need that connectivity to avoid redundant tests, improve safety and coordination, and improve consumer compliance with some of the prevention and disease management guidelines.

Currently, the U.S. healthcare system is highly fragmented and paper-based, and the clinicians that take care of us don't have the information they need to deliver the best care. To address the need for health information mobilization, a number of collaborative organizations involving all stakeholders in healthcare are emerging across our country to develop and implement health information exchange capabilities, and the policies and processes that will sup-

port their ongoing operations.

The eHealth Initiative Foundation recently conducted its second annual survey of State, regional and community-based health information exchange efforts, and we released our results in late August. What the survey results indicated was a dramatic increase in the level of interest in and activity related to mobilizing information. It showed that there are a lot more of them this year, and those that are out there are much more mature in terms of organization and governance, getting all the stakeholders to the table, and the range of functionality provided. Among the 109 health information exchange efforts identified by the survey, there is clear evidence of rapid maturation and movement with 40 respondents in the implementation phase and 25 fully operational, up from 9 last year.

In terms of the barriers to getting to an interoperable healthcare system, we see two: the first being the misalignment of incentives and lack of a sustainable business model for IT; and two, the need for standards adoption and interoperability. Physicians have a real tough time. They face a significant financial hurdle when exploring the purchase of an EHR system. What we found in our 2005 survey was, while these health information exchange initiatives are growing and maturing, the No. 1 key challenge, 84 percent of them actually cited developing a sustainable business model as either

being a very difficult or moderately difficult challenge.

Achieving sustainability for health information exchange efforts stems in part from fundamental problems with our Nation's prevailing reimbursement methods which reward the volume of services delivered instead of outcomes or processes that would result in higher quality care. A lot of progress is being made with the value-based purchasing legislation that is coming out and the leadership of the Centers for Medicaid and Medicare Services, as well as groups such as Bridges to Excellence in the private sector. We have developed a set of principles and policies bringing together employers, health plans, and practicing clinicians, and these community-based efforts that will begin to align incentives that we provide in healthcare, not only with quality and efficiency goals but also with HIT capabilities within the community.

Great progress is being made around standards and operability, interoperability, which we have heard from the other parts of our panel, and a number of efforts are underway with a number of bills in Congress. Finally, in closing, the Office of Personnel Management through its Federal Employees Health Benefits Program has an enormous opportunity to affect change in our healthcare system given that 8 million Federal employees, retirees, and their dependents are reliant on the program. By building into those incentive programs, policies related to health information exchange, we can

make real progress.

So in conclusion, we offer a very brief summary of key points. Without the alignment of financial and other incentives, not just with quality and efficiency but also health information exchange, efforts to accelerate the mobilization of information will continue to move at a slow pace, and the combined purchasing power of both

CMS and OPM can make great progress in this area.

Two, innovative programs designed to facilitate both public and private sector seed funding of these emerging community health information exchange efforts must be developed and implemented, if our goals around widespread interoperability are to be achieved. And three, national efforts designed to achieve consensus on standards and promote their adoption could not be more timely, particularly for our communities across America that are on the ground making this happen.

We are at a unique point in time where we have a lot of momentum moving around these issues. If we focus on moving our quality and efficiency goals, and at the same time those related to health

information technology, we will make great progress.

Chairman Davis, distinguished members of the committee, thank you again for inviting me to discuss our perspectives. I hereby request that the Parallel Pathways Framework for Incentives and our survey of State, regional, and community-based initiatives that are referenced in my testimony be made part of the record.

Chairman Tom Davis. Without objection.

Ms. Marchibroda. We commend you for your leadership. And, again, thank you for the opportunity to join you.

[The prepared statement of Ms. Marchibroda follows:]





House Committee on Government Reform
Statement of Janet M. Marchibroda, Chief Executive Officer, eHealth Initiative and
Foundation

Testimony Before the House Committee on Government Reform

The State of Information Technology and Health Information Sharing and the Progress and Challenges in Developing a National Information Technology Strategy

September 29, 2005

Introduction

Chairman Davis, Congressman Waxman, distinguished members of the Committee, I am honored to be here today to testify before you on the following:

- · The state of information technology and health information sharing;
- The progress and challenges related to developing a national information technology (IT) strategy;
- The exploration of efforts to develop standards for the collection and use of health information to facilitate information sharing, and
- The challenges to achieving interoperability among health IT systems.

My name is Janet Marchibroda. I am testifying today on behalf of the eHealth Initiative and its Foundation. I serve as the Chief Executive Officer of both organizations, which are independent, national, non-profit organizations whose missions are the same: to improve the quality, safety and efficiency of health and healthcare through information and information technology. Both convene multiple stakeholders, including clinicians, consumer and patient groups, employers and purchasers, health plans, healthcare IT suppliers, hospitals and other providers, laboratories, pharmaceutical and medical device manufacturers, pharmacies, public health agencies and representatives of the public sector to reach agreement on and stimulate the adoption of common principles and strategies for accelerating the use of information to support health and healthcare. In addition, it is important to note, that through the eHealth Initiative Foundation, we have built a coalition of almost 1,000 stakeholders involved in over 150 regional and community-based initiatives across America, located in nearly 50 states and the District of Columbia, who are working together to mobilize information within their markets to support health and healthcare.

In my remarks today, I will share the insights of the multiple and diverse stakeholders engaged in our work, as well as findings from our recent survey of 109 communities within the United States who are mobilizing information to support patient care through health information exchange activities.

Current State of Information Technology and Health Information Sharing in Communities Across the U.S.

Despite the recent increase in interest and momentum around the value of information technology in addressing quality, safety and efficiency challenges in our healthcare system, current penetration rates continue to be low—particularly in physician practices, where most of

Testimony of Janet M. Marchibroda, eHealth Initiative and Foundation September 29, 2005 Page 1 America's healthcare is delivered. According to a 2003 national survey from the Commonwealth Fund, only 27 percent of physicians are using electronic health records (EHRs), with small physician practices demonstrating the lowest adoption rates. According to the study, 57 percent of practices with more than fifty physicians are using an EHR, compared to only 13 percent for solo practitioners. This statistic is particularly important given that most of America's healthcare is delivered by small physician practices. According to the 2002 National Ambulatory Medical Care Survey, 68 percent of the almost 900 million physician practice visits in the U.S. are conducted by practices with one to four doctors.²

While installing EHRs can address some healthcare challenges, the real value—in terms of improving quality, saving lives, and reducing costs—comes from the mobilization of data across systems. Connectivity is required to avoid redundant tests; improve safety and coordination among providers; increase administrative efficiency; and improve consumers' compliance with prevention, disease management, and care guidelines. In fact, most of the information that a clinician uses at the point of care comes from somewhere else—such as the hospital, the laboratory, the pharmacy, and the health plan.

Currently, the U.S. healthcare system is highly fragmented and paper-based, and information about the patient is stored in a variety of locations and formats. As a result, clinicians often don't have comprehensive information about the patient when and where it is needed most—at the point of care. Those responsible for improving population health don't have the information they need to measure progress and facilitate improvement. To address the need for health information mobilization, a number of collaborative organizations involving multiple stakeholders are emerging to develop and implement "health information exchange" capabilities, and the policies and processes to support their ongoing operations.

"Health information exchange" is defined as the mobilization of healthcare information electronically across organizations and disparate information systems within a region or community. Health information exchange initiatives are designed to support interoperability and facilitate access to and retrieval of clinical data, privately and securely, to provide safer, more timely, efficient, effective, equitable, patient-centered care.⁴

A number of reports highlight the value and cost savings of standards-based health information exchange. According to a recent study by the Center for Information Technology Leadership, net savings from the national implementation of fully standardized interoperability between providers and five other types of organizations could yield \$77.8⁵ billion annually, or

¹ A.M. Audet et al., "Information Technologies: When Will They Make It into Physicians' Black Bags?" Medscape General Medicine 6, no. 4 (2004), www.medscape.com/viewarticle/493210/14 February 2005); (registration required).

² 2002 National Ambulatory Medical Care Survey: 2002 Summary, contained in the CDC's Advance Data No. 346, dated August 26, 2004.

³ R. Taylor et al., "Promoting Health Information Technology: Is There a Case for More Aggressive Government Action?", Health Affairs 24, no. 5 (2005): 1237.

⁴ Emerging Trends and Issues in Health Information Exchange: Selected Findings from eHealth Initiative Foundation's Second Annual Survey of State, Regional and Community-Based Health Information Exchange Initiatives and Organizations, August 2005

Walker J, Pan E, Johnson D, Walker J, Adler-Milstein J, Bates DW, Middleton B: The Value of Healthcare Information Exchange and Interoperability: There is a Business Case for Spending Money on a Fully Standardized Nationwide System. Health Affairs: Web Exclusive, January 19, 2005.

approximately five percent of the projected \$1.7 trillion spent on healthcare in 2003. According to the report, full national implementation at "level four" interoperability, in which all systems would exchange data using the same messaging, format and content standards, would reap the following net returns annually for stakeholders: providers, \$33.5 billion, payers, \$21.6 billion, independent laboratories, \$13.1 billion, radiology centers, \$8.17 billion, pharmacies, \$1.29 billion, and public health departments, \$94 million⁶. A recent report conducted by the RAND Corporation estimates that effective electronic medical record implementation and networking could eventually save more than \$81 billion annually-by improving healthcare efficiency and safety—and that HIT-enabled prevention and management of chronic disease could eventually double those savings while increasing health and other social benefits.

eHealth Initiative's Foundation recently conducted its second annual survey of state, regional and community-based health information exchange efforts, releasing its results on August 29, 2005. This work, supported both this year and last year by the Health Resources and Services Administration's Office of the Advancement for Telehealth (HRSA/OAT) within the Department of Health and Human Services, will serve as a yearly "report card" on the current state of activities related to interoperability and health information exchange across the U.S., highlighting for both policy-makers and on-the-ground implementers the barriers and strategies currently being utilized by collaborative efforts in almost every state in the nation.

Survey results indicate a dramatic increase in the level of interest in and activity related to mobilizing information electronically across markets to support health and healthcare. Results show that a number of new health information exchange initiatives have emerged over the last year, and in general, such efforts have matured considerably with respect to engagement of key stakeholders, organization and governance, the range of functionality provided, and the technical aspects of health information exchange. These initiatives typically involve a broad range of participants, including hospitals and other healthcare providers, physician practices, health plans, employers and other healthcare purchasers, laboratories, pharmacies, public health agencies, state and local governmental agencies, and most importantly, patients. Among the 109 health information exchange efforts identified by the 2005 survey, there is clear evidence of rapid maturation and movement along six distinct developmental stages, with 40 respondents in the "implementation" phase and 25 "fully operational"—up from the nine efforts considered fully operational in 20048.

The key driver moving states, regions and communities toward health information exchange is perceived provider inefficiencies. Seventy-seven percent of all respondents cited "provider inefficiencies due to lack of data to support patient care" as a significant driver for their health information exchange efforts, with 99 percent of all respondents citing this as a significant or moderate driver for their efforts. Additionally, rising healthcare costs was a significant driver for

⁶ Pan E, Johnson D, Walker J, Adler-Milstein J, Bates DW, Middleton B: The Value of Healthcare Information Exchange and Interoperability. Center for Information Technology Leadership. 2004.

R Hillestad et al. "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings and Costs", Health Affairs 24, no. 5 (2005): 1103

Overhage J, Evans L, Marchibroda J: Communities' Readiness for Health Information Exchange: The National

Landscape in 2004. JAMIA 12:107-112, 2005.

both early stage and advanced stage health information exchange efforts, with 60 percent of respondents citing this as a significant driver.

The Progresses and Challenges of Developing a National Health Information Technology Strategy

eHealth Initiative's work with the multitude of stakeholders in healthcare as well as the hundreds of stakeholders involved in state, regional and community-based efforts across the U.S. reveal the following primary policy barriers that impede widespread HIT adoption and health information exchange: the misalignment of incentives and lack of a sustainable business model for HIT and health information exchange investment and the need for standards adoption and interoperability.

Misalignment of Incentives and Lack of a Sustainable Business Model
Physician practices currently face a significant financial hurdle when exploring the purchase of an EHR system. Costs may be significant and the implementation process can be complex and costly, taking precious time away from taking care of patients. One study indicates that while physicians must make the investment in EHR systems, they accrue only 11 percent of the benefit.⁹

eHealth Initiative Foundation's 2005 survey indicates that while health information exchange initiatives are maturing and increasingly exchanging a range of health care information to support care delivery and performance improvement, one of the key challenges for most efforts is the development of a business model for sustainability. Thirty-one percent of all survey respondents cited "developing a sustainable business model" as a very difficult challenge and 84 percent cited this barrier as either a very difficult or moderately difficult challenge. Similarly, 91 percent cited "securing upfront funding" as a very difficult or moderately difficult challenge, which relates significantly to the lack of a sustainable model¹⁰.

The difficulties faced in securing funding for upfront development costs and achieving sustainability for ongoing operational costs for health information exchange stem in part from fundamental problems with our nation's prevailing reimbursement methods which reward the volume of services delivered instead of either the outcomes or processes that would result in higher quality, safer, more efficient, or more effective healthcare. Progress is being made in this area through leadership demonstrated by several members of Congress through recently introduced legislation related to "value-based purchasing"; the Centers for Medicare and Medicaid Services' leadership and efforts in demonstration projects such as the Medicare Health Care Quality Demonstration (Section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 or MMA), the Medicare Care Management Performance Demonstration (Section 649 of the MMA) and related DOQ-IT Program; and private sector initiatives such as Bridges to Excellence—a non-profit organization representing purchasers,

⁹ J. Walker et al., "The Value of Health Information Exchange and Interoperability," Health Affairs, no. 19, January 2005

^{2005.}Description of Emerging Trends and Issues in Health Information Exchange: Selected Findings from eHealth Initiative Foundation's Second Annual Survey of State, Regional and Community-Based Health Information Exchange Initiatives and Organizations, August 2005

providers and payers which has developed and is implementing programs designed to promote quality and safety through rewards to physician practices and patients. All of these efforts acknowledge the misalignment of incentives and the economic imbalance that exists between those who purchase HIT and those who benefit from its use.

The eHealth Initiative Foundation has taken steps to tackle this issue by engaging purchasers, providers and payers in the development of a set of principles and framework for aligning incentives with not only quality and efficiency goals, but also HIT capabilities within the physician practice and health information exchange capabilities across markets in the U.S. This Framework, entitled "Parallel Pathways for Quality Healthcare¹¹," offers significant guidance to states, regions and communities who are exploring health information exchange as a foundation to address quality, safety and efficiency challenges. As policies and practices that align payment systems with quality and efficiency become more prevalent, health information exchange efforts will have an easier time securing the funding required to support their start-up and sustainability.

The eHealth Initiative Foundation, through its Connecting Communities for Better Health Program, this year funded by HRSA/OAT, will provide seed funding and technical support to a set of "learning laboratories" led by multi-stakeholder collaboratives, who are experimenting with the development of models for sustainability for their health information exchange efforts. We expect to gain knowledge and experience related to principles and strategies for sustainability to support not only those who receive awards, but all communities across the U.S. who are developing health information exchange capabilities. We also expect that lessons learned and shared from these learning laboratories will inform the efforts of policy-makers, and national leaders both in the public and private sectors who must take actions to clear barriers to interoperability and health information mobility.

This year's award program is designed to be a catalyst to build purchaser and payer awareness of the value that health information exchange capabilities can provide and stimulate their ongoing interest in supporting such activities at the state, regional and local levels. Successful awardees will have engaged the commitment of purchasers and payers representing at least 30 percent of covered lives within their markets, to participate in a pilot or implementation of an incentives program that will not only support quality goals, but also directly or indirectly, support the health information exchange capabilities which are necessary to achieve those quality goals. They will also have engaged the commitment of a large percentage of practicing clinicians—including small physician practices—who have committed to both utilizing the health information exchange capabilities, and participating in the incentives program.

Standards and Interoperability

The Administration, a number of members of Congress, some states, and several private sector efforts have introduced policies and initiatives designed to improve the quality, safety and efficiency of healthcare by addressing the issues of standards and interoperability. The Administration signaled its commitment to interoperability and the mobilization of information electronically across our healthcare system when President George W. Bush appointed David Brailer, MD, PhD as National Coordinator of Health Information Technology. Department of

¹¹ eHealth Initiative Foundation's Parallel Pathways for Quality Healthcare: A Framework for Aligning Incentives with Quality and Health Information Technology, May 2005

Health and Human Services Secretary Michael Leavitt's June 2005 announcement of the creation of a private-public sector collaboration—the American Health Information Community (AHIC)—and four related Requests for Proposals to fast-forward work related to privacy and security, standards harmonization, certification, and architecture, all will help pave the way for health information exchange and interoperability.

Many other influential groups have made great strides in both the development and adoption of standards to support a higher quality, safer and more efficient healthcare system enabled by information technology. Within government, the Consolidated Health Informatics Initiative has played an integral role in gaining consensus on the data standards that the Federal government will use in its own operations. The National Committee on Vital and Health Statistics has played a critical role by providing ongoing advice and counsel to the Secretary of the Department of Health and Human Services regarding the standards that should be adopted to promote an interoperable, electronic healthcare system.

Connecting for Health, a public-private sector collaborative funded by the Markle and Robert Wood Johnson Foundations, is developing a number of work products designed to support interoperability, including technical prototypes for a health information network in three markets, which will provide considerable input and support the interoperability movement across the U.S.

In addition to the significant announcements outlined above, the Administration has several programs underway to conduct research, gain consensus on technical standards and practices, conduct demonstration programs, fund grants and contracts, and provide education and technical assistance to stakeholders to support the improvement of health and healthcare through HIT. These programs are under the auspices of the Office of the National Coordinator for Health Information Technology, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Department of Defense, the Health Resources and Services Administration, the National Institutes of Health, and the Veterans Administration.

Congress is also playing a significant leadership role in promoting interoperability and standards adoption. Bi-partisan support has accelerated with the introduction of several pieces of legislation. In June and July 2005, five bills were introduced in the House and Senate that included components related to HIT. A number of the bills introduced in 2005 call for the funding and implementation of regional health information networks to support the national implementation of widespread interoperability.

National efforts designed to achieve consensus on and promote the adoption of standards could not be more timely. Health information exchange initiatives are in the midst of engaging in the difficult work related to getting organized; engaging stakeholders; defining goals, objectives, and priorities; and developing sustainable business models. As this work continues to migrate towards the implementation of technical networks, leadership on both the development of new and communication of the many existing standards at the national level will be critical to enable interoperability across markets.

Exploring Efforts to Develop Standards for the Collection and Use of Health Information Sharing

As noted above, many, many stakeholders benefit from the use of HIT and health information exchange. These efforts enable clinicians to gain more information about the patient and evidence-based practices—at the point of care—where it is needed most; public health agencies to receive necessary information to support and protect the population's health; and purchasers and payers the information they need to support efforts to drive improvements in quality, safety and effectiveness.

Currently, there is a great deal of momentum around two parallel issues: the use of health information technology and the importance of driving accountability and transparency. As noted above, reports from a wide range of philanthropic and private sector organizations, as well as representatives from the public sector both within the Administration and Congress, recognize the value of HIT in addressing quality, safety and efficiency challenges in the U.S. healthcare system. At the same time, the development and implementation of incentives or "value-based purchasing" programs—also called "pay for performance" programs—is on the rise, stimulated by reports from the Institute of Medicine and leadership demonstrated by organizations such as the Leapfrog Group, Bridges to Excellence, the Integrated Healthcare Association, and the Centers for Medicare and Medicaid Services, as well as several other programs initiated by both payers and purchasers. According to one report, almost one-third of health plans say that they now have a pay-for-performance program in place, but most are in the earliest stages of development or implementation.

Pay-for-performance systems provide higher reimbursement for those who perform well on a wide variety of quality, cost and efficiency measures (which are both process and outcome-oriented). Many of these systems have been launched based on the recognition that current reimbursement methods are not effectively curbing both rising healthcare costs and addressing issues related to quality and safety. Many, but not all, of the emerging programs integrate information technology expectations, recognizing that information technology can not only help with the reporting of the quality data typically required for such programs, but can also assist with the achievement of better outcomes—in both quality and efficiency.

It is important to note that most incentive programs in place today use claims-based information and manual patient record abstraction as the means to determine the quality of care received by patients. There are well researched and documented shortcomings to the use of claims data to determine the quality of care delivered, including the lack of timeliness, in some cases, its inaccuracy, and the lack of its ability to provide important physiological data on patients that are the true markers of clinical outcomes. In addition, manual extraction of data from paper-based charts is time-consuming and expensive. And, according to some reports, charts for patients cannot always be located. The use of clinical applications and health information exchange dramatically increase the accuracy, timeliness, and availability of information to support the determination of quality of care by purchasers and payers administering performance-based incentive programs. The development of this infrastructure—through health information exchange efforts—also builds the foundation for an evolving set of expectations without building in additional reporting burden.*

Finally--and more importantly—the use of clinical applications and the mobilization of patient data through health information exchange also creates the foundation and infrastructure for quality and safety improvement by supporting the provision of important patient information at the point of care—where it is needed most--and enabling clinicians to improve the quality and safety of care as it is being delivered to patients.

To address the challenges outlined above, and to provide support to emerging health information exchange efforts, the eHealth Initiative Foundation is developing tools and resources designed to support the diverse stakeholders in markets leverage health information exchange capabilities to facilitate the transmission of data and measures to support quality improvement and performance measurement, including common principles, policies and "how to" guides for physician practices and health information exchange efforts transmitting performance measures. We will also test the effectiveness of these guides in a number of "learning laboratories" in markets across the U.S. It is interesting to note, that according to our 2005 survey, a number of health information exchange efforts are already beginning to provide services that will support improvement, with 32 percent of advanced stage health information exchange initiatives providing disease or chronic care management services and 27 percent supporting quality and performance reporting efforts.

The Office of Personnel Management (OPM), through its Federal Employees Health Benefits (FEHB) Program, has an enormous opportunity to effect change in our healthcare system, given that about eight million Federal employees, retirees and their dependents are covered by the Program. The Program allows OPM to offer competitive health benefits products for Federal workers much like large employer purchasers in the private sector. OPM administers the Program by contracting with private sector health plans.

During its testimony to the House Subcommittee on the Federal Workforce and Agency Organization Committee on Government Reform on July 27, 2005, OPM laid out the various options to provide incentives in the FEHB Program to promote the adoption of interoperable HIT, including the following:

- Encourage plans to link disease management and quality initiatives to HIT systems for measurable improvements.
- Encourage health plans to provide incentives for the adoption of interoperable health information technology systems by key providers under FEHB contracts.
- Consider basing part of the service charge, or profit, for fee-for-service and other
 experience-rated plans and consider introducing performance goals for health
 maintenance organizations (community-rated plans) that are linked to their developing
 incentives for doctors and pharmacies to use paperless systems to fill prescriptions;
 contracting with hospitals that use electronic registries, electronic records, and/or
 ePrescribing; and increasing the number of enrollees whose providers use electronic
 registries, electronic records, and/or ePrescribing.

- Introduce incentives and performance goals for plans that integrate their provider networks with local and national health information infrastructure initiatives.
- Encourage and reward carriers that contract with pharmacy benefit managers which are
 providing incentives for ePrescribing and health information technology linkage.

OPM stated its commitment to using its position as the largest purchaser of employee healthcare benefits to contribute in the expansion and use of electronic health records, e-prescribing and other HIT related provisions and should be commended and supported in its leadership.

Conclusion

In conclusion, we offer a summary of key points related to the use of HIT and health information exchange to support improvements in the quality, safety and efficiency of our nation's healthcare system.

- Without the alignment of financial and other incentives with both quality and efficiency goals as well as electronic health information exchange capabilities, efforts to accelerate the mobilization of information to support patient care will continue to move at a slow pace. The combined purchasing power of the Office of Personnel Management's Federal Employees Health Benefits Program and the Centers for Medicare and Medicaid Services can play a critical role in catalyzing and change across the entire healthcare system. Given its jurisdiction over FEHBP, this Committee may want to consider a demonstration project related to supporting health plans to improve the quality, safety and efficiency of healthcare through IT.
- Innovative programs designed to facilitate public and private sector seed funding of emerging health information exchange efforts must be developed and implemented if goals related to widespread interoperability are to be achieved. While federal efforts can play a critical role in addressing this challenge, they should be designed to stimulate investment by the private sector as well as state and local government agencies to facilitate widespread interoperability.
- National efforts designed to achieve consensus on and promote the adoption of standards are on target and could not be more timely. They should continue to recognize the importance of public-private sector partnership, leverage the work that has already been conducted in the field, and tackle the issues for which we have not yet developed consensus within our fragmented healthcare system. Health information exchange initiatives are in the midst of engaging in the difficult work related to getting organized; engaging stakeholders; defining goals, objectives, and priorities; and developing sustainable business models. As this work continues to migrate towards the implementation of technical networks, leadership on both the development of new and communication of the many existing standards at the national level will be critical to enable interoperability across markets.

We are at a unique point in time, where public and private sector interests are at an all-time high in two key areas: improving the quality and safety of healthcare and moving forward on a health information technology agenda. Approaching these two key issue areas in a siloed manner-without strong integration across both areas-will result in missed opportunities, unintended consequences, and possibly reduced impact in both areas. Implementing an integrated, incremental strategy, which incorporates goals related to quality, safety, and efficiency as well as health information technology and the mobilization of data across organizations offers the foundation for building a healthcare system that is safer, of higher quality, and more effective and efficient.

Chairman Davis, Congressman Waxman, distinguished members of the Committee, thank you again for inviting me to discuss our perspectives on the role of information technology and health information sharing in improving the quality, safety and efficiency of our nation's healthcare system and the progress and challenges related to developing a national IT strategy. We at the eHealth Initiative are committed to working with you, as well as both the public and private sectors to make our vision of an improved healthcare system enabled by information technology and information mobility a reality. We commend you and your Committee for the work that you have done to improve the quality, safety and efficiency of healthcare for patients through information technology. Again, thank you for this opportunity and I look forward to answering any questions you may have.

Chairman Tom DAVIS. Well, thank you very much. Ms. Carr.

STATEMENT OF DIANE CARR

Ms. CARR. Good morning, Mr. Chairman and members of the committee. I would like to thank you for this opportunity to share the experience of a public hospital in New York City in transform-

ing healthcare with technology.

Queens Health Network is the largest healthcare provider in the borough of Queens, New York City. We serve a population of about 2 million people. We include two major teaching hospitals, Elmhurst Hospital Center and Queens Hospital Center, and have a combined total of 771 inpatient beds and see 43,000 annual admissions. We are affiliated with the Mount Sinai School of Medicine and a member of the New York City Health and Hospitals Corp. which is the largest municipal healthcare organization in the United States.

Our service model is unique. I just want to mention that for a moment because, in addition to providing acute hospital care including tertiary care, we also provide a full range of services of primary care and specialty care services. We serve as many of our patients family doctors. We do that, in addition to our on campus locations in 14 freestanding medical clinics and 6 school-based health programs where we provide care to children at their school, similar to what many of us experienced with school nurses. We have a partnership with community-based physician practice groups, and we see over 1 million ambulatory visits a year. So we are a pretty high volume healthcare provider.

I just want to mention about the community we serve because there is some uniqueness to that as well. It is probably the most ethnically diverse region in the world. We have immigrants from over 100 different countries speaking 167 different languages and 87 percent of our patient population is people of color and ethnic

minorities.

Our residents are also some of New York City's poorest. Sixty-five percent of the households in our service area have annual incomes under \$15,000. Because of this, our patient population is also medically under-served. They are denied care in other venues due to inability to pay, and they are generally unaware of preventive practices that promote good health. They present sicker than the general population.

In the mid 1990's, Queens Health Network faced a dilemma, how to maintain and expand services for an ever increasing number of uninsured patients in an ever more demanding marketplace. As part of our business and strategic plan, senior administration proposed implementation of an electronic health record to our medical

staff.

In January 1997, we began with computerized physician order entry. Our doctors started ordering all of their lab and radiology results and looking them up online. We had no idea at the time how early we were undertaking this. Today we have a fully integrated, interdisciplinary health record that is used by over 4,300 people every day. This is all of our doctors, our nurses, our pharmacists, social workers, dieticians, lab and radiology techs use the

system all day, every day, to enter orders, review results, do assessments and plans, histories and physical examinations, and medical orders.

We provide a full range of electronic decision support to improve safety and effectiveness of care. So what we have discovered in the experience of installing our electronic health record is that it is essential to improving patient safety, effectiveness of care and also

in reducing costs.

Chronic disease is the leading cause of illness, disability, and death in the United States today. Nearly half of the population, 100 million Americans, have one or more chronic medical conditions. The costs of the treatment is enormous in accounting for nearly 70 percent of all personal healthcare expenditures in the country. The electronic health record can provide a structure for applying evidence to patient care to improve care of patients with chronic diseases.

So we have targeted heart failure, diabetes, and depression right now as populations of patients who can benefit from analysis and aggregation of data, which helps us to evaluate therapies and treatments on patient outcomes. For example, if we have cardiologists working in adjoining rooms with patients with the same disease, we may not know what is going on with them individually, but when we start to aggregate their data we can look at patterns and see rooms for improvements.

The final point that I want to make is that, with all the discussion of interoperability, I think you also have to start somewhere and that the electronic health record is the place that will provide a starting point. If you don't have electronic health record that you can share your patient information from, interoperability means

nothing, that is it.

Chairman Tom Davis. OK. You have concluded?

Ms. Carr. Yes.

[The prepared statement of Ms. Carr follows:]



Written Testimony

of

Diane M. Carr Associate Executive Director Healthcare Information Systems Queens Health Network

Submitted to

U.S. House of Representatives Committee on Government Reform

September 29, 2005

Mr. Chairman and members of the Committee, I would like to thank you for this opportunity to share the experience of a public hospital system in New York City in transforming healthcare with technology.

I am Associate Executive Director for Healthcare Information Systems at the Queens Health Network in Queens, New York. A member of the New York City Health and Hospitals Corporation (HHC) and an affiliate of the Mount Sinai School of Medicine, the Queens Health Network is the major healthcare provider in the borough of Queens, New York City, employing over 6,000 people.

Queens Health Network and the Community We Serve

Serving a population of 2 million, Queens Health Network (QHN) comprises Elmhurst Hospital Center, Queens Hospital Center, 14 free standing medical clinics and six school-based health centers. Elmhurst and Queens are teaching hospitals, with a combined total of 771 inpatient beds and 43,000 annual hospital admissions. Rotating residents are supervised by attending physicians with faculty appointments. Together, these 800 physicians provide more than 1 million ambulatory care visits each year. QHN also provides 45,000 home healthcare visits annually, and has contracts with hospice organizations whose services include palliative care at Elmhurst.

Queens County in New York City is one of the most ethnically diverse regions in the world, populated by residents who represent more than 100 nationalities and speak more than 167 languages. The residents served by the Queens Health Network are also some of the borough's poorest. A large percentage have median family incomes less than the county's \$34,186, with many more earning below the 2004 Department of Health and Human Services poverty guideline of \$18,850 for a family of four.

No region has been more affected by the wave of immigration into the United States than that served by QHN. Minority populations comprise more than 87% of the patient population served by the Queens Health Network. The service catchment area also has a rate of linguistically isolated households higher than the 11% rate of Queens County as a whole.

These newly arrived immigrants avail themselves of the public hospital system in New York City. The Health and Hospitals Corporation (HHC) is one of the largest municipal health systems in the country. They form a medically underserved population, denied care in many venues because of their inability to pay and generally unaware of preventive practices that promote improved health. Patients come to Elmhurst and Queens Hospitals with more advanced disease processes, complications and co-morbidities than the general population because they often seek care later and may not know where care is provided. Language and cultural barriers present an additional challenge to providing high-quality care in a vital, growing community in a high-volume, inner city healthcare system.

Transforming Patient Care with Technology

In the mid-nineties, the Queens Health Network faced a dilemma: how to maintain and expand services for an ever-increasing number of uninsured patients, in an ever more demanding marketplace. The consolidation of operations and regionalization of services compelled the sharing of patient data throughout a multi-hospital system. The logistics of the exchange of patient records among numerous patient care locations seemed insurmountable, especially when viewed in the light of the problems inherent in providing paper charts to existing locations.

Additionally, emerging population-based "disease management" efforts by health systems directed at major chronic illnesses had increased the emphasis on safe, efficient and cost effective means to enhance patient care and measure outcomes.

In the spring of 1996, implementation of an integrated electronic health record (EHR) was proposed by senior administration to the medical staff as an integral component of the Queens Health Network's strategic and business plans. Design and implementation of an EHR was viewed as essential to the development of an effective infrastructure from which to support the reorganization of care, the design and refinement of quality measures and reporting process, and the practice of evidence-based medicine to improve management of chronic disease.

Quality care for patients across a variety of settings, the locus of which is no longer the inpatient hospital, required ever more rapid retrieval of longitudinal, integrated patient information at the point of service. The decision was made to begin EHR implementation in the ambulatory care setting, then proceed through conversion of diverse legacy computer systems, and on to the hospital inpatient setting.

From Paper to CPOE in Six Months

Computerized physician order entry (CPOE) became a reality in the Queens Health Network in January 1997. Today, doctors throughout ambulatory care document 3,000 patient encounters online every day, and inpatient physicians and emergency room doctors place orders and review results for thousands more. Physicians, nurses, social workers, nutritionists and other patient care providers enter and retrieve data (test and consult orders, assessments, progress notes, history and physical examinations, medication orders, patient/ family education) in the EHR at nearly 3,000 personal computers located in exam rooms, ancillary departments and on inpatient units across the Queens Health Network. Pharmacists verify medication orders online. With the exception of mammography at Queens Hospital, QHN is filmless; radiologists dictate their findings using a voice recognition system, approve reports electronically, and images are stored on and retrieved from a digital imaging system.

The EHR enables real-time access to patient information anywhere in the network. Consider a patient referred from one of the School Based Health Programs to Elmhurst Hospital for a head MRI. The radiologist now can review prior visit history and diagnoses, results of general diagnostic radiography and CT scans, BUN, Creatine and other recent lab values, and ensure that the patient does not have a contrast allergy before

the technologist performs the test. That the patient was seen at another facility in the network is not an impediment to accessing vital information. Availability of clinical information online surmounts one of the biggest obstacles to integrated, seamless care across the entire spectrum of healthcare services. The Queens Health Network (QHN) EHR positions the organization to provide patient care that is safe, effective, timely and efficient.

This integrated, interdisciplinary electronic patient record, located at the point of care, used by physicians and other clinicians to enter and retrieve patient data provides a strong patient information infrastructure. The technology ensures that the Queens Health Network is well-positioned to re-engineer care processes, coordinate patient care across the continuum of time and location, sustain multidisciplinary team functioning, and facilitate performance and outcomes measurement necessary to improve health care quality.

How Do We Measure Success?

The electronic health record has improved the quality of care provided by the Queens Health Network, especially with regard to:

- Patient safety, as computerized physician order entry eliminates transcription
 errors made by caregivers who serve as intermediaries between the physician and
 the patient; legibility of prescriptions, progress notes, care plans, assessments is
 improved; and medication errors can be reduced through use of computerized
 alerts regarding dosing, allergies, and adverse drug reactions.
- Efficiency of care can be improved by reducing redundant laboratory and other testing, improving multidisciplinary communication by integrating patient assessments, and making all patient information immediately accessible at the point of care.
- Effectiveness of care may be enhanced through use of automated decision support features, such as electronic reminders of health maintenance testing and immunizations, displays of certain test results and measurements trended over time, and automatic notification of a patient's condition to providers at other care venues.
- Timeliness of patient information is improved by providing real time availability of clinical information, diagnostic tests and treatment results across the continuum of care

Improving Healthcare in the 21st Century

Chronic disease is the leading cause of illness, disability and death in the United States today. Nearly half of the US population, or 100 million Americans, have one or more chronic medical conditions. The cost of treatment is enormous, accounting for nearly 70% of all personal healthcare expenditures in the United States.

Evidence based care processes, supported by automated clinical information and decision support, offer the greatest promise of achieving the best outcomes from care for chronic conditions. The treatment of chronic disease is different from episodic, because:

- Patient care crosses all care venues: from home, to physician's office, to hospital, to nursing home, and back.
- Treatment of chronic disease is longitudinal; it may span decades.
- Effective care is collaborative and multidisciplinary.
- Communication is essential: personal health information must accompany
 patients as they transition across time and the continuum of care.

The EHR allows the capture of enormous amounts of data in ways that paper records never could. Caregivers working in adjoining offices in the Cardiology Clinic, for instance, may not realize what is going on with each other's patients with the same diagnosis of congestive heart failure. Put the data together, however, and patterns may emerge. Real-time data regarding individual patients and groups of patients with chronic conditions can now be aggregated and analyzed to develop population-based approaches to disease management.

QHN has developed disease registries for patients with diabetes in an effort to facilitate access to information about the performance and results of certain elements of care. Across our healthcare system, we can determine how many patients are receiving follow up care for their diabetes, and how well they are maintaining their Hemoglobin A1C levels below the target range of <6.5%. Patients with congestive heart failure and depression have also been targeted as populations whose outcomes can be improved by studying them as parts of groups, allowing our clinicians to discern subpopulations and/ or patterns of care that can be improved.

The EHR is providing clinicians with a structure for sharing best practices and the tools to improve patient health. A pilot program in Medical Primary Care, which presently includes 10,000 patients, is providing a link to simplify communication between patients and caregivers outside our Network. Named the QHN Health Connection, it includes a credit card-sized "smart card" on which a summary of the patient's clinical information is recorded and updated at the end of each encounter. Patient problems/ diagnoses, medications, allergies and recent lab results are captured on the card.

With installations of card readers in other hospitals in the borough of Queens, the Health Connection Card is providing a tool to share patient information, improve the safety and efficiency of care, and providing a foundation for QHN to work with other healthcare providers to build a regional health information organization.

Conclusion

The experience of the Queens Health Network, a public hospital system in New York City, demonstrates that:

- Electronic health records improve efficiency and effectiveness of care, and patient safety.
- Electronic health records provide the structure to improve outcomes and effectively manage chronic disease in patient populations.
- Electronic health records provide the structure for sharing clinical information across care venues and improving the health of our communities.

In an era of cost constraints and performance expectations imposed by purchasers, regulators and an increasingly informed public, the challenges of providing safe, high quality patient care are formidable. The question is not how can we afford to implement electronic health records. The question is how can we afford not to?

Chairman Tom Davis. Mr. Blue, go ahead. We have a vote, but if we can hurry this up, we can get some questions in.

Mr. Blue. I will try and speak as quickly as I can, Mr. Chair-

Chairman Tom Davis. Then we can go. Otherwise, we have to come back.

STATEMENT OF LARRY BLUE

Mr. Blue. Mr. Chairman Davis and distinguished members of the committee, thank you very much for the opportunity to testify today and for holding this very important hearing on how we can use information technology to improve the quality of healthcare in this country. I would like to focus my remarks today on two specific areas, reducing medical areas and using RFID to fight the rising tide of counterfeit drugs.

First, let me tell you a little bit about Symbol Technologies. Symbol manufactures handheld computers that scan bar codes and read RFID tags. We also manufacture wireless networks that tie together large scale asset management systems, so information is available where it is needed in real time. We help our clients capture, move, and manage information. Today these tools are being used to dramatically improve the delivery of healthcare by making medical information where and when it is needed, at a patient's bedside, in an operating room, or on a battlefield.

Medical errors are a serious problem facing the healthcare industry today. The Institute of Medicine estimates that preventable deaths due to medical errors are between 44,000 and 98,000 annually, and adverse drug events cause more than 770,000 injuries per year.

With aging parents and as a father of three great kids, I was pleased to see that reducing medical errors is one of the central goals of the national healthcare strategy. In our view, the keys to reducing medical errors are: first, converting patient records from paper to electronic records as presented in Dr. Brailer's earlier testimony and by other testimony today; and second, delivering accurate information to the patient's bedside in right time.

Once a medical center adopts electronic patient records, the next step is to adopt mobility technology so that information is available at a doctor's or nurse's fingertips anywhere in the complex. Patients move from hospital rooms to radiology centers to operating rooms in the normal course of their treatment, and their information has to follow them.

Some hospitals now assign a barcode to a patient when he or she checks in. It is put right on their wristband. When a nurse is making rounds and stops in a patient's room, he or she can scan the barcode on the patient's wrist with a handheld computer similar to the PDA many of you carry today. The handheld then wirelessly retrieves the patient's medical records and displays the last times medicines were delivered, when the next dose is due, and exactly how much of which medicines to administer. The nurse can deliver the right medicines in the right doses at the right time, and immediately update the patient's record electronically.

One real life example of this system in action can be seen at the VA. The Veterans Administration deserves an enormous amount of

credit for implementing this type of patient identification and health information mobility system and improving patient care as a result. A hundred percent of VA medical centers are currently using barcode technology to identify patients and medication, and medication errors have been reduced significantly. Unfortunately, the adoption of these important solutions in commercial hospitals is estimated at less than 20 percent.

One of the most significant barriers to hospitals implementing this type of system has been the lack of a uniform barcode on medications. Up until now, healthcare providers have had to develop their own barcodes and apply them to drug packages which is cost-

ly, can be error prone, and is time consuming.

We applaud the FDA's new regulations requiring barcodes on all medications by April 2006. This should make these systems much easier to implement and will enable more effective information exchange within and between facilities during patient transport, treatment, and transfer.

The second topic of my remarks relates to the serious problem of counterfeit prescription drugs. This affects not only patients here in the United States but around the world. The World Health Organization estimates that prescription drug counterfeiting is a \$32

billion global business.

New technologies are being employed to combat counterfeit drugs, and one of them is RFID. RFID stands for Radio Frequency Identification. It is the next generation of barcode. A tiny computer chip attached to an antenna is placed on a product. When it is activated by a reader, it transmits a serial number or unique identifier to an authorized device. That number is then used to retrieve information such as an EHR from a secured data base.

The FDA and private industry are aggressively developing electronic track and trace systems using RFID to stop counterfeiting. The goal of these systems is to create an electronic pedigree for legitimate drugs. Symbol is actively working with Perdue Pharmaceuticals to develop such a system for Oxycontin which is one of the top counterfeited and stolen medications in the United States. Early results of our trials are encouraging, and we are optimistic that this RFID-based system is going to create a real barrier to thieves and black marketeers.

For health IT systems and technologies to be effective, they have to be interoperable; and to be interoperable, we need industry-wide standards. Without standards, data from one company or medical center won't be understood at another, and one company's RFID

readers won't read another company's tags, and so on.

In my industry, I have personally worked to develop standards for RFID and electronic product codes. A group called EPC Global has done a great job getting industry together to create a common RFID data standard. I believe standardization is critical to wide-spread implementation and unlocking the value of a new technology. In this case standards can mean the difference between only one hospital having an electronic patient record and the ability of that hospital to freely share that record with any other healthcare provider needed by that patient.

As the economy has become global, it is now more important than ever for these data exchange standards to be global. Health

care products consumed in the United States are manufactured globally, and global standards is one area where Congress and the administration can help us. If the Federal Government can reinadministration can help us. If the Federal Government can reinforce the message to industry in foreign countries that cooperation on common barcodes, EHRs, and other data exchange standards like RFID is a high priority, that would be very helpful.

Thank you again for the opportunity to testify today, and I would be happy to answer any questions you have.

[The prepared statement of Mr. Blue follows:]

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Opening Statement
Larry Blue
Vice President and General Manager
RFID Business Unit
Symbol Technologies
Before the Committee on Government Reform
September 29, 2005

Mr. Chairman and Mr. Ranking Member, thank you for the opportunity to testify today. And thank you for holding this very important hearing on how we can use information technology to improve the quality of health care in this country. This is an important topic for two reasons. First, because the well-executed deployment of information technology can help improve the quality of patient care in multiple ways. And second, because information technology can help hold down health care costs by streamlining the supply chain.

I'd like to focus my remarks today on two specific areas that highlight how IT solutions are being used today to improve care and reduce costs. The first involves using electronic patient records to reduce medical errors. The second involves using RFID to fight the rising tide of counterfeit drugs.

Before I go into those areas, let me first tell you a little about Symbol Technologies. Symbol manufactures handheld computers that scan barcodes and read RFID tags. We also manufacture wireless networks that tie together very complex asset management systems so information is available where it's needed in real time. We help our clients capture, move and manage information at the point of business activity. For most of our company's thirty-year history, our bread-and-butter has been asset management and inventory control. However, in recent years, these same tools are being used to dramatically improve the delivery of health care — by making critically important medical information available where it's needed — at a patient's bedside, in an operating room, or on a battlefield.

Reducing Medical Errors:

Medical errors are a very serious problem facing the health-care industry. Medical errors cause patient deaths and patient injuries, and they increase the lengths of hospitalizations:

- It has been estimated that adverse drug events a patient receiving the wrong medication, or the wrong dose of the right medication – cause more than 770,000 injuries per year.
- The Institute of Medicine has estimated that the preventable death rate due to medical errors is between 44,000 and 98,000 per year.

In addition to the human suffering, medical errors are costly:

- The average insurance settlement resulting from a medical error is between \$400,000 and \$700,000.
- The costs of medical errors to a single hospital can run as high as \$5.6 million per year, depending on its size.

I was pleased to see that reducing medical errors is one of the central goals of the National Health Care Strategy.

The keys to reducing medical errors are first, converting patient records from paper to electronic records; and second, making accurate information available at a patient's bedside in real-time. Paper records are notoriously error-prone. Handwriting is hard to read, pages get lost, filing systems fall behind. The movement to electronic paper records is a priority for major health care providers, and justifiably so.

Once a medical center adopts electronic patient records, the next step is to adopt mobility technology so that information is available at a doctor's or nurse's fingertips anywhere in the complex. Patients move from hospital rooms to radiology centers to operating rooms – and their information has to follow them.

What some hospital systems are doing now is assigning a barcode to a patient when he or she checks in — it's put right on the patient's wristband. The medical staff is equipped with portable hand-held computers that read those barcodes and retrieve the patient's vital medical information from a central database. So for instance, when a nurse is making her rounds and stops in a patient's room one of the first things he/she does is to scan the barcode on the patient's wrist. The handheld then retrieves the patient's medical record that tells him/her the last time medicines were delivered, when the next dose is due, and exactly how much of which medicines to deliver. The nurse can deliver the medicine and immediately update the patient's record electronically. If the patient has to be moved to another ward or evacuated from a hospital as we saw with Katrina, the exact same information is available on their handhelds, and the information is tied to the patient through the barcode.

One of the organizations that is leading the way in implementing this type of mobility system is the Veterans Administration. They deserve an enormous amount of credit for tackling this challenge and improving patient care as a result. The VA hospitals have established a "Barcode Medication Administration System" that relies on a "Computerized Patient Record." Doctors and nurses are able to verify the time, dose and name of a patient receiving a medication, so the patient gets the right drug, in the right dose, at the right time. One of our partners, CareFusion, is working to implement these systems across every VA Hospital – and medication errors have been reduced significantly. 100 percent of VA Medical Centers are currently using barcode technology to positively identify patients and their medications. Adoption in commercial hospitals is estimated at less than 20 percent.

Another one of our partners, McKesson Corporation, utilizes our technology to implement a system similar to the VA's in private hospitals. They estimate that more than 44 million medications are scanned at the bedside every year. And each week, hospitals nationwide prevent an estimated 56,000 medication errors and issue more than 400,000 alerts to hospital staff of potentially harmful drug interactions.

One of the most significant barriers to hospitals implementing this type of system has been the lack of a uniform barcode on medications. Up to now, health care providers have had to develop their own barcodes and apply them to drug packages, which is costly and time-consuming. The FDA's new regulations requiring barcodes on all medications by April 2006

should make these systems much easier to implement. It is important that this initiative stay on schedule, and I would encourage your strong support for it.

Counterfeit Drugs:

Another serious problem is counterfeit prescription drugs – not only here in the United States, but around the world:

- The Pharmaceutical Security Institute estimated that \$200 million in U.S. prescriptions in 2003 were counterfeit – a sevenfold increase over the previous year.
- The World Health Organization estimates that counterfeit drugs are a \$32 billion global business.
- The San Diego Center for Patient Safety says that 8 to 10 percent of prescription drugs around the world are fake.

Counterfeit drugs are dangerous. The manufacturing process is unregulated. The purity is unknown. The dose is unreliable. New technologies are being employed to combat counterfeit drugs, and one of them is RFID. RFID stands for radio frequency identification. It is the next generation of barcode, or a talking barcode. A tiny computer chip attached to an antenna is placed on a product. When it is activated by a reader, it transmits a serial number or unique identifier to an authorized device. That number is then used to retrieve information from a secure database.

The FDA and private industry are aggressively developing electronic track-and-trace systems using RFID to stop counterfeiting. The goal of these systems is to create an "electronic pedigree" for legitimate drugs — (date and place of manufacture, chain of custody, etc.), that can be verified at any point in the distribution system. It is one of many tools under development that will make it more difficult for illegitimate companies to produce counterfeit drugs. Symbol Technologies is actively working with Perdue Pharmaceuticals to develop such a system for Oxycontin, which is one of the top 32 counterfeited medications. We're optimistic that this RFID-based system is going to create a real barrier to that black market.

Standards are the Key to Interoperability:

Information technologies can be used in many ways to make health care better, safer, and more affordable. I've touched on just two of these today. For these systems to be effective, they have to be interoperable. And to be interoperable, we need industry-wide standards. Without such standards, one company's readers won't read another company's tags, and so on. For example, if we're going to have an effective RFID track-and-trace system to prevent counterfeit drugs, it has to be uniform from one country to the next. An RFID antenna in Mexico City has to be able to read an RFID tag placed on a bottle of pills in London. The electronic code for Lipitor, for example, has to be the same in the United States as it is in Australia. This is a tremendous challenge.

In some cases, industry has done a very good job in working together to produce widely-accepted standards. In other cases, it's important for the government to play a leadership role. In my industry, I have worked to develop industrywide standards for RFID and electronic product codes. It isn't always easy. Sometimes it's a long difficult process. But standardization

is critical to widespread implementation of a new technology. It can mean the difference between one hospital having an electronic patient record, and that hospital being able to share that record with any other health-care provider in the area.

As the economy has become a global economy, it's now more important than ever for those standards to be global. So many products that are used in one country are made in another. Standards for supply chain technology must stretch beyond borders to be effective.

This is one area where Congress and the Administration can help us. The United States should work with other governments to help them understand the value of working together on standards. It is in their long-term interest, as well as ours, to develop uniform standards that will speed international commerce and make it more secure. If the Federal government can reinforce the message that cooperation on standards is a high priority, that would be very helpful.

In addition, continuing efforts like that of the FDA to set standards for barcoding of prescription drugs that all manufacturers can follow will help speed up the implementation of valuable health care IT systems.

Thank you again for the opportunity to testify today. I'd be happy to answer any questions you may have.

Chairman Tom Davis. Thank you very much. Let me start. Mr. Powner, as you know from our FISMA score card, you know this committee likes grades. Can you try to give the administration a grade in its efforts to develop a national strategy for health IT in-

cluding its efforts to define and implement standards?

Mr. POWNER. From a leadership and vision perspective, clearly, Dr. Brailer and the efforts at HHS and the administration deserve an A. If you look beyond that in terms of putting in place plans and getting down to the implementation, we are incomplete. We are far from having plans and marching orders in place and a complete game plan to tackle this enormous challenge.

Chairman Tom Davis. Thank you very much.

Ms. Carr, how long did it take to fully implement electronic health records in the Queens Health Network?

Ms. CARR. Mr. Chairman, in 6 months we went from a twinkle in our eye to having our physicians doing order entry online.

Chairman Tom DAVIS. How did you get the buy-in from physicians?

Ms. CARR. I guess what we did is we had a really serious challenge in terms of the volume of activity that we needed to support. And we demonstrated that with this technology, we could increase our capacity and take better care of our patients.

Chairman Tom Davis. Thank you.

Mr. Blue, do you think that health IT systems are more vulnerable and more attractive to hackers and cyber attack because of the

quantity of personal information they hold?

Mr. Blue. My own personal opinion, Mr. Chairman, is no, I do not believe so. I believe that they are vulnerable to attack like all data bases, but there is a lot of work that has been done both in industry and in Government to assure through opportunities like HIPAA, and I believe one of the prior testimonies discussed the advantage of information technology in protecting that data and also making it more readily available to the people that need it. So I don't believe so.

Chairman Tom Davis. Dr. Diamond, your testimony mentions the problem of patients being concerned that a system of electronic health records could result in the exposure of private health information, which I just asked Mr. Blue a question about. How are you working to manage public perception that privacy could be com-

promised?

Dr. DIAMOND. Yes. Yes, I think——

Chairman Tom Davis. Because we see the credit card companies

and everything else on these things.

Dr. DIAMOND. You took the words out of my mouth. I was just going to say, Mr. Chairman, that I think we have all seen the newspaper stories about credit card data being stolen, and other third party data bases being hacked, and consumers' identity being stolen. I am of the belief that this is a broad IT sector issue that needs to be solved.

But I think for healthcare, in particular, our approach is to build the need to protect privacy and security in on the front end of this technology and architecture. And one of the models we propose, the model we propose to do that is to separate the medical data, the location of the medical data from the actual data itself, so that we are not proposing putting everyone's information in one large central data base, but just having the network and the infrastructure available to know where it is when it is needed, and not have to put it in one place which is a single point of attack or a hacker's dream potentially.

Chairman Tom Davis. Thank you.

Ms. Marchibroda, are State and local health IT initiatives coordi-

nated with Federal strategy?

Ms. Marchibroda. Thank you, Chairman. They would like to be. I think something that EHI is doing right now is taking the national standards and policies that are merging from the Federal Government as well as initiatives like Connecting for Health, and creating tool kits and guides to help these States and regions who very much want to be in sync with national principles and standards, provide them with guides to help them get there.

Chairman Tom Davis. OK.

Ms. Marchibroda. There is still more work to do.

Chairman Tom Davis. I will ask anybody: What metrics would you use to gauge the success of the National Coordinator's Office? Anybody want to take a shot at that? Any volunteers? Go ahead, Mr. Powner.

Mr. POWNER. Ultimately, I think—Mr. Blue mentioned this—I think one of the key metrics we really need to focus on long term here is the reduction of medical errors. When you look at the staggering figures that come out associated with medical errors, the number of people who actually die in a given year, that is clearly a metric where the incorporation of health IT can clearly move us in the right direction.

Chairman Tom Davis. Thank you. We have about 3 minutes left in our vote. I could hold you over for a couple votes, but I think

what I will do is just adjourn the hearing at this point.

We may have some questions for the record from each of you, but we appreciate your statements. It is all in the record and will all be used as we move ahead. I thank you for your time. The meeting is adjourned.

[Whereupon, at 12:03 p.m., the committee was adjourned.]

[The prepared statements of Hon. Dennis J. Kucinich and Hon. John M. McHugh, and additional information submitted for the hearing record follow:]

Statement of Dennis Kucinich U.S. House of Representatives Committee on Government Reform

Hearing: "The Last Frontier: Bringing the IT Revolution to Healthcare" September 29, 2005

Thank you for the opportunity to speak, Chairman Davis about this critical public health issue that will affect all Americans. Integrating IT into health care is a potential technological fix to some of our health care problems. We will hear the case for that in great detail today. But I would like to urge that we proceed with a healthy dose of skepticism about these promises. There is sufficient reason to be concerned that IT in health care could be ineffective at addressing some problems and make others worse.

The risks of centralizing a database of American's personal health records are intuitive. If the information were released – legally or illegally – the road would be paved for discrimination by employers and health insurers. Such risks will intensify as we transition into more personalized health care, which requires the storage of our very genetic code.

There are also potential problems with quality of care. In a critique of a recent RAND paper that discussed the benefits of IT and health care, Drs. Himmelstein and Woolhandler of the Harvard Medical School point out that there are already several case studies in which promised quality improvements did not materialize. In addition, while surrendering some duties to automation in a health care setting can reduce errors, if not done properly, it can also contribute to the deskilling of a workforce. In particular, nurses, who are a critical and highly skilled part of our health care work force, are at risk. A considerable volume of research has linked quality of care to quantity and quality of nursing staff.

Finally, there are serious cost issues that need to be addressed. While some sectors have benefited financially from such a transition (like telecom and

 $^{^1}$ Hope and Hype: Predicting the Impact of Electronic Medical Records; Health Affairs; 24, 5; September/October 2005

retail), others, like retail banking suffered worse efficiency.² The last thing we need right now is a diversion of increasingly scarce health care dollars into software vendors at the expense of patients. In fact, piling on more significant costs could add to an already bloated bureaucracy that is one of the biggest reasons our health care costs are almost twice as high as other industrialized countries. The administrative costs and other overhead costs of private health care total about 12-30% of the health care dollar. But those same costs in Medicare are consistently 2-3 %. The cause is wasteful, profit-seeking ventures and behaviors that do little for quality or efficiency.

There is no doubt that, if used judiciously, IT can improve health care. But it is by no means a panacea. We should proceed with caution in case we do more harm than good. Addressing our increasing costs and declining quality will require much more than a technological fix to a social problem. It will require a hard look at the failure of managed care and competition to achieve the same enthusiastic promise touted in the eighties that IT is currently enjoying. And it will compel us to look at models of health care delivery in the US and all around the world that already work much better than the status quo. We would do well to start by looking at a popular, cost effective model in Medicare.

 $^{^2}$ Hope and Hype: Predicting the Impact of Electronic Medical Records; Health Affairs; 24, 5; September/October 2005

Opening Statement Congressman McHugh "The Last Frontier: Bringing the IT Revolution to Healthcare" September 29, 2005

Mr. Chairman, I want to thank you for holding this very timely hearing on an issue of great importance to both medical providers and all those Americans who are consumers of health care. Health Information Technology can play a critical role in rural regions such as the one I represent by improving access, affordability, and quality of health care through the reduction of medical errors, linking medical records, and increasing efficiency and equity. I believe this hearing will provide Members with a better understanding of the benefits of further investment in Health IT, what progress is currently being made, and what challenges lie ahead. I would like to welcome the witnesses that have been invited today to testify. Mr. Chairman, I appreciate that you have invited a distinguished panel representing both private industry and the federal government to discuss what role Congress can play in the coming months to be of greater assistance in moving forward the successful deployment of Health IT throughout the health care community.

Toward that end, I am pleased to be a lead sponsor, along with Mr. Gonzalez, of H.R. 747, the National Health Information Incentive Act. This bill, like the issue of Health IT itself, has garnered bipartisan support and is endorsed by the American Health Information Management Association, the American College of Physicians, and the Health Information Management Systems Society. Our bill would authorize the creation of revolving loan and grant programs, and refundable tax credits for physicians and other health care providers. Such monies would be used to acquire interoperable electronic health records and electronic prescribing systems. Further, the legislation would build into the Medicare physician payment system an add-on code for Evaluation and Management (E/M) services to identify that a service was assisted by an electronic health records systems with clinical decision support tools. H.R. 747 recognizes that the costs of acquiring such beneficial health information technologies remain prohibitively expensive for most physicians, especially those in small and rural practices. Without offering physicians financial incentives to support the purchase of Health IT, we further delay the most efficient and effective use of health care for patients. Our bill compliments several of the other HIT bills introduced this Congress by targeting small physician practices and going directly to the root of the problem. This is accomplished, in part, by building into the Medicare physician reimbursement system an add-on code for office visits and other evaluation and management services. In this way, we hope it becomes easier to identify whether a service was facilitated by such electronic health data systems. This combination of one-time and on-going financial incentives would substantially speed HIT adoption and improve Medicare beneficiary access to physician practices.

I have the honor and distinction of representing a district that encompasses more than 14,000 square miles and is home to hard working men and women who drive long distances to see a physician and who are struggling with the ever-increasing costs of their health care. Whether they are seniors, farmers or own a small business, they can benefit immensely from coordinated health care, lower costs, and higher efficiency. Likewise, I represent medical providers that are in a region that struggles to attract and retain physicians, specialists, and health care facilities. It is critical that we do all we can to ensure that they are equipped to maximize their time and do not become overwhelmed when delivering vital services to the community. I believe health information technology is one way in which we can do that.

In my opinion, the 109th Congress has already demonstrated a commitment to establishing a health information network. Earlier this year, Health and Human Services Secretary Michael Leavitt announced the creation of the American Health Information Community — a public-private advisory committee that will recommend specific actions to accelerate the adoption of health information technology. The House sent a strong message of support for these goals when it passed the Labor-HHS-Education Appropriations bill, which provided an increase in funding of \$58 million for the promotion of Health Information Technology.

Full utilization of HIT can revolutionize health care delivery by putting real-time, clinically relevant patient information and up-to-date evidence-based clinical decision support tools in the hands of providers for the benefit of their patients. Adoption of HIT will lead to the improvement of quality care and help reduce the high costs for individuals with complex health problems, particularly for those Medicare patients with chronic conditions. The full-scale adoption of HIT will be significant, leading to an even higher standard of quality in the U.S. health care system. Unfortunately, without adequate incentives for HIT adoption, small physician practices will be left behind the technological curve and their patients with them. Hearings such as this give hope that may not occur and that is good news for our constituents.

Thank you again, Mr. Chairman for holding this hearing. I look forward to the testimony of our witnesses.



Written Testimony before the

United States House of Representatives Committee on Government Reform

"The Last Frontier: Bringing the IT Revolution to Healthcare"

Thursday, September 29, 2005

I. INTRODUCTION

Mr. Chairman and Members of the Committee on Government Reform: Thank you for the opportunity to submit written testimony on the development of health information technology (HIT). Our testimony is intended to provide an examination of the movement towards a National Health Information Network (NHIN) through the lens of patient privacy. Engendering the trust and participation of patients is critical to the success of any system of health information technology, and the development of a NHIN must first start with a serious effort to engage and inspire the positive cooperation of consumers. Building privacy and security protections into the foundation of a NHIN is essential to this goal.

The Health Privacy Project (HPP) is a 501(c)(3) nonprofit organization dedicated to raising awareness about the importance of ensuring health privacy in order to improve health care access and quality, both on an individual and community level. HPP conducts research and analysis on a wide range of health privacy issues, including objective analysis of the HIPAA Privacy Rule and state health privacy laws, genetics and workplace privacy, e-health activities, and public health surveillance initiatives. HPP also coordinates the Consumer Coalition for Health Privacy (CCHP), which is comprised of over 100 major organizations representing a broad range of both consumers and health care providers. A complete list of CCHP participants, as well as all of the HPP's resources related to health privacy, can be found at our web site, www.healthprivacy.org.

II. BACKGROUND

The Health Privacy Project's mission is to foster greater public trust and confidence in the health care system, thereby enabling people to more fully participate in their own care and in research without putting themselves at risk for unwanted—and unwarranted—intrusions. It is wrong to force people to choose between seeking health care and safeguarding their privacy.

Unfortunately, when people do have to choose, they very often choose to forgo quality health care. As captured by a 1999 California HealthCare Foundation survey, one out of every six Americans withdraws from full participation in their own health care out of fear that their medical information will be used without their knowledge or permission. These privacy-protective behaviors include patients providing inaccurate or incomplete information to doctors,

patients paying out of pocket to avoid a claim being submitted, and people avoiding care altogether. Consumer fears and behaviors are only compounded by reports of privacy breeches. Consider this:

- A Palm Beach County Health Department statistician and epidemiologist mistakenly attached a list containing more than 6000 names of HIV/AIDS patients to an e-mail sent out to 800 of the department's 900 employees.¹
- A Kentucky state computer that was put up for sale for \$25 contained files naming thousands of people with AIDS and other sexually transmitted infections. The state auditor's office purchased the computer and discovered the personal health information.2
- A person found a webpage used by the Drexel University College of Medicine in Pennsylvania that linked to a database of 5500 records of neurosurgical patients. The records included patient addresses, telephone numbers, and detailed information about diseases and treatments. After finding the database through Google, the person was able to access the information by typing in identical usernames and passwords.³
- About 16,000 patients were notified by Christus St. Joseph Hospital of Houston, TX that a computer was stolen that contained files including their names, social security numbers, and health information. The computer was taken from Gateway File Systems, Inc., which was in the process of converting paper-based medical records to electronic records for St. Joseph.
- Kaiser Permanente Northern California left the names, addresses, phone numbers and lab results of approximately 150 patients posted on a publicly accessible website for up to four years. In violation of both state law and Kaiser's policy, the site was developed without patient consent. It was not until a disgruntled employee linked the website to her online blog that the breach became public. Still, Kaiser did not remove the site until federal civil-rights authorities later learned about it in January of 2005. Further, Kaiser did not inform state regulators or patients about the breach until that March-when it was reported in the media. The state Department of Managed Health Care levied the largest fine for a privacy violation to Kaiser in the amount of \$200,000.5

In recent years, security breaches at a number of larger health care organizations have resulted in

¹ Mary McLachlin, HIV E-mail Leads to Changes, PALM BEACH POST, Feb. 23, 2005, at 1B.
² C. Wolfe, Discarded Computer had Confidential Medical Information, ASSOCIATED PRESS, Feb. 6, 2003, available at www.aegis.com/news/ap/2003/AP030217-html (last visited May31, 2005).
³ Christopher Null, Google: Net Hacker Tool du Jour, WireD News, Mar. 4, 2003, at www.wired.com/news/infostructure/0,1377.57897,00.html (last visited Mar. 26, 2005).
⁴ Robert Crowe, "Patients warned that stolen data could be theirs; Letters are sent to 16,000 whose records were on computers taken from St. Leenth," If the Confidence of the Confid

taken from St. Joseph," *The Houston Chronicle*, April 26, 2005

5 "Privacy Breach Costs Kaiser," *San Jose Mercury News*, June 21,2005

thousands of medical records being available and accessed online.⁶ As electronically connected systems are developed to increase the flow of health information, the potential for a harmful privacy breach increases, underscoring the need to build privacy protections in at the outset.

Undoubtedly, health information technology could play an important role in improving both quality of and access to health care services. A successful NHIN offers the potential for the quick exchange— among authorized users—of more accurate and coherent personal health information. Implemented correctly, a NHIN could also incorporate stronger privacy protections, improving patient access to and control over their own health information. By offering more consumer-friendly methods of access and control, a NHIN could also empower patients and significantly enhance their participation in their own care, with untold benefits to both individuals and the general public.

But the benefits of electronic access to health information are matched by significant risks, and privacy is a critical concern. If a national system of electronic connectivity is to be successful, it must be built on the principles of patient participation and control, and it must reflect the essential role privacy plays in the health care system. Already, our health care system is weakened because of privacy concerns. We cannot afford to develop a NHIN system without ensuring that privacy and security protections are built into the foundation and framework of every local and regional system of electronic connectivity.

III. CONSUMER TRUST AND PARTICIPATION IS THE LIFELINE OF A NHIN

Patients have the largest stake and the biggest role to play in the development of a NHIN, but they have been completely underrepresented in the national conversation about linking health

⁶ See e.g. Robert O'Harrow, Jr., *Hacker Accesses Patient Records; Thousands of Files Easily Downloaded*, WASH. POST, Dec. 9, 2000, at E1 (hacker downloaded health records and Social Security numbers on over 4,000 patients at the University of Washington Medical Center); *Black Eye at the Med Center*, WASH. POST, Feb. 22, 1999, at F5 (University of Michigan Medical Center mistakenly posted thousands of patients' medical records on the Internet for two months). As more health information is collected and shared in electronic form, and more networks are developed that give entities outside of the direct healthcare system internal access, safeguarding security becomes increasingly difficult. As a National Academy of Sciences (NAS) report concluded, it is impossible to assure 100% security for electronic health information. *See* COMM. ON MAINTAINING PRIVACY & SECURITY IN HEALTH CARE APPLICATIONS OF THE NAT'L INFO. INFRASTRUCTURE, NAS, NAT'L ACAD. ENG'G & INST. OF MED., FOR THE RECORD: PROTECTING ELECTRONIC HEALTH INFORMATION 193 (1997). Thus, it is important to be mindful of the risks, take precautionary measures to limit access, and create enforceable privacy rules and policies. *Id.*

information. Their absence is only reflective of the marginalized role patients currently play in the health care arena, but it presents an enormous barrier to achieving an effective NHIN.

Even more troubling is that consumers have significant privacy concerns about the development of electronic medical record (EMR) systems. As a recent Harris Interactive survey showed, 70 percent of Americans are concerned that an electronic medical record (EMR) system would lead to sensitive medical information being exposed because of weak security and 69 percent are concerned that an EMR system would lead to more personal health information being shared without patients' knowledge. That same survey showed that 47 percent of Americans believe that the privacy risks of an EMR system outweigh any benefits. Between the electronic medical record (EMR) system would lead to more personal health information being shared without patients' knowledge.

Consumers need to be informed, assertive, and active in their own care if a NHIN is to meet its full potential. Educating the public is central to creating a system that respects the privacy and security boundaries patients feel comfortable with, and, thus, realizing the need for adequate patient participation. It is imperative that both public and private entities engage in public education efforts designed reach out to consumers with consistent messages about the potential benefits of health information technology. As a part of this, consumers should be adequately informed about their current rights under the HIPAA Privacy Rule and related state laws.

It is critical that consumer advocates are included in strategic discussions about the development of a NHIN. Mechanisms should be implemented that ensure broad participation by consumer organizations in advisory committees and panels, such as the American Health Information Community (AHIC).

IV. THE HIPAA PRIVACY RULE IS NOT ENOUGH

The HIPAA Privacy Rule is the first ever federal requirement for securing health privacy. While it certainly has its flaws, it marked an important and positive step towards securing patients' trust and their right to medical privacy. The Privacy Rule provides an important floor of protection for

⁷ Harris Interactive Inc., "How the Public Sees Health Records and an EMR Program," Conducted for Program on Information Technology, Health Records, and Privacy, Center for Social & Legal Research, February 2005.
⁸ Ibid.

patients' personal health information, but it is just that—a *floor* of protection. It is simply not broad enough in scope to apply to all of the entities who collect, share, and otherwise access personal health information. The Privacy Rule only covers certain health care organizations or "covered entities," defined as health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with specified financial and administrative transactions.⁹

Those who fall outside the reach of a "covered entity" are not regulated by the law, whether they collect and share personal health information or not. For instance, many companies that develop personal health records (PHRs) are not covered by the law. Also, covered entities often draw up contracts with companies to perform certain functions that involve personal health information on their behalf. But, these "business associates" are not directly covered by the law. It is worth noting here that, conceivably, many covered entities would enter into business associate contracts with companies to transfer paper-based records to electronic medical records. In this context, there is simply not enough recourse for consumers who could have their information improperly accessed, used, or disclosed by a business associate.

In addition, lax enforcement of the Privacy Rule by the Department of Health and Human Services's Office for Civil Rights (OCR) has severely limited both the strength of the law and consumers' awareness of it. Currently, OCR relies on an ineffective consumer-based complaint process. In the movement towards building a NHIN, it is important that HHS start by making the rights afforded under the Privacy Rule more real and palpable to patients. Consumers deserve to have a legal right to comprehensive privacy protections, including legal remedies for violations. Better enforcement of the Privacy Rule is important to creating a strong privacy foundation for a NHIN, but additional protections are still necessary.

V. STATES SHOULD RETAIN THE RIGHT AND RESPONSIBILITY TO INCORPORATE STRONGER PRIVACY PROTECTIONS

A basic principle of the Privacy Rule was that the law would provide a foundation of protection

^{9 45} C.F.R. § 160.103

that could be built on. Over and over, the Department of Health and Human Services has reiterated Congress' intent that the Privacy Rule would provide a baseline of privacy safeguards that could be enhanced at the state level. ¹⁰ That states continue to implement and enforce stronger protections for patients is critical to the success of the Privacy Rule. Patients must be able to retain the right to push for and achieve enhanced protections at the state level.

However, there is a growing push to void state laws stronger than the Privacy Rule in the name of uniformity. Not only is this unethical and impractical, but eliminating stronger state laws is simply not necessary to the implementation of a NHIN. In fact, the Privacy Rule was promulgated under the HIPAA Administrative Simplification provisions, which call for the development of electronic health information exchange. As an outgrowth of this, the Privacy Rule was specifically designed to protect medical information especially in the context of the increasing use of electronic communication between and among health providers. Whether or not to keep state laws intact has already been answered as a part of a discussion about moving the U.S. health care system towards electronic exchange. Furthermore, many states voluntarily aligned their laws to be more compatible with the Privacy Rule in the wake of the regulation's implementation, thus creating even more uniformity among states.

Most importantly, the state laws in question provide essential protections for individuals in those states. Many of the laws were crafted to afford heightened protections for certain medical information, such as information related to HIV/AIDS status, genetic testing, and mental health. In addition, some state laws afford patients rights that should be afforded to them under the Privacy Rule, such as the ability to sue for violations.¹¹

VI. Conclusion

Health information technology is promising and could ultimately both improve quality and empower patients to be more active participants in their health care. There is no underestimating

¹⁰ Joy L. Pritts, JD, Georgetown University Health Policy Institute, "Health Care Information Technology: Harmonizing Laws Governing the Confidentiality of Health Care Information," Testimony before the United States House of Representatives Committee on Ways and Means.

Subcommittee on Health, July 27, 2005.

Health Privacy Project, The State of Health Privacy A Survey of State Health Privacy Statutes, Second Edition, 2002, available at http://www.healthprivacy.org/info-url_nwat2304/info-url_nwat.htm.

the vital importance of the ability to efficiently access health information at any point of care, emergency or otherwise. However, with the promise of electronic connectivity comes concern about patient privacy. A NHIN cannot succeed without the cooperation of patients, and the only way to elicit consumer engagement is to provide meaningful assurances that personal health information will be protected.

Organizations signing onto this testimony:

Bazelon Center for Mental Health Law

American Mental Health Counselors Association (AMHCA)

Georgia Rural Urban Summit

Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)

American Federation of State, County and Municipal Employees (AFSCME)

American Association of People with Disabilities

AIDS Project Los Angeles

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