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HEALTH CARE INFORMATION TECHNOLOGY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

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

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HEALTH CARE INFORMATION TECHNOLOGY

WEDNESDAY, JULY 27, 2005

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

The Subcommittee met, pursuant to notice, at 10:26 a.m., in room 1100 Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
July 27, 2005
No. HL–8

CONTACT: (202) 225–3943

Johnson Announces Hearing on Health Care Information Technology

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on health information technology (IT). **The hearing will take place on Wednesday, July 27, 2005, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include representatives from the public and private sectors to discuss the use of IT in the health care sector and the targeted actions that government should take to increase the adoption of health IT. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Greater use of IT in the health care field has the potential to reduce medical errors, improve patient care, and reduce costs; yet adoption of new technology has been slow. Over the past year, beginning with the Executive Order issued by President Bush that established the Office of the National Health Information Technology Coordinator, increased attention has been paid to the issue of the adoption of health care information technology and the need for such technology to be interoperable.

Throughout this dialogue, questions have been raised as to the appropriate and ongoing role of government in facilitating the development of standards for the exchange of electronic health information, ensuring the interoperability of information systems, enabling private sector investments among providers, and harmonizing laws regarding the confidentiality of patient information. The ultimate goal is a nationwide health care information infrastructure that recognizes the role that modern technology can play in the health care system.

Most recently, the Secretary of the U.S. Department of Health and Human Services (HHS) announced the formation of the American Health Information Community, chaired by Secretary Leavitt and comprised of 17 members from the public and private sectors, to develop IT standards and achieve health IT interoperability. At the same time, the Secretary released four requests for proposals seeking private sector input in addressing issues regarding technology standards, certification, confidentiality and security of patient information, and development of a national architecture.

The Subcommittee has held a series of hearings on health IT, covering private sector initiatives, government programs, and electronic prescribing. This hearing will focus on recent developments in this area and ways in which Congress can best act to ensure continued progress.

In announcing the hearing, Chairman Johnson stated, "Greater use of IT can dramatically improve the safety and quality of our health care system while also reduc-

ing costs. I am encouraged HHS is moving forward to adopt health IT, and Congress wants to work with the Administration to shape the final product. I believe that a public-private approach appropriately recognizes the key roles that both the government and the private sector play in the critical area of health IT."

FOCUS OF THE HEARING:

The hearing will focus on the approach currently being taken by the Administration to speed the adoption of health IT and areas where congressional involvement can further these efforts.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "*109th Congress*" from the menu entitled, "*Hearing Archives*" (*http://waysandmeans.house.gov/Hearings.asp?congress=17*). Select the hearing for which you would like to submit, and click on the link entitled, "*Click here to provide a submission for the record.*" Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You ***MUST REPLY*** to the email and ***ATTACH*** your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business Wednesday, August 10, 2005. **Finally,** please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721.

FORMATTING REQUIREMENTS:

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

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

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

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

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

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

Chairman JOHNSON. Good morning, everyone, and a special welcome to Dr. Brailer and the rest of the panelists. My personal apologies to Congressman Stark and Congressman Thompson for the delay in the start of this hearing. As some of you may know, the President was at the Republican Conference and sometimes he is very digressive and covers a lot of territory, and if you are in the middle of the room, you can't get up and walk out, so my apologies, but I didn't anticipate the problem. Today, I am pleased to chair this hearing on the use of information technology (IT) in the health care sector. In the last Congress, we held two hearings on this topic, and today, we have an opportunity to revisit this issue to learn what progress has been made over the last year. In addition, I hope to focus our discussion on what Congress can do to further the efforts of the administration and the private sector in increasing the adoption of health IT. Greater use of IT has the potential to dramatically improve the safety and quality of health care for Americans, while at the same time lowering costs through reductions in clinical errors and elimination of redundant procedures.

Yet despite these benefits, widespread adoption of IT in the health field has been disappointingly slow. I have long supported efforts to increase the use of IT in the health sector. In the 108th Congress, I introduced H.R. 2915, the National Health Information Infrastructure Act. I am currently working on a follow-up piece of legislation that takes a simple, streamlined approach to addressing this issue by focusing exclusively on those areas in which Congress needs to intervene in order to promote greater adoption of health IT by all providers. I am encouraged by the steps that this administration has taken recently to engage in a public-private partnership to move the health IT agenda forward with the announcement of the American Health Information Community (AHIC), and the release of four requests for proposals to address the key areas in this field, that is the development of standards, certification of products, protection of patient information, and creation of a nationwide platform for electronic health information exchange.

I believe that we will see real progress in the months ahead and I just want to commend Secretary Leavitt and Dr. Brailer for the breadth of their vision and the foresight of their work. These dramatic proposals are eliciting new thought from the nation at a level that portends progress in the future at a rate impossible without this kind of leadership. So, I welcome Dr. Brailer and all those who will testify and help us understand the progress that has been made to date in this area and additional ways in which Congress can advance the health IT agenda. Dr. Brailer has been with us before. He was named the National Health Information Technology Coordinator last year. Shortly after his appointment, Dr. Brailer produced a framework for strategic action to guide the Federal Government's effort in this area and he has been leading the administration's efforts to increase adoption of health IT in both the public and private sectors. I have attended a number of the conferences that he has scheduled, and honestly, the breadth of involvement of people from the private sector, not only technology people, but health delivery people and academics, has really been impressive and has made a difference in the speed at which we, as

a nation, can move forward in this difficult but very important area.

On our second panel, I am pleased to welcome a distinguished group who can help us sort through some of the more technical challenges we face in this field. Dr. Don Detmer is President and chief executive officer (chief executive officer) of the American Medical Informatics Association (AMIA), a current member of the Commission on Systemic Interoperability that was created under the Medicare Modernization Act, and a past Chairman of the National Committee on Vital Statistics. He will provide us with his insights as to the need for Federal leadership in the health IT arena and offer specific suggestions of the ways in which Congress can continue to move this issue forward. Linda Kloss is the Chief Executive Officer of the American Health Information Management Association. She will discuss particular challenges we face in coding for new medical technologies and the need to update our coding system to keep pace with the modern medical world. Dr. Allen Weiss, President of the Naples Community Hospital Healthcare System in Florida, will provide us with some real-world insight into the benefits that can be derived from implementing a health care IT system along with a better understanding of the challenges he has faced in making a paperless health care system a reality. Joy Pritts, Assistant Research Professor at the Health Policy Institute at Georgetown University will discuss issues relating to maintaining the confidentiality of patient information so important to all of us.

Finally, Mary Grealy with the Health Care Leadership Council will discuss the challenges that health care providers and others face in navigating the myriad State and Federal regulations geared toward protecting patient information and how the existence of many layers of regulations may impede the adoption of health care IT. Incidentally, I would just say these two contrasting views, with the depth of knowledge and experience behind them, will be very helpful to the Committee. I look forward to hearing from all our witnesses and thank you for being with us today. Mr. Stark, I would like to invite you to make an opening statement.

Mr. STARK. Thank you, Madam Chair. I am afraid that while the administration can get its act together on soliciting votes for the Central America Free Trade Agreement, I wish we could have the same kind of direction on bringing the medical delivery system into the, at least, 20th century before the 21st century is over. We are going to hear this morning from our lead witness about more meetings and conferences than one could believe possible and relatively nothing about getting the job done. Now, on the other hand, another employee of the U.S. Department of Health and Human Services tells us that next week, they are going to get something done, and I am beginning to wonder whether the right and the left hand speak to each other. We are going to hear that we brought a bunch of chief executive officers together from companies with such greater experience in delivering health care as Wal-Mart, but this leadership panel, which had basically no representation for patients or beneficiaries on it, did say that the key imperative that the Federal Government should act as the leader, catalyst, and convener of our IT effort. Yet in the same testimony, we are going to hear that there is an idea that this new community of health

care information will be turned over to the private sector in 5 years. It sounds to me like the administration can't decide what they want to do. They do suggest that—the President suggested in 2004 a deadline. Albeit 10 years, it is something that many of us think might have a good effect on getting people moving.

Now, as I say, we are going to hear an awful lot of discussion about consultation and harmonization, which I used to think was a mathematical result of a wave study, but harmonization may have something to do with doctors and patients gathering information. Dr. McClellan, on the other hand, has told us that on August 1, the Centers for Medicare and Medicaid Services (CMS) staff is going to release the Veterans VISTA program and it will be a stand-alone and allow an in-office electronic health record (EHR) that contains computerized medical records, a medication formula with refill and drug interaction notification. It is a reminder system for preventative services, which I know the chair is interested in, and diagnostic tests, a potential to communicate electronically with other systems in the future. It is free. It is in the public domain. It is an open system. It is scalable and allows major software developers to devise add-on enhancements. It is basically the system that we could start with tomorrow and is acclaimed as being quite good. All it seems to me is it takes is the current administration, and I suspect they have the authority to do this without legislation, but I also suspect that we would be glad to pass it if they need it, why don't we get started? It is beyond me why we are having all these therapy sessions when we could get started and install the software. So, I will look forward to hearing not only about that. The lead witness earlier suggested to us that Health Insurance Portability and Accountability Act 1996 (HIPAA) (P.L. 104–191) was an unmitigated disaster, so I would like to hear a little bit more about how he intends to protect the privacy of the American people, but we will leave that to his testimony. Thank you, Madam Chair.

Chairman JOHNSON. Dr. Brailer, welcome.

STATEMENT OF DAVID BRAILER, M.D., PH.D., NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. BRAILER. Thank you, Chairwoman Johnson and Ranking Member and fellow Californian Stark and other members of the Committee. I have submitted my written testimony, and with your consent, I will give only brief remarks and then answer your questions. Our efforts to advance health IT are now fully underway. There are numerous initiatives that are going on today across the nation in the administration, which I will talk about principally now, but also in numerous States, including many of the States you represent, local and regional grassroots projects, and certainly in other agencies and in the private sector. We certainly welcome the interest in health IT from this Subcommittee and elsewhere in Congress. We are focusing on setting a foundation for health IT that is long-term, not just to solve an immediate problem today, but to create the foundations for a very long-term sustained transformation of health care. We want this to be market-based, to be non-regulatory, and with a primary focus on improving our health

care system's safety and quality, cost effectiveness, and consumer involvement as well as threat preparedness.

Briefly, there are three foundations of what we are doing. First is clinically, and I am sure you know this quite well. We want to make sure that clinicians have access to information that can prevent errors and deaths, that they can make evidence-based treatment decisions and be able to reduce redundant tests and unnecessary treatments. We want to bring together different clinicians so they can work as a team to deliver care and to care for the whole patient. We want to get information to consumers so that they can manage their health, make treatment decisions, and choose providers based on good evidence. There are business foundations of our effort, as well. These arrive from strong support in the private sector for the use of health IT to enable further competitiveness of American industry, to continue to improve the health status of the employees who work in our commercial industries, to bring productivity and employment improvements to health care, as IT has brought to other industry sectors, and as an added benefit, to develop high-tech jobs in the health care industry across the United States. The Federal Government has been called upon to be a leader, a catalyst, and a convener and to use collaborative methods to pull stakeholders together and move this forward and to use our purchasing power to drive results.

We also have a technical foundation that has been set that is built around strong support for interoperability as a foundational element in the health care system. The key findings from the RFI that we sent to industry over the past 6 months have had more than 500 respondents from across sectors, had calls for public-private collaboration, information that is patient-centric, strong and advanced safeguards for privacy, a centralized, regionally governed initiative, and a nationwide communication standard and an architecture. We see two fundamental challenges and, therefore, have two core strategies in our initiative. First is to drive interoperability and second is to drive EHR adoption and the adoption of other related health information technologies. Interoperability is essentially about getting information where it is needed when it is needed. Most clinical value is tied up in the ability to share health information among different providers, yet today, we have very little sharing and health information is often regarded as a proprietary asset of the organization. We can't empower consumers without getting their information together in one place in a usable manner, and this is really the functional test of are we an interoperable health care system. For years, we have sought integratedness and information is now the key strategy that is being focused on.

The other component is getting EHRs into the hands of providers. There is a large gap between the adoption of large and small providers regarding their use of these tools. Large organized health care systems and physician groups have the know-how and resources to put in health IT, to implement it, to use it, to change their practices around it, and they are the ones that are driving most of the reported adoption. Smaller providers, small physician offices, small hospitals, safety net clinics, have substantial economic know-how, business operation and market barriers to health IT. These are not a result of the software, these are the result of

the huge change in their organizations that they stand for. Because of perverse incentives in reimbursement, most health IT adoption is being driven strategically today. We have taken on an interoperability forward strategy. That means that we have focused principally on how to make sure that as IT adoption occurs, it can share information. I will briefly summarize the key strategies we are doing today.

First is standards harmonization, which has the goal of making sure that the United States has one single usable and unified set of information standards. Many other countries already have these and we have lagged behind and we want to make sure that we can protect our hospitals and clinicians from having to deal with overlaps, ambiguities, and gaps in standards. Second is compliance certification. We want to make sure that EHRs and other health IT do meet minimal standards for clinical content, for security, and for information sharing so we can make sure that patient information can be gathered from different sources, we can protect and secure information in these tools, and we can prompt physicians with needed preventative care and orders and other alerts that are part of routine care and treatment. We want to develop an architecture for sharing of information that would be Internet-based and built around the concept of high security that is used in other applications. We want to make sure that we have a capacity in industry to share health information so that doctors do not have to do this without help. Finally, we are focusing on addressing variations in privacy and security practices across states and across covered entities. Our goal is to ensure that not only State-to-State variation can be reduced, but more importantly, that covered entity-to-covered entity variation can be reduced, as well, so that we don't have to choose between flexibility of security and privacy and interoperability. Chairman Johnson, I appreciate your leadership. I appreciate the interest of the Subcommittee and I certainly look forward to answering your questions.

[The prepared statement of Dr. Brailer follows:]

Statement of David Brailer, M.D., Ph.D., National Coordinator for Health Information Technology, U.S. Department of Health and Human Services.

Chairwoman Johnson and Members of the Subcommittee, 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 development and nationwide implementation of an interoperable health information technology infrastructure to improve efficiency, reduce medical errors, raise the quality of care, and provide better information for patients, physicians, and other health care providers. 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 "Framework for Strategic Action: 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.

The *Framework for Strategic Action* and the Federal Health Architecture (FHA) are irrevocably linked in the effort to address critical health care needs. The FHA is now under the leadership of the ONC and will provide the structure or "architecture' for collaboration and interoperability among federal health efforts as specified in the *Framework for Strategic Action.* Moreover, the Consolidated Health Informatics activities are now moving forward under the FHA.

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 increase efficiency and potentially 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 Health Care 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.

Some researchers estimate that 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). However, 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. Further, these are estimates which we have not yet seen realized in the health care system generally.

Therefore, achieving efficiency and potential 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 and systems must be standards compliant and interoperable so that patient information can be communicated to all possible points of care. 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 business foundation.

The Business Foundation: The Health IT Leadership Panel Report

Recognizing that the healthcare sector lags behind most other industries in its use of IT, an HHS contractor convened a Health IT Leadership Panel for the purposes of understanding how IT has transformed other industries and how, based upon experiences of members of the panel, 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 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 also emphasized 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 under-

standing 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, 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.

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 might pose challenges to interoperability; and, developing an architecture for nationwide sharing of electronic health information. HHS has allocated $85 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 Michael 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 is being 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 will be designed as an open, transparent and inclusive collaboration.

HHS is currently soliciting nominations for people to serve on the Community and Secretary Leavitt will appoint up to 17 commission members, including himself as chairperson. It will consist of nine members from the public sector and eight members from the private sector. Public Sector members will be drawn from Department

of Health and Human Services (including the Office of the Secretary, the Centers for Medicare and Medicaid Services, and the Public Health Service), Department of Veterans Affairs, Department of Defense, Department of Commerce, Department of the Treasury, Office of Personnel Management, and a State government representative. The private sector membership will be drawn from purchasers, third-party payers, hospitals, physicians, nurses, ancillary services (e.g., lab or pharmacy), consumer and privacy interests, and health information technology. Nominations for membership are being accepted through August 5, 2005. The Community is expected to be convened early this fall.

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 sunset of the Community, after no more than five years, will be written into the charter.)

The Community will be 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 within five years 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 expect to award contracts based on these RFPs in September and October 2005. Specifically, the RFPs will focus on four major areas:

Standards harmonization

We have issued a Request For Proposal (RFP) 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 have issued an RFP 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). This RFP will also evaluate a process for inspection based on conformance with these criteria.

NHIN Architecture

We have issued an RFP 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. This RFP will fund 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. Through the RFP process, we encourage the development of a complete open source solution.

Security and privacy

We issued an RFP 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 RFP, 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

In addition, 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 working to perform 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 is guiding this second task.

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

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 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.

This concludes my prepared statement. I would be delighted to answer any questions that you or the Members of the Subcommittee may have.

Chairman JOHNSON. Thanks very much, Dr. Brailer. Dr. Brailer, you state in your testimony that the Federal Government should act as a leader, catalyst, and convener of the nation's health IT effort. Why is the Federal Government role so critical in this effort when other industries have managed to incorporate technology without significant Federal intervention, and how do you see the Federal role evolving in the coming decade? At the same time, would you also address, in terms of the Federal Government's role, when you say you want to develop one usable set of standards, at some point, will the Federal Government say, this is the standard and this is the standard everyone has to meet?

Dr. BRAILER. Yes. Thank you. We have seen many industries have long-term conversions to new ways of doing business by using IT and much of the sustained productivity improvements in our economy come from the dividends we are reaping from that. Health

care has lagged behind, and I think there are a couple of reasons that also call for why the Federal Government is involved in this. First, we are a very large purchaser of health care services, as you all know, and without the Federal Government acting, too little purchasing power in the private sector can be focused on the changes that are needed to be done. Second, we do have a number of regulations and practices, including the way we reimburse for care today, that provide disincentives to the kinds of technology that we want to put in place and the kinds of quality that we want to see produced. This has been widely discussed. So, the Federal Government acting as a catalyst and a leader means that we are going to move forward and address our policies and our purchasing practices in concert with the industry so that there is a unified movement toward the kinds of progress that we want to see, both in IT and in quality.

In terms of how our role will evolve over time, we are clearly taking the initiating role leading this forward and our principal focus, as I said, is on interoperability, which means to ensure that as we put IT tools in place in our doctors and hospitals and other settings that they can share information, that we can collect information for bioterrorism threats, that we can make sure that consumers can get access to their information. Over time, we want to shift our attention toward driving adoption of systems. This effort for interoperability, I think of as a 2-year platform to be able to make sure that the next system that is purchased is easier to purchase by a physician, is cheaper for them to purchase, and is able to be used more effectively in terms of staying up to date. So, our whole role will shift as we drive that other component of long-term change. In terms of how the standards will play out over time, we do envision them having significant Federal support. Starting today, we are going to work through a process to let the current voluntary standards efforts move forward, but we have created a new group called the AHIC that you mentioned which will receive the testimony of these standards developers and, after vetting them, will make recommendations to the government about what those final standards should be. We will then turn them over to the National Institute for Standards and Technology (NIST) that will go through a process that will make those standards mandatory for Federal agencies.

This is a very, very expensive change, tens of billions of dollars of change just in Federal systems alone to comply with standards, let alone the private sector. So, naturally, it will be a long-term, incremental change. As that happens, that will then become a necessity of doing business with those agencies is to comply with those standards, as well. So, we are going to drive voluntary adoption with a follow-up in terms of how agencies adopt those, as well.

Chairman JOHNSON. Thank you. That is very interesting. I am going to turn to Mr. Stark, and then at the end, if there haven't been question about your new RFPs, I would like to come back to that. Mr. Stark?

Mr. STARK. Doctor, you have mentioned several times using government purchasing power to drive results, kind of a free market approach, right?

Dr. BRAILER. I think.

Mr. STARK. Why does the administration then object to using its purchasing power to lower pharmaceutical costs for the taxpayers?

Dr. BRAILER. Congressman, I appreciate the question, but I really am here to talk about health IT and I can't speak to that. I would be happy to take that question back——

Mr. STARK. Well, let me ask you, then, as a physician, or as a proponent of the free—you tell us you know something about the free market. I would like to find out what you know. Why wouldn't it make sense to you, as an expert in the free market, that using the purchasing power of $400 to $600 billion would be more efficient in saving money than cutting it up into a couple of $20 billion purchasing powers?

Dr. BRAILER. Congressman, I respect the question, but I am here today as a representative of the administration and not as a private expert, so——

Mr. STARK. It is the administration that isn't using its purchasing power to save pharmaceuticals, and if we don't save any money in pharmaceuticals, we aren't going to have any money left to pay the doctors. It is all in one box, Doctor.

Chairman JOHNSON. Will the gentleman yield?

Mr. STARK. Yes.

Chairman JOHNSON. The structure of the Medicare Modernization Act involved people competing to provide pharmaceuticals——

Mr. STARK. That is what he is talking about.

Chairman JOHNSON. Competition—that is right, and that is the structure of the bill that was structured, the Democrat bill, also, until the final motion to recommit. Both bills were structured to have competing PBMs on the theory that competition drove prices down, and then there is a special way of trying to drive prices down in part B drugs. So——

Mr. STARK. I am with you.

Chairman JOHNSON. That isn't a topic of this hearing, so——

Mr. STARK. It is a topic, Madam Chair——

Chairman JOHNSON. Maybe you would like to go on to your——

Mr. STARK. Madam Chair, when it is convenient, when you are not getting paid big campaign contributions by the pharmaceutical industry, it is convenient not to let the government drive prices down. I suspect that that would be the——

Chairman JOHNSON. I guess what I am getting at is there is a dispute between how you drive them down, whether you drive them through competition or through government negotiation, and that is a big dispute, but that is not the topic we are here——

Mr. STARK. If the Doctor doesn't think it is good and you don't think it is good for driving pharmaceutical prices down, how—now, it may be that you haven't gotten any campaign contributions yet from the IT industry and then you might decide that it, too, is a good idea not to let us use the purchasing power to drive their prices down. The fact is that the drug bill was written by the pharmaceutical industry and has it in it a prohibition——

Chairman JOHNSON. Mr. Stark, I truly find that demeaning——

Mr. STARK. You are interrupting——

Chairman JOHNSON. If you would please——

Mr. STARK. Regular order. If you would like to ask me to yield, I might, but it is my time and I would like to finish and suggest that the reason that this good witness wants to talk about using purchasing power is because it hasn't occurred to them yet that the IT industry will be in making big contributions. I think that this idea of voluntary standards, we are now somewhere around 17th in the world in health care and the Doctor mentioned that we have standards in other countries and none of them are voluntary in those countries that have better medical care than we do. So, it appears, Doctor, that your idea of having a market-based system as a stop to the industry that supports politicians so generously, and not having any regulations is a matter of faith with you, is that correct?

Dr. BRAILER. Well, I certainly do have faith in the private market, sir.

Mr. STARK. That is obvious.

Dr. BRAILER. I believe that in this case, the private market is both being inhibited by government policies around how we reimburse for care——

Mr. STARK. Okay.

Dr. BRAILER. On the other hand, this is one instance where I believe——

Mr. STARK. Would you suggest we do that with the Food and Drug Administration (FDA), then, Doctor? How about having a market-based non-regulatory pharmaceutical approval system?

Dr. BRAILER. I certainly couldn't comment on that. But I would like to tell you that I believe that——

Mr. STARK. Doctor, what do you know about? You went to medical school, didn't you?

Dr. BRAILER. I did.

Mr. STARK. Did you get a Ph.D. someplace?

Dr. BRAILER. I did.

Mr. STARK. In what?

Dr. BRAILER. In economics.

Mr. STARK. You can't comment on what the FDA does in terms—are you familiar with the FDA?

Dr. BRAILER. Sure, and I would be happy to report to Secretary Leavitt and to the White House your interest in the topic and have them come back and speak with you. It is not the topic that I have come for——

Mr. STARK. I am sorry. Thank you, Madam Chair.

Dr. BRAILER. Could I speak to the Congressman's question, please, Chairwoman?

Chairman JOHNSON. Pardon?

Dr. BRAILER. Could I speak to his question?

Mr. STARK. My time has expired.

Chairman JOHNSON. His time has expired. Let me go now to Mr. McCrery.

Mr. MCCRERY. Thank you, Madam Chair. Dr. Brailer, welcome.

Dr. BRAILER. Thank you.

Mr. MCCRERY. It is nice to have you with us, particularly one of your education and expertise. I don't want to belabor Mr. Stark's line of questioning, but I think it is worth pointing out, and perhaps you as an economist understand what the Congressional

Budget Office (CBO) understood and wrote in response to a specific question about the value of having the government directly negotiate prices with pharmaceutical companies. The CBO and their economists concluded that there would be no significant savings to the program if the government were to be allowed to directly negotiate prices as compared with the formula that we did include and pass in the legislation which calls for very aggressive negotiations among plans and providers. So, as an economist, do you understand that the CBO concluded that the market will work just about as well as the heavy hand of the government dictating prices, basically, because of their purchasing power?

Dr. BRAILER. Yes, sir, I am aware of that.

Mr. MCCRERY. Okay. Mr. Stark in his opening remarks did bring up, I think, a useful point that we ought to discuss and explore. In his opening remarks, he suggested that we utilize the existing framework that the VA uses for its IT and get that spread out as the template for the private sector. That may be a good idea that Mr. Stark has suggested, and I think, actually, CMS announced last week, or maybe—yes, I think last week——

Dr. BRAILER. Right.

Mr. MCCRERY. That they intended to do something like that. When Dr. McClellan was here last week, I asked him, and I am going to ask you, in light of your RFPs, which seem to call for private sector involvement in developing standards of interoperability, are we going too fast with putting out a system that is used by the VA and it may not be the best system for our entire health care system? How do you plan, how do you envision dovetailing what may be a worthwhile effort in getting that system out there, as Mr. Stark has suggested, but also developing through the private sector what may be an even better system?

Dr. BRAILER. Sure. Well, I appreciate your interest and Congressman Stark's interest in VISTA. We have been working very closely with CMS and with the Department of Veterans' Affairs since I came to the government to make sure that VISTA can be available to the market and the release that is coming next week is really an important milestone for us. We intend to make sure that that product that is made available is one of many choices that physicians have, and I think it will find particular resonance in physicians that work in safety net clinics and underserved clinics and clinics in other areas where they have significant technology barriers. Also, I think it does play a role in promoting competition, particularly in small physician offices. We have seen that the price performance of EHRs becomes very difficult for physicians to get access to in small practices, and that probably is where the VISTA system will have its best resonance.

We are going through a process now of having a certification process for EHRs, meaning they will be subjected to inspections, and we expect for the VISTA office product to be going through that same process to ensure that it can comply with the standards that are out as well as, hopefully, be a leader in that process for the rest of the market. So, I am very optimistic about what it brings, but it is one of a large portfolio of other choices that we think physicians will make as they pick products and software that

meet their own clinical specialty needs, their own practice setting needs, and their own kind of patient care needs.

Mr. MCCRERY. So, you don't see necessarily getting the VISTA system out there, the software out there, as necessarily deciding by that that that is going to be the platform forevermore.

Dr. BRAILER. Absolutely not. I think at this point, the market is not supply limited. It is demand limited. The principal factor isn't that there aren't good products available. The principal factor is physicians have no incentive to put them in and they have significant technical business and human factors, barriers, to doing that, and I think the VISTA system suffers from the same challenge that any other EHR product does. How does the physician actually implement it and get it up and running? How do they change the way they make decisions and communicate? That human change, that transformation is really what all of these software products are about and none of them have a magic capacity to skip past those. So, I think it is a good solution. It will be really a good solution for particular product or particular practice settings. I don't think it is transformative in terms of how we regard health IT adoption.

Mr. MCCRERY. Thank you very much.

Dr. BRAILER. Thank you.

Chairman JOHNSON. Mr. Thompson?

Mr. THOMPSON. Thank you, Madam Chair. Doctor, thanks for being here today. To pick up on the last point that you made, you had mentioned that incentives to be a good way to bring about these changes. Do you see at any time where we would maybe leave the carrot and go to the stick and rely on penalties, or maybe a combination, to bring this about?

Dr. BRAILER. I think that is a very good question. I believe that before we will come to that debate, the market itself will come to the conclusion that physicians must use EHRs in their practice, and not just any EHR, but ones that can actually deliver safer, better quality care. We have seen reports recently in the literature that some products, some systems, particularly older ones, don't have the kinds of prompts and reminders and could actually increase the rate of errors.

Mr. THOMPSON. What happens to providers who are ahead of the curve? I have one in my district in particular that has been doing IT for quite some time now and I am concerned, as I am sure they are, that if, as we start moving in this direction, they may end up being penalized or be caught in the position where they have invested in one type of equipment and have to switch and do something else. Have you given that any consideration?

Dr. BRAILER. Oh, a great deal of thought. This is a market that is 30 years old. The first EHRs were put into place by the most innovative health care systems in the mid-1970s and we have now seen most of the drivers of this have been really large innovators——

Mr. THOMPSON. Is there some way to protect these folks from——

Dr. BRAILER. Well, I think, first of all——

Mr. THOMPSON. They are kind of being punished for doing what you want them to do.

Dr. BRAILER. Well, I think there is clearly a risk that they could be in the position of having systems that are not compatible with the future standard, and the Federal Government is line with the systems we have in place for care. I think that is one of the reasons that we want to see this be an incremental change that happens over time to make sure that there is not a significant risk that one day, they are——

Mr. THOMPSON. Well, I would hope that we could continue to talk about this——

Dr. BRAILER. Very much. It is a very important topic. It is a principle in our concern.

Mr. THOMPSON. In your testimony, you mentioned that this could bring about some pretty substantial savings. I think you said about 8 percent to about 30 percent of health care costs?

Dr. BRAILER. Yes. There are estimates that frame the range of savings between ten and——

Mr. THOMPSON. What kind of dollars are you talking about?

Dr. BRAILER. I am sorry?

Mr. THOMPSON. What kind of dollars are you talking about?

Dr. BRAILER. I think the general ranges that have been estimated for those are $150 billion up to $350 billion dollars.

Mr. THOMPSON. The CBO agrees with that?

Dr. BRAILER. I don't think CBO has actually issued their own estimates, and we have even cited—these estimates are cited from others in the scientific/academic literature——

Mr. THOMPSON. Who is the benefactor of the savings, the provider or the payer?

Dr. BRAILER. Well, I think the patient is the ultimate benefactor because it is their lives that are saved. It is ultimately money that comes out of wage offsets that goes into health care——

Mr. THOMPSON. There will be some kind of provisions to ensure that that savings is, in fact, passed on?

Dr. BRAILER. Well, I think that is a principal question. Most of the research says that the short-term accrual of the benefits go to payers, those at financial risk, and so that is a question that has really dogged the industry to some degree at this point.

Mr. THOMPSON. Then you also mention in your testimony about the work that you have done looking at how other countries have dealt with this issue. I think you specifically mentioned Canada, the Netherlands, Japan, Australia, Great Britain, and France. It strikes me that there is a considerable difference between their systems of health care and ours, specifically they are either national health care system or single-pay. Given the difference, were you able to learn from your observations there?

Dr. BRAILER. Yes, I think very much. First, it helps us recognize that this is a global phenomenon and it is not simply something that is happening in this country. While it is certainly difficult for us to learn about the kinds of incentives, the mechanisms for financing, the care and accountabilities, because they are so peculiar to each country, the architecture, the design of security, the way the systems are developed and integrated, we have learned a great deal from, and we are watching other countries who are ahead of us. So, certainly, a lot about technology, and I think we will learn also a lot about how to deal with large-scale data assess-

ment research, monitoring of care status from these countries, as well, because they are further ahead than we are today.

Mr. THOMPSON. Thank you. I will yield back, Madam Chair.

Chairman JOHNSON. Thank you. Mr. Ramstad?

Mr. RAMSTAD. Thank you, Madam Chair. Thank you, Dr. Brailer. Like you, Dr. Brailer, I believe that health IT can save lives and improve health care, increase efficiency, and actually reduce costs in our health care system, and I want to focus on that in my line of questioning. I think all of us agree that it is totally unacceptable, totally outrageous that as many as 98,000 Americans, according to your testimony, Dr. Brailer, die each year because of medical errors. Almost 100,000 people in this country die because of medical errors each year. Unlike my good friend from California, the ranking member, and he is a good friend, and believe it or not, he is a good guy, your testimony is very illuminating, I believe, and your recommendations for reform are impressive. I read your testimony, also believe it or not. I did read your testimony and you state therein that health care fraud accounts for 3 percent of health care expenditures, total expenditures each year, which equates to $56 billion, almost $57 billion in fraudulent claims alone. When you include improper claims, again, according to your testimony, with fraudulent claims, improper claims plus fraudulent claims, that is 10 percent of the money we are spending in this country each year on health expenditures, or $170 billion in fraud and improper claims. So, three is no question that we have got to reduce those costs, and my question, my main question is this, Dr. Brailer. In your judgment, how significantly can we reduce the costs of fraudulent claims and improper claims by using automatic, or automated, rather, automated coding software and a national Health IT Infrastructure?

Dr. BRAILER. It is a great question and it is interesting to note that different views have been expressed. There is certainly a minority view that says that, in fact, EHRs will increase the rate of fraud. The overwhelming view tends to be that EHRs will allow us to save and reduce fraud. In fact, we have a product going on today and one of the witnesses from HIMA, Ms. Kloss, will be happy to tell you about their role in that. But we are trying to estimate exactly what those savings are. The key shift that we are trying to drive is to go from fraud prosecution, which is way out after the fact, a very high opportunity cost for the government and the providers, to move toward real-time fraud prevention, so the provider there knows whenever they are making a decision on an EHR what the expectations are for documentation, what the expectations are by law so they can determine there and sign that they have complied with that. We think that is going to be a fundamental shift toward new cyber fraud prevention capabilities over the next few years.

Mr. RAMSTAD. Did I understand you correctly the first part of your response? There is empirical data to suggest it will cost instead of save money?

Dr. BRAILER. I am just indicating that there are those who believe. There is concern in the law enforcement industry that these electronic tools could increase the rate of fraud, but it is a minority view. So, we are taking that project on to estimate what the real

economics of fraud are as a result of IT adoption, but at the same time, developing these new state-of-the-art cyber fraud prevention techniques.

Mr. RAMSTAD. As I understand it, Dr. Brailer, my question will be answered by the results of that study, is that correct?

Dr. BRAILER. That is correct.

Mr. RAMSTAD. That is ongoing?

Dr. BRAILER. That is going on today.

Mr. RAMSTAD. When will that be completed?

Dr. BRAILER. The first phase of that will be done by early spring of 2006 and we will work on a follow-on for various other demonstrations.

Mr. RAMSTAD. Well, I don't think the American taxpayers or the American health consumers can wait much longer, so if you can do anything to expedite that——

Dr. BRAILER. I agree. That is one of the reasons we made it one of our top priorities in the first year, was to define that.

Mr. RAMSTAD. Again, that is encouraging and I thank you. Let me ask, finally, with the few seconds I have, what, in your judgment, are the biggest barriers to implementing IT in health care? What are the biggest barriers? We know there are multiple barriers, but what is the largest obstacle we face?

Dr. BRAILER. The largest two obstacles are perverse incentives. There is not a business case for the typical physician, office, or hospital in doing this. The benefits accrue elsewhere and it is a substantial cost. Second, we don't have the standards or the infrastructure for systems to become compliant with the kinds of information sharing that we want to do. That stops most people from buying these systems and it makes their implementation very risky and very difficult, and that is where we are focusing most of our effort today. Thank you.

Mr. RAMSTAD. Thank you very much, Dr. Brailer, for your testimony. I yield back.

Chairman JOHNSON. Thank you. Mr. Emanuel?

Mr. EMANUEL. Doctor, thank you for your testimony. One of the things—you know, in the United States, some of the report indicate that we spend about 34 cents out of every health care dollar in kind of moving paper back and forth—insurance, hospitals, doctors, patients, and so forth. Other major industrialized nations range on the high end of 24, on the low end, 18 cents of every health care dollar. The one promising area would be this area. I think one of the things that we should set as a goal over the next 10 years to get us into that middle range where Canada, England, France, Germany, and Japan have made advances, this is the one place that you can get low-lying fruit and find the real savings in health care and apply it in other areas, for uninsured, other types of coverage that you want to do or cost containment areas. My concern, though, with allowing the private sector to set the rules is—and I said this when we met as a Committee on a bipartisan fashion, although I generally believe that this is a great area to proceed—is, A, if you look at what happened in the wireless space and with the telephone without any direction from the government, we have so many different competing platforms and models out there that, in fact, our telephone space, wireless space, compared to

where Europe is and individual countries, is not as strong from an infrastructure.

My fear is that if we allow the private sector to take a lead without setting some of the boundaries and programmatic goals for it, even though some would advocate that is the heavy hand of government, I am willing to give them the right to develop, but setting the ground rules, a lot of that synergy and a lot of that cost savings that you want to see would actually get lost and we would not see the full potential. And, in fact, in many ways, whether you want to talk about it as my colleague from Minnesota did as preventing fraud, or you want to see it purely from a cost saving standing, we would literally be leaving money on the table because it would not be developed in the most coherent, organized fashion. I don't think the government has to be the one that develops it, but it surely can set some of the ground rules to ensure that we are not leaving money on the table. I do think that there is a—we did this once. We did it in the wireless space and it is not the most efficient. Although we all like to applaud the private sector as a total model, I will say one thing in defense of the ranking member. The private sector does negotiate for wholesale prices. That is what Sam's Club is about. When you buy bulk, you save. I don't care what CBO says. So, in this case, my worry is that we are going to leave money on the table and not do it in the most efficient way. It can be developed by the private sector. The rules, the goals, and the boundary, that is what the government does, because there is so much here at national risk, which is a huge amount of money we overspend in this country on health care for what we could get for our dollar.

Dr. BRAILER. Well, I appreciate the concern and I think you have really put your frame around this paradox that exists, which is we want to, on the one hand, have uniform and widespread adoption of standards, and on the other hand, we want them to be progressive and stay current and modern over time. The reason that we have not taken a regulatory view of this is because we can achieve one, but at the cost of the flexibility over time. The approach we are taking is to develop these by contract with the private sector under the supervision of our office and then turn those over to a Federal advisory Committee called the AHIC, which would then turn them into a Federal process. The hope is, and this is where I think it is worth a discussion, is would the buying power of the Federal Government allow us to preserve the flexibility or the innovation over time yet have the force of mandate? We think it will, given our huge clout in the health care market, and we have agreed that we are going to use the mandatory internal process to make sure that these standards do become required for agencies.

Mr. EMANUEL. If you——

Dr. BRAILER. So, hopefully, we can have both. I am sorry.

Mr. EMANUEL. No, no, that is okay. There is more of a discussion. In my view, though, if you have competing platforms being developed, what will happen is we will find savings, because clearly, when you are paying 34 cents when other countries are paying 25 cents, you are going to find savings.

Dr. BRAILER. Right.

Mr. EMANUEL. The question is, will you accomplish all that you can, and I am not saying the government has to develop it. We

know this space and given technology moves way too fast for the government's capacity to be the developer. But without setting what our objectives are and what the platform should look like, in fact, we are going to be leaving a lot of money on the table and have actually wasted time and money——

Dr. BRAILER. Right.

Mr. EMANUEL. Rather than really realizing all the potential that exists here in the medical IT space.

Dr. BRAILER. Right. This is why the work of our certification commission will be very important, because we are requiring them to specify potentially hundreds of parameters and what health IT must look like, operate like, store information like, and what standards it uses, and we will then link Federal purchasing, conditions of participation, other things in the future to complying with that.

Mr. EMANUEL. Madam Chair, may I ask one more question, just as an example?

Chairman JOHNSON. We will have a second round of questions, because there are others that——

Mr. EMANUEL. I don't know, given my memory today, whether I will remember it. That is okay.

Chairman JOHNSON. Mr. Hulshof?

Mr. HULSHOF. Thank you, Madam Chairman. Good morning, Dr. Brailer. The word "harmonization" was used earlier this morning in this hearing, and I guess harmonization can have a variety of different contexts. It could be musical performance. It could be mathematics and wavelengths, as was cited. Obviously, it is very important for this subject of IT. Unfortunately, the word "harmonization" doesn't always describe the political discourse around IT. I am encouraged, as most are, I think, about—and Mr. Emanuel even touched on just the extraordinary opportunities through medical devices, through electronic records, I mean, we are just riding on the tip of the iceberg, I think, of some extraordinary positive changes in health care. Having said that, let me make a plug. You mentioned your home State of California. Let me extend kudos to another gentleman from California on this Committee, Mr. Thompson. Mr. Thompson and I have introduced a bill related to telehealth, and while I know that is not the particular subject of today's hearing, let me put in a commercial message on behalf of Mike and myself because we really see that if we are serious about patient care, the quality of a patient's care should not be determined by one's geographic location.

An example at the University of Missouri Medical School has 43 sites scattered throughout the State and what our bill attempts to do, H.R. 2807, is to incorporate other disciplines, and we are trying to deal with some of the same things as far as cross-boundary regulations and what have you. So, I just put that on your radar screen as we talk about this larger issue, as we really hone it down to the underserved areas, especially not just in the rural areas, which is often used in that context, but even in urban settings, as well, where tele-health could really, I think, be on the cutting edge. You mentioned with Mr. Emanuel a little bit about transitioning, not only the government being a payer and provider, but how you envision transitioning to the private sector and somewhat of the ongoing role of the Federal Government in this entity. Let me even back

up a step, because as you know, the Medicare Modernization Act, we did take an important first step, in my view, toward this interoperable health information system through our Commission on Systemic Interoperability, and we are going to hopefully get that report, I think, in October. How will that work if that commission then transitions into the work of the AHIC? Can you give us some thoughts on that?

Dr. BRAILER. Sure. We expressly are preparing for the reports from the Commission on Systemic Interoperability to be handed to the AHIC so they can review them from a perspective of implementation. How do they accomplish the recommendations that the CSI made? Further, Secretary Leavitt has asked the Commission to develop a consumer vision. What does this really mean to America's consumers if we had health IT to ensure that the AHIC is guided by that vision? So, there is a very important handshake between the two and we are actively involved with both as they sunset or start up.

Mr. HULSHOF. I appreciate that. Madam Chair, I yield back my time.

Chairman JOHNSON. Thank you, Mr. Hulshof. Mr. Camp?

Mr. CAMP. Thank you, Madam Chairman. I am interested, as well, in this interplay between the AHIC, this community, and the Commission in the Medicare Modernization Act. I appreciate your service and certainly your credentials and training. In your testimony, you mentioned that the government would act as a leader and a catalyst and convener of ideas and information regarding the Nation's health IT, and then also that the private sector is key as the public will be the purchasers of this. I think it has been important to know that when we have seen government grapple with technology, particularly in the fuel-efficient car area, command and control choice of electric cars has ended up not being the direction that the technology went, primarily because consumers didn't purchase them. So, I think it is very important to have this private sector role, but again, having sort of begun this process in the Medicare Modernization Act, I would like to hear your thoughts on proceeding forward and sort of the time line that you see this taking in the months ahead.

Dr. BRAILER. Sure. I appreciate that very much. We intend to have the AHIC seated in September. This group will meet several times per year, and the first thing they are going to do is prioritize certain breakthroughs where we think health IT can have a short-term impact. One of the ones that we will certainly do is e-prescribing. Because of the Medicare Modernization Act (MMA) (P.L. 108–173), it is already underway. Second, I am sure that we will deal with adverse drug event reporting. This is a necessary component of information collection to make Americans safer as a result of drugs that are on the market. Others will be prioritized by the AHIC Commissioners so we know where to focus our energy, on real things that people can see soon. We will then form work groups that are supported by our contractors to develop recommendations, and one of the real constraints in this process is even if today we wanted to mandate or require something, we don't know what to do. We don't have the standards agreed to or the certification criteria. So, we are going to work through that and make

determinations of what should be done. Then the AHIC will then focus on how do we get it done, how to use purchasing power, how to align our interests with Federal agencies and private sector organizations. So, the prioritization will occur by early 2006. The breakthroughs will be managed on a yearly basis and we expect to see them happen over the course of a two-year period. Two-thousand-seven is where we have set the outside date for the first five breakthroughs to be seen visibly by the American public, and the rest will follow from there. We really focus on this two-year time horizon to have very urgent things done.

Mr. CAMP. Thank you. Thank you, Madam Chairman.

Chairman JOHNSON. Thank you very much. Mr. Stark, is Mr. Doggett——

Mr. STARK. No, he is not returning.

Chairman JOHNSON. He is not returning? Mr. McCrery had a follow-on question.

Mr. MCCRERY. Thank you, Madam Chair. Dr. Brailer, you have said a couple of times today that there are just too many impediments to doctors, for example, purchasing this kind of technology for their offices. I just want to share with you an experience I had recently in my hometown of Shreveport, Louisiana. I had the opportunity to go visit a small group practice in Shreveport of family physicians, I think there are 11 physicians in the group, and they have, in fact, on their own purchased IT and it is in use currently throughout their office, throughout their practice. The doctors have laptops that they can take with them when they are off. They have found it to be extremely useful in terms of providing safer, higher quality care to their patients, and that is why they invested in the technology. It makes them much more efficient. It makes them much more productive during the day. And because of the many elements of the technology that provide them information instantaneously, they feel much better when they prescribe a medication, for example, for one of their patients, because it immediately comes up on the screen, the other medications that that patient is taking, any dangers inherent in the different medications being prescribed. It is all right there. So, how do you reconcile that experience of mine with a relatively small group practice in Shreveport, Louisiana, having made that investment on their own—they are paying for it out of their pocket—with your conclusion that there are too many impediments, not the least of which is cost, to the general health care community?

Dr. BRAILER. Well, I think there are two observations that that example brings through. First is the overwhelming power of why this is inevitable, why physicians using EHRs that can do the things to not only make their patients safer, but to liberate their own professional lives is inevitable. I remember that interns in practice today, interns that started residency, were born the same year the IBM personal computer came out. We should see more of that. That is one of the reasons that in answer to the question about how do we make sure that this is ultimately done, I think professional standards and the discipline of physicians will make this done because of the power of that. Now, on the flip side, those experiences are not that old. Most of the recent adoption that we see really is quite recent, in a couple or 3 years. So, it is really just

now that the industry is digesting that and saying, wow, this really works. This is something that can really be a huge benefit, and that is one of the reasons that we see substantial increases. I would come back to this caveat. Eleven physicians is a large practice in the spectrum of physicians. It seems small as we view it, but that is well above the 50th percentile of size of practice. The real critical challenge are physicians between one and five physicians in practice that make up about 38 percent of our care delivery, and those are the ones that don't have the resources. They look at an 11-physician group as a big group with lots of resources and a lot of help. So, everything is relative in this sense. I think the 100-physician groups will do fine. The 50-physician groups will do fine. The 10 to 50, some will do it, as you have observed, and some may not, and it is going to require some help. But below that, it is a real challenge, and that is where we have focused most of our effort, is how to bring along small physician practices that are ultra-small, up to ten physicians, and there, it is quite hard even though they could themselves see that same vision.

Mr. MCCRERY. Thank you. I just want you to consider that as you go forward in recommending or potentially recommending incentives that the government should pay for as we go forward in this. By the way, the one complaint that this physician group expressed was that their system was not able to communicate with the hospitals they dealt with and so forth, so it was somewhat limited in its application.

Dr. BRAILER. Right. That is the other challenge that we talked about, and that really is the opener of clinical value to doctors.

Mr. MCCRERY. Thank you.

Chairman JOHNSON. Mr. Stark has a follow-on question.

Mr. STARK. Dr. Brailer, earlier, you mentioned to me that you thought HIPAA was an unmitigated disaster, but I have to find out if that is the administration position or not. The administration has repeatedly said that HIPAA is a floor. Most notably two or 3 years ago, you chose not to adopt strong standards for protecting HIV/AIDS information and also eliminated the requirement for patient consent to use or disclose identifiable information. The administration used this argument again, that HIPAA was a floor, to reassure consumers that States would be able to address these personal and sensitive issues by providing a higher standard. Others today, other witnesses today will testify that the HIPAA standards are more than adequate to address the concerns of consumers and that HIPAA should be a ceiling, or put another way, the only protection we have for the privacy of our records. So, my question to you is, what is it? Is HIPAA a floor or is it a ceiling?

Dr. BRAILER. I think that is a critical question and I appreciate it. First, I want to comment that HIPAA really, as you know, is two pieces. It is the privacy and security components, but it is also the transactional standards component. The discussion about standards, I think is one that we have watched very closely, that the standards that are now ensconced in HIPAA for those transactions are quite old. They were old when they began the debate and they are locked. It is very difficult to change those and even to fix errors in those standards, let alone to bring them up to date with current, modern thinking, modern as of 1980s thinking. So, this is one of

the lessons that we have watched, about how do we allow for organic evolution of standards as determined by professional and scientific bodies, yet have the rule of law, and this is a challenge that I think we all grapple with. Now, turning to the privacy questions, I think there is a part of HIPAA that we have focused on a great deal which is not actually the State variation, the State, if you would, rules that could go beyond HIPAA, suggesting that it is a floor, but it is that HIPAA allowed enterprise-level, doctor-level, hospital-level flexibility with respect to privacy and security rules. That means that that flexibility, which meant that Kaiser in your district, for example, would want to have a higher level of privacy and security because it is a cyber target and it is much larger of a risk than a one- or two-physician practice who couldn't afford that, perhaps. That was the determination.

What we see is that that variability, that flexibility is a direct barrier to interoperability because each organization sets their own security and privacy regime, and even if we had standards, even if we had architecture and systems that could connect, if you use a biometric for your password and I just use just a regular old password, I couldn't get your data if you told me that I could, and that is a piece that we are focusing on with one of our projects, which is to illuminate recommendations, policy guidance about how do we close that enterprise-level variation and at the same time advance the security and privacy protections. I will just give one other comment on HIPAA to the spirit of your question. I think HIPAA addressed a different paradigm than the one that we are heading toward and I think there is a very interesting debate about HIPAA. I think, though, there is a separate debate that is beginning around portability of information. The HIPAA was designed in a world that was manually controlled and paper-based for clinical information, and as we move toward data that is electronic and flows around health care, disclosure controls are just one part of that dialog and there are many other pieces. We are trying to map out, what are the right questions to ask about the privacy regime that we would use in a highly portable, highly electronic, automated world of health information exchange? I don't have the answers. I am trying to get the questions assembled, because we want to make sure that health IT is not one example of where science and innovation goes far ahead of social discourse, and that is where we are focused today and that is one of my principal, principal priorities as I come to work every day. Thank you.

Mr. STARK. Is your understanding that the administration's position is that HIPAA is a floor or a ceiling?

Dr. BRAILER. Well, I think, definitionally, HIPAA is a floor because of the state of variability and the enterprise variability. The HIPAA sets a minimum that is set. In terms of where it should be, that is a separate question and I——

Mr. STARK. Is it your opinion that it should remain that, allowing this enterprise flexibility and State flexibility?

Dr. BRAILER. I——

Mr. STARK. I think that is what you just testified. You——

Dr. BRAILER. Yes.

Mr. STARK. As to the enterprise flexibility——

Dr. BRAILER. I will speak to your question, because it is one that I am very worried about. The challenge here is how do we adapt security and privacy regimes that could fit in a 3,000-physician organization and one in a two-physician organization. I am not talking about what we should do, but I am talking, practically, what could be done with the resources and people and systems they have. I think flexibility, therefore, has inherently got to be part of this, because we can't impose multi-million-dollar costs on a small practice in the name of a security regime that results largely from an entity being at higher risk than a small practice. On the flip side, I think we can create interoperability in the kinds of security protections by creating some new kinds of modern protections, like trust brokers or a chain of trust managers who can actually navigate these transactions between different security regimes, at the same time, protecting them. It has been used in other industries. Banking, credit cards, and so forth, use this routinely. We are just exploring it in health care today, and I mean "we" meaning the industry. In the administration, we are watching it. In the private sector, there is some experimentation. Some policy groups, like Connecting for Health and others that I know you have heard from here, have looked at this. It is the question of the day about how far we can go into really modern technology innovations to protect innovation in health care and what that means in terms of the huge variability of types of organizations and practice settings.

Mr. STARK. Thank you.

Chairman JOHNSON. Thank you, Dr. Brailer. That is a very important question and will receive a lot of attention throughout the rest of the panel and I appreciate your thoughts on it. Thank you for being with us.

Dr. BRAILER. Thank you both very much.

Chairman JOHNSON. Thank you. The next panel will come forward. As is customary, we will hear each of the five panelists. You have 5 minutes, but your entire statement will be submitted for the record, and then we will proceed with questions. Good afternoon. Dr. Detmer, would you proceed?

STATEMENT OF DON E. DETMER, M.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, AMERICAN MEDICAL INFORMATICS ASSOCIATION

Dr. DETMER. Good morning, Chairman Johnson, Ranking Member Stark, members of the Subcommittee. I am Dr. Don Detmer, President and Chief Executive Officer of the AMIA, whose 3,200 members include physicians, nurses, computer and information scientists and managers, biomedical engineers, academic researchers, and educators. Over the years, AMIA has provided many of the thought leaders who have pioneered the innovative use of information technologies in health care. As you mentioned in the introduction, I am a member of the Commission on Systemic Interoperability and a former Chair of the NCVHS. It is good to be back in front of the Health Subcommittee. My written testimony covers five major points, and I will summarize three of them now. First, the Office of the National Coordinator for Health Information. Dr. Brailer and his office have done an excellent job with very limited resources. Examples are the strategic framework and the recent

RFPs, including State privacy and business approaches, but others come to mind, as well. His office needs to be established in statute and also given adequate funding. I also believe that the NCVHS as a senior health information advisory Committee will be a very valuable resource and sounding board and partner for him and Secretary Leavitt as the AHIC moves forward.

The HIPAA—we have survived the formulation and early implementation of HIPAA. An evaluation of this experience is prudent, but the evaluation should not take too long and we need to move forward following this review. From my perspective, the privacy rule has been a success in clarifying the individual rights of all patients in relation to their own health information on a national basis and in establishing the responsibilities and legal obligations of all providers with whom patients interact. Undoubtedly, it has put privacy in the face of all patients, including some who may be personally more concerned about the inefficiency that it means and want less hassle. Nonetheless, HIPAA has allowed NHII to move forward, and I think this is a very big plus. As an unfunded mandate, it hasn't yet simplified administration, but it has allowed us to move forward with the NHII in terms of handling secure person-specific information and setting important standards. However, a few big issues remain. Much better funding for clinical standards development and maintenance is needed, with the NLM playing a big role in this. Without this investment, Federal health information standards will not be sufficiently vetted and developed and real problems for the entire system will result. I support this investment, since ultimately, I think we will only get a functional interoperable NHII with real Federal health information standards in key areas. I mean by that essentially establishing meaningful floor-to-ceiling standards that preempt idiosyncratic State and business approaches.

States, in my view, cannot effectively regulate the Internet, and I don't feel they can realistically regulate the information highway for health information. Only Federal leadership can develop this. This is a clear message from international evidence to date and we would do well to seek global collaboration on many of these standards. The NLM can help with this, too, and so, too, can ARC and others. Financing—financing health IT software, hardware, training, and the backbone for the networking dimension is a complicated matter. The Federal Government must play its role in this, as well. So, too, must all the entities affected, and we need innovative financing to support IT in such a way that we will improve access, safety, quality, greater patient involvement, data security, and efficiency. At the networking level, Stark and other fraud and abuse prohibitions have made some key players, such as hospitals and physicians, so totally risk averse that the development and implementation of a functional NHII is being impeded. Those are the big points, but I might add that I had the experience of living four-and-a-half of the past 6 years in England at Cambridge where I consulted to the National Health Service on its own national program for health IT. If you are interested, I might be able to reflect for you on any international dimensions of this important global development. You will note that I didn't stay long enough in East

England to develop a local accent, and it is awfully nice to be back home with all the activity going on now.

The AMIA wishes to publicly thank you, Chairman Johnson, for your outstanding and continuing leadership. Your perseverance has really mattered in this crucial arena of health information and transformation and national security. Mentioning national security, I personally consider the NHII to be as central to national security as the Interstate Highway System was considered during the Eisenhower administration. I thank you again for the invitation to testify. I look forward to responding to any questions you may have.

Chairman JOHNSON. Thank you very much, Dr. Detmer. Ms. Kloss?

[The prepared statement of Dr. Detmer follows:]

Statement of Don E. Detmer, M.D., President and Chief Executive Officer, American Medical Informatics Association

Good morning. Chairman Johnson, Ranking Member Stark, members of the Health subcommittee: thank you for the opportunity to appear before you today. My name is Don Detmer. I am President and CEO of the American Medical Informatics Association, whose 3200 members include physicians, nurses, computer and information scientists and managers, biomedical engineers, academic researchers and educators. Over the years AMIA has provided many of the thought leaders who have pioneered the innovative use of information technologies in healthcare. In addition to my role with AMIA, I am a Professor of Medical Education in the Department of Public Health Sciences at the University of Virginia.

Having been selected by Speaker Hastert, I currently serve on the Commission on Systemic Interoperability, which was created by the Medicare Modernization Act and which will make recommendations concerning the adoption and implementation of health information technology standards in a report to Congress later this year. From 1996 to 1998 I served as Chairman of the National Committee on Vital and Health Statistics, whose mission, broadly, is to advise the Department of Health and Human Services on shaping a national information strategy to improve the nation's health. My tenure at NCVHS coincided with the expansion of the Committee's charge enacted in the Health Insurance Portability and Accountability Act of 1996, which gave the Committee significant responsibilities in regard to administrative simplification and privacy. In my role as NCVHS Chairman, I had the pleasure of appearing before the Health subcommittee on occasion, and today I would like to thank and congratulate the subcommittee for your abiding interest in, and commitment to, the development of health information policies to improve the quality, safety and efficiency of healthcare, while at the same time protecting the security and confidentiality of personal health information.

As you consider the introduction of new legislation relating to health information technology and the development of a national health information infrastructure or NHII, let me comment today on three important issues:

- first, there is a critical need for ongoing Federal leadership in encouraging and shaping an NHII that benefits all stakeholders, especially patients;
- second, we should review "lessons learned" from the rollout of HIPAA standards to date and identify issues to be considered as additional health information standards are developed and disseminated;
- and, third, we should begin to address current disincentives—both real and perceived—that slow the implementation of health information technologies in our healthcare system, the most information-intensive enterprise in our economy.

The Need for Federal Leadership

While it is the undoubted world leader in high technology clinical care and biomedical research, the U.S. healthcare system is an incredibly fragmented mix of very large and very small players, 21st century medical science mixed with uneven access, delivery and outcomes, and cottage-industry business practices. Market forces alone have not driven integration of the interests and needs of disparate participants: hospitals—physicians and other providers—payers—employers—researchers—and, most important, patients. And, it is unlikely that they will. As a result, too few individuals have access to electronic health record systems and there is little

interconnectedness of the systems that exist. Further, despite some progress, initiatives to measure and pay for quality have proven difficult to implement.

Over the last 14 months, the Office of the National Coordinator for Health Information Technology, which is headed by Dr. David Brailer, a Fellow of AMIA's College of Medical Informatics, has done an excellent job in communicating a vision to support widespread adoption of interoperable electronic health records within the next 10 years, particularly in consideration of the resources available to it. AMIA is particularly pleased that among the four requests for proposals (RFPs) issued recently by the Office (ONCHIT) are contracts for an Internet-based national health information network and for the development of processes for the harmonization of the various health information standards that are emerging. In regard to interoperability standards and the development of processes to certify health information technologies that can actually 'talk' to each other and will allow the seamless integration of information systems to facilitate quality care, AMIA is also very supportive of the public-private American Health Information Community (AHIC) announced by Secretary Leavitt just last month.

We strongly believe that HHS should be given explicit responsibility for ensuring the ongoing maintenance and dissemination of health information standards, with authorization for licensing and/or other types of support. To give you a successful example of Federal leadership, I would point to Secretary Tommy Thompson's drive to complete the licensure and distribution of SNOMED–CT, a very useful 'dictionary' of medical terminology, by the National Library of Medicine in 2004. AMIA firmly believes that the Department should draw heavily on the resources and expertise of the NLM, and we hope that the AHIC will use the Library's expertise in the maintenance and dissemination of further content standards.

I understand that the legislation to be introduced soon by Chairman Johnson establishes the Office of the National Coordinator for Health Information Technology in statute, and I believe this step is a crucial one in clarifying Federal leadership. As part of our support for the Office of the National Coordinator, AMIA urges the appropriators on both sides of the Hill to provide for adequate funding of ONCHIT.

Examining HIPAA Lessons Learned So Far

As we move—and we will continue to move—to develop an interconnected, interoperable health information system that will facilitate quality, access and patient-centeredness on a national and international basis, it is prudent to identify lessons we have learned so far from the administrative simplification provisions of HIPAA. Though the road was often difficult, if not actually painful, we have made a great deal of progress in establishing the rights of individuals to expect that their health information will be used appropriately and their privacy and confidentiality protected, and in imposing meaningful and reasonable obligations on health care providers, plans and payers, and others to comply with consistent Federal standards for the use, disclosure and transmission of health information.

Where once some people in the healthcare system may have treated individual health information too cavalierly on at least some occasions, from my perspective it is manifestly clear that since the Privacy Rule took effect in 2003, doctors, hospitals, pharmacies, health plans and others have made really extraordinary efforts to inform individuals of their rights and to establish policies and procedures that protect sensitive health information. Today every individual has a Federal right to access his or her medical record and to expect that the healthcare system will keep that record secure and confidential. And these norms are national—no longer are your rights, or the legal responsibilities of those healthcare providers you deal with, defined by the unique features of the State in which you live. Even if HIPAA may have 'backed' the nation into reasonable privacy and confidentiality protections, the roll-out has proved, on the whole, quite successful.

Notwithstanding what I think have been extremely good faith efforts to ensure that personal data is adequately protected, I do not discount that some people—for instance, those with concerns about the security of especially sensitive information, such as HIV status or relating to mental health treatment—have continued concerns about health privacy. To my knowledge there have not been reports of any large-scale violations of the framework set in place by the HIPAA Privacy Rule. That is, individually identifiable health information is used and disclosed only for "treatment, payment and health care operations" or as otherwise specifically authorized by the individual. Does the Privacy Rule protect against patently unethical or extraordinarily careless acts—like the leaking of a celebrity's medical record to a tabloid magazine or the disposal of old medical records in a dumpster or a straightforward instance of identity theft? Of course not—but we cannot expect even the most carefully crafted information standards to prevent all illegal behavior. In such

instances, active pursuit and strong penalties are needed when intrusions and misuses are identified, as a lesson to dissuade other from similar illegal behavior.

Some will argue that the States must have the capacity to enact 'more stringent' standards for health information—as is true under the Privacy Rule—for all health information standards, including those that are absolutely necessary for the development of an interconnected, interoperable national health information system. In the name of better healthcare, I must respectfully disagree. About half of all Americans live near State lines and multiple State approaches will most likely preclude efficient and seamless transmission of crucial health information. For example, it is not unusual at all for an individual to work in the District, live in Maryland, and receive health care in Virginia, with payments made by an insurer in any or all of these locations. If we are to ensure real-time availability of accurate and complete clinical information at the point of care, we simply cannot have the standards for the use, disclosure and transmission of the patient's health information subject to idiosyncratic requirements of individual States. Certainly, States do not intervene in similar situations, such as in the regulation of ATM use. States may impose varying requirements, like placing limits on allowable service fees, but they do not intrude into the information standards that facilitate the transmission of financial data, for example by requiring me to use a 4-digit pin at an ATM in Maryland but a 9-element alphanumeric pin at my home ATM in Virginia. In other words, the information exchange standards have been developed and agreed to by the banking industry and are national and international in their application.

I doubt that we can get to the common standards and interoperability that must underlie the widespread adoption of electronic health records without Federal preemption of conflicting State laws. But rather than simply assert that proposition, let me note that, in relation to the Privacy Rule, since 1999 AMIA has called for a study of the impact of the lack of Federal preemption and the impact of varying State statutes on the rights and protections afforded to individuals *and* upon the quality, cost and effectiveness of health care. Thus, I am very pleased that the bill to be introduced soon by Chairman Johnson calls upon the Secretary to undertake such a study in relation to standards that have been adopted subsequent to HIPAA. Should the study show that varying State laws and requirements have a negative impact on health care delivery, quality and access, and that HIPAA has established meaningful privacy and security protections, it makes sense to move forward without delay on Federal preemption for all adopted HIPAA standards.

Disincentives That Have Slowed Implementation of Information Technologies

From 1999 through 2003 I had the privilege to serve as the Gillings Professor of Health Management at Cambridge University and to consult to the National IT programme of the National Health Service. As you may know, the British government is investing billions of pounds to implement a fully functional, patient-friendly, electronic health record and system. While this task might appear to be easier in some aspects because of Britain's single-payer system, of particular note to me was the observation that, even before the government's new investment, well over 80 percent of England's primary care physicians were facilitating patient care electronically, from booking appointments and writing prescriptions to making referrals, recording clinical notes and tracking treatment compliance. By contrast, it is estimated that fewer than 20 percent of U.S. primary care physicians utilize electronic health records.

Interestingly, England's primary care practices are 'wired' not because of government investment, but because the British pharmaceutical industry years ago offered to supply the necessary hardware and software to primary care doctors in return for access to anonymized prescribing information. In the United States I think such an arrangement would be seen as unseemly at best, and illegal at worst. While the British are neither less ethical nor more permissive of the misuse of identifiable health information than are Americans, in this country hospitals, physicians and other providers are incredibly reluctant to pursue any innovative financing for health IT, including networks that can securely link together a region's providers, because of their concerns about the Stark self-referral prohibitions and other fraud and abuse standards.

Whether these concerns are reasonable—and perhaps, Mr. Stark, you would say they are not—we have hospital lawyers who absolutely insist that it is simply not acceptable for any third party to furnish any information technologies—whether hardware, software, training or other services—to any provider at less than a full, fair market price. While some healthcare systems and providers are moving forward under the current standards, the general consensus in the healthcare community is that the Stark provisions, while quite important in many respects, are constraining progress toward the roll-out of an interoperable NHII.

It is in the interest of all stakeholders, including patients, that functional electronic health records and an interoperable health information system be deployed as promptly as possible. But the entities that are perhaps key to that deployment, the small and rural physician practices that still provide a majority of health care services in this country, are those that are least able to afford the capital investment for the purchase and hassle of implementing state-of-the art IT systems. Especially because many of the 'savings' of health IT accrue to other system participants, including employers, health plans and patients, financial outlays necessary for the purchase of the very building blocks of an NHII should reasonably come from a wide variety of sources, including government outlays and pay-for-performance programs. Actually, pay-for-performance programs represent a clear argument for payers to provide some of the financing for health IT—because in order to pay for performance you have to be able to track performance and quality in the delivery of care, and to do that efficiently you need sophisticated information capabilities embedded in the healthcare system. Reasonable safe harbors for dissemination of health information technologies and services intended to improve healthcare quality, efficiency and access would encourage deployment of essential health information systems, and I am very pleased to understand that provisions to that effect will be included in Chairman Johnson's bill.

Educating the Healthcare Workforce

There is no question that momentum for bringing healthcare into the information century is building, and this is a very good thing. But hardware and software and standards and certifications will not be enough—we must ensure that we have enough doctors, nurses and information specialists to take real advantage of the opportunities for improved care and efficiency and access that health information technologies and an interconnected national health information infrastructure can provide. Recently, AMIA announced its 10 by 10 program, which aims to realize a goal of training 10,000 health care professionals in applied health and medical informatics by the year 2010; it is off to a great start with an initial partnership with the Oregon Health and Science University, and many other universities are seeking to participate. Our program uses classes, tutorials, web-based and in-person sessions to equip health care professionals to use health information and health information technologies to benefit patient care and to advance medical knowledge. In fact, we know from research that well-trained health providers combined with robust IT systems produce safer, higher quality care delivery.

With the supply of physicians essentially constant and the nursing workforce aging along with the baby boomers, we will only be able to address the increasing demands for care of a growing and aging population by developing a better trained workforce, especially more nurses skilled in the use of information and information systems. Increased Federal support for education and training will be needed to address this workforce reality—and AMIA, along with the American Health Information Management Association (AHIMA), will develop specific recommendations for that support.

A Few Conclusions

In terms of the development and implementation of integrated health information systems with sophisticated capabilities, we have seen a great deal of progress in the last few years. Within the Veteran's Administration, for instance, the case for improved safety and higher quality through the proper use of IT systems—including electronic records, decision-support programs, and process tracking and change analyses—has been largely made. We have seen the creation of the Office of the National Coordinator for Information Technology and a Commission to Certify Health Information Technology. The Commission on Systemic Interoperability mandated by the MMA has been convened, and Secretary Leavitt has announced a plan to create an American Health Information Community that will spearhead a range of public-private initiatives to develop information standards, certify new technologies, and provide long-term planning and governance for the electronic health environment. Someday we may look back at this moment and say, "The rest is history"—but not just yet. Additional legislation and Federal support, and the development of accepted, enterprise-wide standards will be required if true interoperability and connectedness are to occur.

From the start, Chairman Johnson has recognized the potential for improving the nation's healthcare system through the proper use of information technologies. Further, she has been willing to face the complicated and difficult issues involved. All of us in healthcare are grateful and most appreciative for her wisdom, energy and persistence over the years. As I understand the Chairman's current bill, it does not try to address all of the issues involved in creating an NHII to improve healthcare

quality, access and patient-centeredness. But it does forthrightly address some key 'sticking points' that are keeping the nation from moving forward as quickly as we should and among them are first, establishment of the Office of the National Coordinator in statute; second, addressing the impact on patient's rights and on healthcare quality and safety of varying and conflicting State and Federal information standards; and, third, reducing some current disincentives to the adoption of available health information technologies. AMIA looks forward to prompt consideration of the legislation and to supporting its implementation.

It is my strong belief that the development of an interoperable, inter-connected national information system is not only a healthcare issue; it is really a matter of national security. Whether that point will be brought home by an outbreak of avian flu in a U.S. population center or an episode of bioterrorism or the occurrence of transmissible disease in our food supply chain, I do not know—but I do believe that any of those events could occur, and that we will be greatly hampered in our response if we cannot make information that is crucial for the public health and economic interests of our country available to the appropriate authorities in the most timely fashion possible. While a functional NHII will facilitate broad improvements in health care quality, access and affordability, it will also assist in protecting our security and I would urge your leadership in facilitating its development with all due speed.

Thank you for the opportunity to appear before you today. I will be happy to answer any questions.

STATEMENT OF LINDA KLOSS, CHIEF EXECUTIVE OFFICER, AMERICAN HEALTH MANAGEMENT ASSOCIATION, CHICAGO, ILLINOIS

Ms. KLOSS. Chairman Johnson, Mr. Stark, and members of the committee, my topic this morning is the quality of health data in the United States, and I have been asked to speak specifically to the status of the Code sets in place and other on the opportunities to support and enhance improved data for use of health IT. The American Health Information Management Association and its 50,000 professional members are deeply committed to and actively participating in the adoption of standards based and the interoperable health IT. We are on the frontlines in implementing EHRs and other technologies, but technology alone is not enough. We need a concerted effort to ensure the quality of the data is as good as it can be, and we must start by improving the classification system for coding medical diagnoses and procedures. The current system, called ICD–9–CM, was developed and implemented in the 1970s, and we believe it must be replaced by ICD–10–CM to classify diagnosis data, and ICD–10–PCS to classify data about medical procedures. Both of these ICD–10 replacement systems have been developed by Federal agencies, the Centers for Disease Control and the CMS, and both agencies have testified on several occasions regarding the need for better classification systems to improve information used in their programs.

According to HIPAA, the Department of Health and Human Services must approve adoption of new code sets, and I would suggest that Congress can certainly aid in this process by supporting and requiring the Secretary to publish a proposed and then a final rule for adoption as soon as possible, and briefly, here is why. Each time we receive medical care, doctors, nurses, and other professionals collect important information about our health. They record our medical conditions and illnesses and types of treatment we received, any procedures performed, and then each piece of informa-

tion gets assigned a code. This coded data is the foundation for billing, claims processing, payment and pricing. It is used for public health and quality reporting, bio-surveillance, research, pay-for-performance systems, provider credentialing, fraud detection, and many other important uses. In other words, it underlies all of the major programs that this committee oversees and is looking to advance. The problem is that the current ICD–9 classification system is obsolete and it is beyond repair. Nearly every other developed country in the world has already replaced it with a version of ICD–10.

Consider how medical practice has changed over the past 30 years—new diseases, new treatments for those diseases, new medical procedures, threats of bioterrorism. The coding system we are using today was developed in the early 1970s, before MRIs, before laser surgery, before any of us had heard of AIDS or any of the medications used to treat it today, and this is a real problem. The value of a good classification system is its ability to accurately represent procedures that are performed or the illness that is diagnosed, and that is precisely what is missing from our current system. In addition, we are finding that the current system for classifying procedures is actually running out of codes. There are about 70 remaining unassigned codes, and the implications of this for quality reporting, research, and the appropriate payment for advanced medical technology are pretty obvious. We also believe that adoption of ICD–10 and ICD–10–PCS is an essential component of the health IT strategy being advanced by Congress and the administration, not a diversion from it. There are opportunities through ICD–10 to link to SNOMED–CT, which, as you know, has been licensed by the Federal Government. We can create robust mappings from SNOMED to ICD and leverage the opportunities of technology for automated coding going forward, offering a new paradigm for health data capture, aggregation, and reporting. In the future, it will be possible to use a variety of classification systems to meet specific information needs without laborious manual coding, and this is precisely what AHIMA and others are working toward.

According to a 2003 Rand study, the benefits of implementing ICD–10 and PCS will outweigh the costs within a few years of implementation, and Rand noted that the cost of doing nothing may be greater than the cost of going forward with adoption. In summary, we urge Congress to move forward with ICD–10 in the United States and also to leverage through our health IT initiatives to redouble our efforts to ensure uniform coding practice and adherence to coding guidelines. I thank you so much, commend you for your leadership, and I will be very happy to answer questions on this important topic.

[The prepared statement of Ms. Kloss follows:]

Statement of Linda Kloss, MA, RHIA, CAE, Chief Executive Officer, American Health Information Management Association, Chicago, Illinois

Chairman Johnson, Mr. Stark, and members of the committee, thank you for this opportunity to address the quality of health data and actions that are needed to improve it as part of the overall U.S. health IT initiative.

The American Health Information Management Association and its 50,000 health information management professional members are deeply committed to and ac-

tively participating in the adoption of standards-based and interoperable health IT. We are on the front lines in implementing electronic health records and other technologies as well as the implementation of local and national health information exchange and continue to be on the forefront of professional activities including privacy, confidentiality, security, data integrity, consumer and professional education.

My comments this morning relate to the urgent need for the Department of Health and Human Services to immediately initiate the regulatory process for adoption and implementation of ICD–10–CM and ICD–10–PCS code sets (referred to as ICD–10), rules, and guidelines as a replacement for the 30-year-old ICD–9–CM. ICD–9–CM is not meeting current healthcare data needs and cannot support the transition to an interoperable health data exchange in the U.S.[i] HHS must issue a final rule for adoption of ICD–10 as soon as possible to reverse the trend of deteriorating health data and to allow the healthcare industry to prepare for a smooth transition to modern classification systems by 2008.

Specifically we are calling for the following action by HHS and the healthcare industry, and urge your support for these actions:

- HHS must immediately initiate the regulatory processes to permit final implementation and use of upgrades to the deficient ICD–9–CM classification system by October 1, 2008. This upgrade will affect all diagnoses coding currently Volumes 1 and 2 of ICD–9–CM, as well as inpatient procedural coding, currently Volume 3 of ICD–9–CM.
- Adoption of final rules as early a possible in 2006 will give the healthcare industry ample notice to commence systems conversion and other steps necessary to ensure a smooth and efficient implementation.
- A coordinated, collaborative implementation strategy should be developed by industry stakeholder representatives to ensure broad input and a consensus-driven transition process.
- System conversions and upgrades to implement ICD–10–CM and ICD–10–PCS should be accomplished by healthcare entities in conjunction with the UB–04 and CMS 1500 (diagnosis codes only) system changes.
- Robust, rules-based, maps among SNOMED–CT®, ICD–10–CM and ICD–10–PCS, and ICD–9–CM should be developed promptly and distributed via the Unified Medical Language System (UMLS).[ii]

[I have placed a simple "understanding ICD–10" at the end of this testimony and this includes how ICD–10 would impact electronic health records.]

ICD–9–CM should have been replaced nearly 10 years ago. Each year that passes results in further deterioration of the classification system and the data that it produces:

- The ICD–9–CM coding structure and capabilities are in crisis. There are very few unassigned codes remaining to accommodate new diagnoses and procedures.
- In addition to no further capacity for expansion, many of the codes now in use do not accurately describe the diagnosis or procedure concepts they are assigned to represent.
- While the U.S. has used ICD–10 coding to report mortality data since 1999, we are now virtually the only industrial nation that has not upgraded its morbidity classification system. This failure threatens our ability to track and respond to international threats to public health and bioterrorism. Rather than being a world leader in the collection of high-quality health data, the U.S. lags far behind.

At a time when Congress and the Administration are making significant progress toward improving our health information infrastructure, the critically needed upgrade of ICD–9–CM has been delayed with little acknowledgement of the serious consequences and no clear plan for fixing the problem. Further delays in adoption of ICD–10–CM and ICD–10–PCS increase the cost of an eventual implementation once ICD–9–CM completely breaks down. While the U.S. is working hard to adopt

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[i] ICD stands for the International Classification of Diseases. 9 stands for the 9th revision and 10 for the 10th revision. CM stands for Clinical Modification (a U.S. version of ICD–9 or ICD–10) ICD–9 and ICD–10 were developed and copyrighted by the World Health Organization (WHO). The WHO no longer supports ICD–9. ICD–10–PCS is a procedural coding system designed by the Centers for Medicare and Medicaid to replace the current inpatient procedural coding system currently included as part of ICD–9–CM.

[ii] See AHIMA's Position Statement on Implementation of SNOMED–CT®—www.ahima.org/dc/positions AHIMA has also authored a white paper *Coordination of SNOMED–CT®* and ICD–10: Getting the Most Out of Electronic Health Record Systems, which provides a complete description of the roles of terminologies and classifications in EHR systems and the importance of mapping to effectively use clinical information for multiple purposes.

health information technology, it must also accommodate a robust 21st-century classification system.

According to the 2003 Rand study commissioned by the CDC, the benefits of implementing ICD–10–CM and PCS outweigh the costs within a few years of implementation. Rand further noted that the cost of doing nothing may be greater than actual implementation and further delay in adoption is likely to increase future implementation costs. This research did not examine the upgrade to ICD–10 as a component of the overall health IT improvements and thus it did not factor in the potential to change the paradigm of coding through accelerating the development of computer assisted coding tools. Thus, the potential benefits may be accelerated.

Adoption of national electronic health records (EHRs) and interoperable information networks require improved classification systems for summarizing and reporting data. Government and industry leaders cite healthcare initiatives that rely on data but are in fact compromised by the continued use of ICD–9–CM. These include quality measurement, pay-for-performance, medical error reduction, public health reporting, actuarial premium setting, cost analysis, and service reimbursement.[iii] [iv] Classifications systems are key elements of the health information improvement strategy. Failure to upgrade ICD–9–CM diminishes the value of the U.S. investment in SNOMED–CT®. The anticipated benefits of an EHR cannot be achieved if SNOMED–CT must be aggregated into an antiquated classification system like ICD–9–CM. Conversion to ICD–10–CM and ICD–10–PCS will not only produce better information and support development of computer-assisted coding, they will serve as the necessary foundation for continued improvements and expansion of 21st-century classification systems, nationally and internationally

Healthcare providers, payers, and vendors are waiting for a notice from HHS signifying the intent to implement ICD–10 in order to begin planning and preparing for an anticipated use date. Vendors also need this notice to ensure new products will be available to accommodate these more advanced classification systems. U.S. healthcare entities will soon be converting databases and applications systems to accommodate the upgrades to UB–92 and the CMS 1500 claims forms and data sets. It would be effective and efficient to make ICD–9–CM upgrades at the same time. Without some indication that implementation is on the horizon, healthcare providers, payers, and vendors will be reluctant to make these necessary changes concurrently.

As I have noted, the ICD–9–CM coding standard is in serious crisis. Terminologies and classifications from the 1970's no longer fit with the 21st century healthcare system as numerous conditions and procedures are outdated and inconsistent with current medical knowledge and application. New advances in medicine and medical technology and the growing need for quality data cannot be accommodated. Data incomparability continues to increase globally and within the U.S. due to the use of these antiquated code sets. As of the spring 2005 ICD–9–CM coordination and maintenance cycle, the U.S. now has less than 70 remaining codes to represent health technology in the future. Two simple examples of the gross inadequacy of this classification system:

- ICD–9–CM offers two codes for asthma, extrinsic and intrinsic. Current medical knowledge no longer considers this a clinically relevant distinction. In ICD–10–CM asthma codes are differentiated by mild persistent, moderate persistent; and severe persistent, which are the terms used in evidence-based practice guidelines.
- In the area of procedures, ICD–9–CM simply lacks important specificity. There is a single non-specific code for "other revision of vascular procedure" encompassing a wide variety of surgeries on blood vessels. ICD–10–PCS in contrast will allow capture of the type of surgery, the specific artery or vein involved, and use of a device such as a graft or prosthesis. This kind of detail is essential for evaluating outcomes and efficacy and may decrease the supplemental information that is required to adjudicate a claim, in the form of a paper attachment or actual review of the medical record.

Data coded under the ICD–9–CM system are the foundation for billing, claims processing, payment and pricing. It is used for public health and quality reporting, biosurveillance, research, pay for performance, provider credentialing and fraud detection. In other words, it underlies all the major programs that this Committee

[iii] See AHIMA's Position Statement on Consistency of Healthcare Diagnostic and Procedure Coding—www.ahima.org/dc/positions

[iv] See Medicare Payment Advisory Commission March 2005 Report to Congress Chapter 4: *Strategies to improve care: Pay for performance and information technology*—www.medpac.gov

oversees and is looking to advance. However, ICD–9–CM does not meet any of the following criteria:

- Code set standards outlined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA);
- New services and technology that must be acknowledged in CMS payment systems according to the Benefits Improvement and Protection Act of 2000 (BIPA); or
- Characteristics of a procedural coding system outlined by the NCVHS in 1993.

Significant costs are incurred by continued use of severely outdated and limited coding systems. For example, failure of our coding systems to keep pace with medical advances results in the use of vague or incorrect codes often taken from the claims form and thereby requiring excessive reliance on supporting paper documentation (attachments or copies of the health record).

When the need to replace ICD–9–CM was identified in 1993, steps were taken by the National Committee on Vital and Health Statistics (NCVHS), the National Center for Health Statistics—CDC (NCHS) and the Centers for Medicare and Medicaid Services (CMS—then HCFA) to develop a migration plan to ICD–10 for morbidity and mortality coding. ICD–10 use for mortality coding in the U.S. was initiated in 1999, however, while the rest of the industrial countries are now using their variations of ICD–10 for all reporting, the U.S. continues with the unsupported ICD–9–CM (the World Health Organization (WHO) now exclusively supports ICD–10) leading to data incomparability with the rest of its global community.

Extensive work and dedication has gone into developing and evaluating these systems as replacements for ICD–9–CM. While there is significant support for this ICD–9–CM upgrade, there is also a segment of the healthcare industry, clinging to antiquated legacy systems, who continues to argue for further delay choosing to forgo the benefits of improved data and information available through 21st-century terminology and impeding progress toward achieving critical U.S. healthcare goals.

In November 2003, the NCVHS recommended that HHS initiate the regulatory process for the adoption of ICD–10–CM and ICD–10–PCS as replacements for the 30-year-old ICD–9–CM. At that same time, Congress—in language included in the Medicare Prescription Drug, Improvement and Modernization Act (MMA)—urged the HHS Secretary to move forward with promulgation of rules for adopting and implementing ICD–10–CM and ICD–10–PCS. It is now 2005—a year and a half after these distinguished recommendations—and HHS has taken no action.

We believe that adoption of ICD–10–CM and ICD–10–PCS is a component of the health IT strategy being advanced by Congress and the Administration, not a diversion from it. You are aware that the federal government has licensed SNOMED–CT® to make it available at no charge as a reference terminology in electronic health records. Mappings must be built from SNOMED–CT to ICD–10 so robust computer assisted coding applications will be available for adoption.[v] Today, the National Library of Medicine is preparing mappings to ICD–9–CM because there is not yet a final rule for ICD–10. I liken this to putting a model T engine in a Porsche.

Electronic health records based on a reference terminology, such as SNOMED–CT, offer a new paradigm for health data capture, aggregation and reporting. In the future, it will be possible to use a variety of classification systems to meet specific information needs without laborious manual coding. This is what AHIMA and others are working toward. But it will take years for these technologies to be built and fully deployed in all provider and payer organizations throughout the U.S. A date certain for implementation of ICD–10 will drive application development and accelerate adoption of reference terminologies, mappings and artificial intelligence-aided coding engines. It will permit IT vendors, providers and payers to prepare for the change and develop software "crosswalks" between ICD–10 and ICD–9–CM to accommodate organizations that cannot overcome legacy system limitations before the effective date.

In addition to adopting ICD–10, the U.S. must redouble its efforts to ensure uniform coding practice and adherence to coding guidelines. The 1996 HIPAA legislation called for uniformity of transactions and code sets, but states and payers, including CMS, persist in adopting local rules and guidelines that further undermine data integrity and add to administrative costs. If we are to have reliable interoperable data and cost effective fraud-deterring systems, we must promote uniformity no matter where the data originates and no matter who the payer is. This is a first, but important step in improving the quality of health data through standards.

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[v] Background on SNOMED–CT and Mapping

I commend your leadership in supporting health IT improvements and urge you to codify the important work of the Office of the National Coordinator in the Department of Health and Human Services. I also commend your action to safeguard the privacy and security of personal health information. Health information management is fundamentally a field that safeguards patient data—its integrity, its effective use, and its privacy and security.

In closing, we urge Congress to expedite adoption of ICD–10–CM and ICD–10–PCS and standards that will improve the accuracy and consistency of health care data. I stand ready to answer questions and to provide any additional information that is not covered in my written testimony. Thank you.

Understanding ICD–10

ICD–10–CM is a U.S. clinical modification of the World Health Organization's (WHO's) International Classification of Diseases, 10th edition (ICD–10) is maintained by the National Center for Health Statistics (NCHS). ICD–10 is now implemented or being implemented in all highly developed nations except the U.S. ICD–10–PCS was designed under contract by the Center for Medicare and Medicaid Services (CMS), specifically to replace the ICD–9–CM procedural coding system.

The U.S. is the only developed country that has not adopted ICD–10 for mortality and morbidity. A total of 99 countries are currently using ICD–10 for both mortality and morbidity. The U.S. has used ICD–10 since 1999 for mortality reporting only. We need to implement ICD–10–CM in order to maintain comparability between mortality and morbidity data.

Improved Data

ICD–10 provides better data needed to meet the demands of an increasingly global and electronic healthcare environment. The ways in which coded data are being used today go well beyond the purposes for which ICD–9–CM was designed for back in the 1970s. Significant advances in the understanding of disease and treatment have been made over the last 30 years.

ICD–10 provides a significant opportunity to improve the capture of information about the increasingly complex delivery of healthcare. ICD–10 will provide:

- Better data to support quality and patient safety improvement activities
- Better data for improved public health and bio-terrorism monitoring
- Better data for more accurate reimbursement rates.

ICD–10 and the EHR

ICD–10–CM and ICD–10–PCS are better suited for use in electronic health record systems (EHR) than ICD–9–CM. The expanded availability of SNOMED–CT® made possible by recent government licensing agreement increases the urgency of replacing ICD–9–CM with ICD–10–CM/PCS so the development of mapping tools to the ICD–10–CM and ICD–10PCS can be initiated. Valid maps are urgently needed to link from a highly specific terminology to a classification system so that information captured in the reference terminology can utilize the power of summary required for healthcare reporting and indexing offered by the classification systems. ICD–10 medical coding system facilitates more robust mapping from SNOMED–CT clinical reference terminology in the EHR due to its greater size and granularity.

Continued use of the outdated version of ICD (ICD–9–CM) diminishes the value of the U.S. investment in SNOMED–CT®. The anticipated benefits of an EHR cannot be achieved if the reference terminology employed in the EHR, such as SNOMED–CT®, is aggregated into a 30-year-old classification system such as ICD–9–CM for administrative use and indexing. Mapping from SNOMED–CT to ICD–10 will improve the value of clinical data as it will:

- Facilitate retrieval of coded data at the desired level of detail depending on the purposes for which the data are being used
- Allow for administrative reporting functions such as reimbursement and statistical analysis not possible with SNOMED–CT alone.

As part of their recommendations for patient medical record information terminology standards, NCVHS urged the federal government to promote the creation and maintenance of mappings between the recommended core set of terminologies, which includes SNOMED–CT®, and medical code set standards designated under the Health Insurance Portability and Accountability Act (HIPAA).

Replacing ICD–9–CM with ICD–10–CM is necessary in order to maintain clinical data comparability with the rest of the world concerning the conditions prompting healthcare services. The longer the healthcare industry continues to use ICD–9, the more difficult it becomes to share disease and mortality data at the time when such global data sharing is critical for public health. For example:

- ICD–10–CM would have better documented the West Nile Virus and SARS complexes for earlier detection and better tracking
- ICD–10–CM also provides the ability to track bio-terrorism events and other public health outbreaks.

SNOMED–CT:

- Is a comprehensive, precise clinical reference terminology that contains concepts linked to clinical knowledge to enable accurate recording of data without ambiguity;
- Is specifically designed for use in an EHR:
  - It is incompatible with a paper-based health record system.
  - Integrated into software applications, it represents clinically relevant information in a reliable, reproducible manner;
- Supports clinical decision support systems, computerized physician order entry systems, and critical care monitoring;
- Facilitates communication among clinicians and improves the quality of data available for research and measurement of clinical outcomes;
- Ensures interoperability of patient information across software applications for disease management, treatments, etiologies, clinical findings, therapies, procedures, and outcomes;
- Provides a common language that enables a consistent way of capturing, indexing, storing, retrieving, and aggregating clinical data across clinical specialties and sites of care;
- Contains concepts linked to clinical knowledge to enable accurate recording of data without ambiguity;
- Works through implementation in software applications, representing clinically relevant information in a reliable, reproducible manner;
- Contains over 364,400 concepts with unique meanings and formal logic-based definitions; more than 984,000 English language descriptions or synonyms; and approximately 1.47 million semantic relationships.

Mapping

The purpose of mapping is to provide a link between one terminology and another in order to: [v]

- Use data collected for one purpose for another purpose,
- Retain the value of data when migrating to newer database formats and schemas, and
- Avoid entering data multiple times and the associated risk of increased cost and errors.

See the AHIMA white paper, *Coordination of SNOMED–CT and ICD–10: Getting the Most Out of Electronic Health Record Systems,* for a complete description of the roles of terminologies and classifications in EHR systems and the importance of mapping to effectively use clinical information for multiple purposes.

Chairman JOHNSON. Thank you. Dr. Weiss?

STATEMENT OF ALLEN WEISS, M.D., PRESIDENT, NAPLES COMMUNITY HOSPITAL HEALTHCARE SYSTEM, NAPLES, FLORIDA

Dr. WEISS. Chairwoman Johnson, Representative Stark, distinguished members of the committee, thank you for the opportunity to advocate for patients, communities, care givers, and payers, whom we all agree have benefited by the use of IT in health care. My comments are based primarily on my own experiences that I believe may be typical for many care givers and leaders in health care today. More than half of the care in the United States today, as we have already heard, is from solo and small group practices of ten or fewer physicians. Naples, Florida, mirrors these demographics. By brief way of background, I was in solo private practice of rheumatology, internal medicine, and geriatrics for 23 years in Naples, Florida, before becoming President of the Naples Commu-

nity Hospital System in the year 2000. When I was asked to join the leadership team at Naples Community Hospital, we had many independent, stand-alone, best-of-breed computer systems within the building. The interfaces among these systems were always intricate to build, expensive to maintain, and difficult to use.

Learning best practices from other industries, such as manufacturing and banking, showed the wisdom of integration of systems. Having a common data repository accessible in different ways depending on the various needs of patients, providers, and payers, is key to both safety and efficiency. The push for an internal, seamless integration started seriously at Naples Community Hospital about 5 years ago. A dramatic improvement in functionality resulted from integration. This internal integration needs to be duplicated outside the hospital in the community, where the majority of patient care is rendered today. Any action facilitating integration at the time of installation is much more effective than late integration or none at all. Once computer systems are purchased, installed, and functional, they are difficult to change. Birth is easier than resurrection. Clearly, IT in health care will be the ten exchange that Andrew Grove, former chairman of the board of Intel Corporation, referred to in the past. Medical errors have been shown to decrease up to 95 percent at Vanderbilt Children's Hospital in a study published in the January 2004 issue of Pediatrics. Naples Community Hospital's experience shows over a 50 percent decrement in reported medication errors since medicine administration was automated using bar code technology and an electronic medical record. IT's remarkable effect on efficiency will be documented in a study to be published this September by Dr. Richard Homestead, Co-Director of Rand Enterprise Analysis.

Naples Community Hospital's experience with the prevention of pressure ulcers similarly reflects cost savings by decreasing the length of the patient's hospital stay. Pressure ulcers typically form on an area of the body under pressure in frail elderly patients. While the 2005 national prevalence was 7.3 percent, Naples Community Hospital's recent prevalence was 1.7 percent. The use of IT to assess risk and initiate prevention in a timely manner yielded a huge savings in terms of misery and money. The most important problem to be solved today is the propagation of IT with integration. At least four options or combination of options are possible. Number one, allow the current stand-alone best of breed systems to evolve, hoping the purchasers of these systems will only demand integration. Number two, ask State or Federal government to modify rules and regulations that would facilitate propagation of integrated IT. Number three, ask the health care IT industry to work together with payers, providers, and consumers to develop common standards. Number four, ask payers, namely the insurers, both governmental and commercial, to financially support IT, whether by direct funding or implementation or by increased reimbursement for providers who do use IT in their practices, thinking that the cost of care would decrease as care is rendered in a more efficient and safe manner. Thank you for the opportunity to assist in this important endeavor.

[The prepared statement of Dr. Weiss follows:]

Statement of Allen Weiss, M.D., President, Naples Community Hospital Healthcare System, Naples, Florida

Chairwoman Johnson, Representative Stark, distinguished members of the Committee:

Good Morning. Thank you for the opportunity to advocate for patients, communities, care givers, and payers who must benefit by the use of information technology (IT) in healthcare. My comments are based on my own experiences that, I believe, may be typical for many care givers and leaders in healthcare today.

By brief way of background, I was in solo private practice of Rheumatology, Internal Medicine and Geriatrics for twenty-three years in Naples, Florida before becoming President of the Naples Community Hospital Healthcare System (NCH) in 2000. During my last decade of private practice I used a computer system for billing purposes. During my last two years of practice I additionally used an inexpensive, commercially available voice recognition system for recording clinical information. Mine was not a "high tech" office, and I was not a "high tech" person; my situation was rather typical of many offices across the United States at that time and even today where the majority of physicians are in either solo or small group practice.

When I was asked to join the leadership team at NCH, we had many independent "stand alone—best of breed" computer systems. The interfaces among those systems were always intricate to build, expensive to maintain, and difficult to use. Learning best practices from other industries such as manufacturing and banking showed the wisdom of integration of systems. Having a common data repository that can be accessed in different ways depending on the various needs of patients, providers, and payers is the key both to safety and efficiency. The push for internal, seamless integration started seriously at NCH about five years ago. Now, this internal integration needs to be duplicated outside the hospital, in the community where the majority of patient care is rendered.

NCH is typical of many hospitals in terms of size and demographics—two locations with 539 beds, almost 4000 employees, over 35,000 admissions, 4000 births, 600 open hearts surgeries, and 130,000 emergency room visits per year. We care for all who come to our hospital, with approximately 24% of our patients uninsured, unable to pay, or on Medicaid.

We are a not-for-profit community-based system with three core competencies—demonstrative quality, operational efficiency and fiscal responsibility. Operational efficiency, with the extensive use of IT, nurtures demonstrative quality, in turn leading to fiscal responsibility.

In striving to demonstrate quality, we earned a Healthgrades top 5% overall rating and a top 5% rating in cardiac, stroke, and pulmonary along with a top 3% in patient safety. We volunteered to participate in the Center for Medicare and Medicaid Services (CMS) project to demonstrate quality. This project compares us to 277 other hospitals that have also volunteered regarding measures for congestive heart failure, acute myocardial infarct (heart attack), coronary bypass (open heart surgery), community acquired pneumonia, and joint replacement (hip and knee). We also use a balanced scorecard as popularized by Norton and Kaplan. This scorecard stresses both quality metrics and operational efficiencies in addition to the traditional financial metrics. The leadership team at NCH believes that these quality awards were facilitated by the use of IT.

NCH's most fundamental core competency is operational efficiency. Information technology is the tool that allows caregivers to provide better care more efficiently. A common metaphor concerning IT compares a hand and power drill. Both tools can produce the same end product, namely a hole, but the power drill accomplishes the task with a fraction of the energy in a fraction of the time. IT correctly used can not only drill the hole, but also guarantee that the hole was made in the right place without doing any neighboring damage. Moreover, IT's improved ease, speed, accuracy, and reliability in a process can, more fundamentally, encourage other processes to change.

Hospitals are set-ups for tremendous inefficiency. For example, a common scenario is a duplicate laboratory test: the attending physician, after assessing the patient, orders an appropriate test, followed by the consulting physician, not able to read or find the order in the chart, ordering the same test later in the day while the original test was already in progress.

Physicians using computers to enter orders will have instant, clear knowledge. In the example above, the second physician would receive a "pop up" cautionary note stating that the same test is already in progress or that the results were now available. "Do you want to order it again?" would be the question displayed. The physician could exit the order-entry routine, avoiding another needle stick for the patient, another charge for the payer, and another inefficiency for the caregiver. Having the

right information at the right time will make for a safer, more efficient environment for patients and caregivers.

Ordering and administering medicines have become more complex over time. Only 60 drugs were commonly prescribed in 1960. In 2000 almost 6000 medicines were commonly prescribed. Who can keep 6000 drug interactions in mind? No human can, but a well functioning IT system can give instant feedback for incorrect doses, inappropriate interactions, potential allergies, as well as make suggestions based on medical evidence. At NCH's smaller hospital, greater than a 50% decrease in medicine errors has been reported over the last four months since instituting a bar code system: portable bar code readers correctly identify patients wearing wrist bands with bar codes. Medicines are delivered to the bedside in bar coded containers, and nurses wear badges with bar code identification. Once the scanning is complete and the bar code reader states all is proper to proceed with the medicine administration, documentation is done automatically. A pharmacist who can intervene at any time electronically supervises the entire process. NCH's larger hospital has had the same system in place for only two months with similar positive results. IT in this situation makes caregivers more efficient and patients safer.

As previously stated, NCH has strived towards an integrated IT system since 2000. On Saturday, September 8, 2001 our almost 1000 nurses started documenting all of their notes using digital technology. This event was a sea change and retrospectively may have been the tipping point for our institution in the use of IT.

One remarkable result in saving patients from the misery of pressure ulcers has been directly related to the process change facilitated by the use of IT. Pressure ulcers are sores which form on skin areas under pressure in people who are typically debilitated, malnourished, and lying or sitting in one position. These sores, for the most part preventable, usually develop on the sacral area (backside) or the back of the heels. Each pressure sore adds suffering to the patient as well as cost to the healthcare system in terms of length of hospital stay and thousands of dollars in patient care. The national average for prevalence of pressure ulcers was 7.3% in 2005. Patients can be assessed for risk of developing pressure ulcers by using the Braden Scale Scoring System that asks six questions and produces a score from six to twenty-three, inclusive. Starting intervention after doing these scores manually is burdensome to the caregivers, and often is not done. Using IT to facilitate the scoring and alerting the appropriate caregivers has been remarkable in effectiveness.

Every patient at NCH is assessed for pressure ulcers once on admission and if at risk, daily thereafter. An elderly, malnourished, incontinent person with a fractured hip due to a fall in a skilled care facility is an example of a high-risk patient. Having a low score indicating risk for developing pressure ulcers, the patient is immediately seen by a nurse trained in prevention and given specific skin treatment. NCH's pressure ulcer rate was above 12.8% at the start of using IT to measure risk and start intervention. NCH's most recent assessment had a rate of 1.7% with no heel ulcers—a remarkable achievement.

Drexel University has a competition for the best new use of technology in healthcare; our care givers won this year for using IT to decrease pressure ulcers. IT is the "power drill" in this remarkable example that allows for a process change resulting in decreased misery, improved safety, and lower cost. Patients, communities, care givers, and payers all benefit.

Having strong integrated IT within the hospital is only the first step towards safety and efficiency. The goal of sharing health information is to have the patient, caregiver, and payer all have access to the portions of the health record that are appropriate for their respective needs. Granting practicing physicians access to the hospital system has been the most successful portion thus far. Sharing patient information from the physicians' office to the hospital has not. Thus far, information has flowed in one direction only—hospital to physician. Physician to hospital, physician-to-physician, and patient to care giver still depend on patients' and physicians' memories, copied papers, and faxes. Patients and payers continue to depend on care givers sharing clinical information in much the same way as decades ago. We practice and treat using 21st century technology, but we record and archive the same way we did in the 18th century. Demographic information is being shared by hospitals and physicians offices with payers primarily for reimbursement purposes. Having a patient both involved and informed in his or her care are two goals that have been shown to improve health and decrease anxiety. Who isn't anxious waiting for the results of a mammogram or PSA (prostate specific antigen)? Yet, we still can't report these results quickly and safely using the IT currently available. This challenge can be helped by creating a common set of standards and policies to exchange information among patients, communities, caregivers, and payers. Moreover,

neutered data shared within and among communities may be helpful for public health purposes.

Currently, NCH has about 525 physicians on staff. Over 350 of these physicians have secure access to the in-patient IT system from their offices and homes using high speed internet access. This access is in "read only" mode to borrow a term from the computer industry. Each physician purchases a key fob at cost from NCH—seventy-five dollars. Security is maintained by a series of numbers that change each minute by satellite on the fob's screen. To access the system, a person must enter the numeric code for that minute in addition to a password. Early in our process of trying to integrate our physicians with the in-patient IT system, NCH charged five hundred dollars for installation of the system in an office. Physicians in larger groups needed the billing information available on their in-patients and did buy the system primarily for that reason. These physicians needed to have high speed internet access in their offices and gradually came to the realization that it was easier to obtain lab results, vital signs, and other clinical information on their in-patients by going on-line rather than playing "telephone tag" with the nurse on the floor who might be occupied caring for another patient. NCH, realizing that the in-patient nurse became more efficient when relieved of the "telephone tag" process, decided to waive the five hundred dollar charge if the physician would also keep all of his/her hospital chart documentation up to date. NCH made this offer in conjunction with Florida's Doctors' Day in 2003.

Now, physicians may obtain lab results, vital signs, nursing notes, and consultative notes on-line in a "read only" mode at any time and in any place with computer access. Obstetricians can view "read only" fetal monitor strips that are contemporaneous measures of an unborn child's health during the labor process. Soon, physicians will be able to order medicines, lab tests, and other modalities on-line for their patients. This off-site entry capability should facilitate communication and decrease the inherent risk of phone orders which even if read back, could be misunderstood or transcribed incorrectly.

Local nursing homes, visiting home nurse companies, and more recently a mental health facility and the Medical Examiner's office also have secure access to the in-patient record. This capability has replaced the physical need for a person to travel to review a record or to fax dozens or even hundreds of pages per day to another provider. In the case of nursing home transfers, multiple nursing homes can review charts simultaneously to determine which patients are best suited for the home's particular environment. This off-site, pre-discharge review decreases a patient's hospital stay, previously devoted to in-person reviews by successive nursing facilities. In turn, costs are lowered and safety is improved.

When NCH initiated this review process at the suggestion of the Director of Patient Advocacy, concerns about security and privacy arose. The electronic environment, although not perfect, is in fact better—safer—than the paper environment. With paper, anyone in the hospital can casually pick up a chart at the nursing station and browse anonymously. Patient charts have been minimally secured for decades without patients' realization. However, to "open" a patient chart electronically, one must first have a password. Then the record is updated showing the date and time of access, what specifically was examined, and the claimed relationship of the viewer to the patient. To search for unauthorized access, the log of viewers is reviewed both randomly and also using specific algorithms. Not only are searches done on high profile patients and high profile diseases, but also records are examined for viewers with same last names and those designated as "who to notify in case of an emergency." Hospital employees are warned that invasion of privacy will result in immediate termination, and NCH has enforced this regulation already. This termination policy has proven to be an effective deterrent. Long term using IT, health care will have comfort in security now perceived in the banking and finance industry. In the paper age, people had a false sense of security and privacy.

An Electronic Health Record (EHR), for hospitals or physician offices of any size, requires support people with a variety of skills used episodically. Having full time employees to maintain hardware and software and train other employees does not take advantage of economies of scale or scope. Service personnel, as well as replacement parts, are needed for rapid repair to avoid unplanned downtime when computers are on-site. Even as a 539-bed two-hospital system, NCH could not support full time hardware service personnel on-site when needed only occasionally. NCH advantageously outsourced its main hardware, the computer server, to a specialist in remote hosting of computers. Similarly, NCH could not stock replacement parts economically. While remote hosting, web support and internet training do not obviate the need for face-to-face, hands-on employees, the need and cost are greatly reduced.

The cost of purchase, installation, maintenance, and training is a challenge for small or moderate sized groups as well. Smaller groups have the same problems in an exaggerated form. Ideally, by combining five hundred physicians and a 539-bed two-hospital system, the costs of installation, maintenance and training would come down and be manageable for everyone.

However, the major disappointment in our local health care community has been not having seamless EHR shared by the treating physicians and NCH. About eighteen months ago two local groups of physicians (one with approximately fifty-five physicians and the other forty) shopped independently for an electronic health record for their respective practices. Both ultimately purchased excellent IT products which do not interface with the equally powerful hospital system. Moreover, solo and small groups have installed "stand alone" systems that will be hard to integrate in the future. The goal of having one common community system was very attractive for many reasons including patient safety, patient and provider convenience, support personnel training, system maintenance, and overall efficiency. A unified EHR helps make an area attractive for retirees who rank health care as a major concern.

Compounding this problem, Collier County has a summer and winter population variation between a nadir of approximately three hundred thousand and peak of over four hundred thousand people. Moreover, while NCH was previously the sole hospital in Naples, now Cleveland Clinic Foundation of Collier County has an eighty-bed hospital and HMA, a for-profit hospital system, is in the permitting process to build a hundred-bed hospital. Most physician groups want to be able to interact with more than one hospital system. Most hospitals want to be able to service as many physicians and patients as possible in an efficient manner. Ideally, all EHR systems would have seamless interaction without the need for interfaces, but that is currently not the case. Complete integration would solve the problem of information transfer for patients, providers, and payers.

NCH, in spite of relatively good relations with physician groups, could not build a mutual bridge of trust to share IT resources so that patients, communities, care givers, and payers would all benefit. What went wrong or why does Collier County, Florida have three major independent systems along with several additional "stand alone" systems? First, physicians questioned whether a successful outcome was possible given that installing IT in private offices was new territory for hospital services. Second, physicians wanted to be able to practice at all three hospitals in the county and not be locked into NCH if the other two systems chose a different IT system. Third, NCH was prohibited by self-referral laws from giving support services to physicians or groups of physicians.

Any encouragement that could integrate healthcare IT within Collier County would be welcome and of benefit to all involved. Each system has advantages but having multiple different systems more than neutralizes any of the individual advantages as far as patient safety, provider convenience and payer efficiency are concerned. Hopefully, both IT companies and purchasers will understand that the next generation of software must be interoperable.

Having common standards is quintessential for seamlessness, safety, efficiency, privacy, confidentiality, economic feasibility, and the development of evidence based medicine (EBM). Currently, a wealth of clinical information is not shared because it is either in paper form or in isolated digital form. Once a common language exists, large populations may be easily and quickly studied. EBM would advance at a much faster pace than can be done currently with controlled experiments.

Common standards and digitalization of the EHR would also permit patients to have access to appropriate portions of their own medical records such as cholesterol results and blood pressure readings regardless of where they move to in the future. Patients who are involved with their own care are more compliant, are easier to care for, cost less, and have a better prognosis.

IT also allows fungible work to be performed in remote locations. Currently, radiology reading and medical transcription are done abroad. Moreover, while calculations of total parental nutrition (a therapy to assist patients who cannot take in nutrition) are complex, requiring both a pharmacist and dietician's time and attention, the math can be done anywhere in the world. Healthcare workers will always be needed in the workforce because face-to-face contact with patients is not fungible. However, healthcare workers will need to adapt by learning new skills throughout their careers and realizing that their value lies in the human interface.

Is payment for IT implementation holding back its adoption nationally? Thus far, the caregivers have paid for their IT systems, and the care givers have benefited somewhat but not as much as the patients and payers have benefited. Patients cared for in a functioning IT environment have a safer, higher quality experience while not having any additional out-of-pocket expense. Payers benefit by having

fewer duplicate tests in addition to better quality, both of which always lower cost. Similar to the patients, the payers have not had any additional expense for their cost savings. The caregivers who have paid for the installation and maintenance of IT have benefited by avoiding medical errors. However, these care givers ultimately may lose revenue due to decreased patient volume as the power of IT shifts care to the outpatient arena.

Ultimately, the right thing to do in caring for patients is to provide quality using the best tools (IT) available for operational efficiency. During evolutionary times, market share will shift as will profit margins for hospitals, caregivers, and payers. Those with the most to lose will resist the most; but in the free market with the exchange of information, change is inevitable.

The pressing issue to be solved today is seamless propagation of integrated information technology and who pays the cost.

At least four options or combinations these options are possible:

#1 Allow the current "stand alone—best of breed systems" to evolve, hoping that the purchasers of these systems will ultimately demand integration. With this option, the providers—both hospitals and physicians—continue to pay rather than payers (insurance companies) or government. This "do nothing" approach could take too long and ultimately not develop a unified system. Reminiscent of this approach is the Beta versus VHS conflict in video technology, taking time but ultimately producing a sole system.

#2 Ask state or federal government to modify rules and regulations that would facilitate propagation of integrated IT. With this approach, providers could continue to pay or government could financially support its mandate, speeding accomplishment. This government model has the advantage of universal applicability but the disadvantage of possible initial tax payer cost along with additional rules for providers.

#3 Ask the healthcare information technology industry to work together with payers, providers and consumers to develop common standards for seamless information transfer among the in-patient and out-patient environments as well as among patients and payers. Thus far, the IT industry has not produced interoperability. With this option, the providers continue to pay but will be receiving better value.

#4 Ask payers, namely the insurers—both governmental and commercial—to financially support information technology, whether by direct funding of implementation or by increased reimbursements for providers using information technology, thinking that the cost of care would decrease as care is rendered in a more efficient and safe manner. This approach would create more EHR care givers, perhaps allowing Option #1 to evolve faster or pressuring Option #3 to mature sooner.

Thank you for the opportunity to assist in this important endeavor.

Chairman JOHNSON. Thank you very much, Dr. Weiss. Ms. Pritts?

STATEMENT OF JOY L. PRITTS, ASSISTANT RESEARCH PROFESSOR, HEALTH POLICY INSTITUTE, GEORGETOWN UNIVERSITY

Ms. PRITTS. Good morning. Madam Chairman, Congressman Stark, members of the Subcommittee on Health, I would like to thank you for inviting me today to testify on the confidentiality of health information as the National Health Information Infrastructure continues to develop. As I was introduced, my name is Joy Pritts and I am Assistant Research Professor at Georgetown's Health Policy Institute. I have studied medical privacy issues, in particular medical privacy laws, for a number of years now, and I have spent a lot of time looking at State health privacy laws and the Federal privacy laws and how they interact with each other. Everyone seems to agree that as we develop a national Health Information Infrastructure and continue to push for this electronic exchange of health information, that protecting the privacy of the health information is an admirable goal and this is something that

we should be doing. The question remains, even after all that has gone on up to this point, how to accomplish that goal. A comprehensive minimal Federal standard supplemented by Federal privacy laws is what we are working with today. I would say that, at a minimum, that is where we should end up.

Where we should not end up is relying on the HIPAA privacy rule as it is written now as a national Federal standard. The HIPAA privacy rule standing on its own in the absence of higher State privacy protections is simply inadequate. It does not cover many of the people and organizations who will have access to health information on the National Health Information Infrastructure as it is envisioned, and it was designed as a minimal set of standards from the outset. I would first like to briefly address the scope of HIPAA as it is currently written. It is our only generally applicable Federal privacy standard for health information. It is not enough. It is not broad enough. The way HIPAA was written, it covers only a core group of people and organizations that hold health care information: Health plans, health care clearinghouses, and health care providers who transmit health information electronically for certain administrative and financial purposes, usually in connection with processing health insurance and claims and things of that nature.

Because of the way it is written, HIPAA is very limited in who it covers. It doesn't even cover everybody in the core group of those who hold and use health information on a regular basis. For example, it does not cover health care providers who don't engage in health care insurance transactions. That means that health care providers who provide health care services over the Internet and accept credit cards are not covered by HIPAA. This is an increasing area of medical practice. People turn to the Internet for medical care, for one thing, in order to keep their medical information private and out of their other medical records, but also because they don't have health insurance and they have found this to be one mechanism that they can pay for their own health care at a reasonable level, is turning to the Internet. They are not covered by the Federal privacy protections. Beyond this core group that HIPAA does cover, it doesn't cover all of the other entities that receive health care information from the core group. It doesn't cover them directly. It doesn't cover Workers' Comp. It doesn't cover life insurance. In particular, it doesn't cover some of the people who are essential to the use of health care information.

It also does not cover, according to the Department of Justice, employees of covered entities, and that is something that really needs to be remedied as we move forward. I would also like to emphasize that HIPAA sets minimal standards. It was conceived that way. It was written that way. When HHS received comments on the privacy rule and people requested them to set high standards for certain medical conditions, such as HIV, mental health treatment, consumers were reportedly told, this is the floor. We are not set out to set maximum or even best business practices. You can always turn to your State laws, and States have filled that gap where HIPAA has not reached a very high standard. Eliminating State law, as some have proposed to do, to set a uniform standard in order to ease the exchange of health care information would

drastically lower consumer privacy rights and protections. We should not use the development of the National Health Information Infrastructure as an excuse to reduce privacy protections of health information to the least common denominator. Thank you.

[The prepared statement of Ms. Pritts follows:]

Statement of Joy L. Pritts, Assistant Research Professor, Health Policy Institute, Georgetown University

I. Introduction

Madam Chairman and Members of the Subcommittee on Health of the House Committee on Ways and Means: Thank you for the opportunity to testify before you today on protecting the confidentiality of health information and health information technology (IT).

My name is Joy Pritts. I am a lawyer and an Assistant Research Professor at GeorgetownUniversity's Health Policy Institute. In my position at Georgetown, I conduct research and analysis on a range of health privacy issues. Much of my work has focused on the Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), its scope and its interaction with state health privacy laws. I have written extensively on this topic including: *The State of Health Privacy* (2002); *Implementing the Federal Health Privacy Rule in California* (2002); "Altered States: State Health Privacy Laws and the Impact of the Federal Health Privacy Rule," *Yale Journal of Health Policy, Law, and Ethics* (Spring 2002); and "Preemption Analysis Under HIPAA—Proceed with Caution," *In Confidence* (April 2003); and state-specific consumer guides on how to obtain and correct or amend medical records under a combination of the HIPAA Privacy Rule and state law, available at *http://hpi.georgetown.edu/privacy/records.html*.

My testimony today will focus on what, if any, actions the federal government should take with respect to protecting the confidentiality of health information in order to facilitate the electronic exchange of health information, including the development of a national health information infrastructure (NHII). In particular, my testimony will address why, at a minimum, the HIPAA Privacy Rule must be expanded to directly cover all who have access to individually identifiable health information. I will also discuss the importance of protecting the ability of states to build on the floor of federal privacy protections, as is currently permitted by HIPAA.

II. Background

The electronic exchange of health information has the potential to improve the quality of health care. Electronic records will be more complete, legible, and more accessible to providers. These features should lead to improved quality of care, the elimination of repetitive tests and a streamlining of the administrative process. Under the right circumstances, electronic medical records should also be more secure than paper records.

The risks of a computer-based health information system, however, remain real. Computerization of medical records will make large amounts of detailed personal data more readily accessible and transferable not only to health care providers but to others. When a breach in confidentiality occurs, it is often with respect to hundreds if not thousands of records at a time. For example, several thousand patient records at the University of Michigan Medical Center containing names, job status, treatment information and other data were inadvertently posted on public Internet sites for two months.[1]

Unintentional disclosure is not the only threat to heath information in electronic format. Some people improperly access and disclose medical records because they want to make money. A hospital employee sold country singer Tammy Wynette's medical records to the National Enquirer and Star tabloids.[2] Hospital employees in New York sold emergency room patients' information to attorneys and others to use in insurance scams.[3] Recently, an employee of cancer clinic accessed the medical records of a patient with terminal cancer, obtained credit cards in the patient's name, and ran up over $9000 in charges.[4]

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[1] "Black Eye at the MedicalCenter," *The Washington Post*, February 22, 1999, p. F5.

[2] Selling Singer's Files Gets Man Six Months," *Houston Chronicle*, December 2, 2000, p. A2.

[3] Office of the District Attorney, Nassau County, New York, Press Release, November 23, 2004, *available at* http://www.nassauda.org/dawebpage/pressreleases/NUMC%20arrests.htm

[4] U.S. Attorney's Office, Western District of Washington, Press Release, "Seattle Man Pleads Guilty in First Ever Conviction for HIPAA Privacy Rules," August 19, 2004, available *at* http://www.usdoj.gov/usao/waw/press—room/2004/aug/gibson.htm

Others improperly access medical information to use against or embarrass a person. As New York Congresswoman Nydia Velasquez testified before the Senate Judiciary Committee, her medical records—including details of a bout with depression—were faxed from a New York hospital to a local newspaper and television station on the eve of her 1992 primary.[5] On a more local level, the medical records of a Maryland school board member, who had been treated for depression, were sent to school officials as part of a campaign criticizing his performance.[6]

Still others improperly access and disclose medical information out of curiosity. An employee at a major hospital in Washington DC learned that one of her co-workers had HIV when she improperly accessed his medical record to find out why he was hospitalized. The employee revealed the patient's HIV status to other co-workers who ostracized him.[7] When former President Clinton was in the hospital for heart surgery 17 hospital workers who had nothing to do with his health care improperly tried to access his medical records. Perhaps most disturbing was the reaction of the hospital employees, one of whom commented, "I'm not surprised. People are nosy. It happens all the time."[8]

The risks of having medical information improperly accessed and disclosed are shared by nearly everyone: people going through a divorce or custody dispute; people who work in the health care system and who also happen to be patients of that system; people who live in small communities; and people with medical conditions that may subject them to stigma or discrimination. The consequences can be severe. People fear that they will be ostracized, that they may lose their custody battle, a political race, their job, or their insurance.

As we continue to move toward the computerization of medical information, it is imperative to ask whether there are adequate privacy laws in place to reduce, if not eliminate, these risks. The HIPAA Privacy Rule is not sufficient. It is not broad enough to cover all of those who have access to health information, especially the growing number who will have electronic access. Furthermore, because HIPAA is designed to provide a minimal floor of privacy protections it is important that states retain their ability to offer higher levels of privacy protection.

III. Federal Privacy Protections Should Apply To Everyone Who Receives Or Creates Identifiable HEalth Information

HIPAA and the Privacy Rule issued under the Act only directly cover a core group of those who hold and maintain health care information (known collectively as "covered entities"): health care providers who transmit health information electronically in connection with certain financial and administrative purposes, health plans and health care clearinghouses. As the Department of Health and Human Services (HHS) noted, "Unfortunately, this leaves many of the people and organizations that receive, use and disclose protected health information outside of the system of [federal] protection."[9] First, HIPAA does not cover all health care providers. Only providers who transmit health information electronically for certain administrative and financial transactions (largely related to insurance) are covered by HIPAA. For example, an increasing number of health care providers offer health services directly to consumers over the Internet, accepting only credit card payments. These providers are beyond the scope of HIPAA.

Other examples of persons who receive and use information and who are not covered by HIPAA include workers compensation carriers, researchers, life insurance issuers, employers and marketing firms. HHS also lacks the authority to directly regulate many of the persons that covered entities hire to perform administrative, legal, accounting, and similar services on their behalf, and who would obtain health information in order to perform their duties (called "business associates").[10]

Although HHS attempted to fill some of these gaps by requiring covered health care providers and health plans to enter into contracts that require those who perform services on their behalf (known as "business associates") to protect the con-

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[5] A. Rubin, "Records No Longer for Doctors' Eye Only," *Los Angeles Times*, September 1, 1998, p. A1

[6] C. Samuels, "Allen Makes Diagnosis of Depression Public; Medical Records Mailed Anonymously," *The Washington Post*, August 26, 2000, p. V1.

[7] P. Slevin, "Man Wins Suit Over Disclosure of HIV Status," *The Washington Post*, December 30, 1999, p. B4.

[8] J. Lite, D.Epstein and C. Katz, Clinton File Snoopers Rapped," New York Daily News, September 11, 2004, available at http://www.nydailynews.com/news/local/story/230961p–198366c.html

[9] U.S. Department of Health and Human Services, *Preamble, Standards for Privacy of Individually Identifiable Health Information; Proposed Rule*, 64 Fed. Reg. 59918, November 3, 1999, p. 59923.

[10] See 64 Fed. Reg. 59923.

fidentiality of the health information that they receive, HHS has no enforcement authority over these recipients. If business associates violate their contracts, HHS cannot impose civil or criminal penalties against them.

Similarly, it appears that HHS may not have the authority to impose criminal penalties against individuals who improperly obtain or disclose individually identifiable health information even if they act for profit. HIPAA provides for criminal penalties for persons who knowingly in violation of the Act obtain or disclose individually identifiable health information relating to an individual.[11] The Act provides the most substantial criminal penalties for those who commit these acts under false pretenses or with intent to sell or use the information for commercial purposes, personal gain or malicious harm.[12] The United States Department of Justice has recently taken the position that these criminal penalties generally apply only to covered entities. Employees and others who improperly obtain and use health information (even if it is for profit or to cause serious harm to another) may not be prosecuted under this section.[13] Under this interpretation, the hospital employees described above who sold emergency room patient information to lawyers could not be prosecuted under HIPAA.

These gaps in federal privacy protection coverage leave large volumes of identifiable health information vulnerable to improper access and disclosure without any real remedies. The promotion of the electronic exchange of health information heightens the urgency of filling these gaps through federal legislation. Forming a national health information infrastructure without adequate federal privacy protections threatens not only the privacy of patients but also the very viability of such a system.

III. Higher State Health Privacy Protections Should Remain In Place

It is important to preserve the ability of states to impose more protective privacy standards on the use and disclosure of health information as we encourage the electronic exchange of health information. As currently written, HIPAA sets a federal floor for the protection of health information. The HIPAA Privacy Rule overrides (preempts) state laws that are less protective of privacy. However, state laws that provide health information privacy protections that are equal to or greater than those contained in the HIPAA Privacy Rule remain in place. These state laws offer additional privacy protection to people with medical conditions that often subject them to stigma or discrimination, such as HIV or mental health conditions. They give patients greater access rights to their own health information.

Many in the health care industry would like to preempt all state health privacy protections so that the HIPAA Privacy Rule would serve as the uniform, national standard for protecting the privacy of health information. However, doing so would directly contradict a key, underlying premise of the HIPAA Privacy Rule. The Rule was explicitly conceived, written and issued as the minimally acceptable standard upon which states could build. Indeed, the ramifications of nullifying stronger state privacy laws are enormous and could be quite negative for patients on a number of fronts.

In considering these issues, it is imperative to remember how we got to where we are today. States have traditionally exercised power over the health and welfare of their citizens. Over the years, states have developed an extensive range of statutes and regulations that protect the privacy of health information. Every state has some statute or regulation governing the use of health information. These laws can be found in health provider licensing laws, insurance laws, public health laws, the rules of evidence and civil procedures. Many states developed statutes and regulations that specifically address the use and disclosure of health information in a detailed and comprehensive fashion. In response to the needs of their citizens, most states have laws that provide privacy protections specifically for information related to medical conditions that are often associated with stigma or discrimination, such as HIV or mental health conditions.

Additionally, in the 40 years preceding the issuance of the Privacy Rule, most states developed common law through court cases where people sued for the improper disclosure of their health information, often based on invasion of the right to privacy. The level of privacy protection afforded by the states, however, varied

[11] 42 U.S.C. § 1320(d)-6(a).

[12] 42 U.S.C. § 1320(d)-6(b).

[13] U.S. Department of Justice, letter for Alex M. Azar II, General Counsel, Department of Health and Human Services, June 1, 2005, *available at* http://www.usdoj.gov/olc/hipaa—final.htm

widely. Some states had broad, detailed privacy protections for health information while others had few protections.[14]

As efforts to encourage the health care industry to adopt computer technology intensified it became apparent that there was a need for at least minimum federal standards to protect the privacy of health information. Beginning as early as 1980, Congress attempted to pass health privacy legislation. In 1996, Congress once again took up the issue of health privacy, this time within the context of HIPAA. The Administrative Simplification provisions of HIPAA were designed to encourage the development of an electronically based health care system. Recognizing that protecting the privacy of health information was an important component of this system, Congress set itself a 3-year deadline for enacting comprehensive health privacy legislation. If Congress failed to act in that time, HHS was directed to write and issue health privacy regulations. HIPAA expressly provides that these federal regulations will not supercede a contrary provision of state law if the state standard is more stringent than the standards imposed by the federal regulations.

Congress was unable to pass comprehensive health privacy legislation within the 3-year period. No national consensus could be reached on some of the more difficult policy issues surrounding the protection of health information (such as the appropriate level of protection for HIV information or for genetic information and the right of an individual to sue for improper disclosures of information). Accordingly, the duty to craft federal health privacy protections passed to HHS.

Throughout the rule-making process, HHS consistently maintained that it was establishing minimum federal standards, which would not disturb more protective state laws. In explaining its approach to the Privacy Rule, HHS stated:

It is important to understand this regulation as a new federal floor of privacy protections that does not disturb more protective rules or practices. Nor do we intend this regulation to describe a set of a "best practices." Rather, this regulation describes a set of basic consumer protections and a series of regulatory permissions for use and disclosure of health information. The protections are a mandatory floor, which other governments and any covered entity may exceed.[15]

In response to public comments requesting additional privacy protection for HIV/AIDS information, HHS again explained that it was taking a minimalist approach:

Where, as in this case, most states have acted and there is no predominant rule that emerges from the state experience with this issue, we have decided to let state law predominate. The final rule only provides a floor of protection for health information and does not preempt state laws that provide greater protection than the rule. Where states have decided to treat certain information as more sensitive than other information, we do not preempt those laws.[16]

One and half years later, HHS responded to consumer concerns about the elimination of the requirement that covered entities obtain patient's consent to use or disclose identifiable health information for treatment, payment, and health care operations, by reassuring them that state privacy protections would remain in place. HHS stated:

The Privacy Rule provides a floor of privacy protection. State laws that are more stringent remain in force. In order to not interfere with such laws and ethical standards, this Rule permits covered entities to obtain consent. Nor is the Privacy Rule intended to serve as a "best practice" standard.[17]

In short, from beginning to end the Privacy Rule has been built on the understanding that it would serve as a minimal floor of protection and that state laws affording higher protections would be preserved.

As a result, many state laws remain in effect. Some of these state laws afford a higher degree of protection to sensitive medical information, such as information related to genetic testing, HIV or mental health. States continue to afford their citizens the right to sue for improper disclosures of their privacy or to obtain their medical records.

Many in the health care industry would eliminate these higher state health privacy protections in the interest of having more uniformity. The Privacy Rule has set minimal standards in every state. It has effectively created privacy standards

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[14] See J. Pritts, "Altered States: State Health Privacy Laws and the Impact of the Federal Health Privacy Rule," *Yale Journal of Health Policy, Law, and Ethics* (Spring 2002).

[15] Preamble, Standards for Privacy of Individually Identifiable Health Information; Final Rule, 65 Fed. Reg. 82461, December 28, 2000, p. 82471.

[16] *Preamble, Standards for Privacy of Individually Identifiable Health Information; Final Rule*, 65 Fed. Reg. at 82731.

[17] *Preamble, Standards for Privacy of Individually Identifiable Health Information; Final Rule (as Modified)* 67 Fed. Reg.53192, August 14, 2002, p.53212.

in states where few existed and raised standards in those with few protections. By establishing a federal floor of health privacy protections, HIPAA has already substantially evened the playing field. (See App. Fig. 2). Moreover, in response to the HIPAA Privacy Rule, many states have taken the initiative to re-examine their own health privacy laws. As a result, some states have amended their privacy laws, where appropriate, so that they are more closely aligned with the HIPAA standards. In practice, this voluntary action has also produced more uniformity.Preempting all state health privacy protections in the interest of producing yet more uniformity would have serious and wide spread ramifications. As discussed above, the HPAA standards are meant to be minimum standards. They were never intended to serve as the sole standard for protecting identifiable health information. Eliminating state law and relying on the HIPAA Privacy Rule would effectively lower the privacy protections in place for some of the most vulnerable health care consumers (such as mental health patients and those with HIV). (See App. Fig. 3) In many states, it would overturn hard-fought compromises over some of the very issues on which Congress has not been able to reach consensus. Such an approach would eradicate over 40 years of state common law giving consumers the right to sue for the improper disclosure of medical records. Given the variety of state laws that are designed to protect the privacy of health information it is difficult to predict the full range of consequences of such an approach. It is clear, however, that preempting state health privacy protections would seriously undermine states' traditional ability to protect the health and welfare of their citizens.

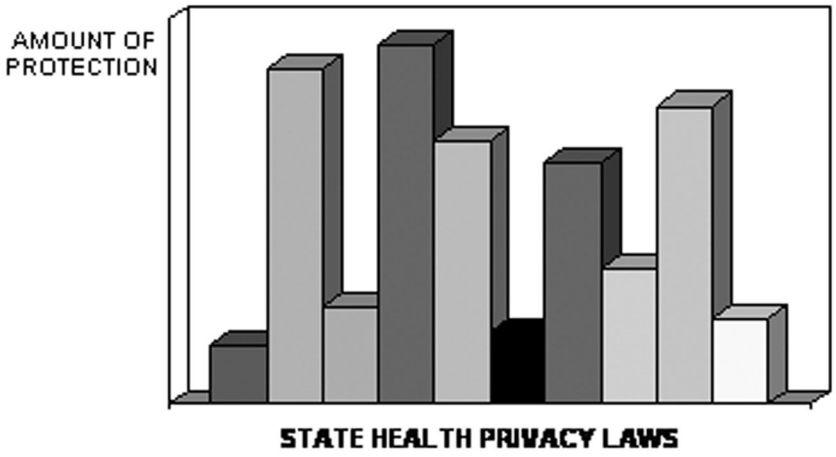
IV. Conclusion

As we continue to move toward the electronic exchange of health information and the creation of a national health information infrastructure it is crucial that the privacy of health information not be compromised in the interest of expediency. Federal privacy protections for health information should be expanded to ensure that standards for using and disclosing health information are in place for everyone who receives or creates identifiable health information. Federal law also should ensure that those who improperly obtain use and disclose health information are subject to civil and criminal penalties.

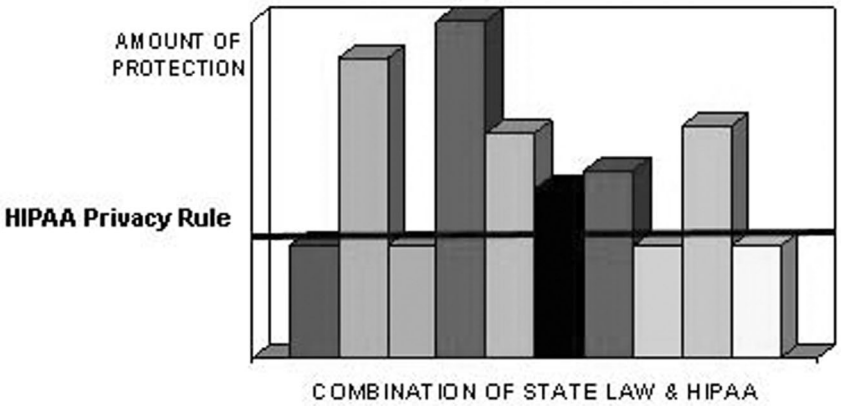
State laws that set higher standards for protecting the privacy of health information should remain in place. The HIPAA Privacy Rule is simply not adequate.

Uniformity—At What Cost?

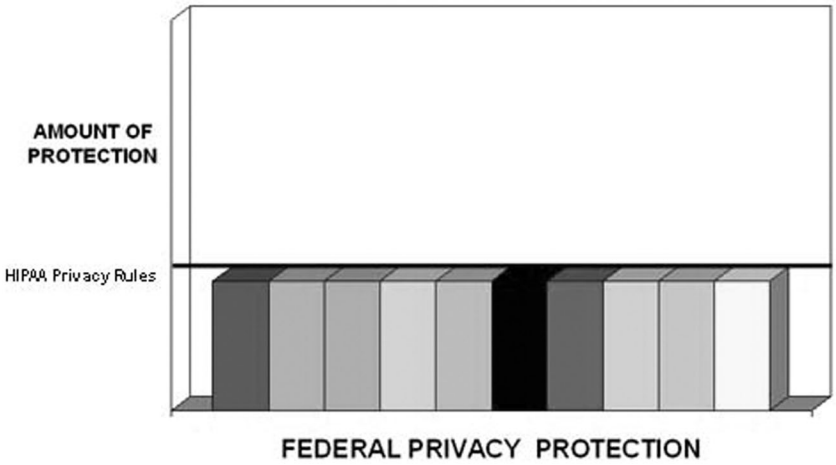
Health Privacy Protections Before HIPAA (Fig. 1)



Healh Privacy Protections After HIPAA (Fig. 2)



Health Privacy Protections—State Law Preempted by HIPAA (Fig. 3)



Chairman JOHNSON. Thank you, Ms. Pritts. Ms. Grealy?

STATEMENT OF MARY R. GREALY, PRESIDENT, HEALTHCARE LEADERSHIP COUNCIL

Ms. GREALY. Thank you, Chairman Johnson, Congressman, Stark, and distinguished members of the Subcommittee. On behalf of the members of the Healthcare Leadership Council, I would like to thank you for this opportunity to testify today. We are pleased to share with you some specific recommendations regarding ways in which Congressional action can clear the way for greater progress in the adoption of health IT. Madam Chairman, there are at least two things that we know with certainty on this issue, one good and one is a matter of concern. We know that the promise of

health IT is enormous. With widespread use of new technology, we can deliver health care with greater efficiency, bring about tremendous advances in patient safety, and literally transform our health care system to better utilize the wealth of knowledge and ideas that are possessed by health professionals throughout the country. We also know that there are obstacles that must be overcome before we can move forward. On that subject, I would like to turn specifically to the issue of privacy. Now, there is a misconception that the HIPAA privacy rules may not adequately protect the confidentiality and security of electronic medical information transmitted across a national health care network. We think that these concerns are not well founded.

The HIPAA privacy and security rules were created specifically to protect electronic transfers of financial and administrative information. Significant civil and criminal penalties exist for improper disclosure. These strong safeguards also exist for clinical records. What is troubling, though, is the fact that the HIPAA privacy rule as it exists today does not always supercede State laws and regulations, and, in fact, it permits significant variations in the ways in which States can regulate medical privacy matters. As a result, providers, clearinghouses, and health plans are required not only to comply with the Federal law, but they also must comply with State privacy restrictions that are more stringent than the HIPAA rule. This will make the creation of an effective health information network, one that crosses that State boundaries, virtually impossible, and I think we heard that from Dr. Brailer this morning. Let us paint a very realistic scenario. A health care provider wants to acquire and implement a new health IT system that will allow them to be part of an interstate information network. This health provider knows that privacy protections vary widely State to State and are found in literally thousands of statutes, regulations, common law principles, and advisories.

So, our hypothetical health care provider must, number one, find and identify every possible privacy-related rule, statute, law, and ordinance. Number two, they must obtain legal opinions as to whether the State laws are contrary to HIPAA and whether the contrary rules are more stringent. Number three, they must figure out how to comply with either the Federal rule, the State rule, or in some cases, both simultaneously. Then they must build their computer systems in a manner that ensures compliance, realizing that these laws can change even before the system is finalized. I have provided the Committee with a much more detailed nine-step process for determining this compliance for just one State. It will be much more complex when dealing with all 50 States. At the HLC, we understand the challenge that HIPAA-covered entities face because we took the initiative to commission a multi-jurisdictional study of State privacy laws and regulations to help with compliance. It is a study that initially cost more than $1 million and must continuously be updated, at considerable cost, to reflect any newly-enacted State privacy rules and regulations. Now, once the National Health Information Network is in place, systems will have to be constantly retooled, staffs continually retrained for these variations among the States. A network that is constrained by myriad State requirements on, for example, prior consent to use health

care records for treatment, will operate at only a fraction of the speed and efficiency necessary to improve patient outcomes. Much of the promise of this new technology will be lost as a result.

So, what is the answer? Madam Chairman, the current patchwork of applicable State and Federal privacy laws will be a severe disincentive for stakeholders who would otherwise be enthusiastic about participating in a national Health Information Network. Our solution is both clear cut and essential. Congress must enact Federal preemption provisions that will establish a unified national privacy standard. A uniform patient privacy framework is critical to the viability and interoperability of National Health Information Network. We stand on the verge of doing something extraordinary for patients, for health care consumers, and for our entire health care system. We urge Congress to take the final steps necessary to make the promise of health IT a reality. The members of the Healthcare Leadership Council, many of whom were the earliest adopters of electronic medical records and pioneers of this technology, look forward to working with you and the Committee on this shared vision. Thank you.

[The prepared statement of Ms. Grealy follows:]

Statement of Mary R. Grealy, President, Healthcare Leadership Council

Chairman Johnson and Members of the Subcommittee, I want to thank you on behalf of the members of the Healthcare Leadership Council (HLC) for the opportunity to testify on the adoption of health information technology (HIT) and areas where Congressional involvement can further these efforts.

The Healthcare Leadership Council supports the efforts of the President, the Office of the National Coordinator for Health Information Technology (ONCHIT), and the Congress, to create a national health information infrastructure. We believe that legislation should especially focus on areas where Congress and the President *must act* to facilitate successful implementation of HIT. We believe that one such area is harmonization of state laws regarding the confidentiality of individually identifiable patient information.

Any regional or national system designed to facilitate the sharing of electronic health information must adequately protect the confidentiality of patient information. Efforts to establish a National Health Information Network or NHIN must take into account the privacy and security challenges associated with exchanging patient information among health care providers, consumers, payers and other authorized entities. Addressing these issues appropriately will be essential to achieving the interoperability necessary to improve the quality and cost effectiveness of the health care system—while still assuring patients' confidence that their information will be kept private.

Confidentiality of patient medical information is governed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) statute and the privacy regulation promulgated thereunder (the Privacy Rule). Although HIPAA establishes a federal privacy standard, it permits significant state variations that will create serious impediments to "interoperability" of clinical information, particularly when information is sent across state lines. The patchwork of applicable state and federal laws will likely be a significant disincentive to participation in a national health information network for virtually all stakeholders. We believe Congressional action to establish a uniform federal privacy standard will help to ensure the viability of a national health information network. This is an important step that Congress can take to facilitate progress toward interoperability.

Before I discuss the importance of these actions, let me first explain the perspective that HLC brings to the issue. HLC is a not-for-profit membership organization comprised of chief executives of the nation's leading health care companies and organizations. Fostering innovation and constantly improving the affordability and quality of American health care are the goals uniting HLC members. Members of HLC—hospitals, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies and academic medical centers—envision a quality driven system built upon the strengths of the private sector. Several HLC member organizations have been among the earliest adopters

and pioneers of health information technology. We believe HIT has the power to transform our health care system and provide increased efficiencies in delivering health care; contribute to greater patient safety and better patient care; and achieve clinical and business process improvements.

Since 1996, HLC has led the Confidentiality Coalition, a broad-based group of organizations who support workable national uniform privacy standards. The Confidentiality Coalition includes over 100 physician specialty and subspecialty groups, nurses, pharmacists, employers, hospitals, nursing homes, biotechnology researchers, health plans, pharmaceutical benefit management and pharmaceutical companies.

During Congressional consideration and subsequent regulatory development of the HIPAA Privacy Rule, the Confidentiality Coalition played a leadership role, working with members of Congress and the administration to advocate for a workable privacy rule. We sought a rule that would strike the appropriate balance between protecting the sanctity of a patient's medical information privacy while, at the same time, ensuring that necessary information is available for providing quality health care and conducting vital medical research. We believe that the Privacy Rule largely achieved this balance and has increased consumers' confidence about the privacy of their medical records while allowing providers and payers to establish the procedures necessary to accomplish the dual goals of privacy protection and the delivery of quality health care.

Under the Privacy Rule, disclosing individually identifiable health information for purposes other than carefully defined appropriate health care activities is prohibited unless the patient grants specific, prior written authorization. For example, among others, information cannot be disclosed to employers, the media, or neighbors. It is important to note that HIPAA has strong penalties for non-compliance. The Department of Health and Human Services (HHS) may impose civil monetary penalties on health plans, providers or clearinghouses of up to $250,000 for failure to comply with a Privacy Rule requirement. HIPAA also has criminal penalties. Persons who knowingly obtain or disclose individually identifiable health information in violation of HIPAA face a fine of $50,000 and up to one year of imprisonment. Criminal penalties increase to $100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses. Penalties for wrongful conduct that involve the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain or malicious harm increase to $250,000 and up to ten years imprisonment. Criminal sanctions are enforceable by the Department of Justice—and there has already been one criminal conviction under the rule. Thus if you use a patient's record, without permission, for reasons other than legitimate health care operations, you could be sanctioned with severe federal civil and criminal penalties.

As Congress and the Administration have considered the issues relating to the facilitation of a national health information network, questions about the privacy and security of electronic medical information have arisen. A common misperception is that the HIPAA rules may not adequately protect the confidentiality and security of electronic medical information in the context of an NHIN. It is important to remember that the HIPAA privacy and security rules were adopted to provide appropriate safeguards for the *electronic exchange* of financial and administrative information, and the regulation expanded this to also include paper records. The electronic exchange of clinical information is no different.

Thus, HLC and the Confidentiality Coalition believe that the existing HIPAA Privacy Rule provides strong privacy protections—effective to address the privacy and security challenges associated with exchanging patient information among health care providers, consumers, payers and other authorized entities in the context of a NHIN.

However, we are troubled by the fact that the HIPAA Privacy Rule's preemption standard permits significant state variation. In general, HIPAA supersedes contrary provisions of state law. For example, the HIPAA standards for the electronic exchange of financial and administrative information, such as health insurance claims, preempt state laws that require billing records to be maintained or transmitted in written rather than electronic form. Congress, however, set a different preemption standard for privacy protections under HIPAA. The Privacy Rule does not supersede contrary state laws that are more stringent than the federal standard. As a result, providers, clearinghouses and health plans are required to comply with the federal law as well as any state privacy restrictions that are more stringent. In the context of HIPAA implementation this has been extremely difficult. In the context of a NHIN it is potentially impossible.

State health privacy protections vary widely and are found in thousands of statutes, regulations, common law principles and advisories. Health information privacy

protections can be found in a state's health code as well as its laws and regulations governing criminal procedure, social welfare, domestic relations, evidence, public health, revenue and taxation, human resources, consumer affairs, probate and many others. The rules typically apply either to specific entities—such as hospitals or county health departments—or to specific health conditions, and no two states are the same in this regard. Virtually no state requirement is identical to the federal rule.

Thus HIPAA covered entities, such as hospitals, physicians and health plans, must find every possible state rule, statute, law, ordinance, etc. concerning every aspect of privacy, obtain a legal opinion as to whether or not the law, regulation or ordinance is contrary to the HIPAA privacy rule, and then determine if the contrary state rule is more stringent than the federal rule. Once this analysis is complete, covered entities must then determine how to comply. Within one state, there may be cases where the federal law applies and in others where both federal and state law applies. At that point, covered entities must build their information technology systems to implement the legal interpretation and hope that there isn't a change in law before the systems are up and running. But since nothing prevents additional state privacy rules and regulations from being enacted, it would take constant monitoring of state action, retooling of systems and retraining of staff.

HLC attempted to assist covered entities in this process by commissioning a multi-jurisdiction study of state privacy laws, case law and regulations that analyzes the relationship between the federal Privacy Rule and state laws. The study is formatted as a website where authorized users can search state laws on a particular subject and determine whether or not they must comply with the state law, the HIPAA Privacy Rule, or both. The study initially cost more than $1 million and costs $100,000 to update annually. The Department of Health and Human Services made it clear when issuing the Privacy Rule that it would not provide this analysis and that covered entities must determine whether federal or federal and state law applies.

The issues associated with privacy compliance are greatly magnified in the context of a NHIN. The creation of a successful NHIN will require a national system of interoperable systems that can exchange health information. Making information available through or to a NHIN conceivably could require entities to comply with a range of different state laws each time they disclose information in the context of a federated system.

Some proposals attempt to address the patchwork of state privacy laws and regulations by suggesting that states should work together regionally to develop privacy agreements or harmonize state requirements. This would require states to review their own laws, regulations and ordinances, reach consensus with the other states on uniform rules, get the agreement enacted within each state without modification and ensure that existing rules are preempted. However, unless all 50 states agree to the same rules, this will not be adequate to address the problem of conflicting state regulation relative to interoperability of HIT nationwide.

My testimony includes, as an attachment, a map developed by the Indiana Network for Patient Care. Each dot represents a patient seen at an Indianapolis hospital during a six month period. While the dots are stacked very deep around Indianapolis as you would expect, patients served by the Indiana health providers during this period were also located in 48 of the 50 states. Looking at this map it is easy to see why regional agreements will not be adequate to address the myriad regulations with which providers and others will need to comply to achieve "interoperability."

One of the most common areas for states to legislate regarding privacy is that of patient consent and authorization for uses of their medical information. There are prolific and varying state requirements regarding who may access patient information, for what reason, and with what type of notice and consent to patients. During promulgation of the HIPAA Privacy Rule, the issue of requiring providers and payers to obtain the prior written consent of patients before using their information was examined and debated at great length. The final rule as modified allows covered entities to use patients' medical information without prior authorization for medical treatment, claims payment or health care operations, or as otherwise permitted or required by the Privacy Rule [1] For any other uses, providers must obtain a written authorization from each patient.

[1] Under the Privacy Rule a covered entity is permitted to use and disclose protected health information without authorization for the following purposes or situations: 1) to the individual; 2) for treatment, payment and health care operations; 3) for uses and disclosures with an opportunity to agree or object; 4) for uses and disclosures that occur incident to an otherwise per-

Continued

Requiring providers and payers to obtain prior consent for treatment, payment and health care operations was rejected because of concerns that a prior authorization requirement would seriously delay and disrupt the care of patients, particularly the most vulnerable elderly and sick patients. For example, elderly patients would not be able to send a family designee to a pharmacy to pick up a prescription without first going to the pharmacy to sign consent forms; pharmacies would not be able to fill prescriptions for patients phoned in by physicians; and emergency medical personnel would be forced to get consent forms signed before treating patients—even when contrary to best medical practice. These concerns were not simply theoretical. Maine passed a law requiring prior consent for health care purposes, the law was suspended just 12 days after taking effect because of the chaos that ensued in hospitals and pharmacies.

One of the primary goals of a national health information network is to improve the quality of health care by giving providers the information they need quickly. A NHIN that is constrained by various state authorization or consent requirements will provide only a fraction of the speed and efficiency necessary to improve patient outcomes. These unnecessary requirements are extremely burdensome for providers, impeding their ability to provide timely and efficient medical services. Even worse, they offer little value to patients. Varying notice provisions which force covered entities to provide notice to patients in triplicate are simply not helpful to patients who are more likely to be overwhelmed by the paperwork these requirements necessitate. It would be much better for patients if they, providers and payers could rely on a uniform standard based on the principles of the HIPAA Privacy Rule—that information can be used and disclosed only by authorized persons in order to provide and pay for medical care—and that information will be kept confidential.

As a NHIN becomes a reality, we fear that states may also begin to legislate the degree to which patients can control their own electronic health record—deciding who can access what information for which reasons. Especially in emergency situations, where treatment is a matter of life and death, electronic health records can be a life-saving tool for clinicians. However, if electronic records are to be utilized as a part of care delivery, patients simply must not be able to selectively provide information that may be relevant for treatment purposes. Should this occur, providers would be unable to rely on the NHIN as a tool for diagnosis and treatment as it may or may not include the facts necessary for the delivery of quality medical care. In addition, providers are very concerned about the liability that might result from their reliance on incomplete information.

In conclusion, I reiterate the belief that the current patchwork of applicable state and federal laws is a significant disincentive to participation in a national health information network for virtually all stakeholders. Indeed, already HLC members working with emerging state consortia are reporting difficulty in navigating the variations in state privacy laws among bordering states.

We believe that it will be extremely difficult to achieve interoperability without a more uniform framework for the protection of patient privacy. Absent such a framework, the barriers to using health information technology to improve the quality and efficiency of health care will be substantial and covered entities will be discouraged from participating. Federal preemption provisions that establish a unified national standard are essential to the viability of a NHIN. We believe the HIPAA Privacy Rules should be the national standard and should supersede state laws. Covered entities already have established HIPAA compliance programs, appointed privacy officers and implemented extensive staff training. But more importantly, we believe that HIPAA provides the privacy and confidentiality protections demanded by consumers and can set a high, uniform standard for health information practices across all states.

The Healthcare Leadership Council appreciates the opportunity to testify on the protection of patient privacy and the development of health care information technology. We look forward to working with the Subcommittee in pursuit of these goals. Any questions about my testimony or these issues can be addressed to me or to Ms. Theresa Doyle, Senior Vice President for Policy, Healthcare Leadership Council (telephone 202–452–8700, e-mail tdoyle@hlc.org).

Chairman JOHNSON. Thank you very much. I would like to throw out a question to the whole panel. We have had two very dif-

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mitted use or disclosure; 5) for public interest and benefit activities; and 6) of a limited data set for purposes of research, public health or health care operations.

ferent opinions about the adequacy of HIPAA even as a national minimum and the role of the State laws. It is hard for me to see how you have a nationally operable system with the extent of variation caused by not just State laws, but all these regulations and subsections of State action. So, this is a very big issue. I hope that some of the studies that both HHS is commissioning now and that I am interested in seeing will begin to focus on what are the little differences that could be easily adjusted and what are the big differences. I would like those of you who face this in everyday life to give us examples of the problems and maybe comment on Ms. Pritts's testimony that too many are left out, that the standards are too minimum, versus Ms. Grealy's testimony that the laws are really quite adequate, but we can't tolerate the degree of variation if we are going to have an interoperable national information system. We will just start down the line.

Dr. DETMER. Thank you. An excellent question, obviously. I agree with you. I think that studies underway are quite important, and I do think there are some place where we will find corrections and some things that need to be done. I think at the end of the day, I think part of what the study has to look at are the real tensions between some of these transformational gains and safety, quality, and so forth against some of the tensions that come where you need access to information, but at the same time, you also want to have privacy, and I think those are real tensions and at some point, I think we are going to have to have real basement-to-ceiling standards for an NIHH to work. A patient who works in the District, lives in Virginia, gets their care in Maryland or something like that may have a provider, excuse me, an insurer in any one of those three locations. You just can't have interoperability, I think, at the end of the day, without it. I think it is going to take, frankly, some will and leadership at that point and I think we will have to face this. As I say, I think the studies are important. I think there are some things that will need to be done. But ultimately, I think we are going to have to deal with this.

Chairman JOHNSON. Thank you. Ms. Kloss?

Ms. KLOSS. I would agree that we will learn from the studies, perhaps, that some of the States have found additional protections that should be added to the current floor we have. I would also suggest that it is incumbent on us in the design of the National Health Information Network to do all we can to use best practices, new best practices and new technologies that, again, weren't necessarily conceived of or available at the time that the HIPAA regulations were crafted.

Chairman JOHNSON. You may in your comments want to differentiate as to Dr. Brailer, between this issue of transaction standards and privacy standards as the public thinks about them. Dr. Weiss?

Dr. WEISS. Thank you. I will answer it in two ways. First, as a solo private practitioner, it is hard for an individual in an office to understand everything that is going on around them. They want to have an interaction with the patient and take care of that patient and move on. They are less concerned about national standards, just because of the practicality of the thing. As a hospital system, we obviously obey all the regulations, but it becomes confusing

and expensive to have multiple regulations, and even more importantly, as we think about globalization—we are worrying now about State versus Federal—we send our night radiology reading to Australia right now. We send some of our dictation—some of our practitioners in our town send our dictation abroad, so that the real standards are not—we are quibbling over something in our country and not realizing that we are a global network, so that really, we need international common standards so that we can share the—and any of the work that is fungible around the world, which will make things more economical for everyone. There aren't ten best ways of doing anything, so to have 50 different ways, be it 50 different States, of doing something is just inane and expensive. So, we really need to do this. We do need this interoperability. Trying to get that perfect to interfere with good will always slow us down. No legislation, with all due respect to all legislation, can be absolutely perfect, so that there will always be exceptions. It is just a question of doing what is best for the common good and sacrificing a little bit of individual freedom, although it is not comfortable, just to make this a viable system.

Ms. PRITTS. Do you want me to wait until last?

Chairman JOHNSON. Ms. Pritts?

Ms. PRITTS. Should I wait until last?

Chairman JOHNSON. All right, fine. Ms. Grealy?

Ms. GREALY. I think the point here is that HIPAA provides us a framework. I think the comments about the studies that will be underway to really look at all 50 States, the key here is that we need to find a single national uniform standard that is a workable privacy rule. So, I think the studies underway are something that will be very valuable, but at the end of the day, we think HIPAA provides a framework. A lot of work has gone into compliance with the current HIPAA standards. Entities have installed privacy officers. They have done staff training. So, we think it does provide us a reasonable framework, but the studies will provide valuable information, as well. The key at the end of the day, as Dr. Brailer said, is reducing the variability, reducing the complexity, and allowing us to use our resources for direct patient care as opposed to trying to comply with this myriad of regulations and making these health IT systems much more expensive than they need to be.

Chairman JOHNSON. Ms. Pritts?

Ms. PRITTS. Well, there are a number of issues that were raised here that I would like to address. First, I would like to say that there are a lot of providers out there who are dealing with this multi-State issue right now and who are doing it successfully, and I would hope that as these studies are being taken place, that they are consulted and their best practices are taken into account, because obviously, there are some ways that people who have embraced this, the privacy rule, and have looked forward with it have been able to function quite well underneath it. I also think that it is really important while we are looking at this issue to understand how we got to where we are today, which is that we have been unable for the last 25 years to reach significant privacy standards in Federal—comprehensive Federal privacy standards in Federal legislation. What has happened is we have a core group of people and

organizations, covered entities, who are covered by HIPAA, but there is this whole other range that is still—and nobody addressed this—that there are lots of people in the National Health Information Infrastructure who won't be covered.

It is a very—I think it is a very difficult issue when you talk about wholly preempting State law. I understand the need to be able to exchange health information, but when you are talking about health privacy laws at the State level, you know, States have been in this business for much longer than the Federal Government has. I mean, traditionally, health, welfare, those are the issues that the States—of their citizens States have been legislating, and they have these laws in every nook and cranny in their codes and regulations and there are very, potentially, severe consequences of preemption of these laws. So, those consequences must be thought of before any action of that kind could even be really seriously considered. We are not looking for perfect here, but we are looking for protections of individuals. The gentleman, Dr. Weiss, said, well, sometimes the good, the common good requires the sacrifice of individual freedoms. The problem is, in our country, it is the individual who is going to bear the burden of—the cost of this in a very—it is not just freedom, it is in a very direct result. Our health care system is funded primarily through employers. People are afraid that if their health information gets out, somebody in their family has some expensive medical condition, they won't get a job. If they don't get a job, they don't get insurance. So, it is all interconnected. It all has to be considered within a context.

Chairman JOHNSON. I think the goal, really, of this discussion at this point in the development of further legislation to guide the development of a national infrastructure is to begin to be sure that we do those studies and we look more carefully at what are the serious differences, what are the non-serious differences, and where do we really have to preempt, because it is—and whether we have to preempt. I mean, it may be that all the States are doing things that we are not doing and they get folded into the national standard. So, this isn't, do we preempt with the existing standards. This is, what do we do about the problem? So, I hope you will be involved in some of those studies. It will be a multi-year process, but it is serious enough that to think that the tensions in the future between privacy and portability may not have to be resolved differently, I think is to kind of ignore the dynamic that has taken place in other parts of the economy. On the other hand, we also don't know how much the capability to protect privacy is going to be developed in the technology and it will have a lot to do with our ability in fraud and abuse, too. I have taken my time and I am going to turn to Mr. Stark.

Mr. STARK. Thank you, Madam Chair. I want to thank Ms. Pritts for, as near as I can tell, the only witness there that has concern for patients and consumers. The pharmaceutical industry is well represented and the interests of physicians are well represented, but somehow, it seems to me that somebody ought to think a little bit more about what those of us who are patients care about our privacy. Some States do a better job. Some States would have tougher requirements for a variety of reasons that we might not be able to pass at the Federal level. It happens in automobile

emissions standards. We are much tougher in California than they are in North Dakota. So, if we took North Dakota's emissions standards, you wouldn't be able to see for the smog in big cities. I think the same thing could very well be true in various States and the standards that would be accepted. Dr. Detmer, you did or do represent this vital health statistics national Committee. You have worked with them. They have a common set of data elements. They have developed a common set of data elements for patient records, have they not?

Dr. DETMER. No, not really——

Mr. STARK. They haven't?

Dr. DETMER. Not truly, no.

Mr. STARK. Okay. So, they haven't developed it?

Dr. DETMER. Well, they work on this because they are mandated to work on it from the HIPAA legislation, but it is not like that has comprehensively been completed.

Mr. STARK. Okay. Do you think that there is a kind of a minimum set of data, like height, weight, blood pressure, that doctors could all agree on that would be sort of a minimal set of statistics that they could collect? Do you think we are——

Dr. DETMER. You know, this is actually one of those very frequently debated points. Do we go toward a, if you will, minimum data set, or do we go toward an infrastructure that really tries to capture all of the things that go on.

Mr. STARK. But you have got to start with the minimum, right?

Dr. DETMER. I have to admit, I guess I tend to be in the population that say, look, I think that health care today really must have the complexities covered, too, because candidly, I practiced 25 years as a vascular surgeon. The kinds of data I typically needed to respond to a patient's personal needs wouldn't necessarily come up in a general practice kind of environment.

Mr. STARK. I have got your thing here on standardization—personal identifier, date of birth, gender, race or ethnicity, residence. I mean, you guys have agreed on that, right?

Dr. DETMER. Oh, yes. There is a set of—there are a set of data, yes.

Mr. STARK. That is what I am trying to get.

Dr. DETMER. I am sorry. Sure.

Mr. STARK. Okay. So, you guys are all in accord, and you suspect that the medical profession would generally say those are okay? They may want more, but——

Dr. DETMER. Yes. I think the question is how the process works. If there are——

Mr. STARK. No, I don't want to know about the process. I just want to know where we are. There are 49 line items here that you guys have agreed on, so that is a start.

Dr. DETMER. Correct. It is a good start, I would say.

Mr. STARK. Now, the question of interoperability and privacy, I would submit to you, either you or Dr. Weiss mentioned credit cards and banking, a subject about which, if my memory would serve me better, I know a good bit. It is quite possible that the—well, the interoperability of the credit card industry and checking accounts is a direct function of Federal mandates, okay. The Federal Reserve basically set the standard for clearing, without which

I could not go into any airport in the world and have the ATM say, you are a bum, you don't have any money and we ain't giving you any more. They know that about me before I get off the plane. The privacy and security requirements in Shannon or Heathrow or San Francisco or Dulles are all different. Yet we are able to operate with an exchange of information. Our privacy standards for financial information are ten times tougher in California than they are in the District of Columbia. If my bank were to give out information even to their subsidiary and solicit me for insurance in California, they would be in deep trouble. Not so in many other areas. So, I guess what I am suggesting is a couple of things, and I would like your comments, Dr. Weiss, if the chair will indulge me with the red light a little longer. One, that we are not going to start or have interoperability until some one entity that can monitor and enforce it says, this will be the standard. Dr. Weiss, you are going to have to do it in Florida, right?

Dr. WEISS. Yes.

Mr. STARK. Dr. Detmer, wherever you practice. You guys are going to have to do it the same way. Now, you can add bells and whistles. I would use the case—let us just try it. Dr. Detmer, Dr. Weiss, do either of you use, what is that thing, the bookkeeping thing, Quicken? Do you use Quicken?

Dr. WEISS. Yes.

Dr. DETMER. I know what you are talking about.

Mr. STARK. Do you use Quicken?

Dr. DETMER. No, but——

Dr. WEISS. I use Microsoft Money, but it is the same thing.

Mr. STARK. Okay, the same thing. Now, you could hook up to your bank or Schwab or some—if you want, and they could import your credit card information into Microsoft Money each month, or you don't have to do it. You could balance your checkbook by hand. Your bank has a different set of security—you have got to have a password—than Microsoft Money. I guess what I am saying is that, yes, we could accommodate more sophisticated systems, and I would submit that Dr. Weiss's practice for each individual physician entering information on his or her laptop or whatever input device isn't any different than the thousands of Kaiser physicians in my district. They have got a bigger system someplace. But at the point of the physician entry, it doesn't make any difference. I guess, if I could get to the point, why shouldn't we, Dr. Detmer and Dr. Weiss, have CMS, for example, say you have got to start with this minimum amount of information and this type of electronic reporting or we will pay you less for Medicare and Medicaid, and then at least we would get started. Does that——

Dr. WEISS. I agree. My fourth option is that as the government and the other payers—you have the commercial payers that pay one or 2 percent more for physicians who are using an IT system that has a minimal set of standards. Those physicians who decide to stick with paper rather than technology——

Mr. STARK. Get less.

Dr. WEISS. Will get one or 2 percent less.

Mr. STARK. Could you live with that, Doctor?

Dr. DETMER. Yes. I think if you make it revenue neutral, then you have dealt with it, too. I mean, I don't think you are necessarily talking about new money.

Mr. STARK. Well, we will—your colleagues——

Chairman JOHNSON. We have to wrap up pretty quickly, so let us add anything in.

Mr. STARK. Thank you.

Chairman JOHNSON. I thought the issue that Mr. Stark raised about global, basically, variation versus a core of standardization is a good one, and if any one of you want to comment on that. In our pay for performance bill that we are going to introduce tomorrow, we do have variable payment structures for just that reason.

Dr. DETMER. No, I agree. It is good. I think that is good. I guess the comment I would make is it comes back to the clinical standards issue. I do think the government needs to invest enough to really make sure that this process is done and kept up and maintained and so forth, and I think the idea that you think you can just sort of do it and then not maintain it is just not going to work.

Chairman JOHNSON. Right. I agree.

Mr. STARK. Somebody has got to start it.

Chairman JOHNSON. Yes.

Ms. KLOSS. I would also follow on to our earlier discussion on certification of EHRs. The approach being taken is to set forth some fundamental standards for functionality, security, interoperability, and to go from there so that at least we know that all EHRs meet that basic set of standards. So, I think that is a sensible way to proceed.

Chairman JOHNSON. Mr. Hulshof?

Mr. HULSHOF. Thank you, Madam Chairman. I will try to be brief. Just a couple of quick comments. A lot of discussion about HIPAA, which the standards were intended to be a minimum privacy standard and yet sometimes, as is the case, at least in my experience, has been that State laws are not necessarily more stringent. It is just that they are different and, therefore, you have entities having to comply with two completely different sets of standards and one may not be more rigorous than the other. So, that is one comment I would make. Let me commend everyone for the written testimony. There is some great stuff, and I know when you are trying to pare it down into a five-minute presentation, a lot of good things get missed, and I would just commend everybody to take all of your written testimony. I wanted to emphasize a point, Ms. Pritts, you made in yours, that you cite in your written testimony a number of instances in which medical information was sold. Isn't that already prohibited under HIPAA?

Ms. PRITTS. Well, it is prohibited under HIPAA, but what has recently happened is the Department of Justice issued guidance to HHS saying that the criminal provisions of HIPAA do not apply to most employees, even of covered entities. So, if you had—the example in my testimony says, if you had a hospital and the hospital will have policies in place saying you may not sell patient information, that the hospital is not going to be prosecuted under HIPAA, and rightfully so, because it is not the one selling the information improperly. The employee who is improperly taking patient information and selling it is not going to be prosecuted under HIPAA

because the Department of Justice has announced they are not covered by HIPAA.

Mr. HULSHOF. Let me emphasize another point that Dr. Weiss made, because again, in your testimony, you talk about privacy. We have been talking a lot about privacy of medical records. But again, Dr. Weiss, thank you for just reminding us that, really, the electronic environment, though not perfect, as you write on page five of your testimony, is better and safer than the paper environment. Right now, anyone in the hospital can pick up a medical chart, browse through it anonymously, whereas on electronic records, you have access—if you have access, you can then call up and see who exactly accessed your information based on privacy. So, again, thanks for those real world examples. Now, Dr. Weiss, in the remaining time I have got, let me ask you this. Can you describe how an exception to the physician self-referral laws and the anti-kickback statute would actually increase adoption, or would it increase adoption of health IT among your physicians, because here is the concern that we have heard from some. Some would argue that maybe a safe harbor like this would create a situation in which hospitals would compete for physicians based on IT spending, or they might create these captive referral systems between physicians in certain hospitals. So, can you respond to that generally, and I will yield you the remaining balance of my time.

Dr. WEISS. Thank you. I will start with a real story that is happening as we speak, where we have 525 physicians on staff. We have a group of 55 physicians in town who are wonderful. We have another group of 40 physicians who focus on an indigent care market. About 18 months ago, these other two small groups were out to buy an IT system. I spent a significant amount of time and energy, as did they, to see if we could get interoperability among the systems. I was advocating that they use the hospital system, which is relative mature. We are not quite a paper-free environment, but we are heading that direction. During that period of time, these two physician groups had three concerns that actually never happened. They ended up buying two excellent systems, but not the same system the hospital has right now, so basically we all have romance languages but we are not speaking to each other. We are doing French, they are doing Italian and Portuguese or whatever. So, we sort of understand, but at the end of the day, we have got to print everything, carry it to and from.

They can read our system anywhere that they have high-speed Internet connection, but they can't get from their system to our system, and so if a patient gets a lab result earlier in the day in his or her doctor's office and gets admitted to the hospital later in the day, we will repeat the blood test because it is too hard to get the results. Now, what actually happens and gets to the regulation question, we looked at the new Stark laws. As a private practitioner, I understand the temptation of self-referral and self-inducement and I applaud those rules. That really does make a difference. There are a small minority of physicians who take advantage of patients economically and do self-referral and the law has been a great law. The actual practicality of it is, when we thought about trying to help physicians, of our 525 physicians, 200 admit patients commonly in the hospital. That leaves 325 whom we would

have to pay for computers for their offices who really aren't associated. There are another 300 physicians in the community who don't use our hospital, so that we don't have the money—we have about a three percent profit margin, we are a not-for-profit community-based hospital and we are doing fine and we reinvest all our money, but that is not the highest—we can't buy computer systems for 800 physicians. It is just practically not economically possible.

Then we have one other hospital in town and we have a third hospital who will be probably coming to town. The physicians were worried about, number one, the hospital's IT department's ability to implement IT or computer systems in his or her office, and being on the provider side before, no offense to government, but it is the "I am from the government, I am here to help you." We say, "I am from the IT department of the hospital, I am here to help you," and it makes you a little bit worried. So, that the doctors were worried about our ability, and our ability is great, but we are used to working inside the hospital. So, the first thing was the ability to make it happen. The second thing was, as an individual physician, they were worried about being married, having—monogamous relationships are necessary for healthy marriages, but not for businesses, so that they wanted to be able to be involved with the other two hospital systems in town and not be married to one hospital. If I were in individual practice the way I was before 2000, I certainly wouldn't want to be married to one system.

The third thing—and the third major point was it just economically wasn't feasible for us to do that, so that even though the rule was relaxed somewhat, it is just not practical. What we really need is the health care industry as an industry to do integration, to do it voluntarily. Right now, I sort of have the idea that everyone wants to become like Microsoft when Commodore and Apple were involved. But really, if you go back to the Sony and VHS in 1975 to 1980, the group that won out was the group that cooperated. The VHS won out because they gave their technology to other people. The group that lost, even though Sony had a two-year lead and arguably a better product, never made it because they didn't connect and collaborate. They tried command and control. In our environment in 2005, command and control does not work. Connect and cooperate does. Thank you.

Chairman JOHNSON. Thanks very much. What I hear you saying is that once sort of the standards are set so that there isn't this worry about the monopolistic relationship and we have a greater flexibility than the Committee-wide exception, that then those things could have happened and the outcome for the public and for the patient would have been far better. I thank the panel very much for their testimony today. It was very, very helpful and very specific. We appreciate it. As we move forward, we will look to call on you for your advice and input. Thank you. The hearing stands adjourned.

[Whereupon, at 12:28 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of James Bayot, McKesson Corporation, San Francisco, California

For more than 170 years, McKesson has led the industry in the wholesale delivery ofmedicines and healthcare products. Today, a Fortune 15 corporation, McKesson

delivers vital pharmaceuticals, medical supplies, and healthcare IT solutions that touch the lives of more than 100 million patients in every healthcare setting. As the world's largest healthcare services company with a customer base that includes more than 200,000 physicians, 25,000 retail pharmacies, 5,000 hospitals and 600 payers, McKesson is well positioned to help transform the healthcare system.

McKesson strongly supports the goal of improving healthcare quality by using healthcare information technology (IT) to reduce medical errors and lower costs. As the largest provider of automation and information technology in the healthcare industry, we deliver innovative technologies at each point in the healthcare system to reduce medication errors, lower costs, and improve the quality and efficiency of healthcare. We are dedicated to making healthcare safer, a goal that requires a deep understanding of healthcare delivery processes and a clear focus on what is required by key stakeholders such as physicians, nurses, pharmacists and patients.

McKesson fully supports the President's goal that every American should have an electronic health record (EHR) in 10 years. To meet this bold vision, McKesson believes that the federal government should pursue a two-pronged strategy to spur the adoption of automation and healthcare IT. First, we need broad deployment today of high-impact technologies that provide unquestionable benefits in the delivery of healthcare. Second, on a parallel track, we need to develop the standards and promote the interoperability of systems that are essential for medical information to be shared among healthcare providers, patients, and public health agencies in a safe, secure manner.

At McKesson, we know that technology itself is not the inhibitor of change in the healthcare system. The technology is available and working. It is intolerable that people die every day from medication errors that could be prevented with bar-code technology, the same technology that is used in every major retail outlet in this country. We conduct sophisticated banking and other business transactions electronically across continents; yet most physicians in the United States still rely on their memories for complex medical information, and write orders using pen and paper.

While deployment of healthcare IT is growing, less than 20 percent of hospitals in the United States today use bar-codes to verify the administration of patient medications, and fewer than 10 percent of physicians in hospitals enter patient prescriptions and medical orders electronically. The numbers are only slightly better outside the hospital: only about 25 percent of large physician offices enter their prescriptions electronically. The number drops considerably for small physician practices.

Three Areas Where High-value, High-impact Technologies Already Make a Difference

We can and *must* make the healthcare system safer and more efficient by accelerating the use of technology in all hospitals and physicians' offices in the United States. There are three areas where high-value, high-impact technologies already make a significant difference:

1. **Bar-code technology.** ***Medications should be packaged in unit-doses labeled with bar codes and scanned at the bedside before they are given to patients.*** Today, on average, there are 27 steps in the medication use process that involve many decisions, multiple handoffs and various people, ranging from the physician who prescribes the order to the pharmacy staff to the nurse who ultimately administers the medication to the patient. Healthcare IT and automation can reduce the handoffs and eliminate, on average, 40 percent of the steps. This results in dramatically improved accuracy, efficiency and safety. In a group of 75 hospitals that use McKesson's bedside bar-coding technology, 400,000 "alerts" are triggered weekly to nurses or other healthcare professionals to advise them that the wrong medication or incorrect dosage is about to be administered. As a result of these on-line warnings, we estimate that these hospitals prevent 56,000 errors each week. Hospitals that deploy bar-code scanning technology report dramatic error reduction in medication administration, as high as 90 percent.

2. **Electronic prescriptions.** ***We must eliminate paper prescriptions.*** Each year, more than three million preventable adverse drug events occur in physicians' offices or other out-patient care settings. Imagine a world where a patient's list of current medications is available to the physician and the physician can order initial scripts or refill them online. All the medication names would be legible, and all orders checked for drug-drug interactions and allergies. Today, McKesson's systems help to ensure safe prescriptions are written and filled 100,000 times each month, but, nationwide, 80 percent of prescriptions are still on paper, and many are illegible.

3. **Secure Web-based access to patient information.** ***We must equip physicians and clinicians with the information needed to make informed decisions about patient care.*** Today, most healthcare is delivered in a paper-based world. It is not uncommon for physicians to provide patients with advice, give directions to other staff and recommend treatment changes without any access to a patient's chart. These blind encounters happen every day. Secure Web-based access to clinical patient information, such as laboratory results, the patient's medical record and diagnostic images, enables physicians to find, within seconds, the information they need to make more informed decisions and initiate or adjust treatment. McKesson currently records 1.8 million logins each month to its Web-based physician portal, almost double compared to a year ago. Remote access via Web portal technology is in common use across many industries; yet, in healthcare, its deployment is only in the 50—60 percent range.

Funding to support these focused initiatives can lead to dramatic progress very quickly. McKesson applauds the leadership shown and initiatives undertaken by the Congress and this Administration. Implementing these three forms of technology will build the required momentum and provider support for adoption of healthcare IT.

Technology is Improving Healthcare Quality Today

Healthcare technologies today save lives, reduce medical errors, improve the quality of care, and reduce overall health costs. The following healthcare organizations are just a few of our customers that have taken these important first steps to improve care for their patients:

Concord Hospital, an affiliate of Capital Region Health Care (CRHC), Concord, NH: Concord was one of the first hospitals in the United States to introduce bedside bar-code scanning of medications in 1994, which reduced its already low medication error rate by 80 percent. This reduced error rate, which has been sustained for more than 10 years, has improved productivity and efficiency as well as increased clinician satisfaction and retention.

Medical Associates Clinic, Dubuque, IA: Medical Associates is deploying an ambulatory electronic health record and e-prescribing system for more than 100 physicians and medical providers, which represent 30 specialties dispersed across 16 locations in three states. With the implementation still underway, physicians are already entering 26,000 e-prescriptions each month, and patient information is available electronically regardless of location. Nurses spend far less time on medication management; they have reduced the time spent on paper charting activities by 24 percent; and, they spend 16 percent more time with patients and their families. In addition to improved quality and better decision-making, this clinic projects an annualized net gain of $1.7 million with full system deployment.

Regional West Medical Center, Scottsbluff, NE: A regional referral center covering more than 12,000 square miles in rural Nebraska, Regional West has used information technology to streamline the delivery of healthcare. Through secure Internet access, physicians and other clinicians can view a single electronic medical record for each patient, which includes diagnostic medical images, pharmacy data and laboratory results. A McKesson pharmacy robot dispenses bar-coded, unit-dose medication packets virtually error-free. Electronic patient charting at the bedside has cut nurses' daily paperwork by nearly 1.5 hours, enabling them to spend more time caring for patients. The hospital has reduced its medication error rate by 30 percent to less than one percent. Before giving a medication, the nurse must capture a three-way bar-code match between his/her badge, the medication and the patient's wristband to check the five "rights": the right patient is receiving the right dose of the right medication at the right time via the right route.

Mary Lanning Memorial Hospital, Hastings, NE: The largest employer in Hastings, Nebraska, Mary Lanning Memorial Hospital has served the healthcare needs of the surrounding community for the past 83 years. Although the hospital's medication error rate was low, a single tragic event highlighted the need for standardized medication administration. Bedside bar-code scanning technology was implemented along with a pharmacy information system to reduce the risk of medication errors. Additionally, medications scanned at the bedside are compared to orders reviewed by pharmacists and screened for allergies, interactions and therapeutic duplications. Preliminary data has shown a 35 percent increase in the reporting of near-miss events related to wrong drug and wrong patient.

Presbyterian Healthcare Services in Albuquerque, NM: Using McKesson's bar-code technology solutions, Presbyterian reduced medication administration errors by 80 percent. Technology has also allowed pharmacists to be redeployed to critical care units to work directly with patients and physicians and enhance the quality of care.

These innovative health systems and others across the country are saving lives and saving money. Physicians, nurses, and pharmacists now spend more time interacting with patients and less time performing administrative functions. More importantly, these organizations are creating a new baseline for patient care in the United States. While making healthcare safer through seamless, rapid and accurate information flow, they are also addressing one-third of healthcare's overall costs: administrative paperwork, clinical errors, manual hand-offs and rework.

Developing Standards and Promoting Interoperability

McKesson fully supports efforts of Congress and the Administration to facilitate standards harmonization, encourage the formation of regional health information organizations and establish a National Health Information Network. Development of the requisite technology standards will allow the computer systems of doctors, hospitals, laboratories, pharmacists and payers to efficiently communicate and share information. We are honored to work with Dr. David Brailer and the Office of the National Coordinator for Health Information Technology as he moves to create a foundation for the transformation of our healthcare system. We are also pleased to be a member of the Commission for the Certification of Health Information Technology, a collaborative public-private partnership to develop standards and certify health information technology systems.

We all remember the incremental steps that were taken by other industries as they moved towards connectivity and interoperability. First, they automated individually and then, collectively, they collaborated to connect the information. Consider the banking industry. A full decade elapsed between the early proliferation of bank-specific automatic teller machines (ATM) and the formation of "shared ATM networks" in the 1980s. Once the automation was complete, connectivity and interoperability occurred very quickly. In the interim, banks were able to realize the cost and efficiency savings of ATMs, and consumers, appreciating the convenience of ATMs, quickly adapted to this new banking system. Connectivity is a natural evolution of automation. We are confident the same evolution will happen in healthcare. Once our nation's healthcare providers are fully automated, it will be possible to connect previously isolated healthcare systems.

Understanding and Overcoming Barriers to Rapid Adoption of Health Technology

The biggest obstacle to healthcare information technology adoption is securing the needed funding and resources. Today, physician practices and hospitals do not have access to the capital necessary to invest in their own technology or, on a larger scale, to fund connectivity.

The federal government can play a key role in financing this healthcare transformation through creative funding arrangements. One option is through the creation of Government Sponsored Entities, which would provide indirect federal support through guaranteed loans for healthcare providers to purchase, adopt, and implement proven health technology solutions that are focused on error elimination and safety. Coupled with the pay-for-performance initiatives that reward providers for the quality of healthcare delivered rather than for services rendered, guaranteed loans or other financial incentives will spur technology adoption.

A combination of financial and performance incentives would help mitigate the initial expense of technology implementation. The reduction in medication errors and improved efficiencies in delivering improved healthcare will also provide a return on investment for healthcare organizations, thereby enabling them to repay the loans.

Conclusion

McKesson believes our healthcare system must adopt and deploy proven technologies today that reduce medical errors in order to save lives, improve the quality of care, and reduce costs. These initial steps should include:

1. Implementation of bedside bar-coded medication administration systems across the United States.
2. Elimination of paper prescriptions through use of e-prescribing in physicians' offices.
3. Secure, online, "anytime, anywhere" access for physicians to critical patient information.

Automated information will enable our healthcare organizations to store and collect patient data, which will ultimately lead to a comprehensive electronic health record. Concurrently, we need to adopt the standards necessary to ensure interoperability among systems that will facilitate communication within our health system. If we execute these initiatives simultaneously, McKesson strongly believes that this

Congress and this Administration will be able to deliver visible and measurable results with a lasting impact on the quality of healthcare for the American public.

As a nation, we have both the will and the means to transform healthcare for the better. This will be a remarkable legacy, and one we should act on today.

We appreciate the committee's interest in healthcare information technology and look forward to working with members of the Subcommittee on Health, as well as other Members of Congress, to address these critical issues.

Statement of Patricia Gibbons, Mayo Foundation, Rochester, Minnesota

OVERVIEW

The proposal to move to the ICD–10–CM/PCS (International Classification of Diseases, 10th Edition, Clinical Modification and Procedure Coding System, hereafter referred to as ICD–10–CM) should to be coordinated with other legislative and regulatory initiatives having to do with the use of standard terminologies for the reporting of clinical information. These include pay-for-performance and quality reporting, the public interest in encouraging the use of SNOMED for the improvement of clinical description, and the establishment of a standards-based national health information network (NHIN). The NHIN should include a roadmap for the adoption of terminologies if true interoperability is to be achieved. If the various terminology initiatives can be synchronized, it will be possible to realize improvements in health care diagnosis, quality, safety and treatment, along with significant cost savings, for the benefit and well-being of all Americans.

CURRENT SITUATION

Neither ICD–10–CM/PCS, nor its predecessor currently in use, ICD–9-CM, allow for the capture of data at the detailed level that is required for the identification and description of case types (groups of patients with a similar diagnostic profile) as specified by most quality measures. Such case types and the optimal interventions prescribed for them are now defined by a combination of ICD–9-CM codes plus *additional* clinical information, much of which cannot be coded at an appropriately detailed level in ICD–9-CM or in ICD–10–CM/PCS. In contrast, SNOMED (the Systematized Nomenclature of Medicine), which has been identified by the NCVHS (The National Committee on Vital and Health Statistics) and by CHI (the federal Consolidated Health Informatics Initiative, now part of the Federal Health Architecture project) must be considered the *preferred* terminology for the expression of clinical information. SNOMED has been shown to be able to handle this level of detail, in two studies on content coverage performed at Mayo Clinic.[1]

SNOMED contains the detail needed for the 1) billing and reimbursement, 2) national health statistics and public health reporting, 3) the real-time measurement and reporting of safety and quality measures, and—most importantly—4) the precise characterization and recording of information about all medical diagnoses, findings, treatments, and events *by care providers*, as they occur.

Important work is currently underway by the National Library of Medicine, in collaboration with HL7, the leading standards development organization for health care, to accomplish the translation of SNOMED codes into ICD–9-CM codes. A similar translation (or mapping) is planned between SNOMED and ICD–10–CM. A mapping already exists, as well, between ICD–9-CM and ICD–10–CM. Work remains to be done. Completion of these mappings should be expedited, tested, and adjusted to assure continuity in moving forward. But that alone is not adequate to achieve the potential benefits of the synchronization. Additional, supportive standards for the specification of clinical statements and templates for clinical documents, under development by HL7, complete the array of standards needed to support SNOMED to ICD synchronization.

The Centers for Medicare and Medicaid Services (CMS) and the National Center for Health Statistics (NCHS), which are today the leading users of ICD–9-CM-coded data *must play a critical role* in providing and maintaining for general use, *a single approved, computer-based mapping* of SNOMED to ICD–9-CM and to ICD–10–CM. This mapping should allow organizations, including providers, payers, and other stakeholders, to "capture the data once," store it as SNOMED expressions, and

[1] Chute, et al, http://www.jamia.org/cgi/content/abstract/3/3/224 The second content coverage study was done in the summer of 2004 and is not yet published, but the findings are very similar to the 1996 study.

produce from it all "derivative" information (such as ICD codes for reimbursement, and for statistics and public health reporting).

TERMINOLOGY NEEDS FOR QUALITY AND SAFETY

Quality indicators and patient safety measures, now characterized by a cumbersome mixture of ICD–9-CM codes *plus* other data, can be better and more consistently captured by SNOMED. If ICD–10–CM is implemented without coordination with SNOMED, a major recasting of indicators into ICD–10–CM terms will still need to be done and calibrated. All indicator-related data not currently encodable into ICD–9-CM will need to be scrutinized for codability in ICD–10–CM, and much of the information will still need to be gathered manually, with different processes for different indicators On the other hand, if SNOMED is specified as the basic nomenclature for reporting of quality indicators, all detailed clinical data needed can be characterized using SNOMED, since SNOMED can handle the content of both the ICD–10–CM codes and the *additional* data required for quality indicator reporting. Not that every element of information available in SNOMED will always be in use, but if a new measure or finding is required, it will be there. By way of analogy, SNOMED will provide a complete dictionary, and grammar, for composing any sentence, whereas today we have no more than a list of pre-formed and pre-selected "sentences" to choose from.

To understand this better, let us look at the findings of the first content coverage study from 1996 which compared SNOMED with ICD–9-CM and ICD–10–CM. **"Content coverage"** is the relative ability to describe full clinical content, including diagnoses, findings, prescriptions and drug information, procedures and other information. It includes the ability to *modify* these expressions in various ways (from "stages" of cancer, to degrees of certainty, to modifiers such as "family history of," "history of," "exposure to"). The versions of SNOMED and ICD–9-CM that were in available at the time were used in the study. Plus, there was a draft version of ICD–10–CM available that was used in the study. The approximate results from the 1996 study are tabulated below: [2]

	ICD–9-CM	ICD–10–CM	SNOMED
Diagnoses	1.61	1.61	1.92
Findings	**1.22**	**1.24**	**1.82**
Modifiers	**0.38**	**0.41**	**1.71**
Other	0.55	0.79	1.52
Procedures/Rx	1.01	1.09	1.79
OVERALL	**0.81**	**0.84**	**1.75**

Figure 1. *Scores by semantic group for major coding systems.* Bar graph of mean scores over all concepts within each semantic domain and Overall. The scale is based on a 0—2 integer scaling reflecting a subjective measure of concept capture. 0 = absent, 2 = complete.

The two content coverage studies show that, despite structural changes and a switch to alphanumeric codes (which theoretically add much expandability to the coding system), ICD–10–CM/PCS does *not* increase *content coverage* in a major way. Overall, both the 1996 and the 2004 studies show similar content coverage for ICD–9-CM and ICD–10–CM/PCS. Content coverage for SNOMED is roughly *twice* that of *either* version of ICD.

There are several reasons these studies do not show a significant increase in content coverage between ICD–9-CM and ICD–10–CM:

1. The study looked at *actual histories*, and although there are some new diseases and procedures, these typically occur in low volumes; once they are recognized, they are added to ICD–9–CM (or–10 or SNOMED) in regular or special updates.

2. Many of the changes in ICD–10–CM/PCS are changes to the *internal way* codes are handled, rather than the addition of new codes. There are some additions that are very helpful, such as the ability to indicate "right," "left" or "both," but in many cases, it is the old pie that is being cut up.

3. ICD–10–CM is largely a recasting of major two types of clinical knowledge, major diagnosis and interventional procedures, which is also captured by ICD–9-CM.

[2] These numbers are derived from the graphic in the published study. See actual study for precise results.

In general, the *scope* of ICD–10–CM/PCS has not broadened to include the range of detailed clinical information covered by SNOMED.[3]

SNOMED, on the other hand, shows particular strength of content coverage precisely *in those areas central to the measurement of clinical quality and safety:* detailed findings and clinical modifiers. All-in-all, SNOMED outperforms either ICD–9-CM or ICD–10–CM/PCS by a margin of *nearly two to one.* This of profound importance when it comes to the specification, collecting, and reporting of quality measures—if what we mean to do is, truly, to create the *foundation of a new generation of medical knowledge which can serve as the foundation for major new improvements and advances in patient care and public health.*

ICD–10–CM provides limited specificity regarding lab findings, non-billable procedures (such as many nursing activities) and pharmaceuticals. SNOMED either maintains links to such information or has developed it internally.[4] Plus SNOMED has a *vision* and *flexible structure* which allows for entire new dimensions to be added in the future.

CHARACTERISTICS OF THE ICD CLINICAL MODIFICATIONS

Although ICD–10–CM allows for greater extensibility (the ability to add more codes in many areas), it remains unchanged in two respects. It is designed for aggregation and/or classification. It retains use of "NOS" and "NEC" codes.[5] This means that it gathers similar diagnoses into common groupings. Sometimes, these "groupings" represent a single clinical expression, but not always, and not fundamentally. The ICD Clinical Modifications have done a reasonable job of serving the functions for which they were designed, statistical reporting, case retrieval for study, and, more recently, reimbursement.

But, to handle the new proliferation of quality indicator reporting, neither ICD–9-CM nor ICD–10–CM/PCS have the detail, the structure, or the ability to adapt to foundational changes to its underlying assumptions; it will still be possible to run out of codes. With genomic data rapidly being linked to symptoms and diseases and with the promise of an ever-changing but always growing set of requirements for detailed and "subtle" quality criteria ("nonbillables"), *any* fixed classification system will be short-lived. Indeed, ICD–10–CM is based on the *First* Edition of ICD–10, and the *Second* was introduced last year, along with a whole new user interface technology. If history is to be the guide, ICD–11 is due out in the next few years, and is expected to be more SNOMED-like in its design. Indeed, ICD–10–PCS, the Procedure Coding System (to be used for inpatient procedures only; it does not replace CPT), a thoroughly U.S.-developed system—uses a SNOMED-like approach.[6]

It is indeed most commendable that AHIMA, which has 40,000+ members involved largely in the coding of medical information into the ICD, CPT and related families of coding systems, is now voicing its strong support for the mapping SNOMED to ICD–10–CM as part of a coordinated strategy in the direction of adequate, "capture once, use many times" clinical description capability. This is a significant step forward. There is every reason to believe that these talented professionals will continue to play a key role in the future of all aspects of clinical information capture.

RECOMMENDATIONS

The following two measures are required in order for the United States to move forward to a detailed, flexible, and clinically useful system for characterizing health related conditions, findings, interventions, and events:

1. CMS and NCHS should provide, for general use, a mapping between SNOMED and both ICD–9-CM, and ICD–10–CM/PCS
2. CMS should require that all data specified for the reporting of newly mandated safety and safety measures should be submitted in SNOMED terms

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[3] http://www.snomed.org/snomedct/documents/July05—CT—FactSheet.pdf

[4] Information on SNOMED inclusions and mappings to other coding systems (including LOINC for lab values and various nurse activity coding systems) is provided at: http://www.snomed.org/snomedct/documents/July05—CT—FactSheet.pdf

[5] NOS means "Not otherwise specified." "NEC" means "Not elsewhere classified." In short, unusual, uncommon, and—importantly—*new* conditions, such as SARS or avian flu, are first likely to be lumped into one of these "other" categories, until their correct etiology or expression are better understood. For reimbursement or statistics this tends to work reasonably well. A new type of flu will end up in "other influenza," for instance, and so be counted and reimbursed in a reasonable manner.

[6] It must be emphasized that the ICD–10–PCS, Procedure Coding System, is not based on any ICD mortality coding system, but was developed under contract by 3M for CMS.

Designated Mapping between SNOMED and ICD–9-CM and ICD–10–CM

CMS and NCHS must help develop, certify and provide for use, an approved mapping of SNOMED codes to ICD–9-CM and ICD–10–CM. It is surely possible that more than one *roll-up* will be possible given the "multiple inheritance" capability of SNOMED.[7] Work is progressing on the mapping of SNOMED to ICD–9-CM, in the joint initiative of the NLM and HL7. Work should begin as soon as possible on ICD–10–CM as well. A mapping to ICD–10-*PCS* may also be considered, although it is not a necessary part of the diagnosis cross-mapping.

CMS and NCHS should, as well, take on the necessary calibration work to assure that in terms of payment and statistics, the disease profiles which result from the mappings to ICD–10–CM are consistent with those derived from ICD–9-CM. Not all health care organizations will be able to go to use of SNOMED at the outset and will likely prefer a more straightforward move to coding into ICD–10–CM. Provider organizations that want to move to automated problem lists which can be used directly by care providers and which can be linked to clinical advice/alerts and medical literature (creating the full cycle of evidence-based medicine), can be expected to enthusiastically embrace SNOMED-based problem lists. These organizations should be assured that any potential decreases in reimbursement due to the ability to provide additional detail should be neutralized initially and factored in over time. A potential source of revenue for handling any such gaps can be expected from decreases in "fraud and abuse," which can result from differences in coding *conventions* between payers and providers. With a system based on SNOMED-level detail, disagreements over which category (ICD code) a condition should be assigned to will be eliminated by the explicit use of the actual description of the condition as the primary data entity. Only consequently will this detailed diagnosis be assigned—by means of a CMS-approved mapping—to an ICD-level category. *Actual* abuse will be *actually* documented and furthermore, will be internally testable, for instance, by the ability to compare a SNOMED-coded diagnosis with a SNOMED-coded lab result to see if they are consistent. Systems will naturally evolve which internally check to assure that such inconsistencies are noticed and attended to.

Requiring Quality Indicators to be Submitted using SNOMED

SNOMED has been designated by CHI as the preferred standard for use for most clinical reporting, and is mapped to LOINC and several nursing terminologies. In short, SNOMED contains the level of detail needed for the direct encoding of the details needed for the reporting of quality indicators. Neither ICD–9-CM or ICD–10–CM/PCS are capable of capturing this level of detail nearly as well as SNOMED. SNOMED, is based on a natural ordering, or ontology, which reflects the natural relationships among health-related entities (states of health and disease, symptoms, findings, events, interventions, medications, and all types of interactions with care providers). And it has the flexibility to be changed as the understanding of these relationships change—as they are certain to do, given the rapid advancement and restructuring of medical knowledge

ADDITIONAL BENEFITS

Major new benefits and 'freedom of (clinical) expression' will result from adopting this approach. Provider organizations will be free to implement EHR systems which use SNOMED as the foundation of all their information needs, enabling them to provide the highest quality patient-oriented care. Systems of medical advice and online access to medical knowledge, for patients and care providers alike, will be enhanced; and *active* quality and safety management can be integrated *into* systems rather than patched *onto* them. And yet it will still be possible for providers to submit the financial and administrative data required of them—only with less bureaucracy and duplication of effort, and a real savings of consumers' and tax payers' dollars. For years we have been moving deliberately to this new vista, and so many of the initiatives are ready to bloom. There is every reason to believe that we are at the verge of the emergence of the long-anticipated "common language of medi-

[7] Indeed, the fact that ICD only allows a condition to be assigned to one category is considered a valuable feature for purposes such as classification and grouping for reimbursement, in reality, conditions often have multiple characteristics and other aggregations may also be useful, not only for research, but also for practice. A bacterial infection of a heart value is both a heart condition and a bacterial infection. Metastatic liver cancer is not only a cancer but has multiple sites that may be characterized. SNOMED handles this kind of multiple characterization much more easily than do the ICDs.

cine" which can make the new era of "collaborative health decision-making" a reality rather than a dream.

Statement of William Hogan and Vergil Slee, The Rods Laboratory (at the University of Pittsburgh), Pittsburgh, Pennsylvania

SUMMARY

It would be a mistake to switch from ICD–9-CM to ICD–10–CM in the Medical Record Health Information System (MRHIS)[1] at the present time.

The resource expenditure required would present an unnecessary, perhaps insurmountable, obstacle to the efforts of the federal government to modernize the healthcare industry with information technology (IT), most especially the adoption by physicians of the electronic medical record (EMR).

The claim that implementing ICD–10–CM is critical to biosurveillance for such threats as SARS and avian influenza is inaccurate—the public health reporting system does not use ICD–9-CM codes for this purpose.

The basic problem that the healthcare system and the federal government need to address is that there is no standard set of codes for diagnosis INPUT. Our system is obsolete. It uses diagnosis OUTPUT codes[2] for diagnosis INPUT —both ICD–9-CM and ICD–10–CM are OUTPUT codes.

Instead of switching to ICD–10–CM, we should develop and implement a modern system for diagnosis INPUT[3] No system for this purpose exists today.

OUR CREDENTIALS

Willian Hogan, MD, MS is an Assistant Professor of Medicine in the School of Medicine of the University of Pittsburgh and a senior analyst in its Realtime Outbreak and Disease Surveillance (RODS) Laboratory. RODS carries out research under funding from DARPA, CDC, NLM, DHS, AHRQ, and NSF. Hogan has extensive experience in building biosurveillance systems, as well as conducting basic biosurveillance research. Prior to joining the RODS Laboratory in 2002, he worked at Health Language, Inc, where he gained expertise with vocabulary standards including ICD–9–CM and SNOMED. He is the expert on vocabulary standards at the RODS Laboratory, and led the effort at the RODS Laboratory to map proprietary codes used by eight hospital laboratories to LOINC[4] and SNOMED CT for electronic laboratory reporting. He has written on vocabulary standards, biosurveillance, and the intersection of the two.

Vergil Slee, MD, MPH, FACP, FACHE (Hon) was responsible for the first deployment of ICD in hospitals as a tool for diagnosis indexing, a task for which ICD was admirably suited at that time (1955). In 1975 he represented the U. S. at the WHO conference which designed ICD–9. In 1976 he became President of the Council on Clinical Classifications which, in collaboration with the U. S. National Center for Health Statistics, developed ICD–9–CM (1978). He has analyzed ICD–10–CM (Reference 6) and has written extensively on the expanding demands on medical record information (Reference 7), demands which have destroyed ICD's suitability for diagnosis input.

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[1] The MRHIS is the information system which originates with data in the medical records of hospitals and physicians' offices. It must first meet the needs of the physician as a memory and communication tool in care of the individual patient. Some medical record content is then used to support billing and to create statistics on health and healthcare.

[2] Output codes are codes which represent the labels of the categories of a classification which has been constructed for statistical purposes. Each diagnosis output category (code) contains a collection of the individual diagnoses which are its input. In both ICD–9-CM and ICD–10–CM, several hundred thousand specific diagnoses are collected into the few thousand categories of the classification. Most individual diagnoses, therefore, have no unique codes.

[3] Input diagnosis codes are codes which exactly represent diagnosis entities as expressed by the physician. The physician may or may not record a diagnosis using its "preferred term;" he may or may not even use a standard synonym. Following input, the computer system will add the "standard code" for the preferred term in order to facilitate finding it in all medical records.

[4] LOINC—Logical Observation Identifiers, Names, and Codes.

STATEMENT OF THE ISSUE:

The Federal government is being urged to replace ICD–9–CM diagnosis codes with ICD–10–CM diagnosis codes in the Medical Record Health Information System (MRHIS)[5] This system uses medical record data for three major purposes:

PRIMARY PURPOSE: Patient care. The medical record's primary, nonnegotiable purpose is to be the memory and communication tool for the physician. It has no substitute for the care of the individual patient.

SECONDARY PURPOSES: (1) Billing and (2) Statistics on health and health care.

BASIC FACTS:

Two essential facts about the MRHIS must be included in discussing the question of switching from ICD–9–CM to ICD–10–CM:

For patient care, the physician must have diagnoses in their greatest detail.

For billing and statistics, diagnoses must be grouped.

"ICD coding," the coding used in the MRHIS, is category coding,[6] which captures only the labels of the groups (categories) in a clinical modification of ICD. The ICD series[7] was designed for the OUTPUT of data for statistics (and, in the U. S., the clinical modification (CM) is essential for billing). The ICD series was never intended for INPUT, the purpose for which we (mis)use it. The precise diagnoses are simply discarded, except in the rare instance where a category has only one diagnosis (see the illustration on page 8). The result is that *ICD coding—category coding—is not useful for the physician in the care of the patient.*

Category coding has an especially pernicious effect for statistics. The coded data are already aggregated, and aggregated data can never be disaggregated—they can only be combined into larger groups (such as DRGs). This means that our health care system is in a "one-size-fits-all" situation and must use the same statistics for such disparate purposes as public policy, quality review, facility management, and evidence-based medicine. Common sense dictates that each of these uses has unique information demands and should have its own grouping of diagnoses. We propose a solution below.

SWITCHING FROM ICD–9–CM TO ICD–10–CM

Proponents of switching argue that switching is a cost-effective and necessary step to modernize our healthcare information system, that we must keep in step with other nations for international comparisons of morbidity, and that ICD–10–CM is more up-to-date, has more room for "things," can more easily accommodate new diseases such as SARS, and is better suited to biosurveillance for terrorist and emerging disease threats.

UP TO DATE: ICD–9, the parent of ICD–9–CM, was written in 1975 and ICD–9–CM was put into use in 1978. ICD–10 was written in 1989 and published in 1992. ICD–10–CM is still in draft form. The U.S. agreement with the World Health Organization (WHO) (the author of the ICD series of classifications) states that any clinical modifications (CM versions) must be "collapsible" back into the categories of ICD itself, which greatly reduces our freedom to keep it current with medical progress.

LACK OF SPACE: A second argument is that ICD–9–CM has few remaining codes to assign to new diagnoses. Actually it uses only about 13,000 codes out of the over 100,000 permitted by its structure. The problem is that it uses an antiquated code structure, where the code indicates the location of a category in a hier-

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[5] NOTE RE PROCEDURE CODING: Proponents of the switch to ICD–10–CM imply that it would also require the switch, for hospital inpatient records, from Volume 3 of ICD–9–CM to ICD–10–PCS (which was written by 3M under contract from HHS). Procedure coding is a separate issue from diagnosis coding. No simultaneous switch is necessary; the system could stay with the present procedure coding or consider the procedure coding available with SNOMED CT (Standardized Nomenclature of Human Medicine—Clinical Terminology). SNOMED CT is a *reference terminology* developed and maintained by the College of American Pathologists (CAP). SNOMED CT has been made available to the healthcare system by HHS under a contract with CAP.

[6] Category coding of diagnoses is coding in which each code (number) represents (the title of) a category of diagnoses, e.g., "Other diseases of the liver." In category coding, the coding of the diagnosis itself and its classifying are combined into one step.

[7] ICD, the International Classification of Diseases, is a serial publication of WHO. The U.S. created ICD–9–CM (a clinical modification, CM) in 1978 for use in hospitals and doctors' offices. ICD–10–CM based on ICD–10, first edition (1992), is now in draft in a version dated June 2003. WHO issued a second edition of ICD–10 in 2004. Presumably the U. S. ICD–10–CM would have to be made to correspond with each new edition.

archy of categories.[8] Modern computer methods do not require that codes be in such a numerical hierarchy. ICD–10–CM (2003 draft) has 67,000 codes, and thus one might expect that it has more clinically relevant detail, but this number is misleading. For example, one category, Code S82 Fracture of lower leg, including ankle, with its mandatory extensions, accounts for 3,248 of the codes in this count.

NEW DIAGNOSES: We have no system for promptly coding new conditions such as avian influenza, SARS, and Gulf War Syndrome (real or suspected) with ICD–9–CM, nor would we with ICD–10–CM. For example, there were no ICD–9–CM codes for SARS until October 1, 2003, nearly 3 months after the WHO lifted all its travel advisories and considered the outbreak under control. Nor is the system ready to uniquely identify avian influenza. The inability of a category coding system to classify new entities is due to the necessity of deciding what they are before deciding where to put them in the classification. There are also the requirements that a committee make the decisions, and that changes, which must be implemented first by human coders dispersed throughout the nation, are only made once a year.

INTERNATIONAL MORBIDITY DATA: The U. S. is under no obligation to use ICD for anything other than mortality data. In personal communication with Dr. Slee, a WHO statistician stated that for virtually all international morbidity studies, special data collection is required.

BIOSURVEILLANCE: Proponents of ICD–10–CM argue that it is essential to make the switch to have better disease surveillance for terrorist and emerging infectious disease threats. However, the current biosurveillance system makes little use of even ICD–9 codes for detecting disease outbreaks. When physicians, hospitals, and laboratories report notifiable diseases to public health, they do not use (nor are they required to use) ICD–9–CM codes. Influenza surveillance relies in part on mortality statistics (which are retrospective, of course), but mortality statistics are already compiled using ICD–10 (not ICD–10–CM) codes. We have already noted the inadequacy of ICD–9–CM for accommodating emerging disease threats such as SARS.

In view of these facts, the arguments as to advantages of ICD–10–CM over ICD–9–CM lose a great deal of their weight.

FINANCIAL IMPACT:

MONETARY COSTS: Two estimates have been made of the cost of switching to ICD–10–CM from ICD–9–CM. The RAND Corporation figure, for the Centers for Disease Control, was from $425 million to $1.125 billion over 10 years. The Robert E. Nolan Company figure, for the Blue Cross Blue Shield Association, was from $6 billion to $14 billion over 2–3 years. The higher figures are likely to be more accurate, because Nolan based its estimates on similar information technology conversions in the past, namely actual costs to the healthcare system of the year 2000 (Y2K) remediation and Health Insurance Portability and Accountability (HIPAA) compliance. Nolan also gave some details of actual costs incurred by Canada, Australia, and the United Kingdom during their switch to ICD–10.[9]

Regardless, the switch would require the commitment of human and financial resources which would thus not be available for solving the underlying problem with health care information: we use diagnosis output codes for diagnosis input. Detailed diagnosis input is a building block on which the entire MRHIS must be (re)built. It is critical that the healthcare system and the federal government devote resources to the solution of this problem, as we discuss below.

SAVINGS: The most optimistic estimate of the benefit of switching to ICD–10–CM is $7.7 billion over 10 years (Rand). By contrast, the projected savings to the healthcare system of a national health information network (NHIN), as envisioned by the Office of the National Coordinator for Healthcare Information Technology (ONCHIT), is $337 billion over the first 10 years, and $77.8 billion per year thereafter (Reference 1). This estimate assumes the use of the EMR, the adoption of which requires diagnosis input codes *in place of* ICD–9–CM codes.[10] Importantly, none of the benefit of NHIN results from switching to ICD–10–CM.

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[8] ICD–10– and ICD–10–CM maintain this antiquated hierarchical code structure, but have a higher number of possible codes. Depending on how our knowledge of disease increases, ICD–10 could also eventually "run out of codes" in some parts of its category hierarchy.

[9] Canada created and implemented its own modification of ICD–10 called ICD–10–CA. Similarly, Australia created and implemented ICD–10–AM. The U.K. uses ICD–10 for morbidity with no modifications. Note that each has used a different version of ICD–10, thus making international comparisons far more difficult than if the same code version (clinical modification) were used.

[10] The ICD–9–CM coding would continue, however, since it is at the heart of the billing process, and financial stability must be maintained.

BUILDING NHIN: Achieving this goal would be seriously delayed. In the event of a switch to ICD–10–CM physicians would have to give the new code system priority over the EMR so that they could maintain revenue. Health plans considering financial incentives to physicians for adopting EMRs would have to divert resources to the ICD–10–CM switch. Hospitals, health plans, physicians, and state governments would all have fewer resources to devote to developing health care data exchange.

INFORMATION COSTS: The costs of the switch in its effects on health and healthcare information cannot be predicted, but they may well be, in the long run, more important than money. One particular effect:

Longitudinal studies (studies which cross the date on which classifications change, e.g., from ICD–9 to ICD–10) usually are seriously disrupted and often have to be abandoned. Disturbance of such studies costs money as well as information. To illustrate with one such study:

ICD–10 has been used for U.S. mortality tabulations effective with 1999 death certificates. In Florida, the AIDS death rate, which had been declining by about 6% per year until 1999 took a sudden *rise* of about 6% in that year. Investigation showed that this 12–13% jump was entirely due to the coding change; the true trend had been badly distorted (See Reference 2).

INFORMATION QUALITY: Information quality always sags, often for several years, simply as the result of changing coding (the effects are prolonged by the fact that implementation cannot be achieved on a single date; all elements of the system, from coders, through computers, must be up to speed before the system becomes reliable).

HOSPITAL AND PHYSICIAN REIMBURSEMENT: Our reimbursement system is in financial equilibrium. Any change in coding would require recalibration, involving collection of both medical and financial information on huge numbers of patients (enough to give statistical validity to each DRG, for example), and parallel operation of both the old and the new systems until reliability could be guaranteed. This is truly a non-trivial aspect of switching.

MODERNIZATION OF THE MRHIS: The switch would delay attention to actually modernizing the system, as outlined below.

MODERNIZATION OF THE MRHIS

We contend that we should not try to put a "band-aid" on our obsolete MRHIS. Instead, we should develop the missing component, a system for INPUT of diagnoses, and bring the system up to 21st century standards. Modernization should start with these steps:

1. **DELAY THE SWITCH** to ICD–10–CM: We should continue to use ICD–9–CM, modifying it as necessary for the reimbursement system, in order to free the resources, human and financial, needed to modernize the system.
2. **DEVELOP A CODED DIAGNOSIS INPUT SYSTEM:** Add diagnosis entity coding [11] to the medical record.

It is a basic principle in science that original observations—in this instance, original medical records—should be preserved permanently, without alteration, in order to permit review and further analysis as needed. Preserving diagnoses only after they have been placed in groups and have lost their individual identity, as we do today with category coding input, is a gross violation of this basic principle. The practice is an embarrassment and should be stopped immediately. Entity coding would permanently preserve the original diagnoses.

The needed input system would be simple and user-friendly for the physician—with no look-up or coding required. This would demand three critical attributes. The system would

a. Accept natural language input for any term the physician wishes to use (See Reference 8 which discusses "free vocabulary" and References 3 and 4 which discuss the need for an "interface" vocabulary for users of EMRs).

b. Map, by computer, this free language term to a standard vocabulary such as SNOMED CT. (SNOMED CT is a *reference* terminology for well-studied conditions, not an input terminology, although its preferred terms are, of course, often those the physician normally uses.)

[11] Diagnosis entity coding, necessary to modernize MRHIS, is coding in which each code represents an individual diagnosis entity. The diagnoses can, with this coding, be placed in ANY classification, e.g., ICD–9–CM, ICD–10–CM, or policy, planning, or research groupings.

c. Provide instant, "realtime" codes for new diagnoses such as SARS—coding for new terms is delayed in the present system for months or years, as was the case with AIDS.

3. **DEPLOY THE INPUT SYSTEM:** Make the entity diagnosis coding system freely and readily available to all elements of health care.

ADVANTAGES OF THE MODERNIZED SYSTEM

The modernized system would

1. Provide physicians the detailed diagnoses they need for patient care.
2. Remove a major barrier to acceptance of the EMR.

America's Health Insurance Plans
Washington, DC 20004
July 26, 2005

The Honorable Nancy Johnson Chairman
Subcommittee on Health
House Ways and Means Committee
1136 Longworth Building Washington, D.C. 20515

Dear Madam Chair:

On behalf of America's Health Insurance Plans (AHIP), I am writing to submit testimony for your subcommittee's July 27 hearing on health information technology.

AHIP and our members are committed to playing a leadership role in developing an interconnected health care system—based on voluntary, national, uniform standards—in which consumers and providers have access to patient-owned Personal Health Records (PHRs) that provide integrated health information, from all clinicians and all settings of care, in a usable form and in a timely manner. Our testimony focuses on several key areas:

- opportunities to deploy health information technology to improve quality, value and efficiency for health care consumers;
- the role health insurance plans are playing in advancing health information technology through the Ambulatory Care Quality Alliance (AQA) and other initiatives; and
- the importance of establishing consumer-centric Personal Health Records (PHRs) that are fully compatible with Electronic Health Records (EHRs).

We are pleased that health information technology has been the focus of bipartisan legislation in both chambers of Congress. At the same time, we have serious concerns about one proposal addressed by several pending bills. Specifically, we strongly oppose provisions that would relax the federal fraud and abuse laws for the purpose of allowing hospitals to support physician use of health information technology. We are concerned about the unintended consequences of tying physicians to hospitals financially through equipment subsidies or electronic record sharing. Moreover, the ability of physicians to cooperate with other providers—and deliver services in a range of hospitals—may be hindered if they become dependent on a hospital-based information sharing network.

Another concern is that the proposed exceptions could unintentionally lead to local information sharing programs that are isolated and impede the development of the interconnected system that is needed to exchange information across the country. We believe that creating new exceptions to the current fraud and abuse laws is not only unnecessary, but will undermine the integrity of the existing regulatory framework.

Thank you for considering our concerns on this issue. We also appreciate this opportunity to submit testimony on the broader issue of advancing an interconnected health care system to improve the delivery and quality of health care in America.

Sincerely,

Karen Ignagni

Statement of Rebecca Marshall, American Academy of Pediatrics, Elk Grove Village, Illinois

Introduction

This statement is submitted on behalf of the American Academy of Pediatrics (AAP), an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists who are dedicated to the health, safety, and well being of infants, children, adolescents, and young adults. The AAP would like to thank the House Committee on Ways and Means for the opportunity to submit a statement for the record on congressional involvement to further the adoption of health information technology (HIT).

Key Principles

In January 2005, the AAP joined with the American Board of Pediatrics, the Child Health Corporation of America, and the National Association of Children's Hospitals and Related Institutions to develop the following key principles of a National Health Information Infrastructure:

1. Every child should have a personal electronic health record that is available 24 hours a day, 7 days a week, in whatever location is necessary to provide care to the patient. If regional networks are formed to facilitate the sharing of data within a community, it is crucial that these networks be built using the same national standards for data, functionality, and transmission so that patient information may be shared across networks when necessary.
2. All information systems must be built on national standards for both data and functionality. The Health Level 7 (HL7) EHR Draft Standard for Trial Use, its accompanying standards, and future versions should be adopted in all health care settings, including hospital, ambulatory care, and public health. The use of controlled medical terminology should be encouraged in the design of any data structure.
3. A standard method of transmission of data among information systems must be established.
4. All information systems and procedures for data transmission must protect the privacy and integrity of patient data through compliance with the Privacy and Security Rules of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Systems must also be flexible enough to enable more stringent controls where required by law. Data sharing will require national standards for authentication of users and verification of access rights, and must support audit tools.
5. The availability of planning and implementation grants to begin building local networks based on national standards and including all health care providers would greatly improve the speed at which the NHIN will develop.

These key principles highlight the need for national standards for data, functionality, transmission, and vocabulary so that a patient's electronic health record is accessible wherever it is needed, whenever it is needed.

Resource Challenges

It is well known that one of the greatest challenges in encouraging physician adoption of HIT is the misalignment of incentives. Pediatricians wishing to implement EHRs face additional challenges.

1. Children, who are generally healthy, account for less than 12% of personal health care spending. Therefore, market incentives have not compelled private industry to focus on the unique IT needs of the health care of children. As a result, the development of IT focused on children's health care progressed more slowly than in other areas. Where it does exist, the provider must have the resources to develop customized IT systems. Of the pediatric dollars spent, 80% are generated by children with special healthcare needs (who in turn constitute approximately 16% of the pediatric population).[i] This figure supports the need for financial incentives for systems that improve care for the most medically complex children. In addition, since these children are living longer, adult systems will eventually need to handle the same functions in order to care for patients who transition out of pediatric care.
2. Because pediatric evaluation and management services are often compensated at lower rates than the equivalent adult services or procedures, children's doc-

[i] Health Care Financing Review/Web Exclusive/December 2, 2004, Volume 1, Number 1, page 2.

tors—pediatricians and family physicians—often are unable to invest either the money or time required to obtain and use IT appropriately.

3. Because pediatricians do not make frequent use of transcription and often practice in solo practice or small groups, the usual components of return on investment (reduced transcription costs and reduced staff support) either do not apply or apply only marginally to practices, making investment in an EHR difficult to recoup.
4. To date most public resources for IT development have been focused on the Medicare population, with quality improvement efforts focused on adult measures. This leaves physicians who care for children at a disadvantage, since there are only approximately 12,000 pediatric Medicare beneficiaries, and risks allowing market forces to drive EHR development based almost exclusively on adult care.

Recommendations

In order to encourage adoption of HIT without impeding progress already being made, Congress should:

1. Ensure that the Office of the National Coordinator for Health Information Technology receives sufficient funding to continue its work.
2. Allow for licensing and support of national health information standards identified by the Department of Health and Human Services.
3. Provide funding to support activities of standards development organizations, which often rely on volunteers for labor-intensive development, refinement, and maintenance of standards.
4. Ensure that legislation impacting healthcare quality improvement activities and incentives for HIT adoption apply to Medicaid and SCHIP populations, in addition to Medicare.
5. The Stark laws and anti-kickback legislation should be relaxed to allow for data-sharing between the hospital and the ambulatory practice. In addition, since large medical centers typically have financial and other resources for development of clinical information technology that small, ambulatory practices do not, there should be some provision for sharing of those resources to assist local providers in accessing the RHIO.

In conclusion, the American Academy of Pediatrics fully supports efforts to speed the adoption of electronic health records across the nation. The Academy is heavily involved in clinical information technology standards-setting and in assisting its members as they make this transition. The fate of our children's healthcare is at stake. We are available to answer any questions you may have regarding this very important subject, especially as it relates to children. The Academy appreciates your efforts, which will assist our members and all those who care for children in improving health care quality and safety.

Statement of Jane M. Orient, M.D., Association of American Physicians & Surgeons, Tucson, Arizona

Madame Chairman and Members of the Committee:

The Association of American Physicians and Surgeons was founded in 1943 to preserve private medicine. We represent thousands of physicians in all specialties nationwide, and the millions of patients that they serve. I am the executive director, and a practicing internist in Tucson, Arizona

Nine years ago, President Bill Clinton signed into law the Kennedy-Kassebaum bill, also known as the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It was the end product of three and a half contentious years of White House and Congressional horse-trading. These efforts resulted in new laws that were supposed to make health insurance easier to purchase, with the capability to follow a worker from one job to another, with policies more responsive to the needs of patients, doctors and hospitals. It was also supposed to help 38 million Americans obtain health insurance.

There are now an estimated 45 million uninsured Americans, according to the U.S. Census Bureau and other government sources. Premium increases grew by 8% in 2000, 11% in 2001, 13% in 2002 and 14% in 2003. We now spend an estimated $480 billion annually on U.S. health care, according to the Robert Wood Johnson Foundation.

We believe that this situation is in large part the unintended consequences of HIPAA. Additionally, many of the rules of HIPAA continue to erode the quality of health care, add to the cost of medical and administrative services, and undermine the patient-physician relationship.

Rather than making medical care portable and more accountable, HIPAA has apparently laid the foundation for a one-size-fits-nobody national health insurance program. Reliance on the Internet and an interoperable technology system may promise cost-savings to the federal government and certain third-party payers, but it will add enormous, unsupportable costs to private practitioners and small facilities. Moreover, many physicians fear that the establishment of an Internet-based health information infrastructure will enable facilitate, or even lead inexorably to an effective hostile government takeover of American medicine.

One of the objectives of HIPAA is the creation of a mandatory electronic coding, tracking and surveillance system that would use a uniform set of codes for every single medical procedure. Every doctor, hospital and clinic would be required by law to submit these coded procedures so that diseases could be tracked and "quality" could be monitored. Even if proponents deny that a national database would be established, the existence of multiple, interoperable databases would be its functional equivalent. In other words, everyone's personal medical history, including the most sensitive and intimate records, would be accessible on the "worldwide web" to persons unknown to the patients, with unpredictable and potentially devastating effects.

Back in 1996, when the "Information Superhighway" began electronically linking all of humankind, it was paved with fiber optics that led to high-speed modems. There were no visible potholes, viruses or worms, and just a few annoying pop-ups. The Internet looked like the answer to our dreams of a modern world, but it has become a dangerous place for storing personal records of any kind.

One only needs to consult the Congressional Record of June 23, 2004 to better understand the intent and scope of medical information technology: Upon introduction of his Health Care Modernization, Cost Reduction and Quality Improvement Act of 2004, legislation (S. 2421, 108th U.S. Congress) amending HIPAA and the Public Health Service Act, Sen. Edward Kennedy explained his vision for medical information technology:

"The legislation we are introducing is an effective way to modernize and improve the health care system, by using modern information technology, by paying for **value and results [emphasis added]** and not simply for procedures performed or patients admitted to hospitals, and focusing in improving quality and preventing disease," Kennedy explained to his colleagues.

In one paragraph, Kennedy proposed that what was supposed to be a way to help seniors pay their medical bills into a command-and-control economy directed from Washington. His assumption that government knows enough to define "value and results" and should have the authority to deny payment for services rendered in good faith illustrates immense chasm of understanding of American health that currently exists between the U.S. Senate and the practitioners of modern medicine

The government takeover begins with so-called Pay-for-Performance (Pay-for-Conformance really) within the Medicare program. Doctors would not be allowed to participate in Medicare unless they met all the information technology requirements proscribed by the U.S. Congress.

But that is just the camel's nose! Even if in compliance with the electronic requirements, doctors would only be paid for what bureaucrats decide should be done, under what circumstances, for whom, and with what results—in other words only for care that follows government "guidelines." (These will be "voluntary," so physicians will be responsible for any untoward consequences, but any "deviation" will have to be justified or punished.) If paid only for "successful" outcomes, physicians who desired to remain financially solvent might be forced to restrict their practice to patients with a relatively good prognosis, who are inclined to follow doctor's orders.

Under the guise of streamlining the practice of medicine by discouraging any procedures that computers might be able to identify as defensive medicine, Pay-for-Performance becomes an obstacle to medicine tailored to the needs of individual patients by focusing only on pre-approved procedures for specific treatments and illnesses.

The electronic surveillance of medicine would make it that much easier for trial lawyers to sue doctors, and doctors who would no longer be paid for defensive medical practices. Under Kennedy's proposal, doctors would not be paid for anything but results

If the House Ways & Means Committee and the U.S. Congress intend to reduce medical costs, increase quality, and eliminate needless tests and administrative

overhead, a good first step would be to complete work on long-overdue and badly needed caps on monetary awards for "pain and suffering," limits on contingency fees that lawyers charge, and penalties for filing unfounded lawsuits.

Instead, the federal government may require use of the Internet to expose private medical records, monitor medical procedures, and dictate the day-to-day operations of doctors' offices, hospitals, and pharmacies.

The government-dictated medical information technology movement and the intrusive, restrictive central planning in American medicine that it would foster would render the practice of modern medicine as we know it today virtually impossible. The quality and privacy of medical care would suffer, as well as availability, because many excellent practitioners are likely to become demoralized and withdraw from active practice as soon as possible, unwilling to perform under constant surveillance by bureaucrats. Advancements in medical technology and groundbreaking treatments for disease would become nonexistent, because the federal government would control all financial incentives for medical research and development.

As the members of this Committee debate the broader issues of medical information technology, and the potential for cost-savings for government programs like Medicare and Medicaid, please keep foremost in your mind the need to protect the sacred relationship between physicians and their patients. In this 109th U.S. Congress, doctors and their patients are facing a deluge of punitive and doctrinaire regulatory proposals including the failure to reform medical liability laws, moratoriums on physician financial interest in specialty hospitals, information technology requirements for physicians participating in Medicare, and now the proposed assault on the actual practice of medicine—pay-for-performance.

The Association of American Physicians and Surgeons is urging restraint, reflection and reassessment of the use of relatively novel information technology and its relationship with government programs and federal and state spending on health care. Forcing technology on medicine by top-down central planning risks an end to advancements in information technology, as outmoded, inappropriate, cumbersome systems are imposed. Physicians and medical facilities will voluntarily adopt technology as they find it serves their patients well, just as they have been quick to use new imaging technology, surgical procedures, and medications.

Please do all you can to roll back destructive federal interference in medicine, so that those with actual knowledge of medicine and of their patients can do their jobs efficiently, economically, and privately. At least, stop adding new burdens to a system already overloaded by counterproductive regulation.

Statement of Robin J. Thomashauer, Council for Affordable Quality Healthcare

The Council for Affordable Quality Healthcare (CAQH) is an unprecedented alliance of the nation's leading health plans, networks and industry trade associations (see Appendix) working collaboratively to help improve the healthcare experience for consumers and providers. Our members, who provide healthcare coverage to more than 50 million Americans, are strongly committed to developing and implementing programs that reduce administrative burdens for physicians and patients and improve quality of care. On behalf of its Board of Directors and members, we appreciate the opportunity to submit a written statement for consideration by the U.S. House Ways and Means Committee for inclusion in the printed record of the Subcommittee on Health July 27, 2005 Hearing on Health Care Information Technology.

The purpose of this statement is to make the committee aware of a public-private, multi-stakeholder initiative that is currently developing an approach to promote and facilitate interoperability between health plans and providers. Facilitated by CAQH, the initiative is called the Committee on Operating Rules for Information Exchange or CORE.

Interoperability

The benefits of an interoperable healthcare system are well understood. However, technology adoption rates, data security, and inconsistency associated with transactions between health plans and providers have made interoperability in the healthcare arena extremely difficult. No quick, effective mechanism exists today for provider practices to access consistent patient administrative data—plan coverage, co-pays, deductibles, etc. Furthermore, the information that is available varies from plan to plan, requiring provider office staff to spend hours of time on the phone or

Web tracking down information. It is estimated that the cost of this administrative work runs in the millions of dollars per year. Incomplete or incorrect data has often been cited as a significant cause of denied claims by insurers. CAQH and its members strongly believe that interoperability between providers and plans is critical to advancing improvements in healthcare data transactions.

The Banking Industry Model

After conducting extensive research on the best approach for facilitating interoperability, CAQH determined that a solution could be found in the banking industry. In that sector, electronic data exchange rules—embraced by the industry—has made ATM transactions and direct deposits an everyday occurrence. Throughout 2004, CAQH worked with NACHA, The Electronic Payments Association, and other experts in the banking field to develop an organizational structure by which all appropriate stakeholders could participate in an initiative to bring interoperability to healthcare. NACHA establishes and enforces the standards, rules and procedures that enable financial institutions to exchange payments on a national basis through the ACH (Automated Clearing House) Network. CAQH drew on the organization's more than 30 years of expertise in developing operating rules for the financial and energy industries.

Committee on Operating Rules for Information Exchange (CORE)

CORE is the result of the collaboration between CAQH and NACHA. Launched in January 2005, CORE is bringing together industry stakeholders to build consensus on a set of operating rules that will govern eligibility and benefits data exchange. It is important to note that the initiative is solely focused on developing operating rules and not software solutions. CORE believes that industry vendors, including those currently participating, will develop software products that adhere to the operating rules and enable consistent data exchange.

Based on that focus, CORE is working to

- Identify common business practices between trading partners that will facilitate ease of information exchange and influence the simplification of data exchange between disparate processing systems by supporting the identified common business practices
- Ensure all recommendations are independent of any technology or vendor solution
- Interact with standard setting bodies to facilitate business rules enhancements (CORE rules will be built on existing HIPAA standards)
- Define clear roles and responsibilities for all stakeholders: technology solution vendors, payers (public and private) and their trading partners, business associates of trading partners and clearinghouses, and providers
- Identify key changes that must be made by trading partners
- Suggest migration steps to promote successful adoption of CORE operating rules
- Promote and encourage voluntary adoption of the rules with tools and support
- Support HHS national health information network Guiding Principles
- Report and monitor successes and status of mission by participating entities and provide tools and assistance, where possible, to assist in the implementation of CORE's mission, vision and strategy

A Phased Approach

CORE was envisioned as a multi-phase initiative (see timeline below). Stakeholders strongly believed that a process allowing meaningful but achievable initial results was particularly important. Therefore, its first set of operating rules, slated for rollout in early 2006, will help standardize delivery of the following set of data to providers:

- Determine which health plan covers the patient
- Determine patient benefit coverage
- Confirm service type
- Confirm the patient's copay amount (as defined in the member contract)
- Confirm the patient's coinsurance level (as defined in the member contract)
- Confirm the patient's base deductible levels (as defined in the member contract)

Initial CORE efforts (Phase I) are building on applicable HIPAA eligibility transaction requirements. Going forward, CORE will create rules for additional components of eligibility transactions, such as the amount the patient owes for services, what amount the health plan will pay for authorized services and coordination of benefits, enrollment/ disenrollment and claims status, prior authorization and referrals. CORE's long-term aim is to standardize a comprehensive set of patient admin-

istrative data, greatly decrease data request response times and eliminate phone calls and website searching to track down the information.

CORE Participation

CORE participation is open to every organization that has an interest in eligibility transactions. To date, the initiative has succeeded in attracting nearly 70 industry stakeholders. These include health plans, providers, vendors, CMS and other government agencies, associations, regional entities, standard setting organizations and organizations from the banking industry (see Appendix).

Participating organizations are contributing input on the operating rules by serving on CORE's Steering Committee and/or its three work groups.

Steering Committee—Accountable for CORE strategic oversight and creation of a long-term vision with objectives and implementation time frames.

Policy Work Group—Developing CORE policies and procedures, such as a contractual participant "pledge" that states commitment to comply with CORE operating rules.

Technical Work Group—Determining the technical specifications for CORE.

Rules Work Group—Writing the detailed business rules that will be reviewed by the Steering Committee and voted on by CORE members.

CORE Timeline

The initiative is on track to finalize Phase I rules and policies by year-end and encourage participant implementation in 2006. All participating organizations recently received a Mid-year Communication Package, which included "strawman" drafts of the CORE Phase I rules, such as the CORE pledge and standards for response times. The rules will be completed and tested by the end of 2005.

CORE's three phases are scheduled as follows:

Phase 1: 2005—Early 2006

- Establish CORE Vision, Steering Committee and Work Groups
- Create operating rules for selected patient eligibility and benefits data elements and create a formal methodology to gain market commitment and adoption

Phase II: 2006—2007

- Promulgate and promote adoption of CORE Phase I operating rules
- Identify other opportunities to enhance market adoption and industry support for interoperability among trading partners
- Create rules for additional components of eligibility transactions, such as the amount the patient owes for services, what amount the health plan will pay for authorized services and coordination of benefits
- Create rules for other business transactions, which may include enrollment/disenrollment and claims status

Phase III: 2007 and Beyond

- Promulgate and promote adoption of CORE Phase II operating rules
- Identify other opportunities for enhanced interoperability among trading partners
- Create rules for other business transactions, which may include prior authorization and referrals

In Conclusion

CAQH, its Board and members and all CORE participants support an interconnected healthcare system that allows for real-time, standardized, quality data exchange among all stakeholders. We are committed to playing a leadership role in achieving that system. And we believe that the time to pursue that goal is now and feel certain that CORE will make a significant contribution.

As Congress works to address the many issues surrounding healthcare IT, we are eager to offer our assistance. CAQH looks forward to a continuing dialogue with committee members on modernizing the healthcare system.

Statement of Richard Trachtman, American College of Physicians

The American College of Physicians (ACP)—representing 119,000 physicians and medical students—is the largest medical specialty society and the second largest medical organization in the United States. Internists provide care for more Medicare patients than any other medical specialty. Of our members involved in direct patient care after training, 50 percent are in practices of 5 or fewer physicians and 66 per-

cent are in practices of 10 or fewer. We congratulate Subcommittee Chairman Nancy Johnson and Ranking Member Pete Stark for recognizing the importance of moving toward an interoperable health information technology infrastructure and the crucial role the federal government has in assisting the health care industry acquire and utilize information technology. Thank you for holding this important hearing on congressional involvement in speeding the adoption of health information technology.

Background

In the Institute of Medicine's (IOM) 2001 Report, "*Crossing the Quality Chasm—A New Health System for the 21st Century*," the authors describe the growing disparity between society's willingness to embrace the advantages of information technology in many aspects of everyday life, with the exception of health care. The IOM report cautions, however, "In the absence of a national commitment and financial support to a build a national health information infrastructure—the progress of quality improvement will be painfully slow."[1] Since that time, numerous studies and other policy experts agree that the full adoption and utilization of health information technology (HIT) can revolutionize health care delivery by improving quality of care and reducing high medical costs.

Meanwhile, Congress and the Administration have taken some initial steps to advance the adoption of an interoperable health information infrastructure model. The 2003 Medicare Modernization Act anointed the Commission for Systematic Interoperability to take the lead in developing a strategy for the adoption of uniform national standards. In the 109th Congress, several bills have been introduced to mold the framework for adopting HIT infrastructure.

President George W. Bush also seized on the opportunity to further HIT adoption. In his January 2004 State of the Union address, Bush first described the benefits that information technology will bring to the health care sector: "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs and improve care."[2] The President backed up this support by proposing additional funding for federal HIT initiatives in his FY 2005 and FY 2006 Budgets.

More significantly, however, was the April 2004 announcement by the President calling for the widespread adoption of interoperable electronic health records within the next decade. To oversee this bold, new, ten-year initiative, the President announced the creation of the Office of National Coordinator for Health Information Technology (ONCHIT), and named its first Director, Dr. David J. Brailer. Subsequently, ONCHIT devised a 10-year funding strategy for policymakers to consider in speeding HIT adoption nationwide. According to ONCHIT's "Framework for Strategic Action," Congress should consider several funding options, including additional Medicare reimbursement as well as the use of loans, tax credits, and grants. It also should consider the easing of fraud and abuse laws to allow the sharing of electronic hardware.

ACP strongly supports the Congress and the Administration in these initiatives to speed the adoption of uniform standards for health information technology (HIT). The College is committed to providing practicing internists with practical tools to help them improve quality. ACP's Physicians Information and Education Resource (PIER) provides ACP members—at no cost to them—with access to "actionable" evidence based guidelines at the point of care for over 300 clinical modules. PIER has also been incorporated into several electronic health record systems. It is currently in the process of aligning its evidence-based content to support a starter set of measures selected by the Ambulatory Care Quality Alliance (AQA). PIER is also creating paper order sets that imbed such quality measures so that physicians who have not made the transition to electronic health records could still utilize PIER content to support their participation in performance measurement initiatives.

ACP's Practice Management Center has developed resources to help internists in the decision-making process on electronic health records and is leading an initiative to provide internists with tools and best practices to help them redesign their office processes to improve health care quality.

But without sufficient financial assistance from the federal government to incentivize providers to purchase the full range of HIT, particularly those in small physician practices, we will be unable to achieve a smooth transition into a fully-integrated HIT society. **We believe it is absolutely essential for Congress to**

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[1] Institute of Medicine, *Crossing the Quality Chasm—A New Health System for the 21st Century*, March 2001, and U.S. Department of Human Services, Information for Health: A Strategy for Building the National Health Information Infrastructure, Report and Recommendations from the National Committee on Vital and Health Statistics, November 15, 2001.

[2] Bush, George W., State of the Union, Washington, DC, January 20, 2004.

begin to immediately fund initiatives to adopt uniform national standards, and to fully fund the pilot testing of HIT integration into all health care sectors.

The Benefits of Interoperable Health Information Technology

Policymakers agree that the universal utilization of interoperable HIT can revolutionize health care delivery by putting real-time clinically relevant patient health information and up-to-date evidence-based clinical decision support tools into the hands of providers. Adoption of HIT at all levels of health care will lead to the improvement of health care quality and reduce the high costs for individuals with complex health problems, particularly for those Medicare patients with multiple costly chronic conditions.

Investment in the adoption of HIT is expected to result in significant return savings. **The Department of Health and Human Services (HHS) and ONCHIT both agree that savings from a universal interoperable HIT infrastructure could achieve between $140 billion to $170 billion per year, close to 10 percent of total U.S. health spending.** They note the majority of these savings would be achieved by reducing duplicative care, lowering health care administrative costs, and avoiding costly medical errors. Independent studies also confirm substantial annual savings as well.[3]

The savings could even be more substantial when the adoption of HIT is coupled with value-based purchasing programs (also known as "pay-for-performance"), now under consideration by key congressional committees. Substantial savings in the Medicare Part A Trust Fund could be captured by preventing unnecessary hospitalizations caused by complications, needless duplications of medical tests and procedures, and the lowering of health care administrative costs. Unfortunately for small physician practices considering whether to make a significant investment in converting their practice to a fully-integrated HIT system, the cost-benefit analysis of making the initial purchase currently favors the public and private payer over the health care provider.

Costs of Acquiring Health Information Technology

The single biggest barrier to achieving fully interoperable HIT across the nation is the substantial cost in acquiring the necessary technology. This obstacle is especially acute for physicians practicing in small office settings, where three-fourths of all Medicare recipients receive outpatient care.[4] An additional related barrier is that public and private payers, not the physicians, will realize the savings from physician investment in acquiring the necessary HIT (i.e., electronic health records, electronic prescribing, clinical decision support tools, etc).

The initial start-up costs for the purchase of a fully interoperable HIT system can be substantial. **Depending on the size of the practice and its applications, acquisition costs on average range from $16,000 to $36,000.**[5] (The Harvard Center for Information Technology Leadership estimates HIT systems cost about $29,000 per physician). The ongoing costs associated with training, maintenance, and system support of the HIT system make these estimates substantially higher over the lifetime of the practice.

Unfortunately, the savings from interoperable HIT will largely go unrecognized for physicians making the investment to convert their practices. In fact, it's more likely the majority of the savings from physician investment will be recognized by payers and patients—through a reduction in duplicative care, the lowering health care administrative costs leading to lower health insurance rates, and avoiding costly medical errors—not to the providers that pay the initial and ongoing implementation costs. **ACP strongly believes that physicians' collective and individual contributions must be recognized in order to achieve Medicare and Medicaid savings through HIT adoption. Current reimbursement policies should allow for individual physicians to share in the system-wide savings that are attributable to their participating in HIT and other quality improvement programs.**

While the College and the physician community recognize the great potential for improving the overall quality of care that HIT brings, the majority of small physi-

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[3] Walker, Jan; Pan, Eric et al., Health Affairs, "The Value of Health Care Information Exchange and Interoperability," January 2005. "Full standardized health care information exchange and interoperability could yield a net value of $77.8 billion per year once fully implemented."

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

[5] Congressional Research Service, "Health Information Technology: Promoting Electronic Connectivity in Healthcare," The Library of Congress, April 13, 2005.

cian practices cannot afford to expend the necessary capital to make the initial investment. For physicians dealing with a multitude of financial issues—ranging from low reimbursement under Medicare and Medicaid, declining fees from managed care, the rising costs of medical malpractice insurance, and the cost of compliance under increasing state and federal regulation—the majority are not in any financial position to make the initial $16,000 to $36,000 investment.

The reality of HIT underinvestment by the typical physician practice is affecting millions of Medicare beneficiaries. The Center for Studying Health System Change (HSC) recently released a study documenting the significant lack of Medicare beneficiary access to physician practices with fully-integrated HIT systems. The study monitored physician practice adoption trends for the following five clinical functions: obtaining treatment guidelines; exchanging clinical data with other physicians; accessing patient notes; generating preventive treatment reminders for the physician's use; and writing prescriptions.

While nearly half of the Medicare outpatient visits used at least one of these five clinical functions, according to the HSC study, only 9 percent of visits were to physician practices with electronic prescribing capabilities. The study concluded that while Medicare is targeting small practices by offering technical assistance and undertaking a chronic care pay-for-performance demonstration, "Broader policy efforts—including financial incentives—may be needed, however, to substantially improve patient access."[6]

The Need for Immediate Congressional Involvement

The current Medicare physician reimbursement system does not reward physicians for quality. Because physicians are paid on a per-procedure or per-service basis, the Medicare reimbursement structure emphasizes volume over quality. In recognition of the need for a Medicare reimbursement system that rewards innovation and quality, Congress is examining the role that value-based purchasing programs might play in the Medicare program.

ACP strongly believes a solution to this problem lies in changing the Medicare physician payment policies to reward those physicians who fully incorporate all aspects of HIT (and value-based purchasing programs) into their practice. Under today's Medicare payment formula,physician payments is based upon several factors: relative value units (RVUs) for each service, reflecting the relative amount of physician work effort, practice expenses, and malpractice insurance expenses involved with furnishing each service; a dollar conversion factor that translates these RVUs into monetary payment amounts; and geographic practice cost indexes (GPCIs) for physician work, practice expenses, and malpractice insurance expenses to reflect differences in physician practice costs among geographic areas.

But in order to speed the adoption of HIT into physician practices, and to take into account the *ongoing*, everyday costs associated with maintaining such systems, the College recommends Congress consider legislation that builds into the Medicare physician payment system an add-on code for office visits and other evaluation and management (E/M) services. This payment mechanism should identify that a service was facilitated by electronic health data systems, such as electronic health records, electronic prescribing and clinical decision support tools, and reimburse accordingly.

In addition, Congress should also allocate the necessary funding for small physician practices to make the *initial* HIT investment to purchase the necessary hardware and software. The majority of bills that have been introduced in the 109th Congress only utilize either grants, loans, tax credits, or a combination of the three. We believe those funding mechanisms alone are insufficient to put the necessary HIT systems into the hands of small physician practices.

Finally, the College is growing deeply concerned over the lack of coordination in the creation of uniform HIT standards. In order to facilitate the seamless and secure transition to an electronic flow of health information, Congress must push for the adoption of uniform standards for everyone to use. To date, several standards have already been developed by a mixture of public and private entities. Unfortunately, these entities are, in most cases, duplicating efforts. We believe Congress must intervene in this process and bring public and private entities together into one decision-making body to agree on existing standards, determine what additional standards are needed, prioritize future standard development, and make sure approved standards are maintained.

ACP is very supportive of the initiative recently announced by HHS Secretary Mike Leavitt to create the American Health Information Community (AHIC), a public-private collaboration that will help develop standards and achieve interoper-

[6] See HSC study, July 2005.

ability of health information. This collaboration will provide a forum for interest ed parties to recommend specific actions that will accelerate the widespread application and adoption of electronic health records and other health information technology. We believe an entity, such as AHIC, should be recognized as the sole organization charged with developing uniform standards and certifying HIT products for industry use. **Therefore, Congress must immediately authorize and provide the sustained funding to begin the development of uniform national HIT standards.**

Once developed, HIT standards will need real-world pilot testing. This should come as no surprise to Congress given the dire situation we found ourselves in 2003 with the implementation of standards mandated under HIPAA Transaction and Code Sets Standard. As with HIPAA Standards compliance, implementation of HIT standards will require time and a significant amount of pilot testing by the full range of health care providers from all sectors with adequate HIT in place. Testing must include physicians in solo/small and large practice settings (rural and urban areas), psychologists, hospitals, community health centers, skilled nursing facilities, laboratories, and pharmacies. All participants in the pilot must utilize the full range of HIT systems and the necessary ongoing training must be provided. **Therefore, we believe Congress must provide the necessary funding to ensure adequate testing of HIT standards across all health care sectors. These pilot tests can begin immediately as standards become accepted. As additional standards are approved, they can be immediately incorporated into the pilot.**

Legislation in the 109th Congress

In the 109th Congress, a flurry of legislative proposals has already been introduced to define the federal role in speeding the adoption of HIT. ACP is supportive of many of the bills that have come forward, especially those we believe will lead to the achievement of universal acceptance and adoption of HIT. We are also appreciatative of the Senate-passed FY 2006 Budget Resolution that creates a HIT "reserve fund" to permit financial incentives which will encourage the adoption of information technology for the period of fiscal years 2006 to 2010. Recognizing the quality and the cost savings benefits, the FY 2006 Budget Resolution provides the authority for the Senate Finance Committee and the Senate HELP Committee to report out language offering financial incentives that encourage the adoption of HIT, anticipating they will pay for themselves within 5 years.

The College is particularly supportive of the bipartisan bill, H.R. 747, the "National Health Information Incentive Act," sponsored by Reps. Charles Gonzalez (D–TX) and John McHugh (R–NY), because it specifically targets those small physician practices who are in need of the most financial assistance. Like most of the legislative proposals introduced so far, H.R. 747 offsets the initial start-up costs and ongoing training and maintenance costs of acquiring interoperable HIT systems by providing grants, loans, and refundable tax credits. But more importantly, the legislation builds into the Medicare physician payment system an add-on code for office visits and other evaluation and management (E/M) services, care management fees for physicians who use HIT to manage care of patients with chronic illnesses, and payments for structured email consults resulting in a separately identifiable medical service from other E/M services. These fees would be triggered if the procedure or service was facilitated by an electronic health data system (such as electronic health records, electronic prescribing and clinical decision support tools) when used to support physicians' voluntary participation in performance measurement and improvement programs. Additionally,H.R. 747 takes the appropriate step of establishing two-year pilot testing of the standards and the determining quality improvements and cost savings of the integration of HIT.

In addition, the College is also strongly supportive of the bipartisan bill, S. 1227, the "Health Information Technology Act," introduced by Sens. Debbie Stabenow (D–MI) and Olympia Snowe (R–MA). Like the Gonzalez-McHugh bill, S. 1227 includes one-time tax credits and grants for the purchase of HIT as well as Medicare physician payment changes that recognize the ongoing costs in maintaining HIT by authorizing adjustments to Medicare payment when an identifiable medical service is provided using HIT.

The College strongly believes Congress should provide the necessary funding to offset the initial costs in obtaining HIT, but it should also recognize the unquantifiable and ongoing costs in utilizing HIT. It is this combination of *one-time* and *on-going* financial incentives put forward by H.R. 747 and S. 1227 that will substantially speed HIT adoption and improve access to physician practices with HIT, resulting in tremendous system-wide savings. **Congress should recognize the collective and individual contributions needed to achieve Medicare and**

Medicaid savings through the adoption of HIT. Therefore, we believe funding initiatives should allow for individual physicians to share in the system-wide savings that are attributable to their participating in HIT and other performance measurement and improvement programs.

Conclusion

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

Statement of William Vaughan, Consumers Union

Madame Chair, Members of the Committee:

Consumers Union is the independent, non-profit publisher of *Consumer Reports.*

Like so many others, we believe expediting the development of a common health care information technology has the potential to bring enormous long-term savings and quality improvements.

But—and this is a big qualifier—there needs to be more consumer involvement in and understanding of how consumers' very personal medical data is going to be used and protected.

A truly modern health care system should enable medical providers to immediately access an individual's medical records, images or drug reactions in an emergency, or quickly put their hands on the complete medical history of a new patient. But the promise of better health care through easily useable medical records is accompanied by deep fear that one's most private medical records might be easily compromised. In recent months, we have seen this compromise of electronic data in the theft of millions of Americans' financial records. Computers are hacked into almost daily; identity theft has become a common story. If these severe problems happen constantly in the financial world, the consumer wonders what is to keep them from happening in the medical world?

The consensus Senate IT bill seems to deal with privacy issues largely through a cross-reference to the Health Insurance Portability and Accountability Act of 1996. Yet the average person on the street has no idea what HIPAA means, or how it may protect their medical recored privacy. Legislation that promotes the use of health care IT needs provisions that educate the American public about what it means, how it will work, and what a person's rights and protections are in the new system. The privacy standards need to be restated and clearly explained, the penalties for willful and malicious violations strengthened, and individuals should be given the right to opt out of the system until they want to join in. Also, if a person's medical record is ever compromised, they should be informed immediately about the breach. It should be clear that individuals should in general be able to see their records and request corrections.

To date, the health care IT process has been largely a technical discussion involving providers and purveyors of IT services. But what hasn't been talked about is the incredibly personal and sensitive information these electronic medical records would contain. Any and all advisory commissions created by any health care IT legislation should include a majority of "ordinary" citizens to make sure that the American consumer is comfortable with measures to protect this sensitive information.

Rather than increasing the sense of powerlessness and vulnerability in our modern computer age, the health care IT system of the future should be a benefit to consumers' quality of life of consumers. Only by including consumers in the process, educating the public about this technology, and strengthening privacy protections will consumers have faith in the new system.

Statement of Richard Patrick Yanes, Clinical Social Work Federation, Arlington, Virginia

Chairwoman Johnson and Members of the Committee, we appreciate this opportunity to address the Committee as it continues its work in examining the issues attendant to the greater uses of the developing information technologies in the health care field. Clearly such technologies offer great opportunities to provide improved and better integrated physical and mental health care services. Just as clearly, however, such technologies carry great risks of harm. Our comments, then, will be directed at our concern that such technologies not put at risk the disclosure of an individual's private health information without the individual's consent.

For decades Congress has recognized the need to protect consumers' personal information and has passed laws ensuring the privacy of information contained in bank, credit card, other financial records, and even video rentals. With respect to an individual's health information, Congress has been no less vigilant. With the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress recognized the importance of protecting the consumers' most sensitive information—health information [1] as did the previous Administration, drafting regulations implementing the Act that required consumers' consent [2] The protection offered in HIPAA, however, was a continuation of the almost three decades long application of the confidentiality regulations developed to protect the consumers of substance abuse services.[3]

With the enactment of these and other legislative policies, Congress recognized the many reasons for safeguarding consumers' health information including that many individuals will refuse to seek timely physical and mental health care for conditions they perceive may have a stigmatizing effect on them should the information not be held in the strictest confidence. *"People's willingness to seek help is contingent on their confidence that personal revelations of mental distress will not be disclosed without their consent.*[4] To delay treatment is to exacerbate the condition and increase costs should treatment be sought later.

The Federal courts have also recognized the critical nature of confidentiality when the United States Supreme Court held in *Jaffe v. Redmond* that patients receiving mental health therapy have a right to privacy in therapist-patient communications and that such communications cannot be used or disclosed without their consent [5] The Court also recognized that all 50 states and the District of Columbia have enacted some form of psychotherapist-patient privilege and it was through that reason and experience that the Court was led to its holding.[6]

As the Subcommittee goes about its work we urge that the Members be mindful that not only has the federal government placed critical importance on the protection of health information but that many states have adopted their own standards of protection as well. Both the Congress and the Department of Health and Human Services (HHS) gave assurances through their enactment of HIPAA and its implementing regulations that federal privacy standards would not supercede state privacy laws *". . . if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation . . ."*[7] and again later when commenting on the adopted Privacy Rule HHS stated that *"State laws that are more stringent remain in force. In order to not interfere with such laws and ethical standards, this Rule permits covered entities to obtain consent."*[8]

In conclusion, as the Subcommittee continues its work to set standards for the development of information technologies and their application to health care information we urge that the Members continue to give the highest priority to the protection of the individual's right to control the disclosure of their private health information.

Appendix A.

The Clinical Social Work Federation, the largest clinical social work organization in the United States, has members and societies in 37states both nationally and in

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[1] 67 *Fed. Reg.* 14775 and 14777.
[2] 45 *CFR* § 164.506
[3] 42 *CFR* Part 2.
[4] Department of Health and Human Services, *Mental Health: A Report Of The Surgeon General*, (Washington D.C., GPO, 1999) p. xvii.
[5] *Jaffe v. Redmond* 518 U.S. 1 (1996).
[6] Ibid.
[7] 67 *Fed. Reg.* 1475 et seq., 264(c)(2).
[8] 67 *Fed. Reg.* 53,212.

Canada. The Federation works for improvement of the standards of the profession, the protection of clients, and the professional development of its members. The Federation provides both clients and members with advocacy on mental health issues before the Congress and regulatory bodies and assists the state societies with advocacy at the state level.

Licensed clinical social workers provide 41% of the mental health services in the United States and work through social service agencies, hospitals and community health centers, health maintenance and managed care organizations, schools, and private practice. Clinical social workers are licensed in all 50 states and diagnose, treat, and engage in preventive services of mental, behavioral, and emotional disorders in individuals, families, and groups.

Both the states and the courts have upheld the confidentiality of the special relationship the clinical social worker has with their clients. Clinical social workers are also recognized and testify as expert witnesses on the diagnosis and treatment of mental disorders. All clinical social workers hold advanced degrees and have undergone thousands of hours of supervised clinical internships prior to licensing.

Appendix B

Clinical social work plays a crucial role in the delivery of mental health services nationally with over 250,000 licensed clinical social workers. Clinical social workers hold advanced degrees and have undergone thousands of hours of supervised clinical internships prior to licensing. In most states, clinical social workers are licensed to diagnose, treat, and engage in preventive services of mental, behavioral, and emotional disorders in individuals, families, and groups.

- **Clinical social workers** provide 41% of mental health treatment in the country (ASWB, 2003) and have clinical training standards that are the equivalent of or stronger than psychologists, mental health counselors, marriage and family therapists, and psychiatric nurses.
- **Clinical social workers** have one of the lowest actionable complaint rates of any mental health discipline with national rates of 0.9% (ASWB, 2003).
- **Clinical social workers** have one of the highest satisfaction ratings of all mental health professionals, as surveyed and reported in a 1995 Consumer Reports article according to 4000 consumers of mental health services.
- **Clinical social workers** are trained to provide diagnosis and treatment through psychotherapy and counseling of all mental health disorders. Both the states and the courts have upheld the confidentiality of the special relationship the clinical social worker has with their clients.
- **Clinical social workers** work through social service agencies, hospitals and community health centers, health maintenance and managed care organizations, schools, and private practice.
- **Clinical social workers** reduce medical problems and health care costs by treating the emotional disorders that lead to 50% of the visits to family practitioners (Office of the Surgeon General, 2000).
- **Clinical social workers** play an integral role in state, county, and city mental health programs throughout the country.

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