

OPPORTUNITIES AND CHALLENGES IN ADVANCING HEALTH INFORMATION TECHNOLOGY

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON
INFORMATION TECHNOLOGY

AND THE

SUBCOMMITTEE ON HEALTH CARE,
BENEFITS AND ADMINISTRATIVE RULES

OF THE

COMMITTEE ON OVERSIGHT
AND GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

MARCH 22, 2016

Serial No. 114-109

Printed for the use of the Committee on Oversight and Government Reform



Available via the World Wide Web: <http://www.fdsys.gov>
<http://www.house.gov/reform>

U.S. GOVERNMENT PUBLISHING OFFICE

23-444 PDF

WASHINGTON : 2017

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2104 Mail: Stop IDCC, Washington, DC 20402-0001

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

JASON CHAFFETZ, Utah, *Chairman*

JOHN L. MICA, Florida	ELIJAH E. CUMMINGS, Maryland, <i>Ranking</i>
MICHAEL R. TURNER, Ohio	<i>Minority Member</i>
JOHN J. DUNCAN, JR., Tennessee	CAROLYN B. MALONEY, New York
JIM JORDAN, Ohio	ELEANOR HOLMES NORTON, District of
TIM WALBERG, Michigan	Columbia
JUSTIN AMASH, Michigan	WM. LACY CLAY, Missouri
PAUL A. GOSAR, Arizona	STEPHEN F. LYNCH, Massachusetts
SCOTT DESJARLAIS, Tennessee	JIM COOPER, Tennessee
TREY GOWDY, South Carolina	GERALD E. CONNOLLY, Virginia
BLAKE FARENTHOLD, Texas	MATT CARTWRIGHT, Pennsylvania
CYNTHIA M. LUMMIS, Wyoming	TAMMY DUCKWORTH, Illinois
THOMAS MASSIE, Kentucky	ROBIN L. KELLY, Illinois
MARK MEADOWS, North Carolina	BRENDA L. LAWRENCE, Michigan
RON DESANTIS, Florida	TED LIEU, California
MICK, MULVANEY, South Carolina	BONNIE WATSON COLEMAN, New Jersey
KEN BUCK, Colorado	STACEY E. PLASKETT, Virgin Islands
MARK WALKER, North Carolina	MARK DESAULNIER, California
ROD BLUM, Iowa	BRENDAN F. BOYLE, Pennsylvania
JODY B. HICE, Georgia	PETER WELCH, Vermont
STEVE RUSSELL, Oklahoma	MICHELLE LUJAN GRISHAM, New Mexico
EARL L. "BUDDY" CARTER, Georgia	
GLENN GROTHMAN, Wisconsin	
WILL HURD, Texas	
GARY J. PALMER, Alabama	

JENNIFER HEMINGWAY, *Staff Director*

DAVID RAPALLO, *Minority Staff Director*

TROY STOCK, *Subcommittee on Information Technology Staff Director*

CHRISTINA HINKLE, *Counsel*

WILLIE MARX, *Clerk*

SUBCOMMITTEE ON INFORMATION TECHNOLOGY

WILL HURD, Texas, *Chairman*

BLAKE FARENTHOLD, Texas, <i>Vice Chair</i>	ROBIN L. KELLY, Illinois, <i>Ranking Member</i>
MARK WALKER, North Carolina	GERALD E. CONNOLLY, Virginia
ROD BLUM, Iowa	TAMMY DUCKWORTH, Illinois
PAUL A. GOSAR, Arizona	TED LIEU, California

SUBCOMMITTEE ON HEALTH CARE, BENEFITS AND ADMINISTRATIVE RULES

JIM JORDAN, Ohio, *Chairman*

TIM WALBERG, Michigan	MATT CARTWRIGHT, Pennsylvania,
SCOTT DESJARLAIS, Tennessee	<i>Ranking Member</i>
TREY GOWDY, South Carolina	ELEANOR HOLMES NORTON, District of
CYNTHIA M. LUMMIS, Wyoming	Columbia
MARK MEADOWS, North Carolina	BONNIE WATSON COLEMAN, New Jersey
RON DESANTIS, Florida	MARK DESAULNIER, California
MICK MULVANEY, South Carolina, <i>Vice</i>	BRENDAN F. BOYLE, Pennsylvania
<i>Chair</i>	JIM COOPER, Tennessee
MARK WALKER, North Carolina	MICHELLE LUJAN GRISHAM, New Mexico
JODY B. HICE, Georgia	<i>Vacancy</i>
EARL L. "BUDDY" CARTER, Georgia	

CONTENTS

Hearing held on March 22, 2016	Page 1
--------------------------------------	-----------

WITNESSES

Karen DeSalvo, M.D., National Coordinator for Health Information Technology, U.S. Department of Health and Human Services	
Oral Statement	5
Written Statement	8
Ms. Jessica Rich, Director, Bureau of Consumer Protection, U.S. Federal Trade Commission	
Oral Statement	13
Written Statement	15
Mr. Matthew Quinn, Federal Managing Director, Intel Healthcare and Life Sciences	
Oral Statement	24
Written Statement	27
Mr. Neil DeCrescenzo, Member, Executive Committee, Healthcare Leadership Council	
Oral Statement	44
Written Statement	46
Mr. Mark Savage, Director of Health IT Policy and Programs, National Partnership for Women and Families	
Oral Statement	126
Written Statement	128

APPENDIX

An April 1, 2016 letter from the National Partnership for Women & Families to Chairman Will Hurd, Chairman Jim Jordan, Ranking Member Robin Kelly, and Ranking Member Matthew Cartwright, Entered by Chairman Will Hurd	152
A December 2014 report from the National Partnership for Women & Families titled, "Engaging Patients and Families: How Consumers Value and Use Health IT", Entered by Representative Matt Cartwright. A copy of the report can be found online here: http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf	

OPPORTUNITIES AND CHALLENGES IN ADVANCING HEALTH INFORMATION TECHNOLOGY

Tuesday, March 22, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INFORMATION TECHNOLOGY, JOINT
WITH THE SUBCOMMITTEE ON HEALTH CARE, BENEFITS,
AND ADMINISTRATIVE RULES,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, D.C.

The subcommittees met, pursuant to call, at 2:06 p.m., in Room 2154, Rayburn House Office Building, Hon. William Hurd [chairman of the Subcommittee on Information Technology] presiding.

Present from Subcommittee on Information Technology: Representatives Hurd, Walker, Blum, Connolly, and Lieu.

Present from Subcommittee on Health Care, Benefits, and Administrative Rules: Representatives Walberg, Gowdy, DeSantis, DeSaulnier, Cartwright, and Lujan Grisham.

Mr. HURD. The Subcommittee on Information Technology and the Subcommittee on Health Care, Benefits, and Administrative Rules will come to order. Without objection, the chair is authorized to declare a recess at any time.

We are expecting votes fairly soon, so I am hoping we can get through opening remarks, go do our vote series, and come back and finish the hearing.

Good afternoon. I appreciate your being here today. You all know that heart disease is a leading cause of death in the United States, according to the CDC. More than 600,000 Americans die from heart disease each year.

The American Medical Association recommends walking as the simplest positive change you can make to improve your heart health. Walking 30 minutes day, or around 10,000 steps, lowers blood pressure, improves movement and mobility, and increases energy. Simply increasing the number of steps you take per day can significantly reduce your risk of coronary heart disease and stroke.

Many of you could glance right now at your smart phones, wearables, or other devices and report your number of steps and calories burned for the same period of time. For most of us, I will bet that number is probably higher than before we had the app or device and we were tracking our steps.

It would not be an extreme exaggeration to say that the proliferation of wearable devices and smart phone apps that track

steps and the accompanying increases in the number of steps some people are taking on a daily basis has saved lives.

This is just one example of the benefits technology has brought to health and health care, and we have barely scratched the surface. We are on the cusp of being able to use technology to truly revolutionize health care and health care delivery.

Leveraging the power of the cloud will enable us to move more health care tasks online, including consultations and data storage and retrieval.

Sensors will make it easier for people to take care of themselves before they get sick. Constituents in rural parts of Texas 23rd, my district, will be able to speak directly with their primary care providers instead of commuting hours each way.

As more devices are connected and more data is generated, medicine will become customized and personalized. Preventative medicine and healthy living practices will increase, costs will decline, and the prevalence of chronic diseases will decrease substantially.

But this will only happen if researchers, hospitals, entrepreneurs, regulators, health care professionals, patient advocates, and lawmakers come together to update antiquated laws and reform outdated institutions.

Right now, old and unclear privacy laws hinder interoperability between health IT systems and devices. Right now, the sheer number of Federal agencies, and often conflicting rules one must navigate to invest in the space, chills investment and entrepreneurship. And right now, a fragmented and bureaucratic system places the patient at the fringe of the process, rather than at the center.

In today's hearing, I hope to hear specifically what laws or regulations need to be changed or updated, and how they should be changed or updated or abandoned.

Health IT is an exciting, innovative field, but to get this right, we must collaborate. We must destroy silos. I am committed to doing so. I know my friend and ranking member, Ms. Kelly, and Ted Lieu are as well.

And I want to thank the witnesses for being here today, and I look forward to their testimony.

Now I would like to recognize Mr. Cartwright for his opening statement.

Mr. CARTWRIGHT. Thank you, Chairman Hurd. I would like to thank you both for calling this hearing so we can hear about how the Federal Government and private industry are working together, and for your interest and efforts at creating the next generation of health information technology.

I represent largely a rural district in northeastern Pennsylvania, and I know quite well how health IT can bring affordable medical care to those who might not otherwise be able to receive it.

In fact, that is why I cosponsored the Medicare Telehealth Parity Act of 2015, the 21st Century Cures Act, and also the TELE-MED Act. Bills like these help medical professionals provide patients with the best health care available anywhere and at any time.

But even with the undeniable benefits technology brings, patient safety must remain our foremost consideration. Technology brings opportunity, but it can also bring unforeseen challenges, and I hope we can talk about that a little today.

As a career courtroom attorney, I have seen too many medical malpractice lawsuits where carelessness caused injuries and death, and where doctors have made grave and avoidable mistakes. Too often these mistakes were due to failures in communication that left physicians and nurses without all of the patient's information that they needed to complete proper assessment and treatment.

We worry that different computer system standards and methods of tracking medical history often mean doctors, nurses, lab technicians, and others involved in the treatment process cannot get a complete understanding of the illness in front of them and the treatment that is needed.

That is why it is so important that technologies like electronic health records, which contain the complete medical and treatment history of a patient quickly and efficiently give providers insight and a comprehensive view into what is going on and all the facts of the case. Standardized, industry-accepted technologies can make that happen, in my view.

In the field of health IT, private industry has a critical role in the process doing what it does best: drive innovation and keep America at the leading edge in medical technology.

The Federal Government also has a role to play, making sure these new technologies meet health care needs without compromising patient safety.

I am looking forward to today's hearing, to the testimony of all of you. I am glad that industry and government are working together to bring about the kinds of technological advances that will improve health care in this country, make it safer, and make it more available to people in all corners and all pockets of this Nation.

I thank you again, Chairman Hurd, and I yield back.

Mr. HURD. Thank you.

I am going to hold the record open for 5 legislative days for any members who would like to submit a written statement.

Ranking Member Lieu is here, and if he is ready, we will have him give his opening remarks.

Mr. Lieu from California is recognized for 5 minutes.

Mr. LIEU. Thank you, Mr. Chairman.

Thank you to the witnesses who will be presenting today.

Today, we are here to learn more about how to make the primary health technology laws work smarter and better. Laws and regulations should be there to protect the public, but done incorrectly, they can hinder innovation, and the same holds true in the health IT space.

The Health Insurance Portability and Accountability Act, HIPAA, contains provisions to create universal electronic medical records and protect patient privacy. The Health Information Technology for Economic and Clinical Health, HITECH, contains provisions to protect consumer privacy and give notice in case of data breach. The Affordable Care Act also contains provisions to improve the quality and efficiency of patient care with EHRs.

However, these laws and regulations were enacted before key technological advances that we now take for granted. HIPAA was passed in 1996 before broad adoption of the mobile revolution.

HITECH was passed in 2009, before much of cloud computing existed.

Some might suggest that rolling back regulations is the answer. While I agree that government regulation is not as nimble as technology, we still need some combination of regulations and enforceable guidance to protect the public.

For instance, last month, the IT system at Hollywood Presbyterian Hospital in Southern California was held hostage by ransomware denying patients and providers access to their medical records. The HITECH law has cybersecurity requirements that require notifications for data breaches, but the law says nothing about notification for data that was frozen or held hostage where it is stored.

I note that today the press reports that two more hospitals in Southern California were hit with malware attacks.

Technology is moving very quickly. Telemedicine and text messaging and mobile smart phone exposure requires that HHS and FTC keep up with technology changes, update guidance reliably, and keep rules and regulations flexible to encourage innovation.

Regulation done wrong or too little regulation makes it difficult to protect the public and ensure that data flows freely. Regulation done right spurs innovation and improves quality of care and protects the public.

I look forward to hearing from the witnesses today about what we can do to encourage innovation and cooperation, and continue to bring government health care into a more modern era of service.

With that, I yield back.

Mr. HURD. Thank you, Mr. Lieu.

If Chairman Jordan joins us and is interested in giving opening remarks, we will let him do that as he arrives.

Again, I would like to thank the witnesses. I would like to recognize you all now. I am pleased to welcome Dr. Karen DeSalvo, national coordinator for health information technology at the U.S. Department of Health and Human Services. Thank you for being here. Ms. Jessica Rich, director of the Bureau of Consumer Protection at the U.S. at the Federal Trade Commission; Mr. Matthew Quinn, Federal managing director at Intel Healthcare and Life Sciences; Mr. Neil DeCrescenzo, member of the executive committee at the Healthcare Leadership Council; and Mr. Mark Savage, director of health IT policy and programs at the National Partnership for Women and Families.

Welcome to you all. Pursuant to committee rules, all witnesses will be sworn in before you testify.

Please rise and raise your right hands.

Do you solemnly swear or affirm that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth?

Thank you. Please be seated.

Let the record reflect that the witnesses answered in the affirmative.

In order to allow time for discussion, please limit your testimony to 5 minutes. Your entire written statement will be part of the record.

We are going to go through as many opening remarks as we can before we get called to votes. If the bells go off while you are in your remarks, go ahead and continue. We will finish after your remarks.

Now I would like to recognize Ms. DeSalvo for your opening remarks.

WITNESS STATEMENTS

STATEMENT OF KAREN DeSALVO, M.D.

Dr. DESALVO. Thank you, Chairman Hurd, and Ranking Members Lieu and Cartwright, and distinguished members of the subcommittees. Thank you all for the opportunity to appear here today.

I am Dr. Karen DeSalvo, and I have the honor of serving as the national coordinator for health information technology at the U.S. Department of Health and Human Services for the past 2 years. I'm proud to be here today representing the remarkable team at the Office of National Coordinator and share with you the current State of health information technology in our Nation and how we are working with others to see that these systems realize their full potential.

The Office of the National Coordinator for Health Information Technology has a strong, bipartisan history. It was established in 2004 by executive order and charged with the mission of giving every American access to their electronic health information. In 2009, it was statutorily established by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which provided the resources and infrastructure needed to foster the rapid nationwide adoption and use of health IT.

In the 7 years since HITECH was enacted, we have seen dramatic progress. Today, nearly all hospitals and more than three-quarters of physicians report using a certified electronic health record. This tripling in rates of adoption puts us as a Nation well ahead of our peer countries, giving us a significant competitive advantage in health care innovation and scientific advancement. And it is working in so many communities across this country.

But I also note that we haven't realized the full potential of health IT for every person in this country.

And this is not just an abstract policy idea to me. It is personal. It is why I came to ONC 2 years ago, because I knew as a doctor the promise of health IT, of having information available for me when I was on call in the evening not at the hospital, such a leap from the days in the early 1990s when I was a medical school student at Charity Hospital and had to physically go up to a lab and pull a lab slip with handwritten results from a wooden box, so that I would understand more about my patients and how to care for them.

Today, that is all available electronically to me and other doctors, and not just to us but to our patients, to really see that they can be empowered and have the information they need to self-care. It is a rapid and remarkable transformation in a very short period of time. But the pace has come with challenges.

Like others, I have been frustrated by the lack of interoperability, by the usability of the systems, and by how hard it can be to select the right system to buy. I hear about these challenges from my colleagues whether at listening sessions but also from consumers and other stakeholders.

We all want to move ahead with technology, but we want it to work better. That is what I came to Washington to do.

Since I've been the national coordinator, we have been focused on fixing those challenges in an urgent fashion to meet the expectations of the people that I serve, the American people. ONC does this in a variety of ways.

For example, we can leverage our electronic health record certification program. We also serve as a coordinator across the Federal Government to see that agencies have shared policy and technology approaches and will send clear signals to the private sector.

We have also worked with the private sector on setting a clear path ahead for our nationwide interoperability. This roadmap that we produced last year lays out who should do what by when to achieve interoperability in the near term to see that electronic health information is available when and where it matters to consumers and clinicians.

ONC and others have been meeting our deliverables from this plan and are advancing drivers of interoperability like payment reform, publishing clear standards, working with States and others on harmonizing privacy and security expectations. The plan has been publicly endorsed by our Federal partners, by the private sector, and we have been so pleased with everyone's willingness to step up and lead where appropriate, to see that we can innovate and accelerate interoperability. Indeed, working with the private sector is how ONC operates.

As another example, we recently convened stakeholders to ask them to make a series of commitments to ensure that electronic health information works better for patients and providers. It is a really tremendous opportunity for the private sector to lead.

So last month, we were able to announce that companies that provide electronic health records for 90 percent of hospitals in this country, and health care systems with facilities in 46 States, including the States for all the members of these two subcommittees, and over a dozen professional associations and stakeholder groups like the AMA and the American Hospital Association, all have agreed to implement three commitments that will help make sure health information flows.

The commitments are that consumers will have access to their electronic health information, that entities will not engage in health information-blocking, and that we will move to federally recognized national standards so that all these different systems will speak the same language.

ONC and our partners in the Federal space and the private sector are working together each and every day to see that we can move this future vision to an immediate reality. And Congress has been one of the great partners in health IT, and I look forward to continuing to work with you all to realize the full potential of health IT for this country.

Thank you for having me here today, and I look forward to your questions.
[Prepared statement of Dr. DeSalvo follows:]

**Testimony before the Committee on Oversight and Government Reform,
Subcommittees on Information Technology and Health Care, Benefits, and
Administrative Rules
United States House of Representatives**

**Statement of
Karen B. DeSalvo, MD, MPH, MSc
National Coordinator, Office of the National Coordinator for Health
Information Technology
U.S. Department of Health and Human Services**

**Hearing on Opportunities and Challenges in Advancing Health Information
Technology
March 22, 2016**

Chairmen Hurd and Jordan, Ranking Members Kelly and Cartwright, and distinguished Subcommittee members, thank you for the opportunity to appear today. I am Dr. Karen DeSalvo, the National Coordinator for Health Information Technology in the US Department of Health and Human Services. I am proud to be here today representing the remarkable team at the Office of the National Coordinator for Health Information Technology (ONC) and to share with you the current state of health information technology (health IT) in our nation, and how we have been working collaboratively with a diverse array of stakeholders to help these systems realize their full potential now and in the future to support clinicians and consumers for better care and healthier people and communities.

ONC was established by Executive Order in 2004 and charged with the mission of giving every American access to their electronic health information when and where they need it most. In 2009, ONC was statutorily established by the Health Information Technology for Economic and Clinical Health Act (HITECH), enacted as part of the American Recovery and Reinvestment Act (ARRA). HITECH provided the resources and infrastructure needed to stimulate the rapid, nationwide adoption and use of health IT, especially electronic health records (EHRs). In the seven years since the HITECH Act was enacted, we have seen dramatic advancement in adoption and use of health IT. By 2014, nearly all hospitals (97 percent) reported possessing certified EHR technology¹. Roughly three-quarters of physicians report possessing a certified EHR². The combined efforts of HITECH initiatives such as the Regional Extension Centers, the ONC Health IT Certification Program, use of standard terminologies, and the CMS Medicare and Medicaid EHR Incentives Programs have brought us past a tipping point in the use of health IT. Today, we are firmly on the path to an interoperable, digital health care system; but, we acknowledge that there is still much work to do to realize the digital dividend.

Prior to becoming the National Coordinator in January 2014, I worked in a variety of settings that provided me with keen insight into and experience working with health IT systems. My previous positions include serving as the Health Commissioner for the City of New Orleans and the Senior Health Policy Advisor to the Mayor of New Orleans, and a professor of medicine

¹ Charles, D., Gabriel, M., Searcy T. (April 2015) Adoption of Electronic Health Record Systems among U.S. Non-Federal Acute Care Hospitals: 2008-2014. ONC Data Brief, no.23. Office of the National Coordinator for Health Information Technology: Washington DC.

² Heisey-Grove, D., Patel, V. (September 2015) Any, Certified, or Basic: Quantifying Physician EHR Adoption. ONC Data Brief, no. 28. Office of the National Coordinator for Health Information Technology: Washington DC.

and vice dean for community affairs at Tulane University School of Medicine. In addition, I have practiced internal medicine for close to a quarter century. In all of these positions, I have established, purchased, utilized, implemented, and studied health IT systems. I not only understand the importance of health IT to improving the overall health care in this nation, but I also understand firsthand the numerous complications and frustrations that we have faced, and continue to face along the way. I came to ONC to build on the incredible progress we have made since 2009, and to move us forward into a new and exciting era of health IT. Thus far, I have focused my energy and attention on what I believe is a fundamental piece of the puzzle to moving us forward, and that is a ubiquitous, safe, and secure interoperable health IT infrastructure.

As a result, since I became the National Coordinator, ONC has been working systematically and intensely to harness the health care industry's energy and consumer demands for interoperability to drive improvement in health. We respect and feel the strong sense of urgency and have acted on it.

We delivered a clear strategy to get to an interoperable health system in "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap version 1.0".³ The Roadmap focuses primarily on impactful, near-term actions we all can take by the end of 2017 to improve interoperability. These actions are as follows: first, "Drivers," which are mechanisms that can propel a supportive payment and regulatory environment that relies on and deepens interoperability; second, "Policy and Technical Components," which are essential for stakeholders to implement in order to enable interoperability, such as shared standards and expectations around privacy and security; and third, "Outcomes," which serve as metrics by which stakeholders will measure our collective progress on implementing the Roadmap. Since we released the Roadmap, we have been working systematically to meet our expected deliverables and milestones. For example, in September 2015, we undertook a project to develop a State Interoperability Roadmap with the National Governors Association. This on-going work will help to guide states in addressing disparate state privacy laws that may impede nationwide interoperability. We also recently launched the Interoperability Proving Ground, a website that provides stakeholders with an open, community platform to share, learn, and be

³ <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

inspired by interoperability projects taking place across the nation. To help support and advance the development of market-ready, user-friendly approaches, in March we launched a \$625,000 strategic investment to connect and accelerate the industry's use of *Fast Healthcare Interoperability Resources* (FHIR)⁴ standards-based application programming interfaces (APIs)⁵ for consumers and providers, which includes two challenge contests to spur private sector innovation.

Additionally, ONC is currently taking advantage of a changing payment landscape that is improving the business case for interoperable health IT. A key component of the Administration's Delivery System Reform initiative is expanding the use of alternative payment models that reward value over volume and support better care coordination and population health. A strong health IT infrastructure is a necessary feature to achieve those goals. ONC actions are designed to drive towards better distribution of information and leveraging technology to support Delivery System Reform. At the same time, the Department's work to advance payment reform directly supports the business case needed to drive towards an interoperable, digitized care system.

Further, recognizing the essential role of the private sector in moving interoperability forward, Secretary Burwell recently announced an important step in furthering several shared priorities. On February 29, the Secretary highlighted that companies that provide 90 percent of electronic health records used by hospitals nationwide, healthcare systems with facilities in 46 states, and more than a dozen professional associations and stakeholder groups⁶ have agreed to implement three core commitments around consumer access, information blocking, and standards. The organizations that made these commitments represent technology developers, hospitals, integrated healthcare organizations, medical groups and physician offices, academic facilities, long-term and behavioral healthcare settings, professional and advocacy organizations, and patients throughout the country.

We understand the importance of a broad, all-of-government strategic approach to achieving interoperability and a better health care system. In October 2015 we issued the Federal Health IT Strategic Plan 2015-2020. This Plan, developed in partnership with over 35 Federal

⁴ FHIR is a standard being developed by a standards development organization, HL7, to support the exchange healthcare information electronically.

⁵ These are technology tools that underpin many consumer applications (apps) and will enable the development of new functionalities to build bridges across systems and provide increased data access.

⁶ www.healthit.gov/commitment

entities, demonstrates the extensive interest across the Federal Government in digitizing the health experience for all individuals and facilitating progress towards a learning health system that can improve health and care. The Plan has been designed to support important changes already occurring in the health landscape, such as the Precision Medicine Initiative and the Department of Defense's Military Health System's acquisition of a new health IT system, as well as longer-range changes, such as FDA's Sentinel program. The Plan's long-term vision of a learning health system relies on the use of technology and health information from a multitude of sources for a multitude of purposes, and working with our Federal partners, with the Congress, and other stakeholders, our strategies will evolve to ensure we can meet this vision for the Nation.

ONC is committed to moving forward by promoting the use of health IT to encourage information exchange, not only across the Department and Government-wide, but also with outside stakeholders, including the Congress. We realize everyone has a role to play in moving health IT systems forward and look forward to the challenge ahead of us. Thank you again for inviting me today.

Mr. HURD. Thank you, Dr. DeSalvo.
Now, Ms. Rich, you are recognized for 5 minutes.

STATEMENT OF JESSICA RICH

Ms. RICH. Chairman Hurd, Ranking Members Lieu and Cartwright, and members of the subcommittees, I am Jessica Rich, director of the Bureau of Consumer Protection at the Federal Trade Commission. I appreciate this opportunity to present the commission's testimony.

Consumers are increasingly taking an active role in managing their health data, and there has been an explosion of new products and services to help them. These range from wearable fitness devices like Fitbit or Jawbone, to dieting apps like My Fitness Pal and Calorie Counter, and to Web sites like WebMD where consumers can get health advice and information.

These products and services offer enormous benefits to consumers, but they raise privacy and security concerns, too. Who has access to all of this data? And is it being stored securely?

Much of this activity now happens outside of the doctor's office and other traditional health care contexts. As a result, it is not protected under HIPAA, which only applies to health data held or generated by covered entities, such as health care providers and health plans. In most instances, however, this activity is covered by the Federal Trade Commission Act, which prohibits unfair or deceptive practices across the marketplace, including in the area of health privacy.

As the primary Federal agency charged with protecting consumer privacy, the FTC has made it a priority to protect consumer-sensitive health information. Our efforts include civil law enforcement, policy initiatives, and consumer and business education.

Three recent FTC cases illustrate the challenges we face in protecting consumer health data and how the FTC is addressing them.

PaymentsMD is a medical billing company that offered an online portal where consumers could pay their bills. The FTC charged that the company misled thousands of consumers who signed up by failing to tell them that it would also seek their highly detailed medical data from pharmacies, medical labs, and insurance companies.

Henry Schein provided office equipment software for dental practices. We charged this company with misrepresenting to clients that its software provided industry-standard encryption of sensitive patient information as required by HIPAA. In fact, we alleged the software used a weaker method of data masking that didn't meet HIPAA standards.

A third example is our settlement with GMR, a medical transcription service. We charged that GMR assured its clients that its services were secure but outsourced them to a third-party service provider without adequately checking its security measures. As a result, consumers found doctors' notes of their physical examinations freely available on the Internet.

Besides enforcement, the commission engages in policy initiatives to encourage stronger protection for health information. Last year, we hosted a public workshop on consumer health data to examine

the products and services consumers are using to generate and control their data and how this data is protected.

We also released a staff report on the Internet of Things, which, among other topics, examined the privacy and security issues raised by connected medical devices and health and fitness products. Of greatest concern, panelists discussed the unique risks if health devices like pacemakers and insulin pumps are not secure and are vulnerable to hackers.

Finally, the commission promotes stronger data protections through consumer education and business guidance. For example, our new IdentityTheft.gov Web site provides customized advice to consumers who have been victims of medical identity theft.

And last year, the FTC launched its Start with Security campaign to educate small businesses around the country about how to develop an effective data security program.

In addition, working with HHS and with FDA, the FTC is currently developing business guidance for health app developers to help them understand which legal requirements apply to them.

The FTC shares the subcommittees' concerns about the need to protect the privacy and security of consumer health data. Although we now use a variety of tools to protect consumers in this area, additional tools would enhance our ability to do so.

To this end, the commission reiterates its longstanding bipartisan call for Federal data security and breach legislation that would allow us to seek civil penalties to deter unlawful conduct and give us jurisdiction over nonprofit entities.

In closing, the FTC remains committed to protecting consumer health data and looks forward to our continued work with Congress on this critical issue. Thanks again for the opportunity to provide the commission's views today.

[Prepared statement of Ms. Rich follows:]

**PREPARED STATEMENT OF
THE FEDERAL TRADE COMMISSION
on
Opportunities and Challenges in Advancing Health Information Technology
Before the
HOUSE OVERSIGHT AND GOVERNMENT REFORM SUBCOMMITTEES ON
INFORMATION TECHNOLOGY AND HEALTH, BENEFITS, AND
ADMINISTRATIVE RULES
Washington, D.C.
March 22, 2016**

I. INTRODUCTION

Chairmen Hurd and Jordan, Ranking Members Kelly and Cartwright, and members of the Subcommittees, I am Jessica Rich, Director of the Bureau of Consumer Protection at the Federal Trade Commission (“FTC” or “Commission”).¹ I appreciate the opportunity to present the Commission’s testimony on Opportunities and Challenges in Advancing Health Information Technology.

Consumers are increasingly taking a more active role in managing their health data. It seems like every day a company announces a new health-related app, device, or service. There are apps that allow consumers to track their diet and exercise habits, devices that help consumers track their glucose levels, and websites where patients with the same condition share information. In addition, consumers are downloading their medical information into personal health records and using this information to make decisions about their health.

Much of this activity now takes place outside of doctors’ offices and other traditional medical contexts, and the tremendous growth in this area is not slowing down. Many of these products and services offer consumers substantial benefits in the form of increased consumer engagement in their health and fitness, reduced healthcare costs, and improved outcomes. But these products and services also raise privacy and security concerns. Consumers may be concerned about the unauthorized disclosure of their health data, which they often regard as highly sensitive and private. In addition, data breaches involving health information can cause serious harms to consumers, including fraud and medical identity theft. Finally, if consumer health data is used for unanticipated, harmful purposes, consumers could lose confidence in the health IT sector. Many of the entities creating these new consumer facing products and services are not covered by the Health Insurance Portability and Accountability Act, or HIPAA, which only provides protections for health information held or generated by certain “covered entities” – namely health care providers, health plans, and health care clearinghouses, and their business associates. The entities creating these new products are, however, within the FTC’s jurisdiction in most instances. As the nation’s foremost consumer protection agency, the FTC is committed to protecting health information collected by these entities. The Commission has engaged in substantial efforts over the years to promote data security and privacy in this area through civil law enforcement, policy initiatives, and business and consumer education. This testimony provides an overview of the Commission’s recent efforts and provides recommendations for next steps.

¹ This written statement presents the views of the Federal Trade Commission. My oral statements and responses to questions are my own and do not necessarily reflect the views of the Commission or of any Commissioner.

II. THE COMMISSION'S PRIVACY AND DATA SECURITY WORK IN THE HEALTH AREA

A. Law Enforcement

The FTC enforces several statutes and rules that impose obligations upon businesses to protect consumer data.² The Commission's primary authority is Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices in or affecting commerce.³ If a company makes materially misleading statements or omissions about a matter, including privacy or data security, and such statements or omissions are likely to mislead reasonable consumers, they can be deceptive in violation of Section 5.⁴ Further, if a company's practices cause or are likely to cause substantial injury to consumers that is neither reasonably avoidable by consumers nor outweighed by countervailing benefits to consumers or to competition, those practices can be unfair and violate Section 5.⁵

The FTC's Section 5 authority extends to both HIPAA and non-HIPAA covered entities,⁶ though generally this authority does not reach nonprofit entities or practices that are in the business of insurance to the extent that such business is regulated by state law.⁷ The FTC Act is currently the primary federal statute applicable to the privacy and security practices of businesses that collect individually identifiable health information where those entities are not covered by

² 15 U.S.C. § 45(a) (Section 5 of the FTC Act); 15 U.S.C. §§ 6801-6809 (GLBA); 15 U.S.C. § 1681 (FCRA); 15 U.S.C. §§ 6501-6506 (COPPA) and 16 C.F.R. Part 312 (COPPA Rule).

³ 15 U.S.C. § 45(a).

⁴ See Federal Trade Commission Policy Statement on Deception, *appended to Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 174 (1984).

⁵ See Federal Trade Commission Policy Statement on Unfairness, *appended to Int'l Harvester Co.*, 104 F.T.C. 949, 1070 (1984) ("FTC Unfairness Statement"); 15 U.S.C. § 45(n). In addition to its FTC Act enforcement, Congress in 2009 directed the FTC to implement a breach notification rule for certain web-based businesses not covered by HIPAA that provide or interact with personal health records. 16 C.F.R. Part 318. The FTC's Rule requires these businesses to notify individuals, the FTC, and in some cases, the media when there is a breach of unsecured, electronic health information. In addition, the Rule requires service providers to these entities to notify them in case of a breach.

⁶ The Department of Health and Human Services (HHS) and the FTC have worked closely in areas of concurrent jurisdiction, as they have common interests in ensuring the privacy and security of health information for individuals, whether that health information is within or outside the scope of HIPAA. For example, FTC staff collaborated with HHS's Office for Civil Rights to bring a set of cases involving faulty data security practices that implicated both HIPAA and the FTC Act. See *Rite Aid Corporation*, No. C-4308 (F.T.C. Nov. 12, 2010) (decision and order), *available at*: <https://www.ftc.gov/enforcement/cases-proceedings/072-3121/rite-aid-corporation-matter>; see also *CVS Caremark Corporation*, No. C-4259 (F.T.C. June 18, 2009) (decision and order), *available at*: <https://www.ftc.gov/enforcement/cases-proceedings/072-3119/cvs-caremark-corporation-matter>.

⁷ 15 U.S.C. §§ 44 & 45(a). The FTC does not have jurisdiction under the FTC Act over most non-profit organizations, although it does have jurisdiction over sham charities or other non-profits that in actuality operate for profit. The FTC's Section 5 jurisdiction also does not extend to banks, savings and loan institutions, Federal credit unions, common carriers, air carriers, or packers and stockyard operators.

HIPAA.

One recent example of FTC enforcement involving health information is the Commission's settlement with medical billing company PaymentsMD, LLC and its former CEO, Michael C. Hughes.⁸ The complaint alleged that the company deceived thousands of consumers who signed up for an online billing portal by failing to adequately inform them that the company would seek highly detailed medical information about them from pharmacies, medical labs, and insurance companies. Specifically, the company allegedly used the sign-up process for its "Patient Portal" – where consumers could view their billing history – to deceptively seek consumers' consent to collect detailed medical information from other entities for use in a separate Patient Health Report service.⁹ The Commission's order prohibits PaymentsMD and Hughes from making future privacy misrepresentations. It also requires respondents to destroy any information collected as a result of its allegedly deceptive sign-up process, and obtain consumers' affirmative express consent before collecting health information about a consumer from a third party.¹⁰

The FTC has also used its Section 5 authority to bring enforcement actions against companies that fail to maintain reasonable and appropriate data security practices regarding consumer data, including health data. Since 2001, the Commission has obtained settlements in approximately 60 cases challenging such failures. In investigating these cases, the FTC determines whether a company's data security measures are reasonable and appropriate in light of the sensitivity and volume of information it holds, the size and complexity of its data operations, and the cost of available tools to improve security and reduce vulnerabilities. The Commission orders obtained in these cases have halted harmful data security practices; required companies to provide strong protections for consumer data; and raised awareness about the risks to data, the need for reasonable and appropriate security, and the types of security failures that raise concerns.¹¹

An example of FTC data security enforcement in the health area is the FTC's settlement with GMR Transcription Services, Inc., and its owners for violations of Section 5.¹² According to the complaint, GMR provides audio file transcription services for their clients, which include health care providers, and relies on service providers and independent typists to perform this work. The complaint charged that GMR exchanged audio files and transcripts with customers and typists by loading them on a file server. As a result of GMR's alleged failure to implement reasonable and appropriate security measures and to ensure that its service providers also implemented reasonable and appropriate security, at least 15,000 files containing sensitive

⁸ *PaymentsMD, LLC*, No. C-4505 (F.T.C. Jan. 27, 2015) (decision and order), available at: <https://www.ftc.gov/enforcement/cases-proceedings/132-3088/paymentsmd-llc-matter>.

⁹ *Id.*

¹⁰ *Id.*

¹¹ See Commission Statement Marking the FTC's 50th Data Security Settlement, Jan. 31, 2014, available at <http://www.ftc.gov/system/files/documents/cases/140131gmrstatement.pdf>.

¹² *GMR Transcription Servs., Inc.*, No. C-4482 (F.T.C. Aug. 14, 2014) (decision and order), available at <https://www.ftc.gov/enforcement/cases-proceedings/122-3095/gmr-transcription-services-inc-matter>.

personal information – including consumers’ names, birthdates, and medical histories – were available to anyone on the Internet. The Commission’s order resolving the case prohibits GMR from making misrepresentations about privacy or security, and requires the company to implement a comprehensive information security program and undergo independent audits for 20 years.

More recently, the FTC settled an action against Henry Schein Practice Solutions, Inc. According to the complaint, Henry Schein, a provider of office management software for dental practices, misrepresented that its software provided industry-standard encryption of sensitive patient information.¹³ The Commission’s proposed order requires Henry Schein to pay \$250,000 as an equitable remedy. The proposed order also prohibits Henry Schein from making misrepresentations about security and requires the company to notify all of its customers who purchased the software during the period when it made the allegedly misleading statements.¹⁴

B. Policy Initiatives

The Commission also undertakes policy initiatives to promote privacy and data security, including by hosting workshops on emerging business practices and technologies affecting consumer data, and coordinating, where appropriate, with other agencies. This testimony describes three examples of such initiatives relating to the privacy and security of health information.

First, on May 7, 2014, the Commission hosted a seminar on Consumer Generated and Controlled Health Data to examine the greater role consumers are taking in managing and generating their own health data, including through apps, connected health and fitness devices, and websites that allow consumers to share information with others who have the same health conditions.¹⁵ During the event, FTC staff presented a snapshot showing the data-sharing practices of twelve health and fitness apps, including two apps associated with wearable devices. The snapshot revealed that the apps collect and transmit information to third parties, including device information, consumer-specific identifiers, unique device IDs, unique third-party IDs, and consumer information such as exercise routines, dietary habits, and symptom searches.

The seminar also brought together a diverse group of stakeholders to discuss issues such as the benefits arising from the movement of health data outside the traditional medical provider context, the types of products and services consumers use to generate and control their health data, consumers’ expectations regarding privacy and security protections, and the actions some companies take to protect consumers’ privacy and security. FTC staff followed up with two blog

¹³ *Henry Schein Practice Solutions, Inc.*, No. 1423161 (F.T.C. Jan. 5, 2016) (complaint and proposed consent order), available at <https://www.ftc.gov/enforcement/cases-proceedings/142-3161/henry-schein-practice-solutions-inc-matter>.

¹⁴ *Id.*

¹⁵ See <http://www.ftc.gov/news-events/events-calendar/2014/05/spring-privacy-series-consumer-generated-controlled-health-data>.

posts providing additional guidance for businesses innovating in this area.¹⁶

Second, at the beginning of 2015, the FTC released a staff report about the Internet of Things (“IoT”).¹⁷ Among other areas, the report examined the growth of increasingly connected medical devices and health and fitness products, ranging from casual wearable fitness devices to connected insulin pumps. The report recommends, among other things, that companies developing IoT products secure personally identifiable information and device functionality by, for example, conducting risk assessments, hiring and training appropriate personnel, monitoring access controls, and utilizing technologies such as encryption.

Third, FTC staff have worked with the Department of Health and Human Services’ (HHS) Office of the National Coordinator for Health Information Technology (ONC) on several initiatives. For example, FTC staff provided comments on the Federal Health IT Strategic Plan, a coordinated effort among more than thirty-five federal agencies to advance the collection, sharing, and use of electronic health information in a manner that protects privacy and security in order to improve health care, individual and community health, and research.¹⁸ FTC staff also participated as ex officio members in the Privacy and Security Workgroup of ONC’s Health IT Policy Committee which, among other things, considered the intersection of big data and healthcare.¹⁹

C. Consumer Education and Business Guidance

The Commission also promotes better data security and privacy practices through consumer education and business guidance. On the consumer education front, the Commission manages a consumer information website and blog with over 300 articles and blog posts related to privacy and security.²⁰ The website gets over 18 million visitors each year, and the blog has

¹⁶ See Using Consumer Health Data? (Apr. 2015), available at <https://www.ftc.gov/news-events/blogs/business-blog/2015/04/using-consumer-health-data>; Using Consumer Health Data: Some Considerations for Companies (Apr. 2015), available at, <https://www.ftc.gov/news-events/blogs/business-blog/2015/04/using-consumer-health-data-some-considerations-companies>.

¹⁷ FTC Staff Report, *Internet of Things: Privacy and Security in a Connected World* (Jan. 2015), available at <https://www.ftc.gov/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things> Commissioner Ohlhausen issued a concurring statement. See https://www.ftc.gov/sites/default/files/documents/public_statements/remarks-commissioner-maureen-k.ohlhausen-ftc-internet-things-workshop/131119iotspeech.pdf; Commissioner Wright dissented to the release of the report. See https://www.ftc.gov/system/files/documents/public_statements/620701/150127iotjdwtmt.pdf.

¹⁸ See https://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf. FTC staff also commented on ONC’s Shared Nationwide Interoperability Roadmap for Health Information Technology Systems, a plan to guide the future development of the nation’s health IT infrastructure. See https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-office-national-coordinator-health-information-technology-regarding-its-draft/1504-roadmaphealth.pdf.

¹⁹ See Health Big Data Recommendations (August 2015), available at www.healthit.gov/sites/faca/files/HITPC_Health_Big_Data_Report_FINAL.pdf.

²⁰ See generally <https://www.consumer.ftc.gov/>.

over 100,000 email subscribers. In addition, as part of IdentityTheft.gov, the FTC provides customized advice for victims of medical identity theft. Among other things, these materials help consumers determine if they have been victims of identity theft, how to correct mistakes in their medical records, how to protect their medical information, and how to check for other identity theft problems.

The Commission directs its outreach to businesses as well. “Start with Security” is the Commission’s latest effort to educate businesses about information security. This initiative kicked off with a business guide that highlighted what businesses could learn from more than 50 data security cases brought by the FTC in recent years.²¹ The FTC is now following up with conferences and webinars around the country, aimed at educating small- and medium-sized businesses in various industries.²² Our goal is to help companies reduce security risks by starting with smart data security practices. In addition, the BCP business blog, which has over 50,000 email subscribers, regularly explains FTC cases and illustrates lessons learned in plain language. The Commission also has released articles directed towards particular non-legal audiences regarding data security.²³ For example, the FTC has specific tips to help mobile app developers build data security in from the start.²⁴ The FTC also has released business guidance about building security into connected devices.²⁵

Recognizing that mobile health app developers are often confused about which legal requirements apply to them, the FTC has undertaken a joint interagency project with HHS to provide guidance on this issue. In cooperation with HHS’s ONC, Office for Civil Rights, and Food and Drug Administration, the FTC is developing an interactive tool that uses a series of high-level questions and prompts to show app developers which laws – including HIPAA, the Federal Food, Drug, and Cosmetic Act, the FTC Act, and the FTC’s Health Breach Notification Rule — apply to them. Once a developer determines which laws apply, he or she can use hyperlinks within the tool to access each agency’s guidance and learn how to comply with relevant laws. This interactive resource will reside on the FTC’s website with links from other agencies. In conjunction with this project, the FTC also plans to release additional business guidance to help mobile health app developers build privacy and security into their apps.

²¹ See *Start with Security: A Guide for Business* (June 2015), available at <https://www.ftc.gov/tips-advice/business-center/guidance/start-security-guide-business>.

²² See *Start with Security – San Francisco*, available at <https://www.ftc.gov/news-events/events-calendar/2015/09/start-security-san-francisco>; *Start with Security – Austin*, available at <https://www.ftc.gov/news-events/events-calendar/2015/11/start-security-austin>; *Start with Security – Seattle*, available at <https://www.ftc.gov/news-events/events-calendar/2016/02/start-security-seattle>.

²³ See generally <https://www.ftc.gov/tips-advice/business-center>.

²⁴ See *Mobile App Developers: Start with Security* (Feb. 2013), available at <http://business.ftc.gov/documents/bus83-mobile-app-developers-start-security>.

²⁵ See *Careful Connections: Building Security in the Internet of Things* (Jan. 2015), available at <https://www.ftc.gov/tips-advice/business-center/guidance/careful-connections-building-security-internet-things>.

III. RECOMMENDATIONS FOR NEXT STEPS

The Commission shares these Subcommittees' concerns about the need to protect the privacy and security of consumers' health data. Although the agency is using a variety of tools to promote better privacy and security of this data, additional tools would enhance the agency's ability to protect consumers. To this end, the Commission reiterates its longstanding, bipartisan call for federal legislation²⁶ that would (1) strengthen its existing data security authority and (2) require companies, in appropriate circumstances, to provide notification to consumers when there is a security breach.²⁷ Reasonable and appropriate security practices are critical to preventing data breaches and protecting consumers from identity theft and other harm. Where breaches occur, notifying consumers helps them protect themselves from any harm that is likely to be caused by the misuse of their data. And although most states have breach notification laws in place, having a strong and consistent national requirement would ensure that all consumers are protected while simplifying compliance by businesses.

Legislation in both areas – data security and breach notification – should give the FTC the ability to seek civil penalties to help deter unlawful conduct, jurisdiction over non-profits, and rulemaking authority under the Administrative Procedure Act. Under current laws, the FTC only has the authority to seek civil penalties for data security violations with regard to children's online information under the Children's Online Privacy Protection Act or credit report information under the Fair Credit Reporting Act.²⁸ To help ensure effective deterrence, we urge Congress to allow the FTC to seek civil penalties for all data security and breach notice violations in appropriate circumstances. Likewise, enabling the FTC to bring cases against non-

²⁶ See, e.g., Prepared Statement of the Federal Trade Commission, "Privacy and Data Security: Protecting Consumers in the Modern World," Before the Senate Committee on Commerce, Science, and Transportation, 112th Cong., June 29, 2011, available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-privacy-and-data-security-protecting-consumers-modern/110629privacytestimonybrill.pdf; Prepared Statement of the Federal Trade Commission, "Data Security," Before Subcommittee on Commerce, Manufacturing, and Trade of the House Committee on Energy and Commerce, 112th Cong., June 15, 2011, available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-data-security/110615datasecurityhouse.pdf; FTC, *Security in Numbers, SSNs and ID Theft* (Dec. 2008), available at <http://www.ftc.gov/sites/default/files/documents/reports/security-numbers-social-security-numbers-and-identity-theft-federal-trade-commission-report/p075414ssnreport.pdf>; President's Identity Theft Task Force, *Identity Theft Task Force Report* (Sept. 2008), available at <http://www.ftc.gov/sites/default/files/documents/reports/presidents-identity-theft-task-force-report/081021taskforcereport.pdf>.

²⁷ HIPAA has a breach notification rule, but HIPAA only applies to certain "covered entities" and their business associates as discussed above. Although the FTC has its own health breach notification rule, *see supra* n.5, this Rule is narrow in scope in accordance with the 2009 legislation and would not cover, for example, many health websites or online newsletters. Nor would it cover health apps or devices that are not vendors of "personal health records" or "PHR-related entities" as defined by the Rule. *See* 16 C.F.R. § 318(2)(f) and (j). In particular, the Rule defines a "personal health record" as information that "can be drawn from multiple sources," such as a doctor's office.

²⁸ The FTC can also seek civil penalties for violations of administrative orders. 15 U.S.C. § 45(f).

profits²⁹ would help ensure that whenever personal information is collected from consumers, entities that maintain such data adequately protect it.³⁰

IV. CONCLUSION

Thank you for the opportunity to provide the Commission's views on Opportunities and Challenges in Advancing Health Information Technology. The FTC remains committed to protecting consumer health information and we look forward to continuing to work with Congress on this critical issue.

²⁹ Non-profits are generally outside the FTC's jurisdiction under the FTC Act. 15 U.S.C. §§ 44 & 45(a).

³⁰ A substantial number of reported breaches have involved non-profit universities and health systems. See Privacy Rights Clearinghouse Chronology of Data Breaches (listing breaches including breaches at non-profits, educational institutions, and health facilities), available at <http://www.privacyrights.org/data-breach/new>.

Mr. HURD. Thank you, Ms. Rich.

Mr. Quinn, you are recognized now for 5 minutes.

STATEMENT OF MATTHEW QUINN

Mr. QUINN. Good afternoon, Chairman Hurd and other esteemed members of the House Oversight and Government Reform Committee. Thank you for the opportunity to testify today on behalf of Intel Corporation.

In my written testimony, I provide some tangible examples of how Intel is working to make good on the promise of today's health technologies and to pave the way toward tomorrow's. Today, I would like to frame my comments in the context of recent personal experiences.

Two Fridays ago, I received a call that no one wants. My sister in Ohio said that dad had just taken a bad fall. He had just left his doctor's office where he was in for a checkup after a recent hospitalization.

Things had gone well, and they stopped by a favorite restaurant for breakfast. As my dad climbed the curb, he became lightheaded, fell to the ground, and tumbled back into the parking lot. As we soon found out, he broke his clavicle, pelvis, and deeply cut his elbow.

To say that my dad is a complex patient would be an understatement. He is the poster child for needing all of his providers and caregivers to be on the same sheet of music and have the whole picture of his health and health care.

Let's begin by thinking of the constellation of my dad's health data. Most familiar are the clinical and claims data captured at clinics, hospitals, and the like. Secondly, there is diagnostic data captured by medical devices and imaging. Adding to this is consumer-generated data. And finally, there is 'omics, vast amounts of information in his genome.

Personal precision medicine in the 21st century will need to make sense of all of this.

The U.S. has made great strides to ensure that each person has an electronic health record. Yet the goal of point-of-care and personal access to comprehensive health information has not yet been achieved.

There are three recurring barriers that often limit data-sharing. First, medical institutions using privacy and security policies and laws like HIPAA as excuses for why they can't share; next, medical professionals lacking easy, affordable tools to share data, especially because vendors fail to use or consistently implement standards; and finally, payment reforms that don't reimburse for new care models like telehealth.

Back to my dad's experience, when he arrived at the ER, the same hospital where he had received his most recent treatment, they pieced together his health history, partly from the EHR and partly from my parents.

I fear that if he was brought to a different hospital, it would've been basically starting from scratch. There exists a local health information exchange, but evidently, this hospital and my dad's nephrologist don't participate. My mom is our de facto health information exchange.

My dad would definitely enjoy the kind of secure, standards-based data-sharing that Intel's own Connected Care program makes available for over 33,000 of its employees. As we have shown, it is all quite possible today, just not as widespread as it could be.

We need to think about interoperability in much broader terms than merely exchange of electronic health record data. That will change as the Internet of Things takes hold and we connect smart devices to the Internet in ways that generate data that can be turned into valuable insights.

How would this affect my dad? Well, first of all, it would allow him to get some sleep. Because the devices monitoring him in the ICU don't talk to each other and his vitals tend to bounce around, there are endless, nearly always false alarms.

What if devices even from different vendors could talk to each other? Innovators could create smart alarms from the new combined data streams and save countless hours of nursing time, countless lives, and just let my dad sleep. The data from all the medical devices could automatically feed the EHR, millions more nursing hours saved.

But let's think bigger. What if when my dad was discharged that he was outfitted with sensors or an app that constantly detected whether his gait was making him prone to falls? Or what if instead of having to drive across town to visit his doctor, he could do so from his home via telemedicine, and his blood and vitals could be automatically analyzed via his home dialysis unit? What if his caregivers could track his progress in getting back up on his feet as he rehabs?

I think we have come up with a half-dozen ideas for new businesses, but all of this relies on there being a solid foundation for the Internet of Things to blossom: security from the sensor to the cloud; connectivity, allowing devices to communicate their status to the system; data normalization to allow devices to speak the same language; and actionable analytics.

So to close, how do we believe Congress can help seize the opportunities and overcome the challenges?

First, sustain momentum toward standards and interoperability for today and for tomorrow. As Intel's Connected Care program demonstrates, a rigorous standard-based approach enables quicker and more rapid efficient deployments today. And to rapidly move forward toward the Internet of Things, Intel invites active Federal participation in industry-led initiatives such as the IIC, OCF, ICE alliance, and Continua.

Second, encourage patient engagement by removing obstacles for patients to access and share their data. Intel invites policymakers to partner with industry to pursue a standardized, machine-readable consent form to allow patients to easily donate their data to ongoing research.

And last but not least, continue to push towards value-based care. We support the HHS goal to move half of care to alternative payment models by 2018. When incentives are aligned to value-based care, the demand for information-sharing goes up. Congress can further drive innovation by providing reimbursement for remote patient monitoring and other promising technologies.

Thank you, and I look forward to your questions.
[Prepared statement of Mr. Quinn follows:]



Testimony of
Matthew Quinn, Federal Solutions Director
Health and Life Sciences
Intel Corporation
Before the House Committee on
Oversight and Government Reform
**Opportunities and Challenges in
Advancing Health Information Technology**

March 22, 2016

Good Morning Chairman Hurd, Ranking Member Cummings and other esteemed members of the House Oversight and Government Reform Committee. I appreciate the opportunity to testify today on behalf of Intel Corporation. Thank you for your leadership in focusing on this important topic. The health of our nation literally hinges on our ability to seize the opportunities and overcome the challenges related to the promise of health information technology.

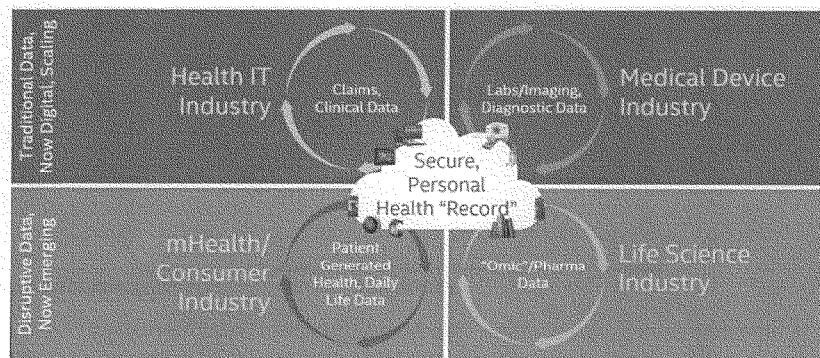
Today I will share some tangible examples of how Intel is working with public and private organizations across the care and research continuum to make good on the promise of today's health technologies and to pave the way toward tomorrow's.

We'll start with an overview of Intel's own Connected Care Program, an initiative for value-based care, in which we're leveraging our purchasing power to both directly contract with healthcare providers and also facilitate secure, standards-based data sharing among hundreds of care delivery organizations and 150 different EHR vendors for over 33,000 employees across the country.

Next, I'd like to highlight three key initiatives that illustrate the promise – and some challenges – of what's ahead with Precision Medicine and “The Internet of Things” or IoT: Our Collaborative Cancer Cloud platform, collaboration with the Michael J Fox Foundation and “You 24x7” employee wellness pilot.

I will focus on two foundational principles – full data interoperability and deep patient engagement – throughout, as solutions or approaches that are required to achieve a high functioning health care system and will also focus on where government should – and as importantly, should not – play in advancing the ecosystem.

Let's begin by thinking of the constellation of our health data over the course of a lifetime. Most familiar are the **clinical and claims data** captured at clinics, hospitals, pharmacies, insurers, etc., including such information as diagnosis codes, prescriptions, program notes, claims, vital signs, and test results. Secondly, there is **diagnostic data** captured by medical devices and imaging equipment. Adding to this now are two new data streams that are rapidly increasing in importance and opportunity: **consumer-generated health data**, captured outside the traditional health system and including such information as patient diaries, observations of daily living, vital sign monitors, fitness wearables, online and smartphone apps, social media and gaming and **'omics** — vast amounts of information contained in each person's genome (and proteome, metabolome) that will increasingly be used to attack disease at its molecular roots. By their very nature, these diverse data (coming from what we at Intel call the "Four Circle Model" depicted below) are collected at multiple sites, across long spans of time, and in a vast array of structured and unstructured formats.



The reality is that personal, precision health in the 21st century will need to make sense of all of this information for deeper insights into population health and individual treatment. These data tell us critical things about one of the most important aspects of anyone's life — our very health and well-being. To me, it's just unthinkable that we would architect a health system — a whole health economy — without

facilitating each person's access to one's own data, as well as the ability to contribute meaningful data about oneself back to researchers and data scientists to gain insights into population health and wellness.

Sharing of interoperable data must be the foundation of targeted, individual care.

The US has made great strides to ensure that each patient has an electronic health record. Today, 8 out of 10 physicians are using an EHR, with 79% of primary care physicians adopting a certified EHR through the Meaningful Use program.¹ Yet the goal of point of care access to comprehensive patient records has not been achieved. Through research in the studies of patient experiences that Intel has done across more than 20 countries—we see three recurring barriers that often limit data sharing among institutions and patients:

- 1) Medical institutions using **privacy/security policies and laws like HIPAA as excuses** for why they cannot risk sending patients their data;
- 2) Medical professionals **lacking easy, affordable, interoperable tools to share patient data**, especially because app and device vendors fail to use—or correctly implement—standards;
- 3) **Payment reforms that reimburse for new care delivery models** that will improve health and reduce the overall “total cost of care” as evidenced by telehealth and remote patient monitoring.

Revisiting the four-circle model described earlier, we can see that, despite a great deal of progress, each type of data is still not readily available to individuals—or even their clinicians—in most cases:

- **Electronic health record data and claims:** Under the Health Insurance Portability and Accountability Act (HIPAA), patients have a right to see and obtain a copy of their medical records. The American Recovery and Reinvestment Act (ARRA) extends those rights through modifications to HIPAA, requiring healthcare providers who utilize EHRs to give patients copies of their medical records in an electronic format, to another person or entity like a doctor, caregiver, a personal health record or mobile health application. The information is typically

¹ https://www.healthit.gov/sites/default/files/briefs/oncdatabrief28_certified_vs_basic.pdf, September, 2015.

provided on paper or through a flash drive or CD, or an online clinic portal. Unfortunately, the regulations have two significant loopholes. First, patients can receive the information in their preferred electronic format *only if* the provider is capable of producing the copy in the requested format; and second, providers *have 30 days* (and an additional 30 if the information is stored off-site) to make the information available to the patient. (Certification for Meaningful Use Stage 2 is a huge improvement by requiring the information to be made available within 4 business days.) Congress must have envisioned a much easier and faster method for patient access to data. This could be much more readily achieved with today's technology, particularly if more of the information was captured as common data sets in standardized formats.

- **Consumer-generated health data:** Today, there is a plethora of apps and services that collect health and wellness data from devices we wear, carry around with us, or use in our homes and workplaces. However, generally speaking, each have different logins, different and confusing user interfaces, and different calibration of sensors, different apps and services. Very few integrate with the systems used by clinicians who make up an individual's care team. And consumers have a very difficult time pulling this information into one repository, controlled by them, that will outlast the particular device, app, employer, or insurance company with which they are currently associated.

As a founding member of Continua (<http://www.continuaalliance.org/>), Intel supports a developing ecosystem of certified devices that "plug and play" to give consumer-friendly connectivity to individuals who wish to better manage their health and wellness no matter where they are. If industry adopts common standards, the information from the various devices can be curated and exchanged with the goal of helping individuals understand their information, track their progress, stay on track with their care plans, and generally take more ownership of their health. The potential is enormous for remote monitoring of patients with chronic diseases, with continuous feedback and more efficient, two-way communication between the patient and clinicians, but only if these data are securely shareable and interoperable.

- **Imaging and diagnostic data:** Medical images make up a large percentage — estimated as high as one-third — of all stored data in the world. Although storage demands are high, fortunately, cloud-computing environments enable much more cost-effective storage of medical imaging, transitioning the hosting of medical images to the cloud for electronic retrieval through healthcare provider systems. However, providing *individuals* with convenient, on-the-go access to these often-large data files remains nascent. Think of the advantage to you as a patient if you were able to log on to access all your X-rays, MRIs, ultrasounds, etc., any time you go to a new provider or the ER, instead of filling out request forms and waiting for the files to be shipped, or paying for an expensive test to be unnecessarily repeated. Since these data types are not usually part of the official EHR per se, the progress on patient access to their own data misses important classes of personal information today.
- **Genomics and other ‘omics:** The data from whole human genome sequencing are so large they are impractical to send back and forth across institutions, and we are in the early days of having tool for clinicians—let alone consumers—to make use of this data. As these new data types begin to scale, it is important that we *start* with commitments to—and validation of—interoperability and standards from the outset so we do not recreate the problems that have plagued us with EHR data. Also, new tools for big data analytics are necessary to scale the potential for precision medicine, such as the Collaborative Cancer Cloud described below.

Because each of these data streams is important to understand each person’s whole health picture, providing the individual with access to parts of electronic health record (EHR) systems is necessary but not sufficient. As the National Institutes of Health builds out the extremely promising Precision Medicine Initiative, the 1 million person cohort, and our national strategy to compete globally in the economic opportunity that precision medicine will present, let’s make sure we build an architecture for individual access to personal health information from the beginning. It cannot be an afterthought, or it will never

happen. We need to learn from the hard lessons of the nation's multibillion investments in subsidies for EHRs and grants for health information exchanges. We must think about interoperability in much broader terms than merely the doctor-to-doctor exchanges of EHR data. We need to continue to support the concept of individual's having personal health records available to them and their care team, anytime and anywhere, and not tied exclusively to a particular institution or company.

To help show what's possible today within the current healthcare ecosystem, with currently available EHRs, data standards, health information exchanges and , I'd like to share what Intel is doing in its own journey to make health care more effective and affordable.

Intel's Connected Care Program – an employer initiative for value-based purchasing:

The Connected Care vision is to improve Intel employees and families' healthcare experiences, outcomes, and reduce costs over time and EHR interoperability plays an important role to help Intel achieve this vision. In 2013, Intel launched the Connected Care program in Albuquerque, New Mexico. It is essentially an employer-sponsored and -facilitated accountable care organization (ACO). In focus groups, we heard from our employees and families that they wanted streamlined access to primary care and specialists. In response, Intel significantly changed its relationship with the healthcare system in the Connected Care Program. We contracted directly with the healthcare supply chain, removing middle men. We built a network of 11 primary care medical homes, including an onsite clinic, and medical neighborhood of specialists and facilities. To ensure timely access to care, Intel and Presbyterian Health Services agreed on protocols for call responsiveness and established acceptable levels of appointment availability. We contracted directly with Presbyterian Health System in an arrangement that aligned incentives and shared risk, with outcomes measured according to the following accountability metrics:

- **Right care:** Use of evidence-based medicine to improve population health, focusing on diabetes, hypertension and depression.
- **Right time:** Timely access to care in the optimal setting, including a nurse hot line.

- **Best outcome:** Patient satisfaction 100 percent of the time.
- **Right price:** Material decrease in the cost of care, per patient per month.
- **Best life:** Rapid return to productivity.

Employee response has been excellent: More than 3 in 4 eligible employees opted to join the Connected Care Program. So far, major successes have included greater member engagement with the healthcare system, very high satisfaction ratings, and statistically significant improvements in diabetes control. We have yet to demonstrate an improvement in costs. In the long term, we believe that promoting proactive primary care with deep patient engagement and accountability should improve health outcomes *and* costs as we iterate this program.

Successful preliminary results in New Mexico drove the decision to scale Connected Care to Oregon and Arizona. These locations which integrated multiple institutions and sites had a deeper need for sharing of our employees' electronic health records. With our healthcare partners, we addressed the data liquidity problem head-on through contracts that called for seamless care that required data sharing across institutional boundaries.

The Connected Care interoperability team at Intel selected the Direct messaging standard and the Healthway eHealth Exchange (recently renamed The Sequoia Project) to support the business and clinical requirements for coordinated care. The Connected Care data exchange model utilizes the HL7 Consolidated Clinical Documentation Architecture (C-CDA), which is a key part of the data interoperability specifications in Meaningful Use. The EHR interoperability model in Oregon is nationally recognized for having an innovative approach for point-of-care access to electronic health records. New care coordination workflows are using data exchange with healthcare information coming to them in real time, resulting in quicker access to care with less work for everyone involved. Having the

most up-to-date healthcare data means a more efficient model where physicians and patients can now make the best possible choices about their care planning, leading to lower costs over time. And, critically, this data exchange model is enabling consumer health pilots that will improve Intel employee experience and improve health engagement.

We relied upon the security, authorization and privacy measures governed by national standards (eHealth Exchange/NHIN and Direct messaging), and HIPAA for exchange of clinical records. This includes end-to-end encryption of data, authorization, PKI/digital signatures and appropriate access controls. The underlying technology standard is called SAML, which is used to assert authentication of the user. Members of the eHealth Exchange secure their communications using x.509 certificates whose chain-of-trust begins with the same Root Certificate Authority (CA), thus facilitating trust between organizations without the need to exchange certificates.

Results: Tens of thousands of records are being queried and exchanged for our 33,000 employees in the Connected Care Program. For more specific information on the interoperability challenges and the value provided from joining Healthway/Sequoia for a query-based system, Intel, Kaiser Permanente, and Providence Health and Services, The Portland Clinic and Premise Health have produced a white paper accessible at the following URL: <https://www-ssl.intel.com/content/www/us/en/healthcare-it/advancing-interoperability-healthcare-paper.html>. I'd like to re-iterate that Intel is making this happen as we speak – with today's EHRs, today's standards, today's health information exchanges and as an employer within today's healthcare system.

How could the federal government use its contracting power to achieve interoperability for beneficiaries of the Department of Defense, Department of Veterans Affairs, Centers for Medicare and Medicaid and Office of Personnel Management or for the hundreds of thousands of

government workers receiving federal health benefits? We have a tried and tested playbook for federal provider contracting that could be a model for both government and private industry.

Next I'd like to shift toward enabling the future. Precision medicine is an emerging approach for disease treatment and prevention that takes into account the individual variability in genes, environment, and lifestyle for each person.

Intel's work in precision medicine

Intel and Oregon Health & Science University (OHSU) recently announced the Collaborative Cancer Cloud, a precision medicine analytics platform that allows medical institutions to securely share insights from their private patient genomic data for potentially lifesaving discoveries. Intel announced that key technology components of the Collaborative Cancer Cloud (CCC) will be opened sourced. Hospitals and research institutions of all sizes could use the technology to advance personalized cancer research. They can also apply it to advance personalized research in other diseases that are known to have a genetic component, including Alzheimer's, diabetes, and more. Intel and OHSU also announced that they will partner with two other large cancer institutions to extend this capability in 2016.

The project combines next-generation Intel technologies and bioscience to enable solutions that can be used to make it easier, faster, and more affordable for developers, researchers, and clinicians to understand any disease that has a genetic component, starting with cancer. It will enable large amounts of data from sites all around the world to be analyzed in a distributed way, without having to move the data itself, preserving the privacy and security of that patient data at each site. The end goal is to empower researchers and doctors to help patients receive a diagnosis based on their genome and potentially arm clinicians with the data needed for a targeted treatment plan. By 2020, we envision this happening in 24 hours — a challenge to the computing and life science industries that we call All in One Day. The focus is to help cancer centers worldwide — and eventually centers for other diseases — share with one another the insights that reside in their private clinical and research data without having to share the data itself.

This approach is designed to protect data privacy and the business models of the research centers while at the same time unlock the insights from far larger datasets to benefit research and inform the specific treatment of individual patients.

Building and Accelerating the Health and Healthcare Internet of Things

Today, we often think of EHRs or health and medical devices in isolation or closed networks: Can we get the EHR from one clinic or hospital to talk to the one across the street? Does that infusion pump talk to that monitor? And we build and maintain a lot of interfaces.

But that's all changing as the Internet of Things takes hold and we connect "smart" devices to the internet in ways that generate data that can be analyzed and turned into valuable insight. Driven by dramatic reductions in the cost of sensors, computing and bandwidth and the drive for improved cost and efficiency, we will have a smart energy grid, smart transportation network and...we hope...a smart healthcare system. All in all, these trends will unleash the IOT opportunity impacting the way we work and the way we live. Some estimate that by 2020, there will be 50B smart devices with 212B sensors generating 44 ZB of data.

Intel and key global partners collaboratively identified five critical IoT tenets which describe how endpoint devices should connect to the cloud:

- Security as the Foundation: With billions of internet-connected devices by 2020, it is important that IoT is secure from the sensor to the cloud, including all hardware and software.
- Connectivity, Device Discovery, and Provisioning: Billions of devices cannot be managed manually. Rather, devices need to be able to communicate their "status" to the rest of the system independently.
- Data Normalization: With so many different data types, there must be some level of interoperability between devices such that they are speaking the same language.

- Actionable Analytics: The data must be turned into meaningful information through analytics.
- Monetize Hardware, Software, and Data Management: The IoT infrastructure must be built to allow developers to manage and monetize innovative applications and services.

To better illustrate these principles, let's look at Intel pilots with specific healthcare applications.

Intel's work with consumer-generated health data:

The Michael J. Fox Foundation for Parkinson's Research (MJFF) and Intel Corporation are collaborating on improving research and treatment for Parkinson's disease — a neurodegenerative brain disease second only to Alzheimer's in worldwide prevalence. The collaboration includes a multiphase research study using a new big data analytics platform that detects patterns in participant data collected from wearable technologies used to monitor symptoms. This effort is an important step in enabling researchers and physicians to measure progression of the disease, improve medication adherence and speed progress toward breakthroughs in drug development.

With wearable technology, the potential to collect and analyze data from thousands of individuals on measurable features of Parkinson's, such as slowness of movement, tremors and sleep quality, could enable researchers to assemble a better picture of the clinical progression of Parkinson's and track its relationship to molecular changes. Wearables can unobtrusively gather and transmit objective, experiential data in real time, 24 hours a day, seven days a week. With this approach, researchers could go from looking at a very small number of data points and burdensome pencil-and-paper patient diaries collected sporadically to analyzing hundreds of readings per second from thousands of patients and attaining a critical mass of data to detect patterns and make new discoveries. It is a dramatic shift from data-poverty to data-wealth — and in my view it signals the future of research and discovery.

MJFF and Intel share a commitment to increasing the rate of progress made possible by open access to data. The organizations' aim to share data with the greater Parkinson's community of physicians and

researchers as well as invite them to submit their own de-identified patient and subject data for analysis. Teams may also choose to contribute de-identified patient data for inclusion in broader, population-scale studies.

What could government do to extend the Parkinson trial to the thousands of Medicare patients suffering from the disease?

Unfortunately CMS has virtually no payment codes to provide services for the MJFF trial described above. However, Congress is recognizing the need for payment reform to encourage Medicare reimbursement for wearables and remote patient monitoring devices for patients with chronic disease through legislation as outlined by HR 4442, the CONNECT for Health Act introduced by Reps. Black, Harper, Welch, Thompson and Blumenauer.

Intel's YOU.24X7 Study

The YOU.24x7 Study, a 6-month observational pilot study of nearly 500 participants uses an end-to-end prototype platform consuming patient-generated data for research into health trends and behaviors to analyze cardiovascular risk factors and potentially improve outcomes. Patient data are collected through a number of devices: a Basis watch to track sleep and activity, plus blood pressure and weight scales in the home. These data are combined with electronic medical record information, labs and other key metrics to give more holistic view of the population. Data scientists and cardiologists are using an advanced analytics platform created by Intel, looking at the de-identified data to gain trending and correlation insights into cardiovascular wellness. Meanwhile, the individual participant has 24x7 access to all of his or her own information through the secure personal health collaboration hub.

As an employer faced for years with unsustainable healthcare cost inflation for the 53,000 employees we are proud to employ in the United States and their 88,000 Intel Health Plan dependents, Intel has initiated these projects for business reasons — both to support a healthy, productive workforce and to grow the

global market for the powerful computing needed to scale precision medicine. We hope these programs can become examples for the rest of the country to build upon.

Congressional action is needed to ensure that these positive examples using Health IT innovation are options for Medicare patients across the country.

1) Sustain momentum toward standards and interoperability for today and tomorrow: As

Intel's Connected Care Interoperability team demonstrated, a standards-based approach for health information technology enables quicker and more efficient deployments to share data from different sources. This provides scalability, interoperability, and innovation as new services can be built upon a common framework of standards, data models and clinical vocabularies. Intel supports an implementation specification compatible with baseline standards that are specific, well-documented, tested vigorously, and shared publicly, as described in HR 6, the 21st Century Cures Act.

Intel invites policymakers to consider standards and interoperability efforts beyond EHRs (electronic health records) and into the domain of the health and healthcare Internet of Things (IoT) through encouraging recognition and active federal participation in industry-led initiatives such as Industrial Internet Consortium (IIC), OCF (Open Connectivity Foundation), ICE Alliance, Continua and other organizations.

- 2) Encourage patient engagement by removing obstacles for patients to access and share their data.** With the adoption of electronic health records comes enormous potential for creating value from data held in millions of patient records. Today, the use of this information is regulated by a series of highly regulated consent requirements constructed by not only the federal government, but by states. Intel invites policymakers to partner with industry to pursue a standardized machine readable consent form to allow patients to donate their data to ongoing research without the need for securing and faxing consent forms each time patient data is requested. The International Rare

Disease Research Consortium has recognized this problem. The Consortium has assembled a task team from the Global Alliance for Genomics and Health to explore the machine readability of consent and its impact on data use and accessibility. PCORI has launched research into patient preferences for consent,² as well as other government and private industry initiatives.

- 3) **Continue to push toward value-based care:** We support the HHS goal announced last year to move 30 percent of care to alternative payment models by 2016 and to 50 percent by 2018. When incentives are aligned toward value-based care and managing population health, the demand for information-sharing goes up. Fee-for-service models work the opposite way, in which providers are paid based on the volume of service they deliver. Based upon Intel's experience with Connected Care, we have seen increased patient engagement and better outcomes based upon shared risk, shared goals and consistent metrics for success. As the U.S. healthcare system moves to outcome-based payments through the Medicare Access and Chip Reauthorization Act (MACRA), Congress can assist through providing funding for new care delivery tools for training and discovery until the 2019 implementation date for remote patient monitoring (RPM), which remains mostly unpaid in today's fee-for-service environment in spite of studies showing as much as a 75 percent reduction in hospital readmissions when provided to chronic care patients.³

- 4) **Facilitate the right mechanisms and incentives for managing and reducing cyber security risk:**

Open collaboration and communication among regulators, industry medical and healthcare practitioners are key to managing and reducing cyber security risk. Public-private partnerships have proven to be successful in helping a wide range of industries improve their cyber security readiness and overall capabilities in the past. More recently, the NIST Cybersecurity Framework has provided a tool for healthcare organizations to review their security posture with a focus on risk management.

The Framework provides an organization the ability to evaluate its current security posture, create a

² <http://www.pcori.org/research-results/2014/demonstrating-respect-and-acceptable-consent-strategies-what-matters-patients>

³ <http://healthaffairs.org/blog/2014/04/04/the-role-of-remote-care-management-in-population-health/> or http://www.telehealthresourcecenter.org/sites/main/files/file-attachments/snell-smalley_hospital_-_physician-summit-feb-2013.pdf

target for risk tolerance and allow the organization to develop a path towards achieving the target.

The U.S. Department of Health and Human Services' (HHS) mapping between the HIPAA Security Rule and the Framework through an effort developed in conjunction with NIST and the Office of the National Coordinator for Health IT (ONC) provides a means for healthcare organizations who have aligned their security programs to the HIPAA Security Rule to be able to use the Framework to identify and address gaps in their security. Collaboratively developed efforts such as the NIST Cybersecurity Framework provide real benefits to healthcare organizations wishing to better understand and improve their organization's cyber risk management processes and posture. Security must be stressed at the outset, rather than **as an afterthought in the design process**.

Cyber security must be baked into the equipment, systems and networks at the very start of the design process - intrinsic to an organization's thought processes, its business processes, and its design, development, and manufacturing processes. It must be embedded in a product or network element so that it becomes an integral part of the product's or element's functioning. This approach is not only more effective; it is less cumbersome and less expensive than trying to lock down systems that are inherently insecure after the fact, as has happened all too often in the past in a wide variety of industries, including health care.

While Information Sharing and Analysis Organizations (ISAOs) and associated liability protection for participation have been proposed to allow increased sharing of information on cyber threats among private sector participants, such proactive information sharing could be a valuable tool in preventing cybercrimes. Gaining active participation in such organizations – whether in support of cybersecurity or patient safety – will require carefully crafted mechanisms and incentives.

- 5) **Ensure privacy as an enabler of innovation:** Intel believes that privacy is a key enabler of innovation in this sector. If individuals are to feel at ease with these technologies and data uses, they

must trust that their devices are secure and data about them is protected and used in privacy respectful ways. Intel endorses the application of long recognized, proven principles of fair information practices to address concerns about data practices and privacy. Intel further endorses implementation of "privacy-by-design" - that is, addressing privacy and building in privacy solutions throughout the design cycle of technologies and data applications.

Privacy and progress in this sector are not values to be balanced or traded off - they are goals that must be pursued in tandem if we are to realize the benefits these technologies promise.

We thank the Committee for inviting Intel to address Congress on the important contributions being made today in the diverse realm of Health IT and for considering our recommendations on how to accelerate deployment.

Matthew Quinn, Federal Solutions Director
Health and Life Sciences
Intel Corporation

Mr. HURD. Mr. Quinn, I appreciate your opening remarks.
Now Mr. DeCrescenzo is recognized for 5 minutes.

STATEMENT OF NEIL DeCRESCENZO

Mr. DeCRESCENZO. Thank you. Mr. Chairman, members of the committee, it is a privilege to be here today.

My name is Neil DeCrescenzo. I am the president and CEO of Change Healthcare. Perhaps our name says it all.

Change Healthcare is headquartered in Nashville, Tennessee, provides its services in all 50 States, and has over 50 offices nationwide. We are a leading provider of software and analytics, network solutions, and technology-enabled services that optimize communications, payments, actionable insights that enable smarter health care.

By leveraging our Intelligent Healthcare Network, which is one of the largest financial and administrative networks in the United States health care system, payers, providers, and pharmacies are able to more effectively manage complex workflows that support value-based health care.

While I am proud to represent the nearly 7,000 people of Change Healthcare, I am testifying today in my role as a member of the executive committee of the Healthcare Leadership Council, a coalition of leading companies and organizations from virtually every sector of American health care. In that role, I would like to share a few thoughts on the role and capability of health information technology to transform our Nation's health care system for the better.

As increasingly is the case in most fields, health care improvement today is driven by data. If our health care system is not improving at the pace any of us would like, this is in large part due to barriers standing in the way of access to data, the ability to share information, and the utility of this information for consumers, providers, payers across the health care continuum.

Our HLC member companies know from firsthand experience that data interoperability can strengthen care coordination, enabling providers, payers, pharmacists, laboratories, and others, to be on the same page when treating a patient. It can boost progress toward an outcome-driven, value-based payment system to replace the outdated and inefficient fee-for-service status quo while also improving our quality measurement capabilities.

With interoperability and access to clinical and claims data, we can accelerate medical research and give hospitals and physician offices real-time access to comparative effectiveness findings. An interoperable system can improve care to rural and underserved areas of the country through improved telehealth and remote patient monitoring. Wellness and prevention will also be enhanced through the better use of patient-generated data.

This future is promising, exciting, and imminently obtainable, once we address some of the obstacles standing in our way.

Last year, HLC, under the auspices of its National Dialogue for Healthcare Innovation initiative, brought together leaders from over 70 organizations representing government, industry, patients, employers, and academia. There we built consensus on how we can move closer to this desirable data-driven future.

Last month, we announced the consensus recommendations emerging from this effort, a number of which are relevant to today's discussion.

On data interoperability, we believe that a firm date of December 31, 2018, should be established by which health information is widely shared among electronic health record systems nationwide. We have the capability to reach this goal in the near term, not a decade from now. Progress toward this nationwide data infrastructure should be driven by private sector innovation, with emphasis placed on secure data-sharing to protect patient privacy, common standards and governance, and a ban on data-blocking.

In addition, we believe that Congress and the administration must address physician health referral laws and Federal anti-kick-back statutes, as well as civil monetary penalty laws.

These fraud and abuse protections were built for a fee-for-service world, but today, they often stand as barriers to the kind of collaboration and information-sharing that is essential for value-based health care approaches and for improving patient care.

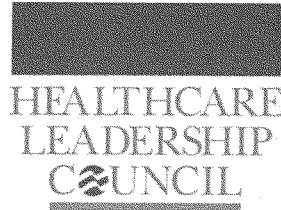
Another barrier to data-sharing is the multitude of diverse and often contradictory Federal and State laws regulating health information that exist alongside the Federal HIPAA regulations. We believe these national and State privacy laws and regulations should be harmonized to facilitate greater information-sharing for the benefit of patients while still protecting their confidentiality.

Members of the committee, I would like to close by applauding you for conducting this hearing and your focus on the issues that can genuinely transform and improve health care for every American.

We can move faster. We can move more collaboratively across the spectrum of U.S. health care. And we can help more Americans maintain or improve their health better than we do today through data, information, and insights.

We look forward to working with you toward our shared goals, and I will be happy to take your questions. Thank you.

[Prepared statement of Mr. DeCrescenzo follows:]



Testimony of

**Neil de Crescenzo
President and CEO, Change Healthcare
on Behalf of the Healthcare Leadership Council**

Hearing on

**“Opportunities and Challenges in Advancing Health Information
Technology”**

**United States House of Representatives
Committee on Oversight and Government Reform
Subcommittee on Information Technology and
Subcommittee on Health Care, Benefits, and Administrative Rules**

**Tuesday, March 22, 2016
2:00 p.m.**



**NATIONAL DIALOGUE FOR
Healthcare Innovation**

Mr. Chairman and members of the committee, thank you for the opportunity to testify today on the importance of health information technology and how we can enable a future that takes full advantage of the potential of electronic health information.

My name is Neil de Crescenzo and I am the President and CEO of Change Healthcare. Change Healthcare is headquartered in Nashville, Tennessee, provides its services in all 50 states and has over 50 offices nationwide. We are a leading provider of software and analytics, network solutions and technology-enabled services that optimize communications, payments and actionable insights that enable smarter healthcare. By leveraging our Intelligent Healthcare Network™, which is the single largest financial and administrative network in the United States healthcare system, payers, providers and pharmacies are able to increase revenue, improve efficiency, reduce costs, increase cash flow and more effectively manage complex workflows that support value-based healthcare. I am proud to represent the nearly 7,000 people of Change Healthcare. Today I am pleased to be here in another important role that I have as an Executive Committee Member of Healthcare Leadership Council.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC—hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies—advocate measures to increase the quality and efficiency of healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to enhance value.

I am speaking here today, in part, because of my role in leading HLC's National Dialogue for Healthcare Innovation (NDHI) effort. HLC created NDHI to allow industry, patients, employers, academicians, and government to examine, discuss, and build consensus on how to address the most important issues affecting the course of 21st century healthcare.

On March 2, 2015, NDHI convened an unprecedented summit with leaders of more than 70 of the most influential public and private organizations in healthcare to identify the barriers impeding progress toward a high-value, innovation-driven healthcare system, and discuss how to remove those barriers. This was an important meeting that atypically focused not on a single, narrow healthcare issue, but rather on how to create a sustainable system equipped to address persistent cost and quality challenges. Many of the priorities that emerged from these talks are relevant to the discussion here today.

INTEROPERABILITY

HLC members are united in our belief that interoperability of electronic health information exchange will make American healthcare more affordable and accessible, that it can reach higher levels of quality, and that it can achieve better health outcomes for individuals and populations. We believe that these objectives can and must be attained through interoperable information exchange and built on innovation that has defined private sector healthcare for generations.

HLC members feel strongly that any discussion of interoperability should be firmly grounded in real-world applications of technology. Interoperability is not a goal unto itself – it is a means to achieve many of our long-held ambitions for a healthcare system that better serves patients, prevents errors, increases value, and improves quality of life. Interoperable health systems have the potential to drive progress in:

- *Care Coordination / Patient Centered Interoperability:* The first goal of interoperability must always be a positive patient experience that helps them maintain and improve their health. Individuals directly in contact with the patient or the patient's health information must be able to share relevant information with one another as well as the patient, regardless of geographic location or healthcare setting. This information sharing needs to be both timely and bidirectional. Interoperation also needs to be expansive—included in this connectivity should be the health information systems of providers, pharmacists, payers, IT connected medical devices, laboratories, and other ancillary services providers—when appropriate. Through this coordination, the patient experience will improve, medical errors will be reduced, and illnesses better treated or prevented.
- *Value-Based Payment:* As initiatives by the private and public sectors accelerate our shift from volume-based healthcare payments to outcomes-driven, episodic payments, stakeholders must have access to relevant data to support the shifts in care paradigm that drive these new payment models. Broader interoperation and integration between organizations will expand the potential and appeal of alternative payment models – driving value and better outcomes in our healthcare system.
- *Quality Measurement:* Effective interoperation among information-holding entities is critical for the alignment of metrics across various government and private sector programs. HLC supports efforts to streamline quality measures to focus on a small, limited core set of quality measures to reduce data collection

costs and administrative burden for providers and payers. These measures should be outcome-focused (rather than “process-focused” measures) endorsed by a consensus body, and aligned across health organizations and systems. Interoperation among systems is necessary for these measures to capture data proving the efficacy and long-term value of interventions on patient outcomes.

- *Clinical and Claims Data Sharing for Research:* Interoperation of clinical data has the potential to accelerate the learning health system by orders of magnitude. As demonstrated by large private sector health systems as well as the Patient-Centered Outcomes Research Institute's (PCORI) National Patient-Centered Clinical Research Network (PCORnet), interoperation can substantially ease the appropriate access to data from electronic health records to conduct comparative effectiveness research using large, real-time datasets from a variety of healthcare settings, including hospitals, doctors' offices and community clinics. Legal and confidentiality issues as well as careful consideration on how to obtain patient consent must continue to be taken into account when using clinical data; however, interoperating systems using a common clinical data set could significantly lower technical barriers to this type of research. Academic medical centers, pharmaceutical and device manufacturers, payers, and others could benefit from expanded clinical data access through interoperability.
- *Telehealth and Remote Patient Monitoring:* One of the most important outcomes of an interoperational system should be the increased ability to utilize telehealth and remote patient monitoring (RPM) throughout the care system. This will enable better provision of care, particularly in rural or underserved areas, at a lower cost, while coordinating care among multiple providers. Additional detail on regulatory barriers which currently stymie wider telehealth adoption is provided later in this testimony.
- *Wellness and Prevention:* Interoperation can provide the basis for dramatic steps toward improving the wellness of all consumers and patients. At a population health level, it would allow for better disease detection and surveillance, which would inform both clinical responses as well as scientific advances. With interoperable patient devices, health care providers could make better use of patient-generated data.

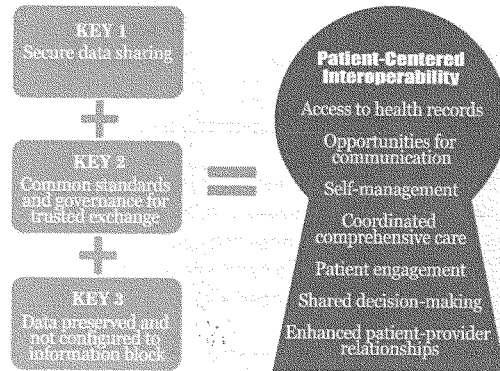
Keys to Patient-Centered Interoperability

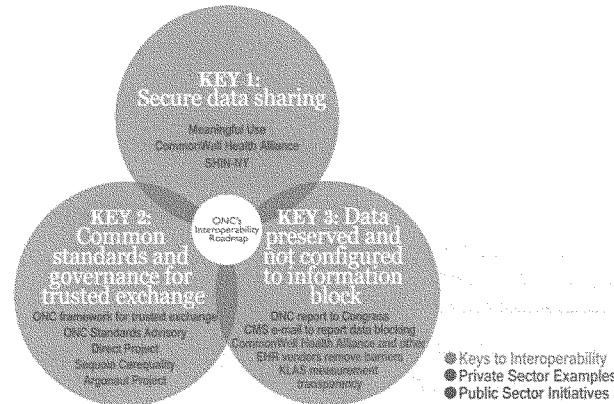
In an effort to show how all stakeholders can move towards an interoperable system, the NDHI effort identified three key goals to support patient-centered interoperability that

are shared across the public and private sectors. Together, these keys will move the U.S. toward achieving a patient-centered interoperable health system

- Key #1: Secure Data Sharing:** Secure data sharing ensures that patients' privacy is protected in the process of data exchange--and while the data is stored.
- Key # 2: Common Standards and Governance for Trusted Exchange:** Consistent implementation of standards to establish the language, structure, and data types required for integration among systems is necessary for interoperability. These standards must be accessible and capable of adapting to changing healthcare technology.
- Key #3: Systems are Not Configured to Information Block:** HLC CEOs have made a commitment not to "information block", by knowingly and unreasonably interfering with the exchange or use of electronic health information. Information blocking can lead to a variety of unfortunate outcomes, such as:

 - Compromising patient safety, care quality, and treatment effectiveness because it withholds information from patients and providers for informed decision making;
 - Impeding progress towards reforming healthcare delivery and payment because sharing information seamlessly across the care continuum is fundamental to moving to a person-centered, high-performing healthcare system;
 - Undermining consumers' confidence in their healthcare providers by preventing individuals from accessing their health information and using it to make informed decisions about their health and healthcare; and
 - Preventing advances in biomedical and public health research, which require the ability to analyze information from many sources in order to identify public health risks, develop new treatments and cures, and enable precision medicine.





HLC Principles on Interoperability

In 2014, the CEOs of HLC came together and agreed to take steps toward an interoperable health IT infrastructure that is both beneficial to consumers and workable for the industry. Functional interoperability is a critical component to support patient-centered care, value, and continued innovation in healthcare.

To support these goals, we made the following declaration to Congress, the Administration, and our peers in the healthcare system:

- Policymakers should **encourage exchange of material and meaningful health data** through the use of technologies and applications that enable bidirectional and real-time exchange of health data currently residing in electronic health record (EHR) systems (e.g., open and secure API technology).
- Policymakers should use appropriate authority to **certify only those EHR technology products that do not block or otherwise inhibit health information exchange**. The HHS Office of the National Coordinator should decertify Meaningful Use products that intentionally block the sharing of information, or that create structural, technical, or financial impediments or disincentives to the sharing of information.
- The federal government, in collaboration with the private sector, should **build on current and emerging best practices in patient identification and matching** to identify solutions to ensure the accuracy of every patient's identity, and the

availability and accessibility of their information, absent lengthy and costly efforts, wherever and whenever care is needed.

- Any interoperability **requirements or incentives should be “technology neutral” and focused on outcomes** – active interoperation between and among systems—rather than on the adoption or use of specified technologies. It is critical that future policies do not stifle potential innovations in health system connectivity.

HLC strongly encourages a continued focus on outcomes-based approaches to measuring progress in interoperability. The ability to exchange health information is not necessarily the same as actual interoperation— meaning patient and provider-authorized information exchange—between and among the many disparate health IT platforms in use today and in the future. A limited role for the federal government may be needed to assist in identifying standards in limited key areas including patient identifiers, terminologies, clinical data query language, security, open application program interface criteria, and clinical decision support algorithms, among others.

NDHI Interoperability Work

In 2015, the multi-sector members of NDHI felt that recent advances in the state of private sector-led interoperability collaborations and technologies allowed for even more ambitious goals and recommendations. NDHI members agreed to build upon recommendations already offered to Congress and the Administration by HLC to continue to work toward achieving an interoperable health IT infrastructure. Based upon these impressive accomplishments, members endorsed two additional declarations:

- There should be a **national objective to achieve widespread exchange of health information through interoperable EHR technology nationwide on or before December 31, 2018** (in parallel to the recommendation made in the Medicare Access and CHIP Reauthorization Act).
- **Consumers should have easy and secure access to their electronic health information**, be able to direct it to any desired location, learn how their information can be shared and used, and be assured that this information will be effectively and safely used to benefit their health and that of their community.

Interoperability Conclusion

As efforts to reform our healthcare system accelerate, all parts – public and private – must move in tandem. Interoperability is also key to achieving the laudable goal set by HHS of tying 50% fee-for-service Medicare payments to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or

bundled payment arrangements by the end of 2018. HHS has also set a goal of tying 85% of all traditional Medicare payments to quality or value by 2016 and 90% by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs. The success of these models in the healthcare system hinges on the deployment of seamless information sharing across all participants.

Meaningful interoperation is a necessary tool to meet the ambitious goals laid out by both private sector organizations and the federal government to enact value-based payment reforms, new care models, and allow greater consumer access and control of their healthcare. These goals can best be accomplished through private sector leadership, with government serving in an outcome-focused guiding role.

BARRIERS TO HEALTH INFORMATION FLOW

There is growing interest in using data to better understand how to optimize the practice of medicine, the delivery of healthcare and new approaches to wellness and prevention of illness. At the same time, these new innovations must be balanced with the federal government's concerns about interoperability and the public's concern about the confidentiality and use of health data.

As data are accessed, it is vital to understand how to safely use these data to generate information for evidence-based care, share the data appropriately, analyze the data, and predict future needs of our complex healthcare delivery system. These data are fundamental to designing, implementing and evaluating innovative approaches to payment and financing reform and value-based delivery system reform, as well as medical breakthroughs.

Allow data-driven accountable care models to flourish by reforming legal barriers to cooperation and care delivery innovation

As the healthcare system transforms to reward better value and a more empowered consumer, the NDHI initiative has found that some laws and regulations that were once important to the healthcare system may no longer be applicable or may inhibit transformation efforts in unintended ways. Laws designed to prevent anticompetitive behavior in a fee-for-service environment, for example, now sometimes hinder the coordination needed for the best patient care.

In general, the fraud and abuse legal framework is designed to penalize arrangements between and among providers and other industry stakeholders that have the potential to encourage overutilization of healthcare resources, inappropriately influence provider

decision-making, decrease competition among competitors, and harm patients. To improve quality of care and reduce costs, new care delivery and payment models are designed to encourage greater coordination of care and payment among providers and other industry stakeholders. These models may align financial interests in ways that conflict with outdated fraud and abuse laws and regulations.

Many federal statutes and regulations are potentially implicated by these new models, including; the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law, Civil Monetary Penalties (CMP) Law, the Civil and Criminal False Claims Acts (FCA), HIPAA, antitrust and tax law, and state laws that overlap with, mirror, or relate to these federal laws.

Through the work of the NDHI initiative, participants agreed upon two realistic legislative priorities:

- *Require the Department of Health and Human Services Secretary to review and assess the Federal Anti-Kickback Statute and Stark Law as well as the Civil Monetary Penalties (CMP) Law in the context of health system transformation, specifically addressing whether the laws create unnecessary barriers to new integrated care models and whether these laws are effective in limiting fraudulent behavior. Changes identified through this assessment may yield opportunities to amend fraud and abuse laws to foster healthcare arrangements that promote increased quality and lower costs.*
- *Grant the HHS Office of the Inspector General (OIG) and CMS broader flexibility and discretion to develop exceptions and safe harbors to the Federal Anti-Kickback Statute and the Stark Law consistent with current health policy objectives (e.g., increased efficiency and quality, decreased cost).*

It is important to note that alignment of the fraud and abuse legal framework with new care delivery and payment models is being discussed at multiple levels across the healthcare system. The recent Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) called for the HHS Secretary, in coordination with the HHS OIG, to consider possible modifications to the legal frameworks to better align with integrated care delivery and payment models.

Patient Matching

As mentioned previously, patient identification and matching that works wherever and whenever care is needed is a critical component of successful interoperability and improved health outcomes. The federal government must work with the private sector to build on current and emerging best practices to identify solutions that ensure the

accuracy of every patient's identity, and the availability and accessibility of their information, without lengthy and costly effort.

Without a systematic means of matching the right record to the right person, providers may have an incomplete view of a patient's medical history. This could result in compromising the patient's safety, care may not be well coordinated with other providers treating the patient, patient records may be overlaid, unnecessary testing or improper treatment may be ordered, and patient confidence may be eroded. The inability to match patients to their records may also cause providers to face costly clinical workflow inefficiencies and potential inaccuracies including ordering duplicate tests. For EHRs to deliver on the promise of interoperability and better healthcare, they need to ensure that patient data are sent and received easily among providers across disparate systems. These shared records must be accurate and useable.

The potential benefits of successfully matching a patient to their health information across all care settings cannot be understated. It is critical to health information interoperability efforts, critical to providing a patient a comprehensive health record upon request, and critical to ensuring that health professionals have the information to safely and effectively treat patients. More effective patient matching could lower healthcare costs by preventing redundant tests and scans, and more effectively prevent adverse events caused by medication interactions. The private sector has taken steps forward to reach these goals, but federal legislators need to facilitate government cooperation in ensuring success in building this infrastructure nationally.

Congress can facilitate this by removing the annual appropriations provision prohibiting the use of federal funds to promulgate a unique health identifier until legislation is specifically enacted approving it. While this provision is narrowly worded, it has discouraged federal agencies from fully joining in partnership with the private sector as we work to develop patient matching systems and standards.

The Need for Consistent Legal Requirements for Health Information

Various laws and regulations create restrictions on data movement and usage at the federal level, which often constrain providers from pursuing alternative payment models and even research initiatives. As health plans and providers and the medical research community continue to focus on outcomes research and innovation, it is important that the exchange and aggregated use of healthcare data be allowed. The HIPAA Privacy Rule strictly defines what constitutes protected health information (PHI) and defines certain institutions, or covered entities that hold such information. The Federal Policy for the Protection of Human Subjects or "Common Rule" defines the protection of human subjects in research. Without modifications to harmonize these rules, unnecessary barriers to data movement will continue to limit the innovative potential of

the healthcare marketplace, especially as PHI continues to migrate out of the traditional healthcare system.

The misinterpretation and lack of alignment around privacy, security, and enforcement regulations – developed to safeguard patients' personal health information – hampers data sharing necessary for better care coordination and medical research. Currently, researchers need to contend not only with the HIPAA Privacy Rule regulating research, but also with state law, and in many cases, additional federal law, for example, the Federal Privacy Act of 1974, the so-called Common Rule, FDA Regulations, and other regulations. This results in a confusing and inconsistent set of requirements, often governing the same study (for example, in the case of a multi-site study in different states).

HIPAA was designed to ensure that individuals' health information is protected while allowing the flow of health information needed to provide high quality healthcare. HIPAA was also designed to protect the privacy of individuals' electronic health information while allowing the adoption of new technologies that will improve the quality and efficiency of patient care.

We believe that the HIPAA privacy and security rules are, generally, serving patients and the healthcare system well and that they should continue to be the guiding rule wherever HIPAA-covered entities are involved. The law was designed to accommodate health information flow and the adoption of new technologies while still protecting individuals' health information. As healthcare payment and delivery systems evolve, and we gravitate toward greater use of electronic health records, we believe that HIPAA continues to be an effective policy foundation with which to govern the appropriate and effective use of patient healthcare data.

However, as our nation embarks upon dramatic transformations in care delivery through new payment models and seeks to achieve full nationwide interoperability of health information, it is critical that we reconcile confusions and barriers that may be caused by conflicting privacy laws while remaining true to patient-serving goals and privacy protections.

Inconsistent Legal Requirements for Health Information Across State lines

One particularly burdensome barrier to nationwide health information exchange is the multitude of diverse – and often contradictory – state laws across the country regulating health information alongside HIPAA and other federal privacy laws. These various state privacy and information sharing laws create enormous complexity resulting in substantial impediments to the implementation of health information exchanges within and across state borders.

Healthcare organizations have long advocated for the harmonization of national and state privacy requirements in order to simplify compliance and facilitate greater information sharing. We believe that a broader harmonization effort that incorporates HIPAA governing standards would benefit the healthcare system without creating any material adverse impact on individuals. This work becomes increasingly important as Americans become more mobile and travel for specialized healthcare services.

There has been excellent work done by the HHS Office of the National Coordinator (ONC) in connection with its important and visionary interoperability roadmap "Connecting Health and Care for the Nation". That roadmap outlines a vision and action steps for the harmonization of conflicting, confusing, and burdensome state privacy laws. This effort provides new hope for efforts to simplify the protection of health information. Efforts to educate states on existing federal standards and begin a dialogue on this important problem are important. With regard to the critical actions outlined in the roadmap, we believe there is both precedent and will for an accelerated timeline with stakeholders acting alongside ONC. Planned discussions with nationwide stakeholders should include possible action items, such as implementation strategies to harmonize and simplify state and federal laws.

Inconsistent Legal Requirements for Research

Similarly, federal rules for human subjects' research, combined with other privacy rules, create a complex and burdensome environment for research. For example, definitions between the HIPAA Privacy Rule and the interagency Common Rule for Human Subjects Research are not always consistent, creating ambiguity and confusion for researchers. There should be one harmonized privacy standard for research institutions so that research and innovation are not delayed. The federal government should streamline the internal review board (IRB) process, clarify researcher and IRB expectations with respect to the scope and intensity of IRB review, and focus IRB resources and attention on those studies warranting the most careful scrutiny.

Government Data Sharing

More than any other public or private entity, the federal government possesses the greatest volume of health data. In recent years, there have been strides made in making more of this information available to entities outside of the federal realm. The 2009 Open Government Directive and the Department of Health and Human Services' Health Data Initiative led to the sharing of valuable information from federal agencies. HLC specifically applauds efforts by Congress and HHS Centers for Medicare and Medicaid Services (CMS) to increase access to data held by the federal government for

health research through the Qualified Entity (QE) program and also the innovative Virtual Research Data Center (VRDC).

We believe strongly that it is the obligation of government health agencies to maximize public benefit from data collected through their operations. Data collected from federal government programs, particularly those funding new and innovative care delivery models or tools, should be available for research, with appropriate privacy protections.

We encourage increased coordination among federal government agencies and others to reduce data “silos” and simplify access processes and requirements. Easily accessed federal data sets, with appropriate privacy and security safeguards in place, provide fertile ground for innovative health services research, for entrepreneurs to create innovative new products, and for health care organizations to benchmark and evaluate performance across the healthcare system.

Health Information Flow Recommendations

In summary, there are several core needs that currently stand as detriments to fully integrating the use of health information into a learning, interoperable health system:

- Create a single national definition for protected health information and privacy standard to protect patients and consumers while mitigating complications from contradictory state laws.
- Update and harmonize federal privacy rules with regard to research to allow for simple, clear requirements for health organizations – many of which conduct research and drive innovation while providing care.
- Support and cooperate with leading private sector organizations in their efforts to match the right patient to the right record with minimal time and effort.
- As part of the “open government” initiative, the administration should further explore and encourage government-wide policies and standards for health data sharing. These would include uniform data access methods and usage agreements across federal agencies in order to simplify the process for organizations seeking data.

Strategic and targeted harmonization of the application and enforcement of federal and state laws relating to health information privacy could help organizations engaged in providing and paying for healthcare keep health information private and secure, while avoiding the expense of unnecessary time and resources to meet overlapping burdens at the expense of other important efforts to improve healthcare quality.

BARRIERS TO TELEHEALTH

HLC supports reexamining restrictive reimbursement and regulatory barriers that make it challenging to use telehealth. Telehealth has been shown to improve healthcare quality and lower costs, while giving more people access to quality healthcare. Telehealth is already available in some circumstances, but expanding it to serve an even larger population is needed to further increase access to quality care.

Benefits of Telehealth

Poor health, treatment complexity, lack of access, the current (and projected) physician shortage, and even the cost of care can discourage patients from getting treatment that they need. In the case of chronic conditions, this is especially detrimental to health and reducing health costs, since so much of chronic disease care is based on early intervention and management, as well as care coordination.

Telehealth is an alternative to traditional healthcare to treat basic, episodic medical conditions as well as chronic disease. Increased access to telemedicine would make it easier for providers to treat patients and improve continuity of care and care coordination by increasing access to medical care for beneficiaries unable to travel and addressing provider shortages in rural or other areas. Telemedicine has been shown by HLC members to improve healthcare quality and lower costs, while giving more people access to quality healthcare. Numerous studies on telehealth and remote patient monitoring (RPM) have shown benefits in quality care and cost savings.

Current Telehealth Restrictions

Regulatory barriers make it challenging to use telemedicine. Collectively, these are often referred to as “1834(m) restrictions” – and they include: limitations on the type of services provided, geographic location, the type of clinical site the patient is located in, type of institution delivering the services, and type of health provider. Store-and-forward technology (e.g., email) is not reimbursable except in Alaska and Hawaii, where it is permitted as part of a federal demonstration program. While RPM is already available in some circumstances, lack of common procedure terminology (CPT) codes and the requirement that RPM activities be bundled into other payments inhibit their widespread use.

HLC Position

- *HLC strongly supports the lifting of the “1834(m) restrictions” that prevent the widespread use of telehealth in Medicare.*
- *For the Medicare Advantage (MA) program, HLC strongly supports telehealth’s inclusion as part of the basic benefit package and not limited to supplemental*

benefit funds available. Similarly, HLC supports providing ACOs the ability to expand use of telehealth.

- *HLC believes payment for telehealth services should always connect to the type of service being provided, not the method by which it is provided, so providers are able to choose the means which is most effective for each patient.*

We also urge Congress to avoid creating separate or additional telehealth-related quality measures. The type of service-delivery method should not detract from focusing on a small set of meaningful outcomes measures. Any statute should focus on the broad benefits of establishing connected care rather than restrictive reimbursement systems or parsing out a menu of connected care tools and approaches that may not keep up with current technology or best care practices.

HLC strongly supports expanding the use of telehealth services without regard to geography or diagnosis to ensure that all beneficiaries are able to access quality, efficient and convenient telehealth services as appropriate. In general, HLC supports telehealth policy frameworks that are site-agnostic and not overly prescriptive. Providers should be able to determine if a patient can appropriately receive care via telehealth in a way that enhances care delivery and quality.

CYBERSECURITY

HLC members, who are leaders in every healthcare field, agree that cybersecurity is critical to protecting sensitive information that is at the crux of transformational changes underway in the healthcare industry. The movement to patient-centered, integrated care coordination requires efficient interoperation of health information technology, an engaged and active patient, and trust among all participants.

Cybersecurity in healthcare poses unique challenges. Our shared national goals for interoperation require secure connections to health organizations nationwide – whether it is a sophisticated health system with access to resources or a small physician practice that may not have the expertise or resources to implement security best practices. At the same time, the FBI estimates that the average cost of even a partial electronic health record on the black market is approximately \$50 compared to \$1 for a stolen social security number or credit card number. EHR data can be used to file fraudulent insurance claims, obtain prescription medication, and advance identity theft. EHR theft is also more difficult to detect, taking almost twice as long as normal identity theft. Given this situation, cyber attacks on healthcare organizations are potentially lucrative, and will not diminish in the near future.

HLC has supported bipartisan congressional efforts to protect health organizations from serious and evolving cybersecurity threats. We have supported efforts that promote voluntary, cyber threat information sharing between government and health care organizations as long as liability and anti-trust protection is guaranteed for organizations that have agreed to share information and protect their systems.

We strongly support a collaborative approach to ensuring health information security. Health organizations that are threatened by malicious external attacks need a trusted partner in the federal government that will support and help to protect them. It is critical that the electronic systems supporting our healthcare providers be protected. These systems are a relied upon component in our nation's first response to major crises, and are necessary to provide critical care to those most in need.

Thank you for the opportunity to provide this written testimony before the committee. For further information, please have your staff contact Tina Olson Grande, Senior Vice President for Policy, at the Healthcare Leadership Council (tgrande@hlc.org).

Appendix 1: Telehealth Legislation Supported by HLC

In the 114th Congress, HLC has supported two bills that would expand access to telehealth.

- 1) The CONNECT for Health Act (S.2484 / H.R.4442), introduced by Senators Schatz (D-HI), Wicker (R-MS), Cochran (R-MS), Cardin (D-MD), Thune (R-SD), and Warner and Representatives Black (R-TN), Harper (R-MS), Welch (D-VT), and Thompson (D-CA), would promote cost savings and quality care in Medicare through telehealth and remote patient monitoring. Over 50 organizations spanning all sectors of healthcare including plans and providers as well as physician groups, patient organizations, academic centers, and many others support this legislation.

The CONNECT for Health Act would:

- Create a bridge program to help providers transition to the goals of the Medicare Access and CHIP Reauthorization Act (MACRA) and the Merit-based Incentive Payment System (MIPS) through using telehealth and remote patient monitoring (RPM) without most of the current regulatory restrictions that limit the use of telehealth based on type of services provided, geographic location, the type of clinical site the patient is located in, type of institution delivering the services, and type of health provider ("1834(m) restrictions").
- Allow telehealth and RPM to be used by qualifying participants in alternative payment models, without most of the aforementioned 1834(m) restrictions;
- Permit the use of remote patient monitoring for certain patients with chronic conditions;
- Allow, as originating sites, telestroke evaluation and management sites; Native American health service facilities; and dialysis facilities for home dialysis patients in certain cases;
- Permit further telehealth and RPM in community health centers and rural health clinics;
- Allow telehealth and RPM to be basic benefits in Medicare Advantage, without most of the aforementioned 1834(m) restrictions; and
- Clarify that the provision of telehealth or RPM technologies made under Medicare by a health care provider for the purpose of furnishing these services shall not be considered "remuneration."

The bill includes requirements regarding cost containment, quality measures, and data collection. An Avalere analysis of three of the major provisions of

the bill (first three bullets above) showed \$1.8 billion in savings over 10 years, with savings resulting from reduced hospitalizations due to the use of RPM. The analysis estimates that in Fiscal Year 2017, a total of 14.7 million Medicare beneficiaries will be using telehealth services and 3.3 million beneficiaries will be using RPM.

- 2) The TELEmedicine for MEDicare (TELE-MED) Act (H.R. 3081/S. 1778), introduced by Representatives Nunes (R-CA) and Pallone (D-NJ) and Senators Hirono (D-HI) and Ernst (R-IA), would improve access to providers across state lines.

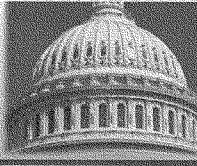
This bipartisan legislation allows Medicare providers to treat patients electronically across state lines without having to obtain multiple state medical licenses. The bill also includes provisions that would direct the HHS Secretary to issue guidance to states to develop a definition of “telemedicine services” using input from relevant stakeholders including patients, health care providers, State government officials, health technology developers, insurers, employers, licensing boards, community health organizations, and other Federal agencies

This bill would allow for expanded access to care, improved patient outcomes, and lower healthcare costs. Medicare beneficiaries are often not able to travel to receive care due to distance health, transportation, financial, or mobility issues, and provider shortages (particularly in certain specialties) may make it even more difficult to access necessary care. These access challenges increase beneficiary and system healthcare costs overall by making it difficult for patients to obtain the best care and treatment at the right time.

HLC MEMBERS

2016

(Alphabetized by Company)



HLC Chair

Susan DeVore
President & CEO

Premier healthcare alliance

Mark Bertolini
Chair, President & CEO
Aetna

Steven Collis
President & CEO
AmerisourceBergen

Rolf Hoffmann
SVP, U.S. Commercial Operations
Amgen

Susan Salka
President & CEO
AMN Healthcare

Joseph Swedish
President & CEO
Anthem

Anthony Tersigni, EdD, FACHE
President & CEO
Ascension

Jonathan Bush
President & CEO
athenahealth

Joel Allison
CEO
Baylor Scott & White Health

Marc Grodman, M.D.
Chairman, President & CEO
Bio-Reference Laboratories

J.D. Hickey
CEO
BlueCross BlueShield of Tennessee

Everett Hoekstra
Sr. Vice President & CFO
Boehringer Ingelheim USA

George Barrett
Chairman & CEO
Cardinal Health

Neil de Crescenzo
CEO
Change Healthcare

Toby Cosgrove, M.D.
CEO & President
Cleveland Clinic Foundation

Tim Ring
Chairman & CEO
C. R. Bard

Alex Azar
President, Lilly USA
Eli Lilly and Company

John Finan, Jr.
President & CEO
**Franciscan Missionaries of Our Lady
Health System, Inc.**

Jack Bailey
President, US Pharmaceuticals
GlaxoSmithKline

Neil Kurtz, M.D.
President & CEO
Golden Living

Daniel Evans, Jr.
President & CEO
Indiana University Health

Jennifer Taubert
Company Group Chairman, North American
Pharmaceuticals
Johnson & Johnson

Jonathan Scholl
President, Health and Engineering Sector
Leidos

Susan Turney, M.D.
CEO
Marshfield Clinic Health System

Brad Bennett
CEO
Maxim Healthcare Services

John Noseworthy, M.D.
President & CEO
Mayo Clinic

John Hammergren
Chairman & CEO
McKesson Corporation

Omar Ishrak
Chairman & CEO
Medtronic

Barry Arbuckle, Ph.D.
President & CEO
MemorialCare Health System

Robert McMahon
President, U.S. Market
Merck

Steven Corwin, M.D.
CEO
NewYork-Presbyterian Hospital

Anna Mohl
Regional Business Head, Medical Nutrition,
North America
Nestlé Health Science

Mark Neaman
President & CEO
NorthShore University HealthSystem

Christi Shaw
US Country Head, President
Novartis Pharmaceuticals

Jesper Hoiland
President
Novo Nordisk

Craig Smith
Executive Chairman
Owens & Minor

Albert Bourla
Group President, Pfizer Vaccines,
Oncology and Consumer Healthcare
Pfizer

Greg Irace
President & CEO
Sanofi US

Chris Wing
President & CEO
SCAN Health Plan

David Chernow
President & CEO
Select Medical

Tim Scannell
Group President, MedSurg &
Neurotechnology
Stryker

Tom Skelton
CEO
Surescripts

Ramona Sequeira
President
Takeda Pharmaceuticals U.S.A.

Jason Gorevic
CEO
Teladoc

Barclay Berdan
CEO
Texas Health Resources

Curt Nonomaque
President & CEO
Vizient

Alex Gourlay
President
Walgreens

James Chambers
President & CEO
Weight Watchers International

Jaideep Bajaj
Chairman
ZS Associates



FINAL REPORT

Viable Solutions:
Six Steps to Transform Healthcare Now

FEBRUARY 17, 2016

PRESENTED TO:
Healthcare Leadership Council
750 9th Street, NW
Suite 500
Washington, DC 20001

PRESENTED BY:
NORC at the University of Chicago
4350 East West Highway
Suite 800
Bethesda, MD 20814

NORC
at the UNIVERSITY of CHICAGO

Executive Summary

There is a broad consensus in the United States among healthcare providers, payers, clinicians, patients, and consumers that the nation's healthcare system does not operate at a level that generates optimal value. There is significant room for improvement in elevating quality, cost-efficiency, and sustainability. There is a gap between the innovations being developed in all sectors of healthcare and the ability to deliver those improved products and practices to patients.

While the Affordable Care Act focused on extending health coverage to tens of millions of Americans, a comparable effort is needed to address the health system's continuing cost, quality, and value challenges.

Through the Healthcare Leadership Council's National Dialogue for Healthcare Innovation (NDHI) initiative, companies from all sectors of healthcare joined with leaders of patient advocacy organizations, federal government officials, and academic health policy experts to build consensus on a broad spectrum of steps necessary to strengthen health system value and enable health innovation to have a greater positive impact on the entirety of the healthcare continuum.

NDHI participants came to the conclusion that healthcare in the U.S. can be significantly improved by focusing on actions that are readily achievable via legislation, regulation, or voluntary actions by various health system players. Positive health system transformation does not require a wholesale remaking of health delivery structures, but rather the enabling and acceleration of patient-centered innovation.

The diverse companies, organizations, and policy experts participating in the NDHI process agreed that focused actions in the following areas can significantly elevate health system value:

- Comprehensive care planning
- Medication therapy management
- Health information interoperability
- Changes to federal anti-kickback and physician self-referral (Stark) laws
- Health information flow improvements focused on patient privacy laws and regulations
- Food and Drug Administration (FDA) reforms

In these areas, there is consensus that the following actions should take place:

Comprehensive Care Planning

Today, over 80% of older adults have at least one chronic condition such as diabetes, congestive heart failure or hypertension, and one of every two seniors have at least two of these illnesses. The need for coordinated care for these individuals is clear. Yet, integrated, comprehensive care has been lacking. This fragmentation can lead to a myriad of difficulties such as lack of patient adherence. For decades,

significant numbers of patients have failed to take the medications prescribed by healthcare professionals. Studies have shown that, on average, 50% of medications for chronic disease are not taken as prescribed. This non-adherence problem may be costing the healthcare system as much as \$300 billion annually. Improved care coordination and adherence can have a dramatic effect on population health while significantly reducing health system costs.

In evaluating the most effective mechanisms to address the care coordination challenge, NDHI participants focused on diabetes – a disease with rapidly growing incidence rates and a patient population with consistently poor care coordination and adherence practices. Current Medicare reimbursement practices exacerbate this problem by, among other flaws, not paying for care coordination or coaching for diabetes management (including remote services), not reimbursing for participating in National Diabetes Prevention Programs, and not recognizing continuous glucose monitoring as a covered benefit.

NDHI participants believe there are three principles that should inform comprehensive care plans and serve as the rationale for government reimbursement of care activities. They are:

- *Comprehensive care planning must address the population's multiple co-morbidities and complex care needs.* This principle addresses the fragmentation of the health delivery system for people with diabetes (and other chronic illnesses). Team-based care should be viewed as essential in care planning.
- *Chronic disease programs must address these illnesses across the entire continuum of care.* Care planning must promote not only screening and identification of risk factors for patients all along the disease spectrum, but also focus on hospital-to-home care transitions for chronic disease patients.
- *Comprehensive care planning must be cognizant of issues related to the individual and community-level context.* Care plans must equip patients with tools they need to successfully manage their conditions and proactively address the challenge of inadequate health literacy in the patient population as well as specific cultural beliefs about health.

Medication Therapy Management

Misaligned incentives have prevented the medication therapy management (MTM) program, part of the Medicare Part D prescription drug program, from achieving significant benefits. In September 2015, the Centers for Medicare & Medicaid Services (CMS) announced its intent to form a Part D Enhanced MTM Model to better align prescription drug plan sponsor and government financial interests while creating incentives for robust investment and innovation in better MTM targeting and interventions.

There are many ways this Enhanced MTM Model should be optimized to achieve greater levels of patient adherence and, thus, improved health outcomes. These include:

- *An accelerated implementation of the Enhanced MTM Model. As it currently stands, the model does not start until 2017, will run for five years and then be evaluated. This means a potential delay of seven to 10 years before the model's benefits can be extended to all Medicare beneficiaries.*

- *The design should be expanded to offer benefits to all Part D members, including those in Medicare Advantage plans, to better align the financial interests of government and prescription drug plan sponsors.*
- *CMS should provide participating plans an opportunity to participate in developing quality measures, measures that should be formed through an intensive, transparent development and evaluation process.*
- *CMS should conduct robust education of providers and pharmacies on the Enhanced MTM model to better achieve optimal therapeutic outcomes.*
- *CMS should reconsider its stance regarding collaboration between pharmaceutical manufacturers and health plans. Such collaboration can encourage appropriate interactions that will result in improved medication adherence.*

Health Information Interoperability

Achieving high-value care requires a system that provides relevant health data to the right individuals at the right time. Comprehensive, readily accessible data is essential for both individual care decisions and population health management. A 2015 report by the Bipartisan Policy Center noted that billions of dollars are being invested in new healthcare delivery and payment systems that will reward better costs and quality outcomes, but that these arrangements will only be successful if greater information sharing and interoperable systems are in place.

Progress in this area had been lagging. As of 2013, only 62% of hospitals had reported being able to exchange electronic health information with any provider outside their organization; but recently the private sector has been driving improvements at a rapid pace. In fact, over the past 18 months the private sector has demonstrated through efforts such as the CommonWell Health Alliance, the Sequoia Project, and the Argonaut Project, among others, that there is a will to make progress toward interoperability through innovative efforts that are not driven solely by government regulation. The participants of NDHI believe that the private sector should continue to lead this progress with a limited role for government. Appropriate government involvement could include a governance structure that defines the “rules of the road,” such as prohibiting information blocking through certification authority or requiring a basic set of standards that the private sector could innovate from (such as open, publicly-available application program interfaces or APIs). Importantly, the participants of NDHI agree that any interoperability incentives from the federal government should be “technology neutral” and focused on outcomes in order to promote accessible and rapid innovation in health information connectivity.

NDHI participants identified challenges to achieving full-system interoperability, including conflicting and competing standards, the need for dissemination of emerging best practices in patient identification and matching, the lack of consensus on clinical workflow and payment reform best practices, and the complex provider collaborations involved in new delivery and payment models.

All of the companies and organizations involved in the NDHI initiative support the establishment of a December 31, 2018 deadline for health information interoperability, on or before which the nation must achieve nationwide exchange of health information through interoperable certified electronic health records (EHR) technologies. According to NDHI participants, this date of December 31, 2018 is achievable if driven by the private sector and the parameters and barriers noted above are sufficiently addressed.

Consumers should also have easy and secure access to their electronic health information, be able to direct it to any desired location, learn how their information can be shared and used, and be assured that this information will be effectively and safely used to benefit their health and that of their community.

Federal Anti-Kickback and Physician Self-Referral (Stark) Laws

To achieve improved care quality and cost containment, new healthcare delivery and payment models are designed to encourage greater integration among providers and other healthcare stakeholders. This raises the need to address the current federal fraud and abuse legal framework to make it more compatible with value-focused, integration-oriented health system transformation.

NDHI participants have focused on two of the primary fraud and abuse laws – the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law – and prioritized both regulatory and legislative options that should be pursued, independently or concurrently, to better support innovative payment and delivery reforms.

The regulatory options include:

- » *Create Federal Anti-Kickback Statute and Stark Law waivers for all Accountable Care Organizations that meet certain conditions.*
- » *Extend existing Anti-Kickback and Stark Law exceptions for donation and financial support of EHR software, and related interoperability-enabling technologies and training beyond 2021.*
- » *Clarify how to establish, document and apply the “volume or value of referrals” standard within the changing healthcare payment environment.*
- » *Expand and revise the definition of fair market value to account for new payment models that incentivize performance.*
- » *Eliminate the “one-purpose” test for Anti-Kickback Statute liability and replace with a balancing test that would require the HHS Office of Inspector General (OIG) to prove either increased costs or actual harm to patients.*
- » *When considering potential regulatory changes to the Federal Anti-Kickback Statute, stakeholders should also consider related changes to the Civil Monetary Penalties (CMP) Law, where appropriate, to ensure consistency in interpretation and application across both laws to encourage patient engagement and improved outcomes.*

The legislative options include:

- *Require the Department of Health and Human Services Secretary to review and assess the Federal Anti-Kickback Statute and Stark Law as well as the Civil Monetary Penalties (CMP) Law (expansion of current MACRA requirements) in the context of health system transformation, specifically addressing whether the laws create unnecessary barriers to new integrated care models and whether these laws are effective in limiting fraudulent behavior. Changes identified through this assessment may yield opportunities to amend fraud and abuse laws to foster healthcare arrangements that promote increased quality and lower costs.*
- *Grant OIG and CMS broader flexibility and discretion to develop exceptions and safe harbors to the Federal Anti-Kickback Statute and the Stark Law consistent with current health policy objectives (e.g., increased efficiency and quality, decreased cost).*

Health Information Flow Improvements

As healthcare systems make the transition to value-based care, accessibility and use of data takes on an exponentially greater importance. Unnecessary barriers to data sharing may impede a physician's ability to accurately diagnose patients and prescribe the most effective treatments, can lead to workflow inefficiencies, and potential inaccuracies in matching records with the correct patient.

At the same time, in today's environment, it is essential that patients be assured that their personal health data is protected and only accessed by those with legitimate and essential reasons to view it. Today, inconsistent interpretations of federal privacy laws as well as varying state privacy laws are leading to confusion and, with it, counterproductive restrictions on the necessary movement and sharing of health data.

NDHI participants have the consensus view that there is a need for a national health privacy standard to mitigate problems deriving from the variation among state laws and regulations. There is also a need for updated and harmonized federal privacy rules to align with new and innovative healthcare research capabilities. All privacy structures must enable the matching of records to the right patients with minimal time and effort.

FDA Reforms

Today, there are unnecessary delays in bringing new, improved treatments and technologies to patients due to redundant and counter-productive regulations from the FDA. Encouraging policy changes that streamline the agency's responsibilities, while ensuring that manufacturers remain accountable, could enable FDA to focus on high-priority activities and speed the approval of new medicines and healthcare products. NDHI participants also identified a series of unnecessary and redundant regulations that, if addressed, can accelerate patient access to new innovations. These include:

- *Eliminate the prohibition on using a single Institution Review Board of record for medical device trials, reducing the cost and time involved in product approvals.*
- *Allow companies to make certain changes to devices without a premarket submission, as long as the companies' quality systems have been certified as capable of evaluating such changes.*
- *Timelier recognition of standards established by international or nationally-recognized standards organizations. This will improve regulatory efficiency and reduce the time to bring medical technology to patients.*
- *Expand the definition of valid scientific evidence to include evidence described in well-documented case histories, including registry data, studies published in peer-reviewed journals and data collected outside the U.S.*
- *Provide greater training and achieve improved understanding of the use of 'least burdensome provisions' to increase efficiency and consistency for the FDA and manufacturers.*
- *Increase the flexibility for biopharmaceutical manufacturers, payers and providers to share scientific and healthcare economic information in order to optimize the clinical benefits of prescribed treatments. This type of information is critical for developing value-based payment systems.*

Each of these recommended steps, implemented individually, will strengthen healthcare quality and improve cost-efficiency. Adopted collectively, they can usher in a new era of healthcare reform, one that will make our health systems more value-focused and financially sustainable while bringing about an unprecedented level of improved population health through greater access to innovative cures, treatments, and medical technologies.

Table of Contents

Introduction.....	1
Approaches to Accelerating Healthcare Innovation.....	3
Addressing Three Key Areas	3
Patient Engagement and Adherence.....	3
Comprehensive Care Planning Principles: Diabetes	4
Background.....	4
Comprehensive Care Planning Principles	8
Conclusions	15
Medication Therapy Management (MTM) Models: Standard versus Enhanced MTM	15
Health Information Interoperability	18
Patient-Centered Interoperability.....	22
Conclusions	26
Outdated and/or Ineffective Laws and Regulations	28
Possible Changes to the Federal Anti-Kickback Statute and Physician Self- Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models....	30
The Current Legal Framework	31
Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law	31
Recent Legislative and Regulatory Changes.....	32
Recent Guidance	34
Regulatory Options	35
Legislative Options.....	35
Health Information Flow and Usage	36
FDA Regulations.....	39
Conclusions	40
Conclusion	41
References	42
Appendix A.....	52
Appendix B.....	55

This report was prepared based on research and discussions with the Healthcare Leadership Council and the National Dialogue for Healthcare Innovation conducted by Cheryl Austein Casnoff, MPH, Roy Ahn, ScD, and Nina Litton from NORC at the University of Chicago. Jane Hyatt Thorpe, JD and Elizabeth Gray, JD, MHA, CHC of the George Washington University Milken Institute School of Public Health contributed content related to the Federal Anti-Kickback Statute and the Physician Self-Referral (Stark) Law. Please note that the recommendations and conclusions included in this report represent those of the NDHI/HLC.

List of Tables

Table 1. Part D Enhanced MTM Model: Positive Features and Areas for Improvement.....	16
Table 2. Patient-Centered HIT Interoperability.....	23
Table 3. Secure Data Sharing Initiatives.....	24
Table 4. Initiatives to Establish Common Standards and Governance for Trusted Exchange ..	25
Table 5. Initiatives to Prevent Information Blocking.....	26
Table 6. Issues with FDA Regulations	52

List of Figures

Figure 1. Drivers of Increased Value and Innovation.....	2
Figure 2. Key HIT and Interoperability Pending Legislation and Laws.....	19
Figure 3. Keys toward Achieving Patient-Centered Interoperability.....	21
Figure 4. Key Public and Private Sector Interoperability Initiatives	21

Introduction

In 2010, the Healthcare Leadership Council (HLC), a coalition of chief executives from all sectors of healthcare – payers, providers, manufacturers, distributors, pharmacies, health information technology firms, and more – created the National Dialogue for Healthcare Innovation (NDHI). The purpose of NDHI is to create a platform through which these various health industry sectors can collaborate with patients, employers, academicians, and government to examine, discuss, and build consensus on how to address the most important issues affecting the course of 21st century healthcare progress.

On March 2, 2015, under the auspices of NDHI, an unprecedented summit meeting took place in Washington, D.C. Leaders of more than 70 of the most influential organizations in healthcare – including high-ranking officials from the Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) – convened to identify the barriers impeding progress toward a high-value, innovation-driven healthcare system, and how to remove those barriers. This was a rare meeting focused not on a single, narrow healthcare issue, but rather on how to create a sustainable system equipped to address persistent cost and quality challenges.

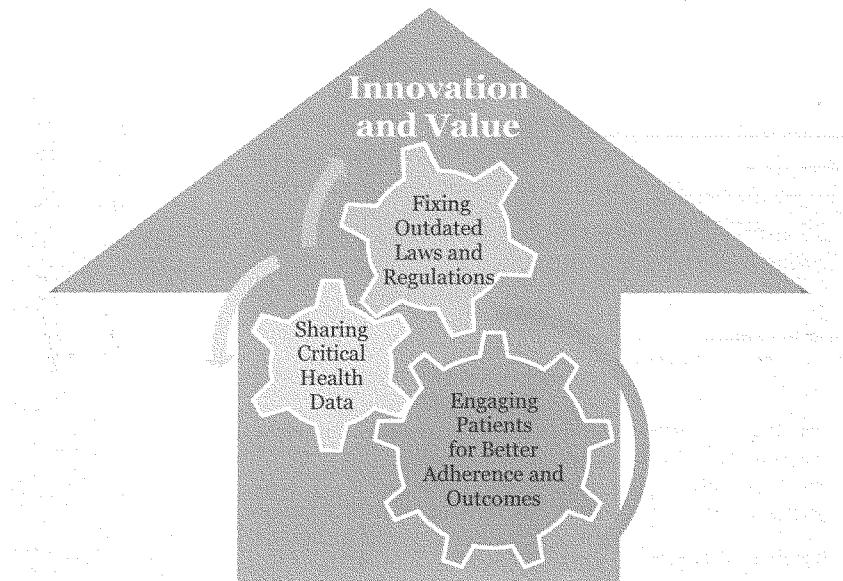
As HLC President, Mary R. Grealy said at the March 2 summit, “There are a lot of voices out there talking about healthcare costs, value, affordability, and sustainability. We’re never going to develop a pathway, though, that will incentivize innovation and strengthen health system value until we bring everyone to the same table.”

Once leaders from across the healthcare spectrum came to the NDHI table, they decided to continue working to develop consensus solutions aimed at achieving greater healthcare quality and cost-efficiency. Following the summit, NDHI participants established three workgroups focusing on (1) Patient Engagement and Adherence, (2) Data Strategy and Electronic Health Records Interoperability, and (3) Outdated and/or Ineffective Laws and Regulations.

The workgroups collaborated throughout 2015 to agree upon policy approaches that transcend the theoretical and are viewed as clearly achievable, whether through legislation, regulatory action, or proactive steps initiated by healthcare organizations.

What emerged from this process is a blueprint that will be offered to executive and legislative branch policymakers and healthcare leaders. The recommendations in this paper, taken in total, can drive health system transformation and a movement toward value and innovation. The consensus viewpoints contained in this report are also consistent with steps currently being taken by the federal government to guide a health system transition from fee-for-service to pay-for-value and toward more integrated, coordinated care.

Figure 1. Drivers of Increased Value and Innovation



Seldom have such diverse interests and perspectives reached a shared view on how to advance value and innovation within the healthcare system. These recommendations can serve as a catalyst for further debate and, optimally, decisive action.

Approaches to Accelerating Healthcare Innovation

Addressing Three Key Areas

The following sections describe key findings from NDHI, which cover three key topic areas:

- Patient Engagement and Adherence;
- Data Strategy and Electronic Health Records Interoperability; and
- Outdated and/or Ineffective Laws and Regulations

Each section provides a framing of the salient issues, potential strategies for addressing these issues, and recommendations to elevate health system value.

Patient Engagement and Adherence

Patient-centered care is the key to value-driven, quality healthcare. By asserting more responsibility in healthcare planning and decision making, the consumer can drive change throughout the healthcare system.

Likewise, without an engaged healthcare consumer, it is difficult for health organizations to drive patient-centered, coordinated quality care.

One key component of value driven care is **patient engagement and adherence**. Patient non-adherence can take many forms. These can include the failure to keep appointments, to follow recommended dietary or other lifestyle changes, or to follow other aspects of treatment or recommended preventive health practices. Medication non-adherence is a particularly complex and growing public health concern to clinicians, healthcare systems, and other stakeholdersⁱⁱ. The lack of adherence to a prescribed treatment regimen is associated with poorer patient outcomes, including unnecessary disease progression, reduced quality of life, and even premature death. It also creates a significant societal burden, including increasing healthcare costs from hospitalizations and invasive procedures to address complications that may have been prevented with continuous intervention.

Reasons for non-adherence are multifactorial and difficult to identify. Patient therapeutic compliance may be associated with certain types of diseases, for example. Evidence shows that non-compliance is less common in acute illness or illness of short duration. In contrast, patients who are suffering from chronic diseases, in particular those with fluctuation or absence of symptoms are more likely to be non-compliant.

Medication adherence and compliance are synonymous terms, while medication persistence is a related but distinct term.

- *Compliance (or its synonym adherence):* "the act of conforming to the recommendations made by the provider with respect to timing, dosage, and frequency of medication taking. Therefore prescription medication compliance may be defined as 'the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen.' Compliance is measured over a period of time and reported as a percentage..."
- *Persistence:* "the duration of time from initiation to discontinuation of therapy"

While the issue of patient adherence has been extensively researched, the rates of non-adherence have not shown significant improvement in the past three decades.

Today, about 80% of older adults have at least one chronic condition, and 50% have at least two. Diabetes, congestive heart failure, and hypertension represent three of the top five most prevalent conditions among Medicare beneficiaries.^{iv} Given that many chronic diseases can be treated and managed through behavior change and medication, this is a ripe area for action to promote patient adherence.

Scope of the Medication Adherence Issue

"Studies have shown that 20 to 30 percent of medication prescriptions are never filled and that, on average, 50 percent of medications for chronic disease are not taken as prescribed. This lack of adherence to medications is not only prevalent but also has dramatic effects on individual- and population-level health. Non-adherence has been estimated to cost the U.S. healthcare system between \$100 billion and \$289 billion annually in direct costs. Strong evidence suggests that benefits attributable to improved self-management of chronic diseases could result in a cost-to-savings ratio of approximately 1:10."^{vii}

To address the complex issues described above, NDHI participants selected two key policy areas for further exploration:

1. Comprehensive Care Planning Principles (with diabetes as a case study); and
2. Medication Therapy Management (MTM) Models

The NDHI sought to identify specific opportunities to improve patient adherence through: (a) improving adherence along the continuum of care via the development of common principles that should be incorporated into any care plan for patients with diabetes; and (b) reforming federal MTM programs by reviewing and making recommendations for streamlining and/or improving these programs. Addressing these issues supports NDHI's overarching objective of enhancing value in healthcare by using innovative therapies, policies, and practices to support improved patient adherence that maximizes quality outcomes.

The next section describes the Comprehensive Care Planning Principles for diabetes in detail.

Comprehensive Care Planning Principles: Diabetes

Background

Definitions and Policy Context

The concept of comprehensive care planning is patient-centered, participatory, and nested within the broader concept of care coordination for people living with chronic illnesses.^v

CMS offers a basic definition of a care plan: "A written plan for your care. It tells what services you will get to reach and keep your best physical, mental, and social wellbeing."^{vi} CMS also provides an operational definition of a care plan that is more detailed and relevant for addressing the complexities facing patients who live with chronic illnesses: "It typically includes but is not limited to the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community and social services ordered,

direction and coordination of the services of agencies and specialists unconnected to the practice, identification of the individuals responsible for each intervention, requirements for periodic review, and, when applicable, any revisions.”^{vii} The issue of comprehensive care planning is receiving considerable attention among policymakers. For example, The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014,^{viii} which mandates common patient assessment data and quality measure reporting requirements for post-acute care (PAC) providers, also establishes new discharge requirements for general acute-care, critical access hospitals, and post-acute providers that are intended to facilitate the flow of patient information to the next healthcare setting. Beginning in late 2016, CMS will require long-term care facilities to develop a care plan for each resident within 48 hours of admission.^{ix} CMS also proposes to require long-term care facilities to document in a beneficiary’s care plan their goals for admission, assess the potential for future discharge, and include discharge planning in the comprehensive care plan for the beneficiary. The agency also proposes to add to the post-discharge plan of care a summary of arrangements for a beneficiary’s follow-up care and post-discharge services, and the discharge summary must include a reconciliation of a beneficiary’s current medications with those that the beneficiary was taking before entering the facility. Additionally, the Care Planning Act of 2015 (S. 1549) is pending legislation that would help severely ill patients (e.g., patients with late-stage diabetes) improve care coordination through patient-centered care planning – via the establishment of “planning services” as a Medicare benefit. Separately, the Government Accountability Office (GAO) recently released a report noting that under the Patient Protection and Affordable Care Act (ACA), there remain concerns that low-income individuals transitioning from Medicaid to exchange coverage may experience coverage gaps, due to the complex nature of coordinating policies and procedures.^x Furthermore, the U.S. Senate Committee on Finance announced in May 2015 the formation of a Chronic Care Working Group that aims to improve care coordination and ensure high quality care for people living with chronic illnesses; notably, the Committee will place a strong emphasis on care coordination.^{xi}

There are a myriad of types of patient non-adherence (i.e., non-adherence related to medication, lifestyle, or exercise guidance from health providers), and the reasons for patient non-adherence are complex as well.^{xii} For example, a 2009 systematic review by RAND^{xiii} found four major types of barriers to medication adherence:

- cost-sharing
- regimen complexity
- medication beliefs
- depression (in patients with diabetes)^{xiv}

(However, it is important to note that much of this research predates the passage of the ACA, which has improved coverage to many individuals who were previously uninsured or underinsured.)

In response to concerns about patient adherence, CMS recently announced the Medicare Part D Enhanced MTM Model,^{xv} which will place an emphasis on “right sizing” MTM and testing innovative regulatory

flexibility and payment incentives to target high-risk beneficiaries and provide them with the appropriate level and intensity of services.

Maximizing the potential for coverage of therapies and care management and assuring that all payers, providers, and patients recognize the value of patient adherence is key to the long term solution to this complex issue.

The Need to Focus on Diabetes

The NDHI developed a set of policy principles on comprehensive care planning for patients living with chronic diseases, using diabetes as a case example. These principles will inform future efforts to provide legislators and policymakers with evidence-based recommendations for addressing the complex needs of people with diabetes – as well as other chronic diseases. Diabetes is an important test case for comprehensive care planning because of its complexity as well as prevalence in the United States (U.S.). Although diabetes is a well-understood disease, individual patients may encounter many different obstacles that would prevent them from reaching optimal health. These barriers range from socioeconomic factors or lack of diabetes management education to the competing demands of family responsibilities and dynamics.^{xvi} Cost of care may also be a barrier to good adherence.

The American Diabetes Association (ADA) cites compelling national statistics in its *Standards of Medical Care in Diabetes—2015* report^{xvii} that underscore the need for effective disease management interventions: “[B]etween 33 and 49% of patients [with diabetes] still do not meet targets for glycemic, blood pressure, or cholesterol control, and only 14% meet targets for all three measures and nonsmoking status.” Furthermore, diabetes, along with congestive heart failure (CHF) and hypertension, represent three of the top five most prevalent conditions among Medicare beneficiaries. These conditions share many of the same common, modifiable risk factors and comorbidities, including obesity and physical inactivity.

Finally, diabetes presents opportunities to intervene at multiple stages of the disease continuum. Those at high risk for diabetes, even if they are asymptomatic, should be screened consistent with screening guidelines (The U.S. Preventive Services Task Force (USPSTF) recommends screening as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese.^{xviii}) so that the disease does not progress unchecked before diagnosis. Even those diagnosed with prediabetes, a condition where blood sugar is higher than normal but not high enough to be diagnosed as diabetes,^{xix} can take steps to delay or prevent progression to Type 2 diabetes.

Diabetes Care Challenges

In spite of the tremendous toll of diabetes, numerous challenges for reimbursement of diabetes-related care hamper efforts to improve patient health:

- Currently in fee-for-service Medicare, CMS provides little or no reimbursement for remote care, care coordination, or coaching (e.g., phone visits, follow-up text messages, online) for the care and management of diabetes.
- Certified Diabetes Educators (CDEs) are not statutorily recognized providers of Diabetes Self-Management Training (DSMT) services, including DSMT by telehealth, under Medicare Part B. Additionally, diabetes case managers and educators receive differential reimbursement and medical nutrition therapy (MNT) and DSMT providers are not reimbursable on the same day.
- The new care coordination Healthcare Common Procedure Coding System (HCPCS) G-code has not been interpreted to include remote care coordination or coaching. Beyond basic evaluation and management services, few other avenues exist to compensate diabetes care providers for the intensive time and effort necessary to provide comprehensive management and support to patients with diabetes. This patchwork of regulation and reimbursement creates unnecessary gaps in patient care and makes healthcare more expensive overall.
- For patients with prediabetes, Medicare does not reimburse for participation in National Diabetes Prevention Programs (DPP, a lifestyle change program that can help prevent or delay the onset of type 2 diabetes) or MNT for people at high risk for developing diabetes.

In addition to undermining provider support, the current reimbursement structure makes it difficult for patients with diabetes to monitor the disease themselves. Medicare does not cover the tools and devices that some individuals need to most effectively monitor their diabetes:

- Medicare does not recognize continuous glucose monitoring (CGM) as a covered benefit. In numerous clinical trials, CGM systems have demonstrated improvement in overall glucose control and reductions in dangerous episodes of hypoglycemia when compared to self-monitoring of blood glucose (SMBG). Since CGM technology is covered widely outside of Medicare, beneficiaries entering Medicare may be forced to give up the diabetes blood glucose monitoring system that they had become accustomed to using with another payer.
- The 2013 competitive bidding program limits choices and access to certain types of diabetes testing supplies, such as blood glucose testing strips, purchased through mail order. If beneficiaries have difficulty finding replacements for familiar products, they may be inappropriately influenced to switch test systems. Product switching can have negative health and economic consequences.^{xx}

Additional challenges include patient adherence for individuals with hypoglycemia, or abnormally low blood glucose levels. Hypoglycemia is the largest single barrier to achieving glycemic control in type 1 and type 2 diabetes^{xxi} and is a significant cause of emergency department visits and hospitalizations, which increases the cost of treatment. Consideration of education and alternate therapies for individuals who experience hypoglycemia may help to alleviate the incidence of hypoglycemia.

Another care management challenge to consider in effective diabetes management are cases of clinical inertia – inadequate intensification of therapy by the provider. For example, newly diagnosed patients

often stay on a specific oral medication alone for about 14 months without additional agents (e.g., insulin) being added, even though they have not met their A1C goal.

Greater alignment between reimbursement structures and appropriate care steps could also lead to better outcomes for both patients and payers. At the healthcare system level, physicians of patients with multiple providers are not incentivized to work as a team, which creates challenges for persons with diabetes receiving coordinated, consistent care across numerous encounters. A 2014 RAND study of nearly 300,000 Medicare recipients^{xxii} found that individuals with better continuity of care were less likely to be hospitalized, less likely to visit hospital emergency departments, had lower rates of complications, and had lower overall costs for their episodes of care.

Diabetes management also faces hurdles in the area of reporting and quality. There is a lack of uniform quality metrics across government programs, coupled with limited diabetes quality measures and alignment across Medicare Part A, B, and D. Payment is not currently tied to meeting appropriate standards of care for all services delivered. These gaps do not incentivize comprehensive diabetes care and make it harder for quality to be assessed and for providers and payers to monitor and respond to data.

Finally, quality diabetes care is often impeded by cost—both to the system and to patients. Every effort should be made to design diabetes care protocols that address this barrier. For example, the provision of additional tools for the patient or the provider or the promulgation of value-based benefit design could help address this issue. Additionally, it is crucial to recognize that the enormous prevalence of diabetes has significant consequences for health system stability as a whole, and efforts must be made to make investments in quality care that focuses on halting or slowing disease progression and the onset of complications.

Comprehensive Care Planning Principles

Below, we describe three Care Planning Principles for diabetes, along with key components/practices that should be included in comprehensive care plans and rationale for government reimbursement of these activities. These components can also inform the promulgation of quality measures related to comprehensive care plans for diabetes. These principles support NDHI's twin objectives of enhancing value in healthcare by using innovative therapies, policies, and practices to support improved patient adherence that maximizes quality outcomes.

These principles closely align with the ADA's *Standards of Medical Care in Diabetes—2015*,^{xxiii} which provide four core recommendations for improving diabetes care, overall:

1. A patient-centered communication style that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care should be used.
2. Treatment decisions should be timely and founded on evidence-based guidelines that are tailored to individual patient preferences, prognoses, and comorbidities.
3. Care should be aligned with components of the Chronic Care Model (CCM) to ensure productive interactions between a prepared proactive practice team and an informed activated patient.
4. When feasible, care systems should support team-based care, community involvement, patient registries, and decision support tools to meet patient needs.^{xxiv}

Principle 1: Comprehensive care planning must address the population's multiple co-morbidities and complex care needs.

Comprehensive, patient-centered care planning must address a key underlying health system issue: the fragmentation of the health delivery system for people with diabetes. The notion of “team-based care” is one that should be championed as part of care planning.

Component 1.1: Care plans should incorporate evidence-based care coordination strategies (defined by the Agency for Healthcare Research and Quality’s (AHRQ’s) as “deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient’s care to achieve safer and more effective care”^{xxv}) that address underlying patient comorbidities (e.g., depression). The ADA suggests that addressing missed treatment goals may require evaluation of barriers such as diabetes-related distress or depression^{xxvi} and the American Association of Clinical Endocrinologists and American College of Endocrinology’s evidence-based clinical practice guidelines for diabetes makes the following recommendation for patients with diabetes and depression: “Patients with depression or [diabetes]-related distress should be referred to mental health professionals who are integrated into the [diabetes] care team.”^{xxvii} For example, Katon and colleagues conducted a trial of “collaborative care” in 14 clinics in the state of Washington, in which nurses provided “guideline-based, patient-centered management of depression and chronic disease.” The researchers found significant 12-month improvements along a number of measures related to both diabetes and depression (e.g., glycated hemoglobin, patient satisfaction, and perceived quality of life) due to the intervention.^{xxviii}

Comprehensive care plans, by definition, should address the full range of health problems of a particular patient – i.e., not limited to diabetes. For example, diabetes care plans should explicitly address comorbidities such as cardiovascular disease. The American Heart Association recognizes a strong correlation between cardiovascular disease (CVD) and diabetes. Heart disease and stroke are the number one causes of death and disability among people with type 2 diabetes and adults with diabetes are two to four times more likely to have heart disease or a stroke than adults without diabetes.^{xxix} In this regard, the ADA notes the need for “a comprehensive plan to reduce cardiovascular risk by addressing blood pressure and lipid control, smoking cessation, weight management, and healthy lifestyle changes that include adequate physical activity” for patients with diabetes.^{xxx}

Component 1.2: Comprehensive care planning should include the use of care coordinators to address the multitude of daily issues facing persons with diabetes. For example, the use of care coordination programs may have potential for managing care transitions and obviating hospital readmissions. Care planning for people living with diabetes needs to include interdisciplinary teams that can meet the holistic needs of individuals and engage community resources outside the hospital sector.

Care coordinators can be deployed to provide a variety of services, including: assessing treatment adherence, coordinating with providers about patient treatment needs, ensuring that patients have transportation, language translation, and other support services needed to access care, and providing health education. An increasingly multidisciplinary approach to the care of these patients may be one answer for improving patient clinical outcomes and healthcare resource utilization. Community health

workers or other non-licensed health providers can also provide critical care coordination services and should be considered a vital part of the care team.

Component 1.3: Comprehensive care planning should be supported by improved communication and data sharing among providers on the interdisciplinary diabetes care team. For example, the National Diabetes Education Program cites the importance of timely information-sharing via the use of health information systems by care teams, which comprise “the primary care provider, endocrinologist, nurse, diabetes educator, dietitian, mental health provider, exercise physiologist, other team members and specialists, as well as hospital-based providers.”^{xxxxi} The contributions of non-licensed, community-based health providers should also be integrated into electronic medical record systems so that records reflect the entirety of patient treatment.

One strategy for achieving communication and data sharing is the increased use of telehealth. While the scientific literature is still emerging on the full benefits of telehealth applications, promising initiatives have been described. For example, a recent randomized clinical trial of a telehealth remote monitoring intervention, in which patients remotely sent their paired glucose tests (i.e., before and after a meal or physical activity) via tablet and subsequently received feedback from certified diabetes educators, led to improvements in A1C levels.^{xxxii} Also, the DiaTel randomized, controlled trial of active care management supplemented by home telemonitoring intervention, demonstrated long-term (> 6 months) reductions in A1C levels in a population of veterans.^{xxxiii}

The use of patient-centered health information technologies for diabetes is one way to ensure communication between patients and providers in care planning and empower patients to express their values, needs, and preferences about their care. Patient adherence can often be improved either through personalized care coordination or through simpler systems of reminders and educational materials. Greater data connectivity can also be used to identify gaps in diabetes care for other important treatment indicators, such as blood glucose monitoring.

For example, remote patient monitoring (RPM) technology enables monitoring of patients outside of conventional clinical settings (e.g., in the home), which may increase access to care and decrease healthcare delivery costs. Incorporating RPM in chronic disease management can significantly improve an individual’s quality of life. It allows patients to maintain independence, prevent complications, and minimize personal costs. RPM is used to monitor a variety of chronic illnesses, including diabetes, and transmit alerts to both the patient and the physician.

Principle 2: Chronic Disease programs must address chronic disease across the entire continuum of care.

Component 2.1: Care planning should promote screening and identification of risk factors for patients all along the disease spectrum. Risk factor identification, screening, and interventions have been successful in identifying and preventing chronic diseases and their associated morbidity and mortality in older adults. Greater impact in this area will require extensive collaboration among stakeholders (providers, health plans, pharmacists, and patients) in order to identify high-risk individuals.

Better effort needs to be made to identify patients with chronic diseases such as diabetes. The 2014 draft USPSTF factor-based screening guidelines for diabetes would have helped address the fact that many people living with Type 2 diabetes currently are not diagnosed with the disease. Prediabetes affects more than 1 out of 3 American adults, but 9 of 10 of them do not know they have it.^{xxxiv} While the final guideline, released October 27, 2015, backtracked from the 2014 draft, it still opened the door for screening for prediabetes.

In patients diagnosed with prediabetes or diabetes, care plans should focus on early intervention to prevent disease progression and complications. Health plans or other providers use data from claims, enrollment, and pharmacies to look for patterns of non-adherence or identify at-risk members. The use of in-home risk assessment also supports early identification of at-risk members, including those with and without diagnosed conditions.

Component 2.2: Comprehensive care planning must focus on care transitions for patients with diabetes. One of the IMPACT Act's stated reasons for collecting standardized data from long-term care hospitals (LTCHs), skilled nursing facilities (SNFs), home health agencies (HHAs) and inpatient rehabilitation facilities (IRFs), is to "improve hospital and PAC [post-acute care] discharge planning." And as the ADA notes in its 2015 *Standards*, "Diabetes discharge planning should start at hospital admission, and clear diabetes management instructions should be provided at discharge."^{xxxv}

Numerous ongoing projects are testing evidence-based models for patient transitions from hospitals into their communities. For example, the Patient-Centered Outcomes Research Institute (PCORI) is funding the \$15 million Project ACHIEVE (Achieving Patient-Centered Care and Optimized Health In Care Transitions by Evaluating the Value of Evidence), which will "develop recommendations on best practices for the design, implementation and large-scale national spread of highly effective, patient-centered care transition programs."^{xxxvi} The identification of evidence-based strategies for transitions, including patient-engagement activities, post-discharge, will be crucial for comprehensive care planning for patients with diabetes.

AHRQ's *Care Transitions from Hospital to Home: IDEAL Discharge Planning Implementation Handbook*^{xxxvii} describes best practices in the management of heart failure, heart attack, and pneumonia, among four high-performing US hospitals (with respect to readmissions). This information could be useful for developing care transition strategies for diabetes.

- "A focus on improving clinical quality and patient care with the belief that reductions in readmissions will naturally occur as a result of these improvement efforts.
- Attention to discharge planning from the first day of patients' stay, typically within 8 hours of admission. This includes staff assessment of patients' risk factors, needs, available resources, knowledge of disease, and family support.
- Care coordination after discharge. Two hospitals scheduled follow up appointments for most of their patients prior to discharge. Because of limited resources, the two other hospitals made follow up appointments on an ad hoc basis for the neediest patients. All hospitals coordinated with home health agencies and connected patients to community resources.
- Empowering patients through educational activities throughout the stay to help patients understand their conditions; manage their diet, activities, medications, and care regimens; and know when to seek care."^{xxxviii}

AHRQ also provides specific guidance on sound practices in discharge planning: (a) medication reconciliation (e.g., “The patient’s medications must be cross-checked to ensure that no chronic medications were stopped and to ensure the safety of new prescriptions”); and (b) structured discharge communication (“Appointment-keeping behavior is enhanced when the inpatient team schedules outpatient medical follow up prior to discharge. Ideally, the inpatient care providers or case managers/discharge planners will schedule follow-up visit(s) with the appropriate professionals, including primary care provider, endocrinologist, and diabetes educator”).^{xvix}

Component 2.3: Care planning should also include end-of-life planning and discussions. Such conversations go beyond a narrow focus on resuscitation and address the broad array of concerns shared by most patients and families. These include fears about dying, understanding prognosis, achieving important end-of-life goals, and attending to physical needs. Good communication can facilitate the development of a comprehensive treatment plan that is medically sound and concordant with the patient’s wishes and values.^{xi}

Principle 3: Comprehensive care planning must be cognizant of issues related to the individual and community-level context.

As noted above, missed treatment goals may have myriad contributing causes. Complex care planning must be aware of and seek to address issues related to the individual patient and their context in which they live.

Component 3.1: Care plans must empower and equip patients with the tools they need to play an active role in managing their diabetes. To best help patients when they return home from the clinical setting, it will be essential for care plans to mobilize and incorporate outpatient resources that help support patient engagement and adherence.

Various studies have been conducted to test outpatient strategies to improve medication adherence for patients with diabetes. For example, the Joslin Diabetes Center developed the Diabetes Outpatient Intensive Treatment (DOIT) program is an interactive, 3.5 day-group education and skills training experience that was supplemented with daily medication management. The program led to significant improvements in A1C levels.^{xii} Furthermore, tailored “health coaching” interventions have also been shown to improve medication adherence among patients with diabetes.^{xlii} Additionally, a community pharmacy-based medication therapy management (MTM) program for patients with both hypertension and diabetes was found to improve blood pressure control.^{xliii} Finally, the American Pharmacists Association has coined the concept of diabetes “patient credentialing” as part of disease self-management interventions to describe “people who have a certain diagnosis and have achieved certain levels of competency in understanding and managing their disease.”^{xliv}

DSMT programs are another important tool. For type 2 diabetes, the 2015 AHRQ Evidence Report on behavioral interventions for diabetes notes that intensive in-person DSMT programs (11 or more hours of contact time) are most effective at achieving glycemic control, and that targeting interventions for particular populations (i.e., minority groups) may also be beneficial: “our analyses showed limited benefit

in glycemic control from DSME programs offering ≤ 10 hours of contact with delivery personnel and suggested that in-person delivery of behavioral programs is more beneficial than communicating the information with incorporation of technology. Behavioral programs seem to benefit individuals having suboptimal or poor glycemic control more than those with good control. Tailoring programs to ethnic minorities appears to be beneficial.^{xlv} Currently, DSMT participation rates are extremely low (7% among those with private insurance and 4% among those with Medicare coverage^{xlvi}), so increased communication among patients and providers about the benefit is needed, as well as greater reimbursement as noted above.

Registered dietitians also play a role in providing patients with the tools needed to manage their disease. Nutrition therapy is an integral component of diabetes prevention, management, and self-management education, and the ADA recommends all individuals with diabetes should receive individualized medical nutrition therapy, preferably provided by a registered dietitian nutritionist (RDN).^{xlvii}

This guidance is consistent with the final recommendation of the USPSTF regarding abnormal blood glucose: “Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity.”^{xlviii}

This type of education has also been shown to improve quality of life for patients. In adults with type 2 diabetes, one study of quality of life assessment reported that self-perception of health status improved and participants receiving MNT from RDNs felt very knowledgeable and motivated after seeing a dietitian. In another study of adults with type 2 diabetes receiving case management from RDNs, 12-month quality of life scores were significantly better than adults receiving usual care. Emotional stress was also decreased in adults with type 2 diabetes. In persons with type 1 diabetes, three studies reported significant improvements in quality of life (satisfaction with treatment and psychological well-being) despite increases in insulin injections or diet requirements.^{xlix}

The use of community health workers (CHWs) to implement diabetes-focused programs – as well as for obesity management, more generally – have been described in the literature. For example, the Mexican American Trial of Community Health Workers (a randomized, controlled trial in which CHWs delivered diabetes self-management training via home visits over 2 years) led to improvements in A1C levels at both the end of Year 1 as well as Year 2 of the intervention. Regarding obesity management as a whole, a 2014 *JAMA* systematic review found evidence for the effectiveness of intensive behavioral weight loss counseling led by trained interventionists, such as medical assistants and registered dietitians.ⁱ Furthermore, trials testing the Weight Watchers program have found promising results with respect to weight loss outcomes.ⁱⁱ

Additionally, Aging and Disability Resource Centers (ADRCs) are one example of a community resource that may provide an opportunity for elderly people living with diabetes to utilize existing community resources. (ADRCs have 5 core functions: “1) information, referral and awareness, 2) options counseling, advice and assistance, 3) streamlined eligibility determination for public programs, 4) person-centered transitions, and 5) quality assurance and continuous improvement. ADRCs perform these functions by

integrating, coordinating, and strengthening different pieces of the existing long term supports and services systems, including Area Agencies on Aging, Centers for Independent Living, state and local Medicaid offices, and other community-based organizations.”^{lii})

As the health system seeks to mobilize and incorporate community-based health and support, it may be helpful to draw on the experience of Medicare Advantage (MA) plans. Currently, the only tool health plans have to offer flexibility to the individual are medical management tools that must be offered to an entire population regardless of need (e.g., waiving or eliminating copays on certain medications for one population, providing additional transportation to individuals with more frequent medical appointments or waiving the copay on a type of specialist visit based on an individual’s health needs). MA plans should be given flexibility to permit providers to develop individualized care plans that tailor tools to support patient needs. Further, some services plans want to provide do not fall within medical necessity. Examples of such services are: homemaker services, home-delivered meals, personal care services (assistance with bathing and dressing), transportation escort services, inpatient custodial level care, in-home caregiver relief, adult day care services, and non-Medicare-covered medical and safety equipment (e.g., the purchase of a refrigerator to store insulin, an air conditioner in geographies with severe summer temperatures or railings to help prevent falls).

Online and community-based and health providers such as Weight Watchers, Y-USA, and Omada Health that provide CDC-certified diabetes prevention programs offering DPP are also examples of organizations that care plans should look to for assistance in helping patients maintain adherence to treatment plans. Community-based programs such as these are especially important for patients in traditional underserved and minority communities or communities with a high level of mistrust of the traditional medical system.

Component 3.2: Diabetes care plans should use health literacy assessments as a tool to inform appropriate interventions for individual patients. A study in *JAMA* on health literacy and diabetes^{liii} found that patients with inadequate health literacy were less likely than patients with adequate health literacy to achieve tight glycemic control, were more likely to have poor glycemic control, and report having diabetic retinopathy. By using data to identify which patients are most at risk of becoming non-adherent, physicians can best determine which patient engagement strategies to utilize. This also reduces the level of outreach to low-risk patients (those most likely to adhere) and ultimately allows for more targeted deployment of resources and time to the most at-risk patients.

Furthermore, care plans should adopt best-evidence practices in reaching low-literacy patients. As an article in the *American Journal of Health Behavior* on health education for low-literacy audiences noted, “Materials should be focused on offering practical strategies for behavior change, the ‘need to do’, rather than focused on teaching facts, the ‘need to know.’”^{liiv}

Component 3.3: Diabetes care plans should incorporate best practices in person-centered, culturally-appropriate guidance for patients with diabetes to address specific cultural beliefs about health (e.g., in some cultures one does not seek healthcare until symptoms have already developed). To the extent that these beliefs modify health-seeking behaviors, care plans need to adopt strategies described in the

literature, such as the use of culturally-salient metaphors for describing diabetes as a disease in terms that certain community members will identify with.^{iv}

Guidance from the American Association of Diabetes Educators and the National Standards for Diabetes Self-Management Education and Support may be particularly useful guidelines in this regard:

"[T]he prudent diabetes educator provides important information, care, and support to persons affected by diabetes in a manner that:

- Acknowledges that cultural perceptions of health can be unique for each individual.
- Considers the context of learning experiences already present when developing collaborative efforts with the patient to identify barriers to diabetes care success.
- Conveys accurate information in a fashion that is understandable to the learner. Proactively addresses limitations to self-management plan adherence and designs/brokers culturally appropriate goals.
- Utilizes educational materials and resources appropriate for culture, age, literacy level, and learning readiness.
- Includes resources that address access limitations to diabetes-care needs and considers the milieu in which the care plan is to be executed.
- Incorporates sensitivity and respect when educating all people irrespective of ethnicity, race, age, and socioeconomic status."^{iv}

Conclusions

Comprehensive care planning for diabetes requires a holistic, patient-centered approach that spans the continuum of care. These three principles and their components underscore NDHI's vision to ensure patient adherence and maximizing quality outcomes for diabetes. Thus, comprehensive care planning for diabetes may provide useful lessons for action to address other chronic diseases.

Medication Therapy Management (MTM) Models: Standard versus Enhanced MTM

A critical component of providing coordinated care includes medication adherence. This section explores improvements to a specific program -- Medicare's medication therapy management (MTM) program, which needs to be improved in order to provide better value.

The Medicare Modernization Act (MMA), which created the Part D program, requires that every Part D plan offer a medication therapy management (MTM) program as a quality improvement feature. However, misaligned incentives inhibit the program from achieving significant benefits. In September 2015, CMS announced its intent to form a Part D Enhanced MTM Model to test changes to the Part D program that would achieve better alignment of prescription drug plan (PDP) sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions.¹

Below, we examine the new "enhanced" model and areas for improvement.

¹ All quotes in this document are from Centers for Medicare & Medicaid Services. CMS Part D Enhanced Medication Therapy Management Model Fact Sheet, September 28, 2015.

Table 1. Part D Enhanced MTM Model: Positive Features and Areas for Improvement

POSITIVE FEATURES		AREAS FOR IMPROVEMENT	
GENERAL			
<ul style="list-style-type: none">■ Emphasis on regulatory flexibility will allow targeting of high-risk beneficiaries and provide appropriate level and intensity of services (allows PDPs to stratify services by beneficiary risk; allows different levels and types of MTM services).■ Waivers will allow various providers to offer interventions of a type that are not usually furnished in traditional MTM programs.		<ul style="list-style-type: none">■ Timing of the model delays beneficial change. The model will result in a potential delay of seven to 10 years from today before the model's benefits can be extended to all beneficiaries since the model does not start until 2017, runs for five years, and will be evaluated.■ The design does not address the value of offering these benefits to all Part D members (including MA-PD plans) to achieve better alignment of PDP sponsor and government financial interests and optimize therapeutic outcomes.■ Restriction of the model over the five year demonstration creates unfair competitive disadvantage for plan sponsors outside the designated regions. Additionally, all PDF plans under a single contract should be able to participate, rather than be forced to split the contract (creating administrative burden for CMS and plans, as well as denying the benefits of the enhanced model to some patients served by the contract).	
SPECIFIC			
Payment Incentives <ul style="list-style-type: none">■ "Prospective payment for more extensive MTM interventions that will be "outside" of a plan's annual Part D bid"; and■ "A performance payment, in the form of an increased direct premium subsidy, for plans that successfully achieve a certain level of reduction in fee-for-service expenditures and fulfill quality and other data reporting requirements through the [Enhanced] model."		<ul style="list-style-type: none">■ CMS should invest in research to determine whether these payment incentives will offset participating plan sponsors' increased resources in the Enhanced MTM model.	
Quality Measures <ul style="list-style-type: none">■ "CMS will develop new MTM-related data and metric collection requirements for both monitoring and evaluation purposes."		<ul style="list-style-type: none">■ CMS should provide participating plans with an opportunity to participate in developing the quality indicators that comprise the uniform set of MTM data elements.■ CMS should rely on measures that have been developed through an intensive, transparent development and evaluation process such as employed by national quality organizations like the Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF).■ CMS should work with stakeholders to choose measures that address clinical outcomes for the conditions selected by plans for enhanced MTM services to determine any potential effect that these services have on overall quality of care.■ CMS should employ a public comment process that allows a full range of stakeholders to provide input into the final measure set, performance standards (e.g., for purposes of determining performance-based payments), and evaluation methods.	

POSITIVE FEATURES	AREAS FOR IMPROVEMENT
	<ul style="list-style-type: none"> ■ CMS should address the expected differences in Star Ratings between Part D regions CMS has selected to participate in the demonstration and those that are prohibited from participating so as not to penalize those non-selected regions. ■ CMS should consider the different requirements of plans with high levels of low-income subsidy (LIS) enrollment (e.g., any application of financial incentives to plan payments must be appropriately adjusted for plans serving high concentrations of LIS members who may be more difficult to reach out to and serve—especially as this could impact LIS benchmarks also). ■ CMS should also consider how to fairly measure quality for plans serving many LIS-eligible enrollees as they develop quality metrics for monitoring and evaluation of the model.
Emphasis on learning activities and plans to promulgate lessons	<ul style="list-style-type: none"> ■ CMS should be more explicit about how plans' proprietary information can be appropriately protected. ■ Lessons learned should be shared with plans outside of the model's geographic limitations. ■ CMS should take the lead in robust education of providers and pharmacies on the Enhanced MTM model test, particularly as it compares to the standard MTM program. Additionally, increased plan flexibility to customize their communications about the model could create confusion for many physicians and members about how this model test relates to the traditional MTM benefit.
Stakeholder Collaboration	<ul style="list-style-type: none"> ■ CMS should reconsider its stance regarding manufacturer and health plan collaborations to allow for appropriate interactions that will result in improved medication adherence.

Health Information Interoperability

Beyond patient engagement and adherence, a key goal of NDHI was establishing a learning health system² that operationalizes high-value care through the provision of relevant data to the right individuals at the right time. Providers must be able to use patient data from many different sources for individual care decisions and population health management. NDHI recognizes that integrated information collection and sharing through expanded data and electronic health records (EHR) interoperability is critical to achieve this goal. Ultimately, a system in which health information technology (HIT) systems interoperate will increase trust in the health system by all stakeholders and reduce the need to rely on expensive and burdensome tracking and reporting systems to demonstrate safety and quality.

While challenges still remain, the past decade has brought tremendous progress towards the adoption and meaningful use of HIT. As a first step toward building a system for electronic health data exchange among providers, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009. The Act included provisions for Medicare and Medicaid EHR Incentive Programs to promote the adoption and meaningful use of qualified electronic health records through financial incentives, and mandated that the Office of the National Coordinator for Health Information Technology (ONC) coordinate nationwide efforts to implement HIT.^{lviii} Since the law passed, the federal government has invested over \$28 billion in HIT and has established requirements and measures for Meaningful Use (MU) stages that providers must meet in order to receive incentive payments,^{lix} and the adoption of EHRs among hospitals and physicians has increased significantly. In 2008, 9.4% of hospitals and 16.9% of doctors had adopted an EHR system.^{lx} As of 2014, 75% of hospitals and 80% of physicians had adopted an EHR system.^{lxix} Interoperability of EHR systems has not been achieved at similar rates, however. For example, as of 2013 only 62% of hospitals had reported being able to exchange electronic health information with any provider outside their organization.^{lxiii}

Since the passage of HITECH, several other major efforts by the public and private sectors have been undertaken to move toward an interoperable healthcare system. All stakeholders agree on the fundamental components of interoperability, but definitions of and timing for national interoperability differ. In an effort to move toward comprehensive interoperability, Congress passed the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which declares that achieving interoperability by

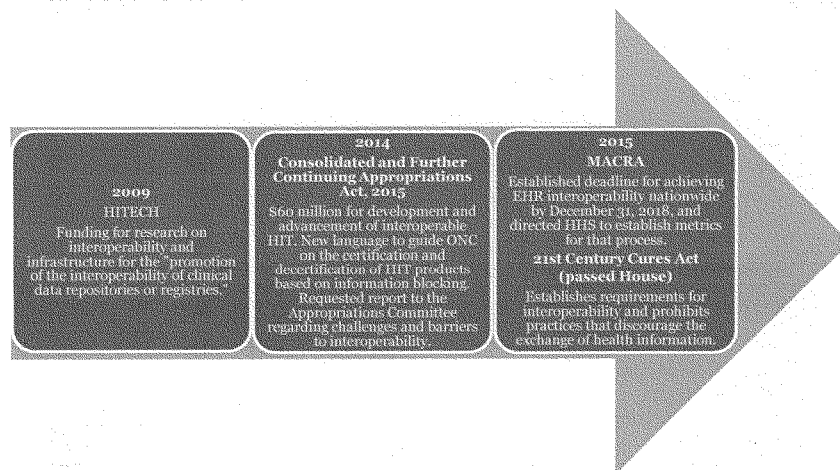
“[I]nteroperable EHR systems could better enable patients and providers to:

- view results from diagnostic procedures conducted by other providers to avoid duplication;
- evaluate test results and treatment outcomes over time regardless of where the care was provided to better understand a patient's medical history;
- share a basic set of patient information with specialists during referrals and receive updated information after the patient's visit with the specialist to improve care coordination;
- view complete medication lists to reduce the chance of duplicate therapy, drug interactions, medication abuse, and other adverse drug events; and identify important information, such as allergies or preexisting conditions, for unfamiliar patients during emergency treatment to reduce the risk of adverse events.”^{lvii}

² According to IOM, a learning health system is one “in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.”
<http://iom.nationalacademies.org/-/media/Files/Activity%20Files/Quality/VSRT/Core%20Documents/LearningHealthSystem.pdf>

December 31, 2018 is a national objective and directs HHS to establish related metrics. Congress also directed the GAO to review the efforts of non-government organizations to develop the infrastructure needed to support nationwide interoperability of healthcare information. In addition to reviewing selected nonfederal interoperability initiatives, they described key challenges related to EHR interoperability and the extent to which selected private sector initiatives are addressing these challenges. GAO noted that private sector stakeholders are using different approaches to address these key challenges: (1) insufficiencies in health data standards, (2) variation in state privacy rules, (3) accurately matching patients' health records, (4) costs associated with interoperability, and (5) the need for governance and trust among entities, such as agreements to facilitate the sharing of information among all participants in an initiative.^{xiv} Although many efforts focus on the interoperability of EHRs, leaders in HIT are also working to incorporate other types of data into an interoperable system. For example, Ascension Health's Center for Medical Interoperability is working to incorporate medical device data into an interoperable system that includes EHR data and other HIT data.^{xv}

Figure 2. Key HIT and Interoperability Pending Legislation and Laws



Building on these efforts, ONC published the final “Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap” in October 2015 that outlines a vision for interoperability with a timeline and public/private sector opportunities for achieving the goals of interoperability. ONC’s goals for interoperability align with those identified by NDHI:

- Focus on value
- Be person-centered
- Protect privacy and security in all aspects of interoperability and respect individual preferences
- Build a culture of electronic access and use
- Encourage innovation and competition
- Build upon the existing health IT infrastructure
- One size does not fit all
- Simplify
- Maintain modularity
- Consider the current environment and support multiple levels of advancement

Stakeholders Identified by ONC Who Can Affect or Are Affected by Interoperability:

- People who receive care or support the care of others
- People and organizations that deliver care and services
- Organizations that pay for care
- People and organizations (governmental) that support the public good
- People and organizations that generate new knowledge, whether research or quality improvement
- People and organizations that provide health IT capabilities
- People and organizations that govern, certify and/or have oversight
- People and organizations that develop and maintain standards^{xvi}

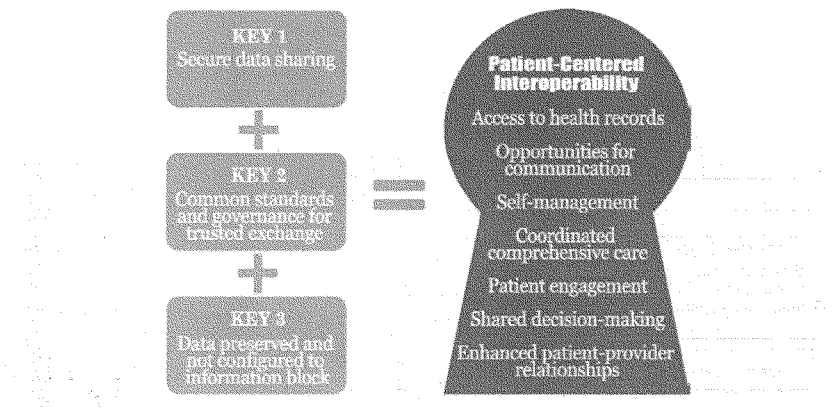
ONC calls on the private sector and many other stakeholders to join in “helping consumers easily and securely access their electronic health information when and where they need it most; to enabling individual health information to be shared with other providers and refrain from information blocking; and to implementing federally recognized, national interoperability standards and policies so that we are no longer competing between standards, but rather innovating on a set of core standards.”^{xvii}

Despite progress in the public and private sectors towards interoperability, NDHI also identified the following remaining challenges:

- Not all EHR vendors are members of initiative alliances
- Point-to-point transfer does not focus on content exchanged or complex scenarios
- Conflicting and competing standards
- Lack of consensus on clinical workflow and payment reform best practices
- Limited funds to achieve patient-centered interoperability
- Integrating clinical, billing and administrative data
- New payment models and complex provider collaborations

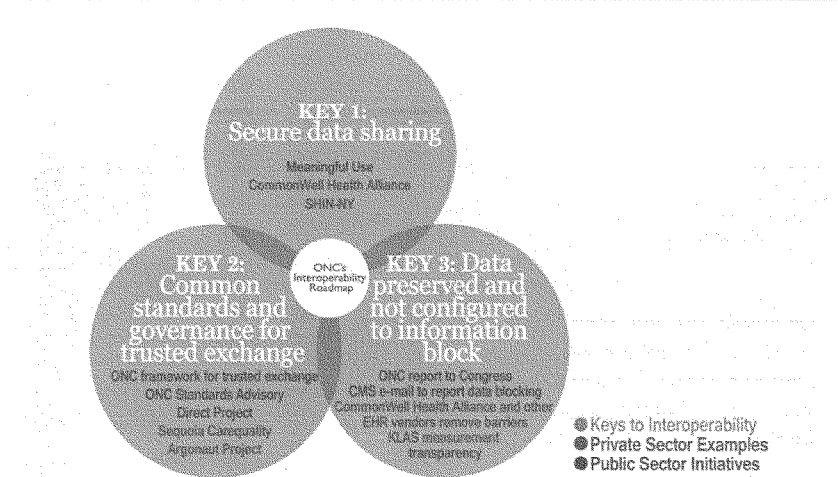
In an effort to show how all stakeholders can move towards an interoperable system, NDHI identified three key goals to support patient-centered interoperability that are shared across the public and private sectors. Together, these keys will move the U.S. toward achieving a patient-centered interoperable health system (Figure 3).

Figure 3. Keys toward Achieving Patient-Centered Interoperability



Figures 3 and 4 highlight examples of public- and private-sector initiatives, and the “keys” (i.e., goals) to patient-centered interoperability they aim to achieve: (1) Secure Data Sharing; (2) Common Standards and Governance for Trusted Exchange; and (3) Data Preserved and Not Configured to Information Block.

Figure 4. Key Public and Private Sector Interoperability Initiatives



Patient-Centered Interoperability

NDHI participants recognize that the patient must be the focus of emerging interoperable systems, and that an interoperable system facilitates patient-centered care. According to the Institute of Medicine (IOM), patient-centered care is defined as “providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.”^{lxviii}

A December 2015 report by the Bipartisan Policy Center (BPC) also emphasizes the need to create a patient centered system and notes that “billions of dollars are being invested by federal, state, and private sector organizations in new healthcare delivery and payment arrangements that reward better cost and quality outcomes. These arrangements will require greater information sharing and interoperable systems. For example, clinicians and care teams will need to have access to information about the patient—regardless of where care has been delivered—as well as clinical decision support tools, to inform coordinated, clinical decision-making at the point of care and between visits.”^{lxix} The BPC also notes that patients will play a critical role in improving cost and quality outcomes and that information sharing is critical to helping patients manage their health, make informed healthcare decisions, and navigate the healthcare system.^{lxx}

Ultimately, interoperability allows for patient-centered communication mechanisms that meet the needs of patients, providers, and caregivers and has positive effects on a variety of outcomes (see Table 2). Those outcomes include: provider and patient access to health records; patient self-management support; increased opportunities for communication between providers, providers and patients, and providers and caregivers; patient engagement; shared decision making among the provider, patient, and/or caregiver; enhanced patient/caregiver/provider relationships; and coordinated, comprehensive care.^{lxxi}

Table 2. Patient-Centered HIT Interoperability¹

HIT User	Key HIT Functionality	Patient-Centered Communication Mechanisms	Patient-Centered Care Outcomes
Patient	<ul style="list-style-type: none"> ■ Access to health records and reports ■ Information exchange ■ Prevention modalities and wellness strategies ■ Evidence-based data on risks/benefits of treatments ■ Self-management ■ eVisit 	<ul style="list-style-type: none"> ■ Facilitation of patient-physician interactions ■ Increased opportunities for communication ■ Educated patients have increased decision control ■ Increased patient engagement ■ Opportunity to discuss psychological and social context 	<ul style="list-style-type: none"> ■ Patient health behaviors ■ Symptom management ■ Healthcare process outcomes ■ Disease specific outcomes ■ Health knowledge ■ Reduced medical cost and time ■ Reduced medical error ■ Access to care
Caregiver	<ul style="list-style-type: none"> ■ Continuity of care ■ Access to patient records and reports ■ Caregiver resources ■ Partnership with provider 	<ul style="list-style-type: none"> ■ Caregiver involvement reinforces patient-provider interactions ■ Patient advocate provides insight on patient perspective ■ Assists in translating health information to patient ■ Caregiver support in decision making ■ Partnership fosters relationships 	
Healthcare Provider	<ul style="list-style-type: none"> ■ Coordinated and comprehensive care ■ Collaboration between providers ■ Electronic Medical Record access ■ Standardized reporting ■ Pharmaceutical dosing systems ■ Intervention management 	<ul style="list-style-type: none"> ■ Improved and efficient communication between providers and patient ■ Behavioral management and support outside of clinic context ■ Improved communication on decision making with other providers and patients 	

¹Table recreated from "Figure 1. Using health information technology (HIT) to impact patient-centered care through patient-centered communication" in Finney Rutten LJ, Agunwamba AA, Greene SM, et al. Enabling patient-centered communication and care through health information technology. *Journal of Communication in Healthcare*. 2014; 7(4): 255-261.

The following section provides additional details about the three keys to achieving patient-centered interoperability.

Key #1: Secure Data Sharing

Secure data sharing ensures that patients' privacy is protected in the process of data exchange--and while the data is stored. ONC explains the importance of secure data sharing: "[I]t serves as the basis for trust by ensuring that electronic health information can be shared in a secure and private manner and not altered in an unauthorized or unintended way, while still making the information available when needed by those authorized to access it."^{xxii} The initiatives in Table 3 are examples of private and public sector efforts that promote secure data sharing (e.g., Meaningful Use), or have been successful in implementing systems that practice secure data sharing (e.g., Statewide Health Information Network of New York).

Table 3. Secure Data Sharing Initiatives

Sector	Initiative	Initiative Description
Private	CommonWell Health Alliance (CommonWell)	The interoperable network includes identity management, record locator, consent management, and trusted data access. CommonWell is committed to robust privacy and security for interoperability. ^{1cxxx}
Public/Private	Statewide Health Information Network of New York (SHIN-NY)	New York's health information exchange is an example of secure electronic data sharing between providers that participate in a statewide network. ^{1cxxx}
Public	ONC Interoperability Roadmap	ONC describes its commitment to helping consumers easily and securely access their electronic health information when and where they need it most, and outlines a strategy for accomplishing this goal. ^{1cxxx}
Public	Meaningful Use	According to ONC, "MU privacy requirements address patients' rights both to: (1) have their health information protected from unauthorized access; and (2) access their health information.... The Meaningful Use security requirements protect Protected Health Information (PHI) against unauthorized access." ^{1cxxx} Meaningful Use Stage 3 includes a measure to "conduct or review a risk analysis including addressing the encryption/security of data stored in CEHRT, and implement security updates as necessary and correct identified security deficiencies as part of the EP's, EH's, or CAH's risk management process." ^{1cxxx}

Key # 2: Common Standards and Governance for Trusted Exchange

According to the GAO, standards "establish the language, structure, and data types required for integration among systems.... Consistent implementation of the standards by the vendors that build and sell EHR systems and by providers who use these systems is necessary for interoperability."^{1cxxxiii}

ONC explains that the standards "must be accessible nationwide and capable of handling significant and growing volumes of electronic health information, to ensure no one is left on the wrong side of the digital divide."^{1cxxxix} ONC describes its vision for a system in which "we are no longer competing between standards, but rather innovating on a set of core standards."^{1cxxxx} Examples of private and public sector efforts working toward common standards and governance for trusted exchange are highlighted in Table 4.

Table 4. Initiatives to Establish Common Standards and Governance for Trusted Exchange

Sector	Initiative	Initiative Description
Private	Argonaut Project	The purpose of the Argonaut Project is to develop a first-generation Core Data Services specification to enable expanded information sharing for electronic health records and other health information technology based on Internet standards and architectural patterns and styles. ^{lxxxix}
Private	Sequoia Carequality	The public-private collaborative builds consensus among exchange programs to develop a common set of standards and specifications that enable an interoperable connection among them. ^{lxxxii} The collaborative established policy for linking data sharing networks, and a framework for implementing data sharing goals. ^{lxxxiii}
Public	Direct Project	"The Direct Project specifies a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet." ^{lxxxiv} "The policy direction for the Direct Project is provided by the Nationwide Health Information Network Workgroup of the HIT Policy Committee, and oversight related to technology standards is provided by the HIT Standards Committee." ^{lxxxv}
Public	ONC Interoperability Standards Advisory (ISA)	ONC reports that the purpose of the ISA is: "1) To provide...a single, public list of the standards and implementation specifications that can best be used to fulfill specific clinical health information interoperability needs. 2) To reflect the results of ongoing dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available. 3) To document known limitations, preconditions, and dependencies as well as known security patterns among referenced standards and implementation specifications when they are used to fulfill a specific clinical health IT interoperability need." ^{lxxxvi}
Public	ONC's Governance Framework for Trusted Electronic Health Information Exchange	"The Governance Framework for Trusted Electronic Health Information Exchange (the Governance Framework) is intended to serve as the Office of the National Coordinator for Health Information Technology's (ONC's) guiding principles on HIE governance. It is meant to provide a common conceptual foundation applicable to all types of governance models and expresses the principles ONC believes are most important for HIE governance. The Governance Framework does not prescribe specific solutions but lays out milestones and outcomes that ONC expects for and from HIE governance entities as they enable electronic HIE." ^{lxxxvii}

Key #3: Systems are Not Configured to Information Block

ONC defines information blocking as occurring "when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information."^{lxxxviii} ONC and CMS have made clear statements that they will not tolerate practices that block information exchange. ONC explains that consequences of this "blocking" of information exchange include:

- Compromising patient's safety, care quality, and treatment effectiveness because it withholds information from patients and providers for informed decision making;
- Impeding progress towards reforming healthcare delivery and payment because sharing information seamlessly across the care continuum is fundamental to moving to a person-centered, high-performing healthcare system;
- Undermining consumers' confidence in their healthcare providers by preventing individuals from accessing their health information and using it to make informed decisions about their health and healthcare; and

- Preventing advances in biomedical and public health research, which require the ability to analyze information from many sources in order to identify public health risks, develop new treatments and cures, and enable precision medicine.^{xxxix}

Some key government initiatives to prevent and address data blocking, as well as some private sector initiatives to address the issue are described in Table 5.

Table 5. Initiatives to Prevent Information Blocking

Sector	Initiative	Initiative Description
Private	CommonWell and other EHR vendors	CommonWell believes health data should be available to individuals and providers regardless of where care occurs, and that provider access to this data be built-in health IT at a reasonable cost for use by a broad range of healthcare providers and the people they serve. ^{xxviii} Other EHR vendors have removed costs for providers to exchange data as well.
Private	KLAS measurement transparency	On October 2, 2015, a broad group of EHR stakeholders agreed by consensus to objective measures of interoperability and ongoing reporting and to have an independent entity publish transparent measures of health information exchange that can serve as the basis for understanding our current position and trajectory. ^{xxix}
Public	CMS e-mail to report data blocking	In June 2015, CMS released an e-mail address for stakeholders to use to report instances of data blocking. ^{xxx} CMS hopes to use those reports to better understand and address the problem of data blocking. ^{xxxi}
Public	ONC's Report to Congress	In response to the 2015 Appropriations Act, ONC was "urged to use its certification program judiciously in order to ensure certified electronic health record technology (CEHRT) provides value to eligible hospitals, eligible providers and taxpayers. ONC should use its authority to certify only those products that clearly meet current meaningful use program standards and that do not block health information exchange. ONC should take steps to decertify products that proactively block the sharing of information because those practices frustrate congressional intent, devalue taxpayer investments in CEHRT, and make CEHRT less valuable and more burdensome for eligible hospitals and eligible providers to use." Congress requested "a detailed report from ONC no later than 90 days after enactment of this act regarding the extent of the information blocking problem, including an estimate of the number of vendors or eligible hospitals or providers who block information. This detailed report should also include a comprehensive strategy on how to address the information blocking issue." ^{xxxii} ONC issued the report in April 2015 and notes that information blocking occurs when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information" and notes that "there is little doubt that information blocking is occurring and that it is interfering with the exchange of electronic health information." ^{xxxiii}

Conclusions

NDHI strongly believes that the nation must move towards an interoperable health IT infrastructure that is both beneficial to patients and their caregivers, and workable for industry. Functional interoperability is a critical component to support patient-centered care, value, and continued innovation in healthcare. A system built on accessible information and secure, meaningful data sharing will elevate healthcare delivery, advance quality and cost-efficiency, and enable new strides in medical research.

NDHI members agreed to build upon recommendations already offered to Congress and the Administration by HLC to continue to work toward achieving an interoperable health IT infrastructure. All NDHI members agreed that:

- Policymakers should **encourage exchange of material and meaningful health data** through the use of technologies and applications that enable bidirectional and real-time exchange of health data currently residing in EHR systems (e.g., open and secure API technology).
- Policymakers should use appropriate authority to **certify only those EHR technology products that do not block or otherwise inhibit health information exchange**. The HHS Office of the National Coordinator should decertify Meaningful Use products that intentionally block the sharing of information, or that create structural, technical, or financial impediments or disincentives to the sharing of information.
- The federal government, in collaboration with the private sector, should **build on current and emerging best practices in patient identification and matching** to identify solutions to ensure the accuracy of every patient's identity, and the availability and accessibility of their information, absent lengthy and costly efforts, wherever and whenever care is needed.
- Any interoperability **requirements or incentives should be "technology neutral" and focused on outcomes** – active interoperation between and among systems—rather than on adoption or use of specified technologies. It is critical that future policies do not stifle potential innovations in health system connectivity.

Furthermore, the multisector members of NDHI felt that recent advances in the state of interoperability collaborations and technologies allowed for even more ambitious goals and recommendations. Based upon these impressive accomplishments, members endorsed two additional declarations:

- There should be a national objective to achieve widespread exchange of health information through interoperable EHR technology nationwide on or before December 31, 2018 (in parallel to the recommendation made in the Medicare Access and CHIP Reauthorization Act).
- **Consumers should have easy and secure access their electronic health information**, be able to direct it to any desired location, learn how their information can be shared and used, and be assured that this information will be effectively and safely used to benefit their health and that of their community.

NDHI believes that, by bringing together the ideas and technological expertise from both the public and private sectors, interoperability is an achievable goal that can and should be accelerated through innovation and partnership between government and the private sector. Interoperability is also key to achieving the goals set by HHS of tying 30% of fee-for-service Medicare payments to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payment arrangements by the end of 2016, and 50% of payments to these models by the end of 2018. HHS has also set a goal of tying 85% of all traditional Medicare payments to quality or value by 2016 and

90% by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs.^{xvii}

Therefore, as efforts to reform our healthcare system accelerate, all parts must move in tandem. Meaningful interoperability is a necessary tool to meet the ambitious goals laid out by both private sector organizations and the federal government to enact value-based payment reforms, new care models, and allow greater consumer access and control of their healthcare.

Outdated and/or Ineffective Laws and Regulations

As the healthcare system transforms to reward better value, increased coordination, and a more empowered consumer, NDHI finds that some laws and regulations that were once important to the healthcare system may no longer be applicable or may inhibit transformation efforts in unintended ways. These outdated and/or ineffective healthcare laws and regulations, enacted with the consumer's best interest in mind, no longer serve the best interests of the healthcare consumer or healthcare system as a whole. As our healthcare system shifts from fee-for-service to value-based models evaluated through outcomes, many burdensome rules governing process have become unnecessary and redundant. Once payment and outcomes are aligned, there is less need for government regulation on process, since consumers and healthcare organizations share healthcare goals and responsibility for achieving them. Laws designed to prevent anticompetitive behavior, for example, now sometimes hinder the coordination needed for the best patient care. Additionally, wide variation among the regulatory approaches of agencies, states, and others leads to compliance efforts that cause more harm to patient outcomes than the risks they are intended to mitigate. Duplicative and outdated laws and regulations may impose an unnecessary burden on various sectors of the health system, which can negatively affect innovation and hinder care coordination.

For example, the Federal Anti-Kickback Statute and the Physician Self-Referral (Stark) Law are designed to ensure the integrity of federal healthcare programs and prevent inappropriate or undue influence on clinical decision-making that may lead to unnecessary overutilization of federal healthcare resources. These laws and their regulations prohibit certain financial arrangements between and among providers and other stakeholders. However, in their current form, they may inhibit current priority initiatives – such as medical homes, bundled payments and accountable care organizations (ACOs) – that are designed to promote value and care coordination among providers by aligning financial incentives for improved outcomes. For example, waivers of these laws and regulations were created to protect ACOs participating in the Medicare Shared Savings Program so that participants will not face liability for aligning financial incentives among providers provided certain requirements are met. Further, in the context of priority payment and delivery arrangements that can improve quality and lower costs (e.g. bundling, gainsharing), these laws and regulations may foreclose such arrangements because such arrangements were not envisioned when the laws and regulations were originally developed and any safe harbors and/or exceptions do not provide specific protection. For example, a physician who adopts a bundled payment arrangement in collaboration with a team of physicians and other providers may violate the Federal Anti-

Kickback Statute. Or, a physician who seeks to provide additional services like patient reward programs or add-on care management services, may implicate the Federal Anti-Kickback Statute or the civil monetary penalty (CMP) law prohibiting beneficiary inducements. While these laws and regulations are intended to protect patients and federal health programs from fraud and abuse, their broad scope and application implicates virtually all healthcare arrangements between and among providers and other industry participants. This complex web of laws and regulations and related compliance efforts may now inhibit arrangements designed to encourage hospitals and doctors to collaborate to improve patient care in a clinical integration program.

Further, various regulations create restrictions on data movement and usage, which often constrain providers from pursuing alternative payment models and even research initiatives. As health plans and providers and the medical research community continue to focus on outcomes research and innovation, it is important that the exchange and aggregated use of healthcare data be allowed. The HIPAA Privacy Rule strictly defines what constitutes protected health information (PHI) and defines certain institutions, or covered entities that hold such information. The Federal Policy for the Protection of Human Subjects or “Common Rule” defines the protection of human subjects in research. Without modifications to harmonize the rules, unnecessary barriers to data movement will continue to limit the innovative potential of the healthcare marketplace, especially as PHI continues to migrate out of the traditional healthcare system.

The misinterpretation and lack of alignment around privacy, security, and enforcement regulations - developed to safeguard patients’ personal health information – hampers data sharing necessary for alternative payment models and research. Currently, researchers need to contend not only with the HIPAA Privacy Rules regulating research but also with state law, and in many cases, additional federal law, for example, the Federal Privacy Act of 1974, the so-called Common Rule, FDA Regulations, and other regulations. This results in a confusing and inconsistent set of requirements, often governing the same study (for example, in the case of a multi-site study in different states).

Finally, advances in technology and data sharing allow for better outcome tracking and faster iteration of improvements in breakthrough treatments and technologies while manufacturers are still limited by outdated regulations from the FDA that delay access to breakthrough treatments and technologies. Various policies within the FDA’s purview have facilitated delays in both the approval of and access to innovative medical technology and treatments. Encouraging policy change that streamlines FDA’s responsibilities, while ensuring that companies remain accountable, could reduce FDA’s workload, allowing it to focus on higher-priority activities, and would represent a significant cost and time saving for the private sector and the federal government.

In an effort to accelerate the development of new treatments, improve care coordination, and facilitate health system transformation, NDHI identified three key categories in need of reform: the regulation of competition in healthcare, the flow of health information between health organizations, and modernization of key FDA rules and regulations—while ensuring that innovators remain accountable.

Possible Changes to the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models

As the U.S. healthcare system continues to move toward quality-driven, value-based care delivery and payment models, policy and implementation challenges arise as these models may implicate the federal fraud and abuse legal framework. In general, the fraud and abuse legal framework is designed to penalize arrangements between and among providers and other industry stakeholders that have the potential to encourage overutilization of healthcare resources, inappropriately influence provider decision-making, decrease competition among competitors, and harm patients. To improve quality of care and reduce costs, new care delivery and payment models are designed to encourage greater integration and coordination of care and payment between and among providers and other industry stakeholders. These models may align financial interests in ways that trigger fraud and abuse concerns.

As such, stakeholders across the healthcare system as well as policymakers, and legislators are considering whether changes to the current framework are needed to make it more compatible with healthcare delivery system transformation while retaining appropriate protections against fraud and abuse.

Many other federal statutes and regulations are potentially implicated by these new models (e.g., Civil Monetary Penalties (CMP) Law (including the beneficiary inducement and gainsharing provisions), the Civil and Criminal False Claims Acts (FCA), HIPAA, antitrust and tax law, and state laws that overlap with, mirror, or relate to these federal laws. However, NDHI participants decided to focus their efforts primarily on the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law as primarily and respectively enforced by HHS, Office of Inspector General (OIG), and CMS.

CMS Payment Waiver Policy

CMS should expand the waiver for patient incentives under the Medicare Shared Savings Program (MSSP) to all CMMI demonstrations. The current waiver gives ACOs the flexibility to encourage preventive care and patient compliance with treatment regimens without facing CMP due to beneficiary inducements. PPACA does authorize the waiver of the program integrity laws for CMMI demonstrations, but CMMI has largely issued guidance regarding such waivers on a case-by-case basis. While this information helps to ameliorate the concerns of would-be participants in CMMI demonstrations, concrete assurances in the form of prospective, bright line waivers could spur greater confidence and participation. Additionally, CMS should expand these permissions (such as the ability to waive copays) to private sector ACOs, which operate with the same incentives as those in CMS demonstration programs.

While this report does not address the other federal and state laws noted above, it is particularly important to note the relationship between the Federal Anti-Kickback Statute and the Civil Monetary Penalties (CMP) Law as they relate to both beneficiary inducement (i.e., providing anything of value to a patient in order to encourage the patient to utilize a particular provider, device, or pharmaceutical) and gainsharing (i.e., sharing savings among providers). It is common for arrangements between industry stakeholders (e.g., medical device and pharmaceutical manufacturers and providers) to potentially implicate both the Anti-Kickback Statute and the CMP law. For example, routinely waiving patient co-payments potentially implicates both the CMP Law's beneficiary inducement provisions as well as the Anti-Kickback Statute, which prohibits a co-payment waiver because it constitutes something of value provided to a patient. As

such, when considering potential changes to the Anti-Kickback Statute, stakeholders also should consider related changes to the CMP Law to ensure consistency in interpretation and application across both laws.

For reference, this report provides some background information on the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law as well as an overview of recent regulatory and legislative changes that provide additional context for the discussion of possible options to modify these legal frameworks.

It is important to note that alignment of the fraud and abuse legal framework with new care delivery and payment models is being discussed at multiple levels across the healthcare system. The recent Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) called for the HHS Secretary, in coordination with the OIG, to consider possible modifications to the legal frameworks to better align with integrated care delivery and payment models. In addition, CMS solicited feedback on possible changes to the Stark Law in the 2016 Physician Fee Schedule Proposed Rule indicating that the agency is thinking about these issues and open to dialogue regarding modifications. In the Final Rule, CMS stated that it will consider the comments received when preparing MACRA-mandated reports to Congress.

The Current Legal Framework

Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law

The Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law regulate arrangements between and among healthcare industry participants. The Anti-Kickback Statute prohibits any individual from knowingly and willfully offering, paying, soliciting, or receiving anything of value in return for a referral or to induce the generation of business reimbursable by a federal healthcare program.^{xvii} This prohibition applies to all healthcare industry participants, including institutional and individual providers and medical device and pharmaceutical manufacturers and suppliers. The Stark Law prohibits physicians from referring Medicare patients for certain services to an entity with which the physician (or an immediate family member) has a financial relationship.^{xviii} The Stark Law also prohibits healthcare organizations from billing Medicare for services provided pursuant to an improper referral.

The Anti-Kickback Statute is a criminal law and intent is required for liability to attach; penalties for violating the statute include imprisonment and substantial fines. In contrast, the Stark Law is a law of strict liability, meaning that no intent to violate the law is required. Civil monetary penalties may be levied for violations of the Anti-Kickback Statute and the Stark Law, and entities that violate either may be excluded from participation in federal healthcare programs.

There are exceptions to each law (referred to as “safe harbors” for the Anti-Kickback Statute and “exceptions” for the Stark Law) that protect certain types of business arrangements and transactions that are considered to present a minimal risk of fraud or abuse when structured appropriately (i.e., in accordance with exact requirements of an exception). The exceptions and associated requirements are not the same across both laws, though there is overlap. Generally, exceptions include payments made in the

course of legitimate business dealings (e.g., salaries paid to bona fide employees) and payments made for services integral to healthcare delivery (e.g., personal services contracts).

Recent Legislative and Regulatory Changes

1.) General Changes to Fraud and Abuse Laws: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)^{xcix} contained several provisions relevant to the fraud and abuse laws in general, including:

- Requiring the Secretary of HHS, in consultation with the OIG, to:
 - i. Study the applicability of fraud prevention laws under alternative payment models (APMs), identify aspects of APMs vulnerable to fraud, and examine implications of waivers to APMs. The Secretary must report to Congress on its findings and provide recommendations on how to reduce APMs' vulnerability to fraud by April 16, 2017;^c and
 - ii. Submit a report to Congress by April 16, 2016 with options for amending existing Medicare and Medicaid fraud and abuse laws and regulations through exceptions or safe harbors to permit gainsharing or similar arrangements between physicians and hospitals that would improve care while reducing waste and inefficiency.^{ci}
- Narrowing the gainsharing Civil Monetary Penalty Law^{cii} so that it only applies to reductions or limitations of medically necessary services.^{ciii}

2.) Stark Law Changes in Physician Fee Schedule: CMS routinely uses payment rules to amend the Stark Law regulations. In July 2015, CMS issued a proposed 2016 Medicare Physician Fee Schedule^{civ} in which it referenced its history of using such rulemakings to make changes to the Stark law, detailed proposed changes to the law, and requested public feedback about these changes, which included:^{cv}

- Two new Stark exceptions (covering payments to physicians to employ non-physician practitioners and timeshare arrangements for the use of office space, equipment, personnel, supplies, and other services that benefit rural or underserved areas);
- Guidance and clarification related to financial relationship documentation and requirements specific to certain financial relationships; and
- Clarifying Patient Protection and Affordable Care Act of 2010 (ACA)-mandated limitations on the whole hospital exception.

CMS finalized the proposed changes with minor modifications on October 30, 2015 in a final rule with comment period.^{cvi} In the proposed rule, CMS sought public comment regarding the impact of the Stark law on healthcare delivery and payment reform, and specifically asked for feedback on perceived Stark-related barriers to clinical and financial integration.^{cvi} CMS also posed specific questions for stakeholder input regarding the need for guidance on the application of aspects of the Stark regulations to physician compensation unrelated to participation in APMs. In the final rule, CMS stated that it will carefully

consider comments received in response to these questions when preparing reports to Congress as mandated by MACRA^{cxviii} and in determining the necessity of additional rulemaking on these issues.^{cxix}

- 3.) Medicare Shared Savings Program: The ACA made several changes that impact the fraud and abuse laws. One major change was the creation of the Medicare “Shared Savings Program” (MSSP), which allows groups of providers to create ACOs and share in the savings generated by reducing the overall cost of providing care to an assigned population of Medicare beneficiaries. CMS and the OIG published interim final rules on November 2, 2011 waiving certain provisions of the Stark Law and the Anti-Kickback Statute that would limit ACO arrangements within the MSSP.^{cx} These provisions were extended through November 2, 2015 by a continuation notice published in 2014. CMS has authority to issue waivers of the federal fraud and abuse laws as may be necessary to test models for improving care delivery or reducing expenditures and is likely to do so in relation to other CMMI models. Three other changes made directly to the fraud and abuse laws by the ACA include:
 - Relaxed the Anti-Kickback Statute’s intent requirement (clarifying that an individual or entity need not intend to violate the Statute or even know the Statute exists to have the requisite level of intent);
 - Added disclosure requirements to the Stark Law’s in-office ancillary services exception applicable to certain imaging services; and
 - Removed the “whole hospital exception” (commonly referred to as specialty hospitals) to the Stark law, with limited grandfathering for existing arrangements.
- 4.) E-prescribing and EHRs: The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 mandated the development of an Anti-Kickback Statute safe harbor and a Stark exception to promote e-prescribing technology adoption. In 2006, CMS and the OIG issued final rules furthering this mandate via two exceptions: (1) certain providers and health plans may subsidize 100% of e-prescribing system hardware, software, training, and support for certain related entities; and (2) through 2013, any provider or health plan may subsidize up to 85% of electronic health record (EHR) software and/or related technology and training services for any provider.^{cxj} The preambles of both final rules provide an illustrative but non-exhaustive list of EHR software and related technologies that would be considered covered technology within the donation exception.^{cxii} These examples include: connectivity services, clinical and information support services related to patient care, maintenance services, and secure messaging. The final rules specifically exclude certain items and services, including storage devices and software with core functionality other than electronic health records, such as payroll software. On December 27, 2013, the OIG and CMS issued joint final regulations extending the EHR exception through 2021 and modifying some of its requirements.^{cxiii} In response to stakeholder concerns about the scope of covered technology, the final rules note the importance of maintaining flexibility in the definition, particularly as health information technology evolves.^{cxiv} The rules declined to expand on the illustrative list provided in the 2006 final rule or to memorialize that list within the regulatory text and noted that revising the definition could inadvertently narrow the exception. The final rules emphasize whether specific items and services are

considered covered technology under the exception is dependent on the particular items or services. Specifically, donated items or services must be necessary and used predominantly to create, maintain, transmit, or receive electronic health records to qualify for the exception. The final rules suggest the possibility of expanding the scope of covered technology in the future.^{cxv}

Recent Guidance

- 1.) **Information Blocking:** The OIG issued an Alert on October 6, 2015 dealing with information blocking and the EHR safe harbor exception to the Anti-Kickback Statute.^{cxvi} The Alert notes that donation of [EHR] items or services that have limited or restricted interoperability due to action taken by the donor or anyone on the donor's behalf would not fall within the EHR donation safe harbor. OIG believes that charging fees to deter non-recipient providers and suppliers and the donor's competitors from interfacing with the donated items or services would pose "legitimate concerns" that parties were improperly locking-in data and referrals and thus that the arrangement in question would not qualify for safe harbor protection.
- 2.) **Medicare and Medicaid Discharge Planning Requirements:** CMS released a proposed rule on October 29, 2015 revising Medicare and Medicaid discharge planning requirements for acute care, long-term care, and critical access hospitals, inpatient rehabilitation facilities, and home health agencies.^{cxvii} The rule would implement the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014's discharge planning provisions, which modifies conditions of participation (COPs) to require post-acute care providers, hospitals, and critical access hospitals to account for quality, resource use, and similar measures in the discharge planning process. The rule would require these entities to use and share data on quality and resource use measures to assist patients in selecting post-acute care providers.

The list below represents potential priority regulatory and legislative options to modify two of the primary fraud and abuse laws (the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law) to better support innovative and integrated care delivery and payment models. These changes may be pursued independently or concurrently and some of the options may lend themselves to both regulatory and legislative action. It is not intended to be, nor should it be construed as an exhaustive analysis of the universe of potential modifications to these laws. The priority options, categorized as either Regulatory or Legislative, were selected by the National Dialogue for Healthcare Innovation initiative based on the following criteria:

Feasibility: Willingness of Congress, CMS and/or OIG to address

Impact: Potential to alleviate and/or eliminate perceived and/or real barriers to developing and implementing new models of care delivery and payment based on fraud and abuse framework

Timeliness: Whether meaningful action may/can be taken in the next 6-12 months

While the options are categorized as regulatory and legislative, it is important to note that they may be pursued independently or concurrently and some of the options may lend themselves to both regulatory and legislative action.

Regulatory Options

- Create Anti-Kickback Statute and Stark Law waivers for all ACOs that meet certain conditions, whether those ACOs are participating in the Medicare Shared Savings Program (MSSP) or not.
- Extend existing Anti-Kickback Statute and Stark Law exceptions for donation and financial support of EHR software, related technologies, and training beyond 2021. As part of an extension, ensure range of relevant and appropriate interoperable technologies that enable meaningful improvements in healthcare delivery and health information exchange are included based on the evolving technological environment.
- Clarify how to establish, document, and apply the “volume or value of referrals” standard within the changing healthcare payment environment.
- Expand and revise definition of fair market value to account for new payment models that incentivize performance^{cxviii} (e.g., payment for consulting services or other professional services, such as medical directorships).
- Eliminate or redefine the “one purpose” test for Anti-Kickback Statute liability and replace it with a balancing test that would require the OIG to prove either increased cost or actual harm to a patient.^{cxix} This would potentially allow, for example, arrangements where providers and/or medical device or pharmaceutical manufacturers provide items or services of value to patients to assist with prescription medication adherence or access to healthcare services. The OIG could assess the arrangement’s overall impact on quality of care and weigh these benefits against the potential risk of fraud and abuse to determine whether the transaction is permissible, regardless of whether one purpose of the arrangement is potentially problematic.
- See references under Legislative Options to changes that may be made through legislation and/or regulation to the Anti-Kickback Statute, Stark Law, and the CMP Law based on the HHS Secretary’s findings related to the assessment of the application of the laws in the current context of healthcare transformation.

Legislative Options

- Expand the parameters of the MACRA-mandated gainsharing report (due by April 16, 2016) and alternative payment model report (due by April 16, 2017)^{cx} and require the HHS Secretary to review and assess the Anti-Kickback Statute, the Stark Law, and the CMP Law in the context of the transformation of the healthcare system, specifically addressing: (1) whether these laws create unnecessary barriers to integrated care delivery and payment models; (2) whether these laws are effective in limiting fraudulent behavior; and (3) whether these laws should be modified to more effectively limit fraud and abuse without limiting new care and payment models aimed at providing better care at lower costs. The review process for both reports should include subject matter experts

from CMS and the OIG and the Secretary also should consult with the Department of Justice (DOJ), Internal Revenue Service (IRS), and the Federal Trade Commission (FTC). In addition, the Secretary should allow for opportunities for stakeholder input that would include medical practitioners and administrators, pharmaceutical and medical device manufacturers and suppliers, consumers, and legal and policy experts to review the Secretary's findings and assessment. Findings from the assessment along with stakeholders' feedback could be included in both reports, which also should include plans of action to address any suggested changes to the legal frameworks that arise from the assessment, as well as a description of the actions needed to achieve those changes.

- Changes identified through the assessment and reports noted above may yield opportunities for either legislative or regulatory action to amend the Anti-Kickback Statute, Stark Law, and CMP Law to protect arrangements that promote increased quality and lower costs.
- Congress also may consider granting OIG and CMS broader regulatory flexibility/rulemaking discretion to develop exceptions/safe harbors that are consistent with broad policy objectives (e.g., increase efficiency and quality and decrease costs) and adapt the Anti-Kickback Statute, the Stark Law, and the CMP Law to the current healthcare environment.^{xxx} Note that OIG and CMS already have statutory authority to create safe harbors and exceptions, but Congress could direct them to do so with respect to specific areas and/or in specific ways based on findings from the assessment and/or reports.
- The HLC and the NDHI will participate actively in opportunities for comment and will consider further suggestions based on the Secretary's findings.

Health Information Flow and Usage

There is growing interest in using data to better understand how to optimize the practice of medicine, the delivery of healthcare and new approaches to wellness and prevention of illness. At the same time, access to data needs to be balanced with the public's concern about the confidentiality and use of health data.

As data is appropriately accessed, it is vital to understand how to safely use these data to generate information for evidence-based care, share the data, analyze the data, and predict future needs of our complex healthcare delivery system. These data are fundamental to designing, implementing and evaluating innovative approaches to payment and financing reform and value-based delivery system reform, as well as medical breakthroughs.

Consistent Legal Requirements

Section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) defines "health information" as "any information, whether oral or recorded in any form or medium, that (A) is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and (B) relates to the past, present, or future physical or mental health or condition of any individual, the provision of healthcare to an individual, or the past, present, or future payment for the provision of healthcare to an individual."^{xxxii} HIPAA was designed to ensure that individuals' health information is protected while allowing the flow of health information needed to

provide high quality healthcare. HIPAA was also designed to protect the privacy of individuals' electronic health information while allowing the adoption of new technologies that will improve the quality and efficiency of patient care. Therefore, as noted by ONC, it is important to reconcile barriers that may be caused by HIPAA at the same time that the goals and protections are maintained.^{cxiii}

One particularly burdensome barrier to nationwide health information exchange is the many diverse state laws across the country regulating health information alongside HIPAA. These many state privacy and information sharing laws create enormous complexity resulting in substantial impediments to the implementation of health information exchanges within and across state borders. Healthcare organizations have long advocated for the harmonization of national and state privacy and security requirements in order to simplify compliance and facilitate greater information sharing, and promote patient access. We believe that a broader harmonization that would clearly incorporate the Health Insurance Portability and Accountability Act (HIPAA) governing standards would benefit the healthcare system without creating any material adverse impact on individuals.

Recent work by ONC^{cxiv} to outline a path forward for harmonization of conflicting, confusing, and burdensome state privacy laws provides new hope for efforts to simplify the protection of health information. Efforts to educate states on existing federal standards and begin a dialogue on this important problem are important. With regard to the critical actions outlined in the roadmap, we believe there is both precedent and will for an accelerated timeline with stakeholders acting alongside ONC. Specifically, a discussion with nationwide stakeholders should include possible action items, such as harmonization of state and federal law.

Patient Matching

Creating a balance between safe and legal sharing of information with the need to consistently and accurately match patient data creates a number of problems for physicians and other healthcare providers. Without accurate sharing, providers may have an incomplete view of a patient's medical history, care may not be well coordinated with other providers treating the patient, patient records may be overlaid, unnecessary testing or improper treatment may be ordered, and patient confidence may be eroded. Barriers to data sharing may also cause providers to face costly clinical workflow inefficiencies and potential inaccuracies including identifying the correct patient record, ordering duplicate tests, and failing to protect patient privacy preferences.^{cxv}

For EHRs to deliver on the promise of better healthcare, they need to ensure that patient data are sent and received easily among providers across disparate systems. These shared records must be accurate and useable. Patient matching is critical to the successful sharing of patient records, but patient data matching is an ongoing obstacle to seamless information exchange between organizations.

The ONC recently performed an assessment of current industry capabilities and best practices for patient identification and matching with a focus on matching records among different organizations providing care to a specific individual. The Patient Identification and Matching Initiative focused on identifying

incremental steps to help ensure the accuracy of every patient's identity, and the availability of their information wherever and whenever care is needed.^{cxvii} In addition, the Care Connectivity Consortium (CCC) and the Sequoia Project believe patient privacy should be at the center of patient identity management strategies. Specifically, they want to help advance the ability of patients to protect the confidentiality and integrity of their data, and to help patients stay aware of and in control of their data. CCC spells out three principles to achieve these goals: (1) allow for anonymous or pseudonymous patient identities; (2) correct identification of patients so that their privacy preferences can be determined and honored; and (3) enable correct matching of patients to their records (whether anonymous or identifiable).

The potential benefits of successfully matching a patient to their health information across all care settings cannot be understated. It is critical to health information interoperability efforts, critical to provide a patient a comprehensive health record upon request, and critical to ensuring that health professionals have the information to safely and effectively treat patients. More effective patient matching could lower healthcare costs by preventing redundant tests and scans, and more effectively prevent adverse events caused by medication interactions. The private sector has taken steps forward to reach these goals, but federal legislators need to facilitate government cooperation in ensuring success in building this infrastructure nationally.

Harmonization of Federal Research Rules

Similarly, federal rules for human subjects research, combined with other privacy rules, create a complex and burdensome environment for research. For example, definitions between the HIPAA Privacy Rule and the Common Rule for human subjects research are not always consistent, creating ambiguity and confusion for researchers. There should be one harmonized privacy standard for research institutions so that research and innovation are not delayed. The federal government should streamline the internal review board (IRB) process, clarify researcher and IRB expectations with respect to the scope and intensity of IRB review, and focus IRB resources and attention on those studies warranting the most careful scrutiny.

Health Information Flow Recommendations

In summary, there are several core needs that currently stand as barriers to fully integrating the use of health information into a learning, interoperable health system:

- Create a single national definition for protected health information and privacy standard to protect patients while mitigating complications from state laws.
- Update and harmonize federal privacy rules with regard to new and innovative research to allow for simple, clear requirements for health organizations – many of whom conduct research and drive innovation while providing care.
- Support and cooperate with leading private sector organizations in their efforts to match the right patient to the right record with minimal time and effort.

In this dynamic environment of information sharing, stakeholders have growing concerns about open access to data and sharing data among and across providers because of the fear of breaching data confidentiality. Varying interpretations of HIPAA as well as different state privacy laws are also leading to confusion and a fear of violating the rules which is then resulting in restrictions to the movement and sharing of data. In addition, a growing number of data breaches are leading major health systems to be more cautious about sharing data. Building on these concerns, NDHI supports the need to review and simplify the complex web of laws regulating health information in light of the movement towards value based care and other information-based changes to the healthcare environment.

FDA Regulations

Manufacturers face unnecessary and redundant regulations from the FDA that delay access to breakthrough treatments and technologies. Various policies within the FDA's purview have facilitated delays in both the approval of and access to innovative medical technology and treatments. Encouraging policy change that streamlines FDA's responsibilities, while ensuring that companies are accountable, could reduce FDA's workload, allowing it to focus on higher-priority activities, and would represent a significant cost and time saving for the private sector and the federal government.

NDHI identified a series of unnecessary and redundant regulations from the FDA that delay access to innovative treatments and technologies. Addressing these barriers will help promote the development and availability of breakthrough treatments and technologies:

- **Reduce Regulatory Burdens on Multicenter Clinical Trials** - Eliminate the prohibition on using a single IRB of record for device trials, conforming the statute to the requirements for drug trials and the practice for other types of multicenter trials, and require FDA to develop guidance on the use of such single IRBs in device trials.
- **Reduce FDA Premarket Submission Rule** - Reduce the review burden on FDA and companies by allowing companies to make certain changes to devices without a premarket submission if their quality system has been certified as capable of evaluating such changes.
- **Recognition of Standards** – Timely review of a request for recognition of a standard established by an internationally or nationally recognized standards organization would improve regulatory efficiency. Through greater use of standards and more transparency in this area, FDA review will be more efficient and the time to bring medical technology from the bench to the bedside will be reduced.
- **Valid Scientific Evidence** – Expanding valid scientific evidence to include evidence described in well-documented case histories, including registry data, studies published in peer-reviewed journals, and data collected in countries outside the U.S. would allow greater flexibility in the FDA review of medical devices and improve access to new therapies for patients (Cures Section 2222).
- **Training and Implementation of Least Burdensome** – Training related to the meaning and implementation of the least burdensome provisions would increase efficiency and consistency for the FDA and manufacturers, allowing greater innovation for patients. Improved understanding and use of

the least burdensome provisions would minimize the time involved in bringing new treatments to patients, while maintaining FDA's high standards for safety and efficacy (Cures Section 2223).

- **Increase flexibility to share scientific and healthcare economic information with population health decision-makers**—Biopharmaceutical manufacturers can and should partner with payers and providers in efforts to communicate about and optimize the clinical benefits of prescribed treatments. The push for value-based payment is accelerating demands by payers and providers for a growing range of information about the clinical and economic outcomes of their products. Biopharmaceutical companies routinely develop data describing the cost-effectiveness of various treatment options, data based on post-market use of these medicines, as well as safety and efficacy information. Application of these data can enhance patient care and the efficiency of the healthcare system, but companies are not currently permitted to share such information proactively with healthcare professionals or payers.

Table 6 in Appendix A provides more detailed descriptions of these issues.

Conclusions

NDHI recognizes that these FDA regulatory barriers are all addressed in some way through the House 21st Century Cures effort. The bill would provide additional resources to the NIH and to the FDA and benefits patients, researchers, and clinicians by supporting new opportunities for breakthrough treatments and cures. The bill is also designed to remove unnecessary regulatory burdens with an emphasis on patient centered research and care and break down barriers among healthcare silos to promote innovation and communication among researchers, scientists, and innovators. Finally, the bill includes an accelerated pathway for FDA approval and Medicare and Medicaid coverage for products that represent significant improvements in treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions that would stimulate development of new diagnostics and treatments and assure prompt availability of those treatments to patients. NDHI will continue to address and support these issues in the Senate and through other opportunities as they arise.

Conclusion

There is a broad consensus in the United States among healthcare providers, payers, clinicians, patients, and consumers that the nation's healthcare system does not operate at a level that generates optimal value. There is significant room for improvement in elevating quality, cost-efficiency, and sustainability. There is a gap between the innovations being developed in all sectors of healthcare and the ability to deliver those improved products and practices to patients.

Through the Healthcare Leadership Council's National Dialogue for Healthcare Innovation initiative, companies from all sectors of healthcare joined with leaders of patient advocacy organizations, federal government officials, and academic health policy experts to build consensus on a broad spectrum of steps necessary to strengthen health system value and enable health innovation to have a greater positive impact on the entirety of the healthcare continuum.

NDHI participants came to the conclusion that healthcare in the U.S. can be significantly improved by focusing on actions that are readily achievable via legislation, regulation, or voluntary actions by various health system players. Positive health system transformation does not require a wholesale remaking of health delivery structures, but rather the enabling and acceleration of patient-centered innovation.

The recommendations in this paper are intended to drive health system transformation and a movement toward value and innovation. The consensus viewpoints contained in this report are also consistent with steps currently being taken by the federal government to guide a health system transition from fee-for-service to pay-for-value and toward more integrated, coordinated care. These recommendations should serve as a catalyst for further debate and decisive action.

References

- ⁱ Cramer JA, Roy A, Burrell A, et al. Medication compliance and persistence terminology and definitions. *Value Health*. 2008; 11: 44-47.
- ⁱⁱ Ho PM, Bryson CL, and Rumsfeld JS. Medication adherence: its importance in cardiovascular outcomes. *Circulation*. 2009; 119: 3028-3035.
- ⁱⁱⁱ Viswanathan M, Golin CE, Jones CD, et al. September 2012. Medication Adherence Interventions: Comparative Effectiveness. Closing the Quality Gap: Revisiting the State of the Science. Evidence Report No. 208. (Prepared by RTI International–University of North Carolina Evidence-based Practice Center under Contract No. 290-2007-10056-I.) AHRQ Publication No. 12-E010-EF. Rockville, MD: Agency for Healthcare Research and Quality. www.effectivehealthcare.ahrq.gov/reports/final.cfm
- ^{iv} Centers for Medicare & Medicaid Services. 2012. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD.
- ^v Agency for Healthcare Research and Quality. Care Coordination. AHRQ website. Accessed 10/23/2015. Available at: <http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html>
- ^{vi} Centers for Medicare & Medicaid Services. Glossary. CMS website. Accessed 10/22/2015. Available at: <https://www.cms.gov/apps/glossary/default.asp?Letter=ALL>
- ^{vii} Centers for Medicare & Medicaid Services. May 2015. Chronic Care Management Services. ICN 909188. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf>
- ^{viii} Centers for Medicare & Medicaid Services. IMPACT Act of 2014 & Cross Setting Measures. CMS website. Accessed 10/02/2015. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html>
- ^{ix} Centers for Medicare & Medicaid Services. July 16, 2015. Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities. Federal Register website. Accessed 10/05/2015. Available at: <https://www.federalregister.gov/articles/2015/07/16/2015-17207/medicare-and-medicicaid-programs-reform-of-requirements-for-long-term-care-facilities#h-21>
- ^x United States Government Accountability Office. October 2015. Medicaid and Insurance Exchanges: Additional Federal Controls Needed to Minimize Potential for Gaps and Duplication in Coverage Report to Congressional Requesters. GAO-16-73. <http://www.gao.gov/assets/680/673026.pdf>
- ^{xi} United States Senate Committee on Finance. May 22, 2015. “Dear Stakeholders” letter. Available at: <http://www.finance.senate.gov/newsroom/chairman/release/?id=9f9f2d3e-401e-409b-a53a-22bbe3f56f2c>
- ^{xii} Martin LR, Williams SL, Haskard KB, et al. The challenge of patient adherence. *Ther Clin Risk Manag*. 2005 Sep; 1(3): 189–199.

-
- ^{xiii} Gellad WF, Grenard J, McGlynn EA. 2009. A Review of Barriers to Medication Adherence: A Framework for Driving Policy Options. Cited from page 5. RAND: Santa Monica.
- ^{xiv} Gellad WF, Grenard J, McGlynn EA. 2009. A Review of Barriers to Medication Adherence: A Framework for Driving Policy Options. Cited from Page 5. RAND: Santa Monica.
- ^{xv} Centers for Medicare & Medicaid Services. September 28, 2015. CMS Announces Part D Enhanced Medication Therapy Management Model. CMS media release. Accessed 11/04/15. Available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-09-28.html>
- ^{xvi} American Diabetes Association. Strategies for improving care. *Diabetes Care*. 2015; 38(Suppl. 1): S5–S7.
- ^{xvii} American Diabetes Association. Standards of Medical Care in Diabetes 2015. *Diabetes Care*. 2015; 38(Suppl. 1).
- ^{xviii} U.S. Preventive Services Task Force. December 2015. Final Recommendation Statement: Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening. U.S. Preventive Services Task Force website. Accessed 12/31/15. Available at: <http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes>
- ^{xix} Joslin Diabetes Center. 2015. What is Pre-Diabetes? Joslin Diabetes Center website. Accessed 12/31/15. Available at: http://www.joslin.org/info/what_is_pre_diabetes.html
- ^{xx} Tucker ME. January 29, 2014. Medicare's Diabetes Testing Supply Program Found Lacking. Accessed November 13, 2015. Available at: <http://www.medscape.com/viewarticle/819908>
- ^{xxi} April 29, 2015 Hypoglycemia Stakeholder Roundtable hosted by the Endocrine Society and Merck.
- ^{xxii} Hussey PS, Schneider EC, Rudin RS, et al. Continuity and the costs of care for chronic disease. *JAMA Internal Medicine*. 2014; 174(5):742-748.
- ^{xxiii} American Diabetes Association. Strategies for improving care. Sec. 1. In Standards of Medical Care in Diabetes 2015. *Diabetes Care*. 2015; 38(Suppl. 1): S5–S7.
- ^{xxiv} American Diabetes Association. Strategies for improving care. Sec. 1. In Standards of Medical Care in Diabetes 2015. *Diabetes Care*. 2015; 38(Suppl. 1): S5–S7.
- ^{xxv} Agency for Healthcare Research and Quality. Care Coordination. AHRQ website. Accessed 10/15/15. Available at: <http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html>
- ^{xxvi} American Diabetes Association. Strategies for improving care. Sec. 1. In Standards of Medical Care in Diabetes 2015. *Diabetes Care*. 2015; 38(Suppl. 1): S5–S7.
- ^{xxvii} AACE/ACE. Clinical practice guidelines for developing a diabetes mellitus comprehensive care plan – 2015. *Endocrine Practice*. 2015 Apr.; 21 (Suppl 1).

^{xxviii} Katon WJ, Lin EHB, Von Korff M, et al. Collaborative care for patients with depression and chronic illnesses. *N Engl J Med*. 2010; 363: 2611–2620.

^{xxix} American Heart Association. Cardiovascular Disease & Diabetes. American Heart Association website. Accessed 10/23/15. Available at: http://www.heart.org/HEARTORG/Conditions/Diabetes/WhyDiabetesMatters/Cardiovascular-Disease-Diabetes_UCM_313865_Article.jsp#.ViqPgpcvn_Q

^{xxx} American Diabetes Association. Strategies for improving care. Sec. 1. In Standards of Medical Care in Diabetes 2015. *Diabetes Care*. 2015; 38(Suppl. 1): S5–S7

^{xxxi} National Diabetes Education Program. Nine Essential Functions of an Information System for Optimal Diabetes Care. NDEP website. Accessed 10/22/2015. Available at: <http://ndep.nih.gov/hcp-businesses-and-schools/practice-transformation/information-systems/functions.aspx#phct>

^{xxxii} Greenwood DA1, Blozis SA, Young HM, et al. Overcoming clinical inertia: a randomized clinical trial of a telehealth remote monitoring intervention using paired glucose testing in adults with type 2 diabetes. *J Med Internet Res*. 2015 Jul 21; 17(7): e178.

^{xxxiii} Stone RA, Rao RH, Sevic MA, et al. Active care management supported by home telemonitoring in veterans with type 2 diabetes: the DiaTel randomized controlled trial. *Diabetes Care*. 2010; 33: 478–484.

^{xxxiv} Centers for Disease Control and Prevention. Prediabetes: Am I at Risk? National Diabetes Prevention Program website. Accessed 10/23/15. Available at: <http://www.cdc.gov/diabetes/prevention/prediabetes.htm>

^{xxxv} American Diabetes Association. Standards of Medical Care in Diabetes 2015. *Diabetes Care*. 2015; 38(Suppl. 1): S80.

^{xxxvi} Patient-Centered Outcomes Research Institute. Project ACHIEVE (Achieving Patient-Centered Care and Optimized Health In Care Transitions by Evaluating the Value of Evidence). PCORI website. Accessed 10/22/2015. Available at: <http://www.pcori.org/research-results/2014/project-achieve-achieving-patient-centered-care-and-optimized-health-care>

^{xxxvii} Agency for Healthcare Research and Quality. Care Transitions from Hospital to Home: IDEAL Discharge Planning Implementation Handbook. http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/systems/hospital/engagingfamilies/strategy4/Strat4_Implement_Hndbook_508_v2.pdf

^{xxxviii} Agency for Healthcare Research and Quality. Care Transitions from Hospital to Home: IDEAL Discharge Planning Implementation Handbook. Accessed 10/22/2015. Available at: http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/systems/hospital/engagingfamilies/strategy4/Strat4_Implement_Hndbook_508_v2.pdf

^{xxxix} American Diabetes Association. Diabetes care in the hospital, nursing home, and skilled nursing facility. Sec. 13. In Standards of Medical Care in Diabetes 2015. *Diabetes Care*. 2015; 38(Suppl. 1): S80–S85

^{xl} Balaban RB. A physician's guide to talking about end-of-life care. *Journal of General Internal Medicine*. 2000; 15(3): 195–200.

-
- ^{xli} Polonsky WH, Earles J, Smith S, et al. Integrating medical management with diabetes self-management training. *Diabetes Care*. 2003; 26: 3048-3053.
- ^{xlii} Melko CN, Terry PE, Camp K, et al. Diabetes health coaching improves medication adherence: a pilot study. *American J Lifestyle Medicine*. 2010; 4(2): 187-194.
- ^{xliii} Planas LG, Crosby KM, Mitchell KD, et al. Evaluation of a hypertension medication therapy management program in patients with diabetes. *J Am Pharm Assoc*. 2009; 49: 164-170.
- ^{xliv} Watson LL, Bluml BM, Skoufalos A. Patient credentialing as a population health management strategy: a diabetes case study. *Popul Health Manag*. 2015 Jun; 18(3): 179-85.
- ^{xlv} Pillay J, Chordiya P, Dhakal S, et al. September 2015. Behavioral Programs for Diabetes Mellitus. Evidence Report/Technology Assessment No. 221. (Prepared by the University of Alberta Evidence-based Practice Center under Contract No. 290-2012-00013-L.) AHRQ Publication No. 15-E003-EF. Rockville, MD: Agency for Healthcare Research and Quality. www.effectivehealthcare.ahrq.gov/reports/final/cfm
- ^{xlvi} Li R, Shrestha SS, Lipman R, et al. Diabetes Self-Management Education and Training Among Privately Insured Persons with Newly Diagnosed Diabetes — United States, 2011–2012. *CDC Morbidity and Mortality Weekly Report (MMWR)*. 2014 Nov 21; 63(46):1045-1049. Accessed 11/04/15. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6346a2.htm>
- ^{xlvii} American Diabetes Association. Standards of Medical Care in Diabetes 2015. *Diabetes Care* 2015; 38(Suppl. 1)
- ^{xlviii} U.S. Preventive Services Task Force (USPSTF). Final Recommendation Statement. Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening. USPSTF website. Accessed 11/24/2015. Available at: <http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes>.
- ^{xlix} Bastiaens H, Sunaert P, Wens J, et al. Supporting diabetes self-management in primary care: Pilot-study of a group-based programme focusing on diet and exercise. *Prim Care Diabetes*. 2009; 3(2): 103-109.
- ⁱ Wadden TA, Butryn ML, Hong PS, et al. Behavioral treatment of obesity in patients encountered in primary care settings: a systematic review. *JAMA*. 2014 Nov 5; 312(17): 1779–1791.
- ⁱⁱ Pinto AM, Fava JL, Hoffmann DA, et al. Combining behavioral weight loss treatment and a commercial program: a randomized clinical trial. *Obesity*. 2013; 21: 673-680.
- ⁱⁱⁱ Aging & Disability Resource Center. About the Aging and Disability Resource Center Grant Program. Aging & Disability Resource Center website. Accessed 10/22/15. Available at: <http://www.adrc-tae.acl.gov/tiki-index.php?page=NewSite>
- ⁱⁱⁱⁱ Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. *JAMA*. 2002; 288(4): 475-482.
- ^{lv} Seligman HK, Wallace AS, DeWalt DA, et al. Facilitating behavior change with low-literacy patient education materials. *Am J Health Behav*. 2007; 31(Suppl 1): S69–S78.

-
- ^{lv} Tripp-Reimer T, Choi E, Skemp Kelley L, et al. Cultural barriers to care: inverting the problem. *Diabetes Spectrum*. 2001 Jan; 14(1): 13-22.
- ^{lvi} American Association of Diabetes Educators. July 28, 2015. Cultural Considerations in Diabetes Education. AADE Practice Synopsis. American Association of Diabetes Educators website. Accessed 10/23/15. Available at: <https://www.diabeteseducator.org/docs/default-source/default-document-library/cultural-considerations-in-diabetes-management.pdf?sfvrsn=0>
- ^{lvii} United States Government Accountability Office. September 2015. Electronic Health Records: Nonfederal Efforts to Help Achieve Health Information Interoperability. <http://www.gao.gov/assets/680/672585.pdf>
- ^{lviii} Index for Excerpts from the American Recovery and Reinvestment Act of 2009 (ARRA). https://www.healthit.gov/sites/default/files/hitech_act_excerpt_from_arra_with_index.pdf
- ^{lix} The Office of the National Coordinator for Health Information Technology (ONC). Report to Congress 2015: Report on Health Information Blocking. https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf
- ^{lx} Hsiao C-J and Hing E. 2014. Use and Characteristics of Electronic Health Record Systems Among Office-Based Physician Practices: United States, 2001–2013. NCHS data brief, no 143. Hyattsville, MD: National Center for Health Statistics. <http://www.cdc.gov/nchs/data/databriefs/db143.htm>
- ^{lxi} Heisey-Grove D and Patel V. September 2015. Any, Certified, or Basic: Quantifying Physician EHR Adoption. ONC Data Brief, no. 28. Washington, DC: Office of the National Coordinator for Health Information Technology. https://www.healthit.gov/sites/default/files/briefs/oncdatabrief28_certified_vs_basic.pdf
- ^{lxii} Charles D, Gabriel M., Searcy T. April 2015. Adoption of Electronic Health Record Systems among U.S. Non-Federal Acute Care Hospitals: 2008-2014. ONC Data Brief, no.23. Washington, DC: Office of the National Coordinator for Health Information Technology. <https://www.healthit.gov/sites/default/files/data-brief/2014HospitalAdoptionDataBrief.pdf>
- ^{lxiii} Swain M and Galvez E. May 5, 2014. Health Information Exchange among U.S. Hospitals Continues to Grow, but Significant Work Remains. Health IT Buzz website. Accessed 11/3/15. Available at: <http://www.healthit.gov/buzz-blog/health-information-exchange-2/health-information-exchange-hospitals-continues-grow-significant-work-remains/>
- ^{lxiv} United States Government Accountability Office. September 2015. Electronic Health Records: Nonfederal Efforts to Help Achieve Health Information Interoperability. <http://www.gao.gov/assets/680/672585.pdf>
- ^{lxv} Center for Medical Interoperability. 2015. <http://medicalinteroperability.org/>
- ^{lxvi} The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

^{bxvii} The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

^{bxviii} Institute of Medicine. March 2001. Crossing the Quality Chasm: A New Health System for the 21st Century. <https://iom.nationalacademies.org/~media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf>

^{bxix} Bipartisan Policy Center. December 2015. Improving Health through Interoperability and Information Sharing: Advancing Medical Innovation for a Healthier America. <http://bipartisanpolicy.org/wp-content/uploads/2015/11/BPC-Improving-Health-Interoperability.pdf>

^{bxix} Bipartisan Policy Center. December 2015. Improving Health through Interoperability and Information Sharing: Advancing Medical Innovation for a Healthier America. <http://bipartisanpolicy.org/wp-content/uploads/2015/11/BPC-Improving-Health-Interoperability.pdf>

^{lxxi} Finney Rutten LJ, Agunwamba AA, Greene SM, et al. Enabling patient-centered communication and care through health information technology. *Journal of Communication in Healthcare*. 2014; 7(4): 255-261.

^{lxxii} The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

^{lxxiii} CommonWell Health Alliance. 2015. Services. CommonWell Health Alliance website. Accessed 10/26/15. Available at: <http://www.commonwellalliance.org/services/>

^{lxxiv} HealtheConnections. What is the SHIN-NY? HealtheConnections website. Accessed 10/26/15. Available at: http://www.healtheconnections.org/wp-content/uploads/2015/04/what-is-the-shin-ny_rob.pdf

^{lxxv} The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

^{lxxvi} The Office of the National Coordinator for Health Information Technology. April 2015. Guide to Privacy and Security of Electronic Health Information: Version 2.0. <https://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide.pdf>

^{lxxvii} Myers E. May 11, 2015. Presentation: Stage 3 Meaningful Use Proposed Rule Overview. eHealth: Centers for Medicare & Medicaid Services. https://www.cms.gov/eHealth/downloads/Webinar_eHealth_May11_ONCStage3.pdf

^{lxxviii} United States Government Accountability Office. Report to Congressional Requesters. September 2015. Electronic Health Records: Nonfederal Efforts to Help Achieve Health Information Interoperability. <http://www.gao.gov/assets/680/672585.pdf>

^{lxxxix} The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

^{lxxx} The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

^{lxxxi} HL7 International. September 24, 2015. Main Page/Background. HL7 International website. Accessed 12/15/15. Available at: http://argonautwiki.hl7.org/index.php?title=Main_Page/Background

^{lxxxii} The Sequoia Project. 2015. What is Carequality? The Sequoia Project website. Accessed 12/15/15. Available at: <http://sequoiaproject.org/carequality/>

^{lxxxiii} The Sequoia Project. 2015. What We Do. The Sequoia Project website. Accessed 12/15/15. Available at: <http://sequoiaproject.org/carequality/what-we-do/>

^{lxxxiv} The Direct Project. October 11, 2010. The Direct Project Overview. <http://wiki.directproject.org/file/view/DirectProjectOverview.pdf>

^{lxxxv} The Direct Project. October 11, 2010. The Direct Project Overview. <http://wiki.directproject.org/file/view/DirectProjectOverview.pdf>

^{lxxxvi} Office of the National Coordinator for Health IT. 2016 Interoperability Standards Advisory: Best Available Standards and Implementation Specifications. https://www.healthit.gov/sites/default/files/2016interoperabilitystandardsadvisoryfinalv2_02.pdf

^{lxxxvii} The Office of the National Coordinator for Health Information Technology. May 2013. Governance Framework for Trusted Electronic Health Information Exchange. https://www.healthit.gov/sites/default/files/GovernanceFrameworkTrustedEHIE_Final.pdf

^{lxxxviii} The Office of the National Coordinator for Health Information Technology. April 2015. Report to Congress: Report on Health Information Blocking. https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

^{lxxxix} The Office of the National Coordinator for Health Information Technology. April 2015. Report to Congress: Report on Health Information Blocking. https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

^{xc} CommonWell Health Alliance. 2015. Services. CommonWell Health Alliance website. Accessed 12/15/15. Available at: <http://www.commonwellalliance.org/services/>

^{xci} Moore M. October 19, 2015. Healthcare Vendors Agree to Interoperability Metric During KLAS Keystone Summit. KLAS Research Press Release. Accessed 11/2/15. Available at: <http://www.klasresearch.com/about-us/press-room/2015/10/19/healthcare-vendors-agree-to-interoperability-metric-during-klas-keystone-summit>

^{xcii} Green L. June 2, 2015. Are You a Victim of Data Blocking? The Obama Administration Wants to Know. Modern Healthcare. <http://www.modernhealthcare.com/article/20150602/NEWS/150609979>

^{xciii} Green L. June 2, 2015. Are You a Victim of Data Blocking? The Obama Administration Wants to Know. Modern Healthcare. <http://www.modernhealthcare.com/article/20150602/NEWS/150609979>

^{xciv} The Office of the National Coordinator for Health Information Technology. April 2015. Report to Congress: Report on Health Information Blocking. https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

^{xcv} The Office of the National Coordinator for Health Information Technology. April 2015. Report to Congress: Report on Health Information Blocking. https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

^{x cvi} U.S. Department of Health and Human Services. January 26, 2015. Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value. HHS Press Release. Accessed 12/9/15. Available at: <http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html>

^{xcvii} 42 U.S.C. § 1320a-7b(b) (2015).

^{xcviii} 42 U.S.C. § 1395nn(a) (2015).

^{xcix} Pub. Law 114-10, 129 Stat. 87 (“MACRA”) (Apr 16, 2015).

^c MACRA, § 101(e)(7).

^{ci} MACRA, § 512(b) (i.e., “Gainsharing Report”).

^{cii} Social Security Act 1128A(b)(1)

^{ciii} MACRA, § 512(a)

^{civ} CMS, “Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016,” 80 Fed. Reg. 41686 (July 15, 2015).

^{cv} 80 Fed. Reg. at 41909-30.

^{cvi} CMS, “Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016” 80 Fed. Reg. 70886 (November 16, 2015). Comment period ends at 5 pm (EST) on December 29, 2015.

^{cvi} 80 Fed. Reg. at 41929.

^{cvi} APM report (MACRA §101(e)(7)) and Gainsharing report (MACRA § 512(b)).

^{cix} 80 Fed. Reg. at 71341.

^{cx} OIG “Final Waivers in Connection With the Shared Savings Program” 76 Fed. Reg. 67992; CMS “Medicare Shared Savings Program: Accountable Care Organizations” 76 Fed. Reg. 67802.

^{cxi} OIG “Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute” 71 Fed. Reg. 45110 (August 8, 2006); CMS “Physician Referrals to

Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangement” 71 Fed. Reg. 45140 (August 8, 2006)

^{cxii} OIG, 71 Fed. Reg. at 45151-2; CMS, 71 Fed. Reg. at 45151.

^{cxiii} OIG “Electronic Health Records Safe Harbor Under the Anti-Kickback Statute” 78 Fed. Reg. 79202 (2013); CMS “Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships: Exceptions for Certain Electronic Health Records Arrangements” 78 Fed. Reg. 78751 (2013).

^{cxiv} OIG, 78 Fed. Reg. at 79216; CMS, 78 Fed. Reg. at 78765.

^{cxv} OIG, 78 Fed. Reg. at 79216; CMS, 78 Fed. Reg. at 78766.

^{cxvi} Office of the Inspector General. October 6, 2015. OIG Policy Reminder: Information Blocking and the Federal Anti-Kickback Statute. <http://oig.hhs.gov/compliance/alerts/guidance/policy-reminder-100615.pdf>.

^{cxvii} 80 Fed. Reg. 68126 (Nov 3, 2015).

^{cxviii} Public Interest Committee, American Health Lawyers Association (AHLA). White Paper: A Public Policy Discussion: Taking the Measure of the Stark Law (“AHLA White Paper”). 2009; 21: 14-16. <https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf>

^{cxix} Paulhus ME. The Medicare Anti-Kickback Statute: in need of reconstructive surgery for the digital age. *59 Wash. Lee L. Rev.* 2002: 677; 706-07.

^{cxx} Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”), Pub. Law 114-10, 129 Stat. 87, § 512(b) (Apr 16, 2015).

^{cxxi} Public Interest Committee, American Health Lawyers Association (AHLA). White Paper: A Public Policy Discussion: Taking the Measure of the Stark Law (“AHLA White Paper”). 2009; 21: 13, 21. <https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf>

^{cxxii} Health Insurance Portability and Accountability Act of 1996, Pub. Law 104-191, 110 Stat. 1936 (August 21, 1996).

^{cxxiii} The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

^{cxxiv} The Office for National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

^{cxxv} The Sequoia Project. 2015. A Framework for Cross-Organizational Patient Identity Matching Available Now for Public Comment. <http://sequoiaproject.org/framework-for-cross-organizational-patient-identity-matching/>

^{cxxvi} Audacious Inquiry, LLC. February 7, 2014. Prepared for the Office of the National Coordinator for Health Information Technology. Patient Identification and Matching Final Report.
https://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf

Mr. HURD. Thank you, sir.

Mr. Savage, you are recognized for 5 minutes.

STATEMENT OF MARK SAVAGE

Mr. SAVAGE. Good afternoon, Chairman Hurd, Ranking Members Lieu and Cartwright, and distinguished committee members. Thank you for the opportunity to testify today.

I am Mark Savage, director of health IT at the National Partnership for Women and Families, a nonprofit, nonpartisan organization that for 45 years has worked to improve the lives of women and families. We are deeply invested in improving the value and experience of health care and ensuring that new models of delivery and payment help make consumers partners in their care with access to the right care at the right time.

I am delighted to be able to share today the values, experiences, and needs of patients and consumers who are using health information technology, such as online access and electronic data-sharing with doctors to improve their health and care.

The national partnership leads the Consumer Partnership for eHealth coalition and can speak broadly to the great opportunities that health IT presents and the obstacles that still make it difficult to realize its full potential.

Health IT is the essential infrastructure for improving quality, care coordination, and value in our health care system today.

It is a critical tool for engaging consumers who clearly recognize its value, according to a national survey we commissioned in 2014. We found that nearly 9 in 10 patients with online access to their health information use it. Notably, people who use online access frequently are much more likely than infrequent users to report that health IT motivates them to improve their health.

Patients recognize that health IT is essential to improving their access to care, as well as their access to their health information. They know what we know, that health IT helps patients and family caregivers communicate with their health care providers, share information and manage their care; improves patients' knowledge of their health and empowers them to take charge of their care plans; allows patients to correct errors or outdated information in their medical records, such as a missing drug allergy; enables patients to share treatment outcomes, such as pain levels, functional status, and whether their health improved after the office visit; helps health care providers answer questions from patients by secure email and provide care with telehealth and see the patients who need the most; gives patients more control over how much personal medical information is shared and how it is used; and much, much more.

Like electronic access in so many other parts of our lives, such as banking and retail, health IT enables real-time access to care and information, and provides individuals with the convenience and control they need and expect in the 21st century. Health IT can also enhance patient trust and the privacy and security of patient data through encryption and other means.

The country has seen a rapid increase in health care providers' adoption and use of health IT in recent years, but much work remains before the potential benefits reach all patients. We have an

urgent imperative to break down barriers and continue the progress.

First, that begins with removing barriers to health information. The national partnership runs the Get My Health Data campaign, and, through it, we have learned that many patients continue to face astonishing barriers to getting their digital health records from their health care providers. We need to change that by advancing policies and programs that promote patients' online access to and use of their health information.

Second, we need to clarify privacy and security requirements for sharing health data, because confusion persists about patient access rights. That means, for example, adding proactive education initiatives about what HIPAA requires and what it does not, and encouraging mobile app developers and technology vendors to post their privacy policies and data-sharing practices in standardized ways.

Third, we need to enhance the usability of health information so that when patients access their medical data, they can understand and use it. For example, innovative apps could help patients organize their health information in ways that they find most useful.

And fourth, we need to bridge existing digital divides to help identify and reduce disparities in care. That means, for example, promoting online access to health information across diverse communities, and innovation in mobile apps can help.

In sum, patients and consumers applaud the progress to date and they need more. Patients have a unique vantage point for they are at the center of the health care and information-sharing we are all working to improve.

Our goal must be to leverage health IT so it helps patients become real partners in their care and health. Only if we do that will we realize the full promise of health information technology. Thank you very much.

[Prepared statement of Mr. Savage follows:]



**Testimony of Mark Savage
National Partnership for Women & Families**

**HEARING ON
OPPORTUNITIES AND CHALLENGES IN ADVANCING HEALTH INFORMATION TECHNOLOGY**

**U.S. House of Representatives
Committee on Oversight and Government Reform
Subcommittee on Information Technology and
Subcommittee on Health Care, Benefits, and Administrative Rules
March 22, 2016**

Good morning, Chairmen Hurd and Jordan, Ranking Members Kelly and Cartwright, and distinguished committee members. Thank you very much for the opportunity to testify here today.

My name is Mark Savage, Director of Health IT Policy and Programs at the National Partnership for Women & Families. I am delighted to be with you today to share the values, needs and experiences of patients and consumers as they use health information technology (or health IT) to improve their health and care. After all, patients and family caregivers are at the center of the health care and information we seek to improve.

The National Partnership is a national, non-profit, non-partisan organization that, for 45 years, has worked to improve the lives of women and families across the country. We represent individuals across the country who are the health care decision-makers for themselves and their families and who want and deserve affordable, high-quality health care services. We are deeply invested in improving the value and experience of health care and committed to ensuring that new models of health care delivery and payment help women and families be partners in their care and have access to the right care at the right time.

Because health IT is now the essential infrastructure for needed improvements in health care quality and value, the National Partnership has a dedicated health IT team and serves as a leading consumer voice with great expertise about patients' and consumers' needs and experiences with health IT. We represented the patient and consumer perspective in development and implementation of the HITECH Act. We lead the Consumer Partnership for eHealth, a coalition of more than 50 leading consumer groups working at the federal, state and local levels to advance private and secure health IT in ways that measurably improve the lives of patients and families.

Today, I am here to speak to the great opportunities that health IT presents to help patients and family caregivers partner with their health care providers to improve care, and to the remaining obstacles to realizing the full potential of an electronic health ecosystem.

Why Health IT Matters to Patients and Consumers

Improving the Quality and Value of Care

Electronic health information exchange is fundamental to improving quality, care coordination and value for our health care system. New models of care require the ability not just to share data, but to integrate relevant individual and population data across various sources (e.g. doctors, hospitals, laboratories, pharmacies, registries and patients).

Patients likewise recognize and value the great benefits of health IT to their clinical care. According to a nationwide survey released by the National Partnership in December 2014, patients overwhelmingly believe that electronic health records (EHRs) are essential to making sure providers have timely access to information that can help avoid medical errors and repeat tests.¹

Engaging Patients as Partners in their Care

Consumers experience significant direct benefits from the use of health IT. Health IT can make it easier for patients and their family caregivers to access care and information, navigate the health system, and communicate with their providers to better manage their own health or care for a loved one.

Health IT is a critical tool for engaging patients in ways that empower them to partner in their health and care. Technology facilitates patient access to their medical information so they and their families can make informed decisions, in partnership with their care providers, about treatment and health that reflect their needs, values and preferences.

Like electronic access in so many other parts of our lives, such as banking and retail, health IT enables real-time access to care and information, providing individuals with the convenience and control they need and expect in the 21st century.

- **Access to CARE:** Health IT transforms the environment, expanding patient access to care from what, for many, was access only during the occasional 10-minute office visit to **access to care anytime and anywhere needed**. For example, the effective use of telehealth services could improve access to care and enhance timely treatment and support. Telehealth is just one example of innovation in health information technology that can support patients and families in their own health and care.

¹ National Partnership for Women & Families, *Engaging Patients and Families: How Consumers Value and Use Health IT* (Dec. 2014), available at <http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf>.

- **Access to INFORMATION:** Online access to health information helps patients and family caregivers do things like share information with their providers and manage their care across multiple doctors. For example, health IT makes it possible for a patient who needs surgery to send her test results to another doctor for a second opinion. Or a daughter or son caring for parents in another state can keep up-to-date on their medications and treatment recommendations, with health IT.

Patients already recognize and value these benefits. That's why almost nine in 10 patients who have such access use it. Online access to health information can also help patients set and achieve personal health and wellness goals, which is particularly important for those managing chronic health conditions. Notably, **people who use online access to their health information more frequently are much more likely than infrequent users to report that it motivates them to improve their health.**

Digital Tools that Help Patients and their Providers

Improving Communication and Coordination

Online access to health information improves patients' ability to communicate with their doctors and improves their knowledge of their health, according to our national survey. Secure email messaging enables patients to communicate with their doctors in timely and efficient ways; to correct inaccurate or outdated information; and to share treatment outcomes, such as pain levels and functional status.

In addition to promoting safe and appropriate care, electronic communication can benefit providers as well as patients by offering more efficient means to address patients' and caregivers' questions and concerns electronically, allowing more in-person interaction with providers for patients who need it most.

One program that has helped significantly to bring online access and timely two-way information sharing to patients across the county is the Electronic Health Record ("Meaningful Use") Incentive Program. In 2017-2018, Stage 3 will provide critical new tools to support coordination and interoperability between patients and their providers—for example, access through Application Programming Interfaces (APIs) so that patients can access and coordinate their health data with new tools such as smartphone applications (apps) and other devices. Private-sector innovators can develop new apps that make patient health data more accessible and useful to patients and providers alike.

The National Partnership asked people to share in just six words why all patients need easy online access to health information and secure ways to email their doctors. People across America shared their six-word stories. Here are three:

- **"Second opinions matter. Information prevents redoing."**
Kathryn B., California
- **"Had cancer. Information helpful. Removed doubt."**
Debbie G., Illinois
- **"Shared accurate records save patients' lives."**
Eloise D., Pennsylvania

Enhancing Privacy Protections

A foundation of strong security and privacy protections is essential to public trust and the ultimate success of health IT. While people continue to be concerned about the privacy of their health information, those concerns are increasingly understood in the fuller context of the benefit of EHRs and electronic health information exchange. Indeed, health IT provides opportunities for *enhancing* the privacy and security of patient data, including encryption of electronic personal health information and electronic audit trails.

Health IT can also give patients more control over how their personal medical information is used. Different people may deem different kinds of health information to be especially sensitive, such as psychotherapy notes or substance abuse information. Continued development and testing of approaches that enable patients to segment their data and direct which care team members can see certain information can enhance consumer trust and use of electronic health information exchange.

Patients' online access to their health information can also improve trust. Our survey found that patients who use online access more frequently have significantly greater trust that their providers will protect their privacy and other rights than patients who use online access infrequently or never use it. Accessing and seeing one's electronic medical information is a significant factor in increasing patients' trust that their information is safe and that their doctors are protecting their privacy.

Key Actions to Leverage Health IT and Improve Health Care

The country has made substantial progress in the past few years, including a rapid increase in adoption and use of certified electronic health records (97 percent of hospitals, and 74 percent of office-based physicians through 2014²). For patients, their online access to their health information has doubled in three years, increasing from 26 percent in 2011 to 50 percent in 2014, according to our national survey. This adds up to profound and very welcome change. However, much more work remains before the benefits and opportunities of health IT will reach all patients.

To move to a system where patients' access to and use of their health care information is the norm, we must break down barriers on a variety of fronts. None of these actions require legislation; they can be done through federal guidance or assistance that further spurs private sector innovation, by public-private collaboration and by industry advancements. The following recommendations reflect what we have heard from consumers across the nation about their experiences getting and using their health information.

(1) Address barriers to access to important health information

Consistent with our commitment to improve consumer and patient access to their health information, we worked with leading technology, consumer and provider organizations to convene the GetMyHealthData campaign. GetMyHealthData is

² Office of the National Coordinator for Health Information Technology, *Report to Congress on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information* (Feb. 2016), pp. 27-28.

dedicated to making it easier for patients and families to request their medical records and other health information, and to use their data to improve their care and health. In leading the campaign, the National Partnership has learned a lot about what the process of getting and using health data is like in the real world. We have learned from our volunteers that, despite longstanding policies designed to improve access to health information, patients continue to face many barriers to getting electronic copies of their medical records and other health data. Too often:

- Accessing health information is a confusing and difficult process for patients.
- Confusion surrounding HIPAA persists, and both providers and patients misunderstand patients' rights to access their health information. This often means that patients do not get the access to information they need for themselves or a loved one, despite their rights to their health data.
- Unreasonable fees for copies of health records pose barriers to patient access, further impeding their ability to get and use their health data.

Accordingly, the campaign has worked to bridge these gaps by developing innovative tools and guidance to make it easier for patients and families to request access to and use their health information.

Key actions to remove barriers to access:

- Public and private-sector efforts need to advance policies and practices that promote patients' online access to and use of their health information.
- Public and private-sector efforts to address interoperability among health IT systems and users must **explicitly include consumers as equal users** and address operational and technical barriers that impede the ability of patients and family caregivers to send, receive, find and use their health data.

(2) Clarify privacy and security requirements for sharing health data

One significant point of friction in patients' access to their health information is providers' and patients' **misunderstanding of patients' access rights**.

Key actions to clarify privacy and security requirements:

- Policies to promote patient access must be supplemented with comprehensive and proactive education initiatives to enhance understanding of patients' rights to their electronic health information and providers' responsibilities when responding to patient requests.
- Mobile app developers and other technology vendors should join voluntary efforts to post their privacy policies and data sharing practices embedded in their products in standardized ways. This will help consumers quickly and easily compare such policies and practices (such as whether the developer sells consumer data for marketing or pharmaceutical research).

(3) Enhance the Usability of Access to Health Information

Even when patients can access their medical data, the data may be difficult to interpret, use and translate into meaningful and actionable information that can inform their care or the care of loved ones. Does a particular blood test value mean that one is healthy or that one needs care? Health data often need context, explanation or interpretation to help consumers understand their meaning.

Key actions to improve usability:

- Public and private entities, including technology and app developers, should work together to improve the usability of patient health data so that, for example, consumers and patients can incorporate their data into apps that display the data in formats and with options that consumers find meaningful, useful and actionable.

(4) Bridge the Digital Divide

Barriers to electronically connected and coordinated care tend to be even greater, for example, in rural and underserved communities, and for the 60 million Americans with disabilities and the 60 million who speak languages other than English. We need to design and build digital health tools for patients that reflect their diverse needs and bridge existing digital divides.

Key actions to bridge digital divides:

- The public and private sectors should improve and promote online access to patient health information across all communities, and remove the barriers that impede access and use for too many people today. Innovation in mobile apps can help. The more consumers across diverse communities can share information that reflects their needs and experiences, the greater potential we have to identify and ultimately reduce disparities in care. Additionally, public-private partnerships are an important component of increasing broadband adoption.

Patients have a unique vantage point: They see multiple providers and thus know whether their care is being coordinated. They know whether they have to provide the same information over and over again, or whether tests have to be repeated because the results were lost or inaccessible. They can spot and correct errors in their medical records. They know and can report the many factors outside the clinical setting that are integral parts of their health and care, such as the family caregivers who assist them, the community resources they access and the social determinants that affect their health. **Taking the steps described above, we can leverage health IT to enable patients to contribute all of these critical resources as partners in their care.**

Mr. HURD. Thank you, Mr. Savage.

We are going to keep going. We are expecting votes in about 10 to 15 minutes, so we will try to get through as many members' questions as we can.

To kick us off this afternoon is the distinguished gentleman from North Carolina, Mr. Walker.

Mr. WALKER. I thank you, Mr. Chairman.

I appreciate the panel being here today and taking your time and being really a valuable resource for us.

I married into the medical community. My wife is a family nurse practitioner at Wake Forest Baptist Medical Health Center. Every time I feel like I have, by osmosis, learned more medical knowledge, after 23 years, she reminds me that I don't really have a good base of understanding.

But this is something that concerns. I remember even as a minister for 2 decades sometimes trying to get information about a patient to family members or to others, and trying to figure out how we can meet those needs. Sometimes there were problems to do that, even good laws.

I also want to paint a picture here of some friends. I recently tagged along with a surgeon there in Moses Cone Hospital in Greensboro that has been so burdened with some of the software and some of the regulation. It has impacted him negatively, as well as other physicians who have talked about this.

So I want to address a couple of these issues. Maybe, Mr. DeCrescenzo, if I could start with you, you both mentioned in your testimony obstacles. You also mentioned the word "barriers." Talk to me for just a minute, if you would, about what specifically are the obstacles and barriers to getting where this needs to go.

Mr. DECRESZENZO. I think some of the barriers and obstacles, Representative, are some of the things that I mentioned and some of the other folks here on the panel.

First of all, there is a lot of activity underway around collaboration in the industry, but it is one that we think needs to be supported broadly. We have both private sector and combined private sector and government initiatives, things like the CommonWell Alliance, the Sequoia Project. There are technical standards from committees like HL7 that are trying to push the ball forward to make these systems talk to themselves, to each other, a lot more adeptly and easily than they have historically.

I think support for that, as exhibited by the ONC report that came out last year, to push us down a roadmap where those efforts can be channeled into a way that they ultimately come to a harmonized approach between the State regulations and laws and standards, Federal, State, Federal laws, regulations, and standards, and private sector initiative, really is one of the ways that we can make the most against some of the obstacles and barriers that exist today where the systems don't have those standards to make it easier for them to talk to one another.

Mr. WALKER. Thank you for responding to that. Are you familiar with the Press Ganey scores?

Mr. DECRESZENZO. The patient satisfaction scores.

Mr. WALKER. Exactly right. I want to make sure that we are also being an advocate for the health care providers, that we don't put

these guys in a bind. In fact, earlier this morning, we had a very passionate hearing—compassionate, I should say as well—as far as the heroin and opioids. And we know sometimes patients can be very manipulative in this process.

Can you take a moment, Dr. DeSalvo, and speak to that to make sure, as we move forward with this, we are not putting our providers in a more vulnerable position?

Dr. DESALVO. Thank you for the question, Congressman.

As a doctor, I know full well the challenges of making sure that you are being compassionate but also being evidence-based in the practice of medicine.

I wanted to touch on the patient access piece, because you mentioned it, and it is so critically important. The electronic health information is theirs. They have the right to access it. And we have worked with the private sector to see that we are creating innovative ways that they have more ready access to that information, so they can make their own care decisions, but also it can be available in the care setting.

As an example, just in the last few months, working with the Office of Civil Rights, who has the primary responsibility for HIPAA access, put out some guidance directed at consumers, so that they would know what they have the right to access. This is a common refrain that we hear from consumers but also from docs who want to make sure that the information is getting out.

In the space of opioids, as an example, we certainly want to make sure that we are doing everything to support clinicians on the frontlines.

My husband is an emergency medicine doctor, so this is a very everyday occurrence for him. The tools like PDMPs, the prescription drug monitoring programs that are electronic in many States and have really made it easier for us to access information to make sure that we are appropriately giving opioids to people who have pain, are needed, but also trying to help folks stay out of trouble.

We have been working with SAMHSA and with States and with the industry to see that those become more aligned within electronic health records, so you don't have to go to another place and sign on. That's an added burden.

Mr. WALKER. Before my time expires, let me also look at this. Health care certainly is very important as we move forward in having the right perspective. As a Member of Congress, we also have a financial fiscal responsibility as well. We spend more than \$2,000 per patient than any other country in the world.

Can we make a case out of this that is something that can drive us to be more health care cost conscience as well?

Mr. QUINN OR MS. Rich, would one of you like to address that?

Mr. QUINN. I will use as an example Intel's Connected Care program. Where Intel, as a large purchaser of health care on behalf of its 53,000 employees in the U.S., said how can we make our employees the healthiest in the country, retain them, and also try to save some money doing it?

We have been very successful in the first two. The third has been more challenging, although there has been a great progress there.

The key to it, I would say, and this is also the key potentially for driving data-sharing and information-sharing in our broader

health care system, is focusing on value-based care, rather than fee-for-service. That was the engine that drove this, and we have seen a massive amount of actual use of this health information exchange because, of course, the technical pieces are there with the Sequoia Project and building this, but also the incentives for using it are there for the health care providers.

Mr. WALKER. Thank you, Mr. Quinn.

I yield back, Mr. Chairman.

Mr. HURD. The plan is to go to Mr. Connolly, and then we will go into recess to get to votes.

I now recognize the gentleman from Virginia, Mr. Connolly, for 5 minutes.

Mr. CONNOLLY. I thank the chair.

And I thank Mr. Lieu and Mr. Cartwright for their gracious consideration. Thank you so much. I have seven hearings in a day and half, so I'm running back and forth.

Mr. Quinn, thank you for sharing your story. Boy, could I relate to that. Both of my parents are in their 80s, and I have witnessed scenes where one is in the hospital in the emergency room, and the other one is being asked to give the history, the medical history. I'm thinking, what could go wrong with this scenario? Thank God they are both alert and have mental acuity, but you know, memory sometimes fails us in moments of stress.

It is hardly an ideal system, and surely technology exists that would allow us to have a comprehensive picture of the patient in question without relying on human memory and such.

So I really related to what you had to say, and I hope your dad is doing well.

Dr. DeSalvo, picking up on Mr. Quinn's narrative, according to HHS's 2016 report to Congress on the adoption of health IT, your agency found that 97 percent of hospitals and 74 percent of physicians possessed a certified electronic health record system. But only 76 percent of hospitals and 42 percent of physicians with electronic health record systems were sharing the information for the coordination of care. Why that big gap?

Dr. DESALVO. Well, thank you for the question. I certainly identified with Mr. Quinn also, both as a doctor who takes care of those kinds of patients but also because of family members as well. So as I said in my opening, it is pretty personal to all of us to see that the data is moving.

The good news story in the data that you present is that, over the course of the last many years, we have dramatically increased not just adoption but the opportunity to move and share data. So those are snapshot numbers. But if you look back at the trajectory, every year it improves both for doctor offices and hospitals. We are not where we want to be yet, but we are making progress.

There are areas like the national capital region where health information exchanges like CRISP make that data available, such that if somebody arrives in an emergency room, their primary care doc will get a ping and be able to have the opportunity to send that med list or problem list, so that we will actually know more about the person in the ER.

There are even more exciting advances happening, like in Mississippi, where the State of Mississippi has been working with local

vendors to see that all of long-term data from their Medicaid program is available to the doctors in the University of Mississippi Medical Center, so that when somebody arrives, you have a picture like you mentioned.

Mr. CONNOLLY. You mentioned CRISP, but doesn't that require a voluntary decision to participate?

Dr. DESALVO. You are touching on the challenge that has emerged since we have been adopting electronic health records and moving to a digitized system, and that is that State laws vary, and so there is a need to harmonize that.

Mr. CONNOLLY. Right. That is a particular challenge here in the national capital region, since we have three jurisdictions with three different political cultures and sets of laws and so forth.

I have actually encountered that, where Maryland has one set of standards on this kind of communication and Virginia has another, and we are not always talking, which what could go wrong with that for someone's health? I mean, you could jeopardize someone's health without intending to.

Now, do we need, from your point of view, and I welcome Ms. Rich as well, or anyone else, but is this a case where, frankly, we do need to look at some Federal legislation?

We regulate blood supply for safety. Well, electronic record-keeping is not just a nice thing to have. In the digital age, it may be very critical to someone's health and the care they get, especially in an emergent situation.

Dr. DESALVO. In the short run, we have been working, the Office of National Coordinator, with the National Governors Association on developing a toolkit so States themselves can harmonize their privacy expectations, so that won't be an unnatural impediment to information flow.

Over the long term, clearly, the health IT landscape has changed a lot since HITECH was passed in 2009. We were on iOS 3 then and now we are up to 6, just as one example. But apps and cloud computing have really evolved.

So we certainly are leveraging all the opportunities that we have at ONC and our partners, the Office of Civil Rights and other agencies, to see that we are protecting consumers and that data is going to flow. But there are areas where we know that there may be some opportunity, like information-blocking, where we would need some additional support.

Mr. CONNOLLY. Thank you so much for this fascinating conversation.

Again, Mr. Chairman, thank you.

Mr. HURD. Sure.

Votes have been called. The committee stands in recess until immediately following votes.

[Recess.]

Mr. HURD. The Committee on Oversight and Government Reform Subcommittees on Information Technology and Health Care, Benefits, and Administrative Rules will get started again.

I appreciate our witnesses' and guests' patience as we went to go vote. We shouldn't be interrupted.

To get us restarted is my friend from California, Mr. Lieu. You are recognized for 5 minutes.

Mr. LIEU. Thank you, Mr. Chair.

Dr. DeSalvo, in your opening statement, you mentioned data-blocking. Can you explain what that is and how it works?

Dr. DESALVO. Yes, certainly, Mr. Lieu. Thank you for the question.

Congress asked us to provide a report on health information-blocking, which we did last April. We thank you for that, because it generated a national conversation and set into motion some actions that we have been taking in partnership, for example, with the Office of Inspector General, also with the Office of Civil Rights, to see that we unblock data that has been collected in electronic health records.

This is a new challenge we wouldn't have had years ago when we did not have a digitized system. It has emerged since 2009 when the HITECH Act put ONC and our authorities into place.

An example of it would be that I'm in a health system and my patient records have been collected or digitized, and a patient ends up in the emergency room at another hospital across the street, and for whatever reason I'm not sure I can share it, because I don't understand HIPAA, or maybe I don't have a business associate degree that I think you need to have to share data. And so when that patient shows up across the street literally, the data is not moving. And it is just because of a lack of understanding.

So that would be sort of an unknowing example. And by educating about HIPAA, which is something we have been actively doing, we hope to unblock that sort of data.

Sometimes it is more around business practices. People want to hold onto patients or hold onto data and don't share it.

So we have asked and gotten pledges from the health IT industry to say they won't block data. Now we are acting on making sure that we can put some teeth to it.

But if I may, Congressman, it is an area where, since 2009, the world has really evolved. That is why in our budget request, we did put forward a proposal asking for some more opportunities for us to be able to address blocking, and to see that, where data could move, that it would.

We really welcome the chance to talk with you more about the ways that we think we could have more opportunities to address it.

Mr. LIEU. Just so I understand, sometimes you have data-blocking because the doctor or hospital may not have interpreted HIPAA correctly. Are there times where, in your opinion, they are intentionally doing it to gain a competitive advantage?

Dr. DESALVO. We certainly heard plenty of reports about the use of it to gain a competitive advantage.

Mr. LIEU. What about vendors? Do vendors sometimes do that as well?

Dr. DESALVO. Occasionally. The way that will occur with vendors is they will require added fees, unexpected fees, to create the interfaces, and that is a form of lack of transparency but can also be a form of blocking.

Mr. LIEU. And in the HITECH law, do you believe there are gaps that could address this? What can this committee or Congress do to help on data-blocking?

Dr. DESALVO. Yes, sir.

What we have asked for as part of our budget request are some additional opportunities around defining it and giving us an opportunity to require that vendors, for example, can't use gag clauses to prevent providers from talking about some of the contractual elements. Those are just a couple of the examples that we've asked for.

So, yes, we do believe that, since the world has evolved, there is a new need for us to have some additional opportunities to protect the people who are using the systems and, more importantly, to protect the data of the consumers.

Mr. LIEU. Let me switch to cybersecurity.

Hollywood Presbyterian Hospital in Southern California had been attacked with malware. They had to give a ransom to get their data essentially unencrypted, unblocked. Two more hospitals, it was disclosed, were recently attacked in Southern California.

What do you think we can do to help prevent those attacks?

And my understanding is that it is the Office of Civil Rights that does cybersecurity?

Dr. DESALVO. That's correct.

Mr. LIEU. And do you think that would be the appropriate office or not?

Dr. DESALVO. The Office of Civil Rights does have the primary responsibility for privacy and security, and for security breach investigations. We work with them in a variety of ways to see that we are educating providers, clinicians, and others to make sure that the functionalities, the capabilities in electronic health records that we require to keep the data secure, are actually used in the field.

We all know that there is a mix of both physical and cybersecurity expectations, so tools like our security risk assessment tool is a way that we educate providers to know in a simple way how they can protect the data that is in there. So there are some opportunities that we leverage, but we work largely in partnership with the Office of Civil Rights.

Mr. LIEU. And does that office have a team of computer folks that deal with cybersecurity issues?

Dr. DESALVO. It is very tight partnership. They certainly have experts in the area of HIPAA and cybersecurity and privacy, and we work very hand in hand with them.

We, for example, recently released some additional guidance for providers but also for consumers about access and security, and have posted a series of joint blogs to make sure there is a shared understanding of what security expectations there are.

You all, for example, asked the department to put together a cybersecurity task force, and we have been working along with others across the department to see that we put together that task force. It just met for the first time last week, so we thank you guys for raising that issue.

Mr. LIEU. Thank you. I yield back.

Mr. HURD. I would like to pick up where Mr. Lieu left off. So in OCR, they have lawyers so they understand HIPAA. Do they have technical folks that can actually help with a breach or the next ransomware attack?

Dr. DESALVO. Congressman, I would not want to speak specifically to the skill sets of their staff. What I can share with you is that the Office of the National Coordinator, which has technical staff, partners very tightly with the Office of Civil Rights, just like we do with other agencies, to make sure that we are bringing that talent to the table if it is necessary.

Part of this task force as an example, which is with the private sector, is to bring together the best minds in cybersecurity and to work with not only ONC but OCR to see that we are helping to advance the health care marketplace to adjust to any new changes they need to in cybersecurity.

Mr. HURD. Ms. Rich, why is there so much confusion around HIPAA?

Ms. RICH. I can't speak to why there is confusion around HIPAA, but I do know that there are many entities that are outside of HIPAA that are under our jurisdiction, and that includes all the health apps and the Web sites that take in consumer-generated information, and that consumers may be confused about whether there is a regulation that protects their privacy in those areas, which is one of the reasons why we think there ought to be a regulation that protects the privacy and data security for the information collected by those entities directly from consumers.

Mr. HURD. Does FDA have responsibility in some type of regulation in this space?

Ms. RICH. The FDA regulates medical devices, and that includes some health apps. But generally, they are looking at safety issues surrounding whether the app does what it says it does. The privacy and data security issues of such entities is generally in our care. And we have been working in this area for over 15 years, and we have an extensive program to look at the data security of these entities and take action—well, educate them to start with and then also take action in appropriate instances.

Mr. HURD. So if it is a HIPAA violation, that is OCR's jurisdiction. If it is generally something else, it may be you, it may be FDA, it may be SAMHSA, or the PPACA. There are so many of these different regulatory bodies, and my fear is that it is hurting innovation. It is hurting the proverbial two guys or two gals in a garage from creating something that can change the way that we deliver health care.

Ms. Rich, I will get back to you on another question.

I wanted to ask Messrs. Quinn, DeCrescenzo, and Savage, and then, Ms. DeSalvo, you answer after them, meaningful use, this is a term that I have been hearing a lot over the last 16 months that I have been in Congress and how it was originally designed to kind of spur companies from participating in EHR programs. But what I am hearing is that it is actually getting in the way of innovation.

I would like for you three gentlemen to comment on your opinions on meaningful use. And, Ms. DeSalvo, I will let you be the cleanup batter.

Mr. Quinn?

Mr. QUINN. So meaningful use was quite successful in driving adoption of electronic health records. Without meaningful use, we wouldn't have the rates of adoption today that we see.

As is the case with my dad's example, that each individual health care organization has an electronic health record and may be beginning to exchange data doesn't mean that the net result of it is the coordinated care, the shared health information, that we all need. And the prescriptiveness of this led some vendors and health care organizations to play to the test.

What we need is to think ahead about the next generation of technology that is needed to embrace, for example, the Internet of Things, consumer-generated health data, the data that is being unearthed with the genome, and these other sources, and incorporate them into this so that we are not just thinking about this program as an end unto itself, but as an enabler of new technologies, new care models, et cetera.

Mr. HURD. Thank you.

Mr. DECRESSENZO. Thank you, Mr. Chairman. I would certainly second Mr. Quinn's opinion that meaningful use as it has been affected in the last few years to dramatically increase use of the EHRs, as Dr. DeSalvo mentioned earlier, in addition to some of the new technologies that you mentioned, need now to be considered, and also suggest that over the last 4 or 5 years under meaningful use, we have learned a lot about how technology is used and what are some of the other process and incentive issues, including things like reimbursement mechanisms that may or may not incent further use of electronic medical records and other types of electronic digitization of health information in a sharing around that.

So going forward, we believe that we need to be thoughtful about what we have learned over the last 4 or 5 years, as we look at additional regulation or requirements for expanding the use of electronic medical records and allied technologies.

Mr. HURD. Mr. Savage?

Mr. SAVAGE. We agree that the meaningful use program has been a major catalyst for improved adoption and use of health IT. Patients have been seeing a lot of the benefit of that. As I said in my testimony, there are still obstacles to overcome, and more needs to be done.

But with the meaningful use program in our surveys, we saw a doubling of online access from 2011 to 2014, from 26 percent of patients with online access to 50 percent.

We see them using it for the kinds of things that are really critical for delivery system reform that is coming. So the access is important, but the meaningful use program is also in 2017 to 2018 to provide much more robust functions around patients sharing data with their providers, nonclinical data that is nonetheless relevant to care, better correction of errors, wearables, remote monitoring. And it will, indeed, stimulate the kind of innovation that we are all looking for.

The version that is coming up also has APIs. We have tech developers who are writing apps for using those APIs.

So important catalyst. Critical things are coming for patients and family caregivers to help them with their care planning.

Dr. DESALVO. Thanks to these folks, I'm just going to talk about going forward, because the health IT landscape and health care has absolutely been changing and evolving. We are looking to go forward after listening to providers, after seeing where the health IT

landscape is, to take the opportunity that was made from the doc fix or the MACRA legislation and make this program going forward more flexible, much more focused on clinical outcomes and on interoperability.

Mr. HURD. Thank you.

Mr. Cartwright, you are recognized for 5 minutes.

Mr. CARTWRIGHT. Thank you, Chairman Hurd.

I want to follow up that discussion with Mr. Savage a little bit. I think a cornerstone of the health IT field are the electronic health records, the digital version of a patient's paper chart containing not just the patient's current condition but also his or her medical history.

I have here, it looks like a Harris poll that NPWF commissioned. Is that correct, Mr. Savage?

Mr. SAVAGE. That is correct.

Mr. CARTWRIGHT. So this is entitled, "Engaging Patients and Families: How Consumers Value and Use Health IT."

I will ask that this be made a part of the record, Mr. Chairman.

Mr. HURD. So moved.

Mr. CARTWRIGHT. It is a result of the Harris poll. I cannot imagine how long this poll went, Mr. Savage, but it's pretty hefty.

It was done in the spring of 2014, correct?

Mr. SAVAGE. Correct.

Mr. CARTWRIGHT. Toward the end of it, there is a global summary. And it showed that more than 50 percent of patients want the ability to review their treatment plans, right?

Mr. SAVAGE. Correct.

Mr. CARTWRIGHT. And that nearly 60 percent wanted to see their doctors' notes, and that fully 75 percent of patients wanted access to their test results electronically.

Have I got that correct, Mr. Savage?

Mr. SAVAGE. Yes, we found great interest in all of those.

Mr. CARTWRIGHT. So that is the sort of information that would be available in an electronic health record, correct?

Mr. SAVAGE. Yes.

Mr. CARTWRIGHT. Okay. Is it easy for patients to get access to their electronic health records right now?

Mr. SAVAGE. The survey that you are referencing does identify increased numbers of access, doubling from 26 percent to 50 percent. For those who have it, it has become easier, but the national partnership has also done work with the Get My Health Data campaign, which has found that there are also people without the access that they need and that there are some barriers.

So I can either talk about on the survey side, or I can share with you some of the barriers we found with the Get My Health Data side.

Mr. CARTWRIGHT. The barriers I'm interested in.

Mr. SAVAGE. We have tracers, volunteers who report to us their experience with trying to get data, and everybody's story is unique. But we do find some commonalities among those stories.

Some of the significant barriers are a very complex, time-consuming process in order to get access. So you and I, in order to get access to our banking records, we just go down to an ATM or access

it through the Internet. That is not a time-consuming process, for the norm.

But for access to health records, yes, it has been very time-consuming for these individuals.

Records provided in a format that is not useful. You may ask for it in an electronic format. You get a piece of paper by snail mail.

Misunderstanding of what patient's rights to access are.

And perhaps one of the things that we've discovered most recently is the use of unreasonable fees in order to—before you can get access to your records. That may take the form of you have asked for your information and, sure, here's the copy and here's the bill, and it is a bill that you never expected. Surprise. Or you are charged a per page fee when it is an electronic record.

So there's actually been—the Get My Health Data campaign has recommended that there be some comprehensive education initiatives to try to help providers and patients alike understand the requirements better.

And the OCR guidance that recently came out provides some examples of the kind of innovative education efforts that we really do need to see.

Mr. CARTWRIGHT. Dr. DeSalvo, pick up from there. What kind of examples?

Dr. DESALVO. So consumers have more access to their information than they did previously, though it is not where we think it needs to be. And as Mr. Savage mentioned in his earlier comments, we have been pushing through the meaningful use program and through other ways to get increased consumer access.

We, in fact, just put out a challenge grant through the Office of National Coordinator calling on the private sector to take advantage of this API expectation that we put in electronic health records to create very consumer-friendly apps that would be on a smart phone and allow somebody, any patient, to be able to access their health information and have more opportunity to control it. So we are really excited to see what the private sector is going to develop in the next few months to make it easier to get more access.

The kinds of examples that get in the way of that, technology certainly Mr. Savage mentioned, but they are sometimes just a misunderstanding of HIPAA. The Congressman had asked earlier why doctors don't understand HIPAA, and part of it is we are not really well-trained in it in medical school.

This is, I think, a really important opportunity that the medical education field has along the way to see that we understand what HIPAA is and is not, and do not let it get in the way. Also, the way sometimes it is enacted gets in the way of consumers having access to their information.

It is, in essence, a form of blocking.

So, again, back to this comment of, the world has really evolved and now there is data to be free, data to move. And the primary concern is to see that it is there for that clinical moment when you need it.

There are also many other important uses, so we are leveraging all the tools we have, whether that is education or clarity on rules and regs, but there's probably also some additional needed atten-

tion and maybe some additional support to see that blocking is never a reason that people do not get their data.

Mr. CARTWRIGHT. So last question, my sense of it is that the better access patients have to their medical records, the better we all are in terms of patient safety.

Does anybody disagree with that? Let the record reflect they are all shaking their head no, Mr. Chairman, and I yield back.

Mr. HURD. Thank you, sir.

I would now like to recognize Ms. Lujan Grisham for 5 minutes.

Ms. LUJAN GRISHAM. Thank you, Mr. Chairman. I think I probably want to take off from where my colleague was leading you all, Mr. Cartwright.

I actually think in addition to the blocking and misunderstanding that we have seen two principles in HIPAA be determined—and as an attorney, I feel bad about this—but sort of a legal opinion that you have two mutually exclusive premises. One, patient protection, and the other would be the portability of that information, and they err on the side they are absolutely in their minds mutually exclusive, so they go to privacy.

I just had this happen with a very large, very recently, health care provider who argued with me—and HIPAA, I spent a lot of time dealing with HIPAA, so it wasn't—I won, because the CEO of the health care company refused to provide the patient information from provider to provider.

Actually, I was trying to do them a favor, right? I have labs that are 45 days out. I get a patient who calls my office as a constituent and says I have to have them because my specialist can't do what they need to do without the records from this other provider. I said, let me just call, because I know I don't need really anything else, provider to provider, just do it. And basically I'm helping you, because God forbid we find something in those labs that indicate to your lawyers that you have a real liability.

And then second, they wouldn't do it, because HIPAA prevents that, as you all know it absolutely does not. For the audience, it does not prevent that. It explicitly provides for that.

Then in addition, to make it easy for them, I was willing to get the patient on the phone, with plenty of patient identifiers. And HIPAA, according to this provider, also explicitly prohibits not having someone where you have really restrictive proof that that is the patient. I said that is nowhere in there. That is your own system, which gets to that it is proprietary, it is not interoperable, and that while we are to doing I think great strides to make this information available, that unless we deal with that, you can't really create a patient record.

I have to have apps for, right now, let's see, I'm old, that would work with about 47 different providers. Now that I am lucky enough to have this job, I have to have to add all the providers that are in D.C. that I guarantee you do not speak to any of my providers in Albuquerque.

So that was a typical-for-me, long-winded statement that our intentions here and meaningful use and all the incentives and including many of the accountability mechanisms really haven't gotten us to what we really want, which is very effective patient records, because if we want patients to be part of problem-solving, and you

do. If I get access to my record, I find all kinds of stuff that my docs didn't see because they are busy. I feel bad about that. I love them. They are my docs, so I really like them, or my practitioners.

But they do not have the time to search through stuff, which is why every time you go, they have to do a whole new history because they have to ask me, because it is much faster. But what happens when about 20 years from now, I can't remember for a whole variety of reasons?

So what additional incentives can we use? And you sort of floated around many, right?

But I also want a milestone check, because I have also been working on telehealth for more than 2 decades. Quite frankly, the reimbursement issues and the other barriers really simply have not made it available in the places where the technology, not only in juxtaposition to physician consultations or physician-to-patient consultations, but now you have the ability to do incredible online diagnostics. And yet, we aren't really doing it.

So what are some really great milestones and mechanisms that this committee can help you achieve, to that end?

Anyone? All of you? Everyone?

Ms. RICH. I would just like to comment that I do think an obstacle to uptake on the part of consumers is concern about privacy, an obstacle to uptake of use of electronic records.

Regardless of what a lot of consumers think about privacy in other contexts, we do know that they care a lot about privacy when it comes to their health records, which can reveal truly personal information. So from the perspective of somebody that is talking about privacy, we would like to see stronger protections that make sense. Yes, it is a balance. Stronger protections for data —

Ms. LUJAN GRISHAM. Where do you see the balance? And nobody I think on this committee is making any sort of statement that we should reduce privacy protections. But when they become an obstacle—that does not diminish the protection of privacy, we have a really big problem here.

I gave you one illustration. There are many. But what is a milestone to not diminish the protections that we are all interested in, but to get us to real patient records, serious interoperability, not just provider to provider because of proprietary, but as you mentioned in an earlier meeting, within our hospital equipment, which creates huge patient outcome issues, that is not a privacy issue, and gets us to telehealth, all the different kinds of things I know that you all are promoting?

I don't know if the chairman is going to let me keep going. What a good guy.

Mr. HURD. Mr. Quinn can answer that question.

Mr. QUINN. I would say a wonderful milestone is getting to 50 percent alternate payment models by 2018, as HHS has proposed, and that Intel, eating our own dog food or, as my colleague says, drinking our own champagne, including in Albuquerque, where we have a huge facility —

Ms. LUJAN GRISHAM. We would like that to be bigger.

Mr. QUINN. Thirty-three-thousand employees are today participating in our Connected Care program. The real enabler of this is, of course, that there is something called the Sequoia Project that

makes interoperability possible in connecting 150 different EHRs, but more importantly, that we are directly contracting with the providers in that area and we have purchasing power.

We are doing this in Albuquerque. We are doing it in Portland. We are doing it in Arizona.

Intel is a big purchaser, and we said you are going to participate as part of this, and we are going to collect these metrics.

The same is happening on this national basis, this 50 percent. Fifty percent I think is a real tipping point, because you can't live in two different worlds. You can't live in the fee-for-service world and the alternate-payment world.

The sooner we can get there, the better. We can't let up on the accelerator.

Ms. LUJAN GRISHAM. Okay, thank you.

Mr. HURD. Thank you, Mr. Quinn.

Raise your hand if you have suggestions on how to harmonize privacy laws, and which privacy laws and regulations need to be harmonized?

Mr. Savage, your organizations don't have opinions?

Mr. SAVAGE. We do. We don't look at them as harmonization. We look at them as protecting privacy for patients in all the different States.

Mr. HURD. So I would like all of you all to submit those ideas, those white papers, to the committee for the record, so we can review those and see if that can be an area that we look at.

I would be remiss if I don't ask a cybersecurity question.

Ms. Rich, this is for you, and I am not interested in any particular company or something like that. What do you think is the biggest threat right now to health information and our citizens' health data?

Ms. RICH. There are a few. One is failure by companies still to take this as seriously as they should. There has been a lot of progress in recent years, but we are still seeing not enough attention focused on this issue.

Congressman Lieu also mentioned ransomware, which is something that is on the rise and is particularly on the rise when sensitive information is collected, because of the great interest in protecting that information, so the ransomware tactics are more likely to succeed.

We are seeing that more and more in our cases, and we are looking at this issue ourselves, and maybe doing something publicly on that.

But the number one issue is still the failure to pay enough attention to this issue, among many, many companies.

Mr. HURD. Mr. DeCrescenzo?

Mr. DECRESSENZO. Obviously, Ms. Rich has her perspective, what I think at the HLC, we are taking this very seriously. And we see across providers, payers, pharmacies, everybody who is part of HLC, an enormous amount of investment and forward-thinking on what to do about the problems that you described, for example, at Hollywood.

I think one of the challenges everyone needs to recognize is that we are also trying to constrain costs as much as practicable in the U.S. health care system. And all these things come at a cost. And

there is not necessarily as much freedom, or maybe should there be, to be able to capture reimbursement in order to reflect those costs.

So I think it is a very difficult barrier when you think of the resources that are applied anywhere from telecommunications to banking to other industries around cybersecurity, the fact that we have all described the importance of personal health information, and recognizing that many of these institutions, including many hospitals I'm sure in your districts, are already struggling to deal with a number of other aspects of successfully providing patient care.

So I think we certainly see people taking it very seriously. As I'm sure you're aware, many people go into the medical profession because they have that commitment to patients, their data, and privacy.

So I think one of the things we need to consider is how well is reimbursement reflecting the cost of doing a good job at it.

Mr. HURD. Ms. Rich, what has been the biggest fine that FTC has issued on a private company for violating our privacy? We don't need to know the situation, just what is the dollar amount? And can you describe the situation?

Ms. RICH. We actually, in the initial instance, don't have fining authority in the data security area in general. We do when it involves kids' information or consumer credit data. But in the general data security work we do, we do not have the authority to obtain any penalties.

That is, I think, something that we seriously need in order to create different incentives here.

Mr. HURD. If a private company would have lost the information on 23 million records, what would FTC have done?

Ms. RICH. In the abstract, it is hard to say. Each violation, if we had civil penalty authority, just borrowing from the authority that we have in other areas, every violation could amount to a \$16,000 penalty. So if you add that up over millions of consumers, it's potentially infinite. But, of course, we take the ability to pay, et cetera, into account.

But the fines could be quite high for a company that had very serious violations and injured a lot of consumers.

Mr. HURD. Thank you.

Now to close this out, Mr. Blum, you are recognized for 5 minutes.

Mr. BLUM. Thank you, Chairman Hurd, for holding this most important hearing.

And thank you to all the panelists today for your insights. I appreciate it very much.

Telehealth, telemedicine, has absolutely intrigued me since I have been in office the last 15 months. When we talk about rising health care costs in the country, I know many citizens want a silver bullet, one answer, one thing that is going to solve the increasing health care costs.

I kind of believe, pardon my pun, I believe it has been death by 1,000 cuts, the increase in health care costs. It has been a lot of small things. And I think one piece of the puzzle, the solution to keeping health care costs in line, is telehealth or telemedicine, and

particularly in our veterans' care system with the psychiatric care, PTSD.

I know in Iowa, it is rural, so we don't have a lot—in all the outpatient clinics for vets, we don't have a psychologist or psychiatrist on staff. So telemedicine is a great application there.

I would like to ask all the panelists, what policy changes do you think are necessary so there is 100 percent—100 percent—telehealth participation by providers and by hospitals? I see it as critically important to saving the government money and also improving the outcomes of our patients.

So whoever would like to take that, jump on it, please.

Dr. DESALVO. Congressman, perhaps I will begin and say that I share your enthusiasm for telehealth. As a doctor, I have had the opportunity to use that, particularly for access to psychiatric care in my home community of New Orleans after Katrina, when we had really a lack of services. As a rural State, we have been able to leverage that as well.

So as a care delivery model, very well-received, and can also save people money, because they don't have to take off of work and find health care, et cetera, to go to the sites. It is less of a technology issue and more of, I think, an opportunity as we move to alternative payment models.

So as the VA has been able to show and the private sector, and certainly through some of the work that the department has done with these models in the Center for Medicare and Medicaid Services, we have been working to advance that as an administration, in partnership with the private sector.

I think it is something that we see as a department an opportunity in the delivery system reform work that is moving to alternative payment models, such as in the MACRA legislation that is required for docs. It is going to give us a lot of opportunity to really enable and support new kinds of care models.

So from our standpoint, we believe that, with the department, we really believe that we are moving forward into this world and that the MACRA legislation for docs, in particular, is going to be helpful.

Mr. BLUM. You are a medical doctor, correct?

Dr. DESALVO. Yes.

Mr. BLUM. I know you cannot speak for the medical community, but what is your impression or your opinion of the medical community's opinion of telemedicine? Is it a good one? Or do they say this isn't that good?

Dr. DESALVO. So I can't speak for the medical community, so I will speak for myself and my peers, that there are some real benefits to it.

Speaking purely as a doctor, I think one of the challenges is there is a lot that you gain from being in the room with a patient, you can touch them, you can listen to them in a way you can't necessarily through technology. So a mix of kinds of interaction is typically what we want. We wouldn't want it to all to be remote, because you also gain something from that touch in that exam room.

Mr. BLUM. Absolutely.

Others? Yes, sir?

Mr. DECRESSENZO. Congressman, one other thing I would mention is harmonization of standards across the States.

Obviously, with telemedicine, as you described, it is something that brings the ability to provide care across distance. And, of course, many of the States are quite large, so it is urban to rural and various other ways. It certainly would facilitate the growth of telemedicine in a very important fashion.

But in addition, there is quite a patchwork of regulations and standards on a State basis across the country, so the ability to leverage perhaps highly specialized care outside the State is often more difficult for somebody looking to put together a national network or even nationally focused providers like Cleveland Clinic and others who have a very large footprint across the country.

Mr. BLUM. And what would the solution to that be? Is there an easy one? I like easy solutions.

Mr. DECRESSENZO. Well, we have 50 States, so I doubt there is an easy one.

But I think there is increasing, I would say, similarity between the regulations of different States as they become more familiar with this. And perhaps like a lot of the work ONC and others have done around harmonization of technology standards, we would hope there would also be a similar effort to harmonize the standards and regulations around telemedicine.

Mr. BLUM. Yes, ma'am?

Ms. RICH. The FTC in the competition area, which I don't personally work, but we have done a good deal of work on breaking down barriers to competition that may hold back certain alternative forms of medicine.

For example, we have commented to States that may have laws that favor certain medical techniques over others in a way that interferes with competition through State laws. So competition is very important in this area.

Mr. BLUM. Do I have time for one more question, Mr. Chairman?

Mr. HURD. Thirty-nine seconds.

Mr. BLUM. One of the major barriers preventing a focus on home-based health care versus expensive hospitalization—another area I am very interested in, is keeping that person in their home as long as we possibly can or getting them back to their home as quick as we can. Thoughts on that?

Mr. SAVAGE. I would jump in and say that is a good illustration of perhaps an interoperability issue. We want to make sure that the patient's home is connected with the system.

So you want access. You want the patient to be able to send remote monitoring information to the doctor's clinical record. These are things that are actually in the process of being developed on a national level.

That kind of two-way communication between the home and the doctor's system also contributes to care planning, so that you actually have working together to manage the care and to move from care to health.

Mr. BLUM. This could apply to nursing homes as well, correct?

Mr. SAVAGE. That's correct.

Mr. QUINN. I would say that one of the things that really is lacking today is ensuring that those home-based applications have a

market. So today without the reimbursement for many of those things, the market hasn't blossomed the way that it could. Many of the applications and the tools aren't necessarily designed for a 78-year-old or maybe somebody with disabilities who is at home.

Ensuring that that, frankly, consumer marketplace with the technology that is rigorous enough to be trusted and incorporated into the health care system is built and that there is a marketplace for it, because there is reimbursement, there is a path for investors to say there is something here.

Mr. BLUM. That's a good point. Thank you very much for your input. I appreciate very much.

With that, I yield the time that I do not have.

Mr. HURD. I would like to thank Mr. Lieu and Mr. Cartwright for the bipartisan nature in working on this topic. It is important for an exchange of information.

And I appreciate our witnesses taking the time to appear before us today and for your patience.

If there's no further business, without objection, the subcommittees stand adjourned.

[Whereupon, at 4:22 p.m., the subcommittees were adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD



April 1, 2016

The Honorable Will Hurd
Chairman
Subcommittee on Information Technology
House Committee on Oversight
and Government Reform

The Honorable Robin Kelly
Ranking Member
Subcommittee on Information Technology
House Committee on Oversight
and Government Reform

The Honorable Jim Jordan
Chairman
Subcommittee on Health Care, Benefits,
and Administrative Rules
House Committee on Oversight
and Government Reform

The Honorable Matthew Cartwright
Ranking Member
Subcommittee on Health Care, Benefits,
and Administrative Rules
House Committee on Oversight
and Government Reform

Re: Recommendations on Harmonization of Privacy Laws

Dear Chairmen Hurd and Jordan, and Ranking Members Kelly and Cartwright:

Thank you very much for the opportunity to testify at the Subcommittees' joint hearing on health information technology (health IT) on March 22, 2016. I am pleased to provide additional comments regarding the harmonization of privacy laws.

Secure and private electronic information exchange can enable safe, more effective and more coordinated care; greater consumer engagement in health; and ultimately improved patient experiences and health outcomes. However, misunderstanding and confusion persist about when health care providers and other entities covered under the Health Insurance Portability and Accountability Act (HIPAA) are permitted to share a patient's protected health information – with other providers and with patients themselves.

Ultimately, this confusion can result in organizational policies and practices more likely to restrict appropriate health-related data sharing, rather than enable or promote it.

To address this multifaceted issue, **we offer the following recommendations:**

- Efforts should focus now on harmonizing HIPAA-covered entities' organizational practices with current law and guidance on data sharing, which may alleviate confusion without having to harmonize laws.
 - Education initiatives are necessary to inform both patients and providers on the correct application of data sharing and privacy laws.
 - This will in turn help to harmonize patient experiences so that they are consistent regardless of provider, setting of care, or state of residence.
- For health IT and patient data not governed by HIPAA (for example, stored in apps and other electronic platforms), consumers need transparent, easy-to-follow information about how their data are collected and used.

The issue: Misinterpretation of HIPAA poses significant barriers to data sharing

HIPAA governs the collection, use and disclosure of individually identifiable health information by covered entities. Specifically, the HIPAA Privacy Rule and Security Rule set forth requirements to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care.

HIPAA sets baseline rules for how health care entities may collect, use and share patients' health information whether in paper or electronic form. But as the health landscape changes rapidly due to the transition from paper-based to electronic health records (EHRs) and the increase in consumer digital health tools (including wearables, telehealth, and smartphone applications), many providers struggle to understand how to comply with data sharing and other patient privacy requirements in the electronic health ecosystem. This confusion is compounded by individual state laws that may provide greater protection, or additional restrictions, with regard to sharing of certain categories of patient data such as psychotherapy notes and substance abuse information.

Early feedback from our GetMyHealthData campaign¹ has illuminated the numerous barriers that individuals face in accessing and using their electronic health data. Consumers navigate a complex, confusing, time-consuming and costly process to request their medical records and other health information under the traditional HIPAA records request process. Sometimes, uncertainty or confusion over HIPAA permitted disclosures of health information leads providers to refrain from sharing patient data with patients themselves. For example, Adele (last name withheld) shared:

"Medical providers treat my data as if it were top secret. I understand their concern about revealing my data to third parties, but many are reluctant to reveal it to me. How can I make informed decisions about my own health if I don't have information?"

Additionally, many providers do not understand the rights that patients have to copies of their health records and other information in digital formats. Under the HIPAA amendments made by the HITECH Act, consumers have a legal right to an electronic copy of their health information. The Administration recently clarified that consumers can exercise this right with any covered entity as long as the provider can produce the data electronically, noting that making digital copies available is a matter of capability rather than willingness. Again, numerous GetMyHealthData volunteers have reported being told that electronic copies of their health records are not available to patients; as more than one volunteer was told, "We don't do that."

There is also persistent confusion and misunderstanding regarding the fees that providers are legally allowed to charge patients. For instance, we have collected examples of patients being charged per-page fees for electronic copies of their record and being charged

¹ GetMyHealthData is a national campaign, coordinated by the National Partnership for Women & Families, in partnership with AHIMA, Amida, Alliance for Nursing Informatics, Code for America, Flip the Clinic, the Genetic Alliance, Health Data Consortium, NATE, and other individual thought leaders/experts. The campaign helps patients gain access to their health information in electronic, computable formats, offers educational resources to patients and providers, and advocates for advancements in policy and practice.

expensive fees upon receiving their record, with no estimate provided in advance. These costs often pose significant barriers for patients in accessing their health information.

One of our GetMyHealthData volunteers is the mother of a child with a rare genetic syndrome. Megan shared her story of overcoming many obstacles – from high fees to puzzling policies and procedures – to get copies of her daughter's medical records from five hospitals in the mid-Atlantic area so she could better coordinate her daughter's care. The costs associated with getting records from each hospital differed wildly (see Appendix A). This kind of variation, between providers in the same region as well as across all fifty states, creates additional stress and confusion for consumers and patients who are trying to access and use their health data to improve their own health, or manage the care of a loved one (see Appendix B).

Therefore, the first task at hand is to harmonize providers' practices with existing laws for securely and appropriately sharing health information between providers and with patients. While we recognize that the relationship between diverse federal and state privacy laws complicates the process of sharing health information, **from a consumer perspective, increasing education and consistent application of existing federal laws and regulations is the critical first step in facilitating the secure and appropriate sharing of data, both between providers and with patients.**

Recommendation: Clarify how existing laws (such as the HIPAA Privacy Rule) apply to access to health information and data sharing

The Department of Health and Human Services' (HHS) Office of Civil Rights (OCR) recently published guidance that provides clarification on components of providing patients access to their health information, including how long providers have to respond to requests, the format in which providers must provide copies, and what reasonable fees they are allowed to charge.

However, federal guidance and enforcement alone are not sufficient. Complementary education efforts are needed to help providers proactively and successfully bring their practices into compliance with privacy laws.

Recommendation: Provide transparency about data sharing practices for digital health tools not covered under HIPAA

The rapid transition to digital health information sharing has also spurred innovation of new devices, applications and technologies. While other regulations may apply, HIPAA's privacy and security protections do not apply to many commercial apps and personal health records (PHRs) unless provided by HIPAA-covered entities such as providers, payers or their business associates.

As consumers increasingly use health apps and devices not covered under HIPAA, it is critical that they understand the data use and sharing practices of these apps to make informed choices on where to store and access their data. **A standardized, consumer-friendly disclosure of data sharing practices and privacy policies gives patients this kind of transparent view into these tools.** This useful way of explaining uses of data is important

because almost 90 percent of consumers report that it is important to them to know how their information is collected and used.²

The federal government continues to take steps to make it easier for the private sector to provide patients this kind of transparency. Notably, the Office of the National Coordinator for Health Information Technology (ONC) creates and promotes a Model Privacy Notice – a template that technology developers can voluntarily use to explain the data sharing practices of their personal health record product or application in a simple, usable way. The second iteration of this Model Privacy Notice is under development to reflect the diversity of technology and data that individuals can now use to manage their health and wellness, as well as new business models.

While the Model Privacy Notice is a great tool to disclose data sharing and privacy practices to consumers, many technology developers do not know that it is available to them. We encourage the federal government to work with the private sector to disseminate the tool and educate developers about why its use is important for consumers and essential to promote patient trust overall.

Therefore, **we suggest that robust education and implementation efforts be the first step towards harmonizing provider practices with existing law and ensuring consistency of patient experience accessing and using their data**, in order to equip patients and providers with the information and tools they need to appropriately share and use health data.

Thank you to the Committee for its interest in advancing health information technology and for the continued opportunity to share the consumer perspective on privacy and data sharing. If you have any questions about our recommendations, please contact Mark Savage, Director of Health IT Policy and Programs, at msavage@nationalpartnership.org or (202) 986-2600.

Sincerely,



Mark Savage
Director of Health IT Policy and Programs

Attachments:
Appendix A
Appendix B

² National Partnership for Women & Families, *Engaging Patients and Families: How Consumers Value and Use Health IT* (Dec. 2014), available at <http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf>.

Appendix A

Hospital and Department Name	Fees	Additional Details
A Medical Records and Health Information Management Department	<ul style="list-style-type: none"> \$0.49 per page for pp. 1-10 if patient is willing to receive records by email \$0.76 per page for pp. 11+ if patient wants mailed copies No fee if doctor requests records 	<ul style="list-style-type: none"> Medical Records Release form available online Records could be emailed or mailed No electronic records or CDs available
B Care Management Department	<ul style="list-style-type: none"> \$1.45 per page No fee if doctor requests records or if records go to another facility 	<ul style="list-style-type: none"> Authorization can be faxed if doctor is authorizing If family is making request, mail is used Release form must be mailed
C Medical Records Request Department	<p>Electronic:</p> <ul style="list-style-type: none"> No charge if released to MyChart \$0.13 per page for CD or thumbdrive \$10.00 per CD for radiology images No charge for continuing care <p>Paper:</p> <ul style="list-style-type: none"> \$0.50 per page for pp. 1-50 \$0.25 per page for pp. 51+ \$1.00 per page for Microfilm No charge for continuing care 	<ul style="list-style-type: none"> Authorization to Release/Disclose Protected Health Information forms available online, but a hard copy must be signed and sent to the office If picked up, CD takes 5-7 business days to prepare If mailed, CD arrives in 15 business days
D Health Information Management Department	<ul style="list-style-type: none"> \$0.50 per page for pp. 1-50 \$0.25 per page for pp. 51+ No fee if doctor requests paper records Providers pay \$0.50 per page if records are emailed 	<ul style="list-style-type: none"> Had to go in person to access records
E Health Information Management Department	<ul style="list-style-type: none"> \$0.39 per page No fee if doctor requests records 	<ul style="list-style-type: none"> Authorization for Release of Medical Information form available online Doctor's authorization required Records will arrive in 21 business days to patient/caregiver

Appendix B

Medical Records Copying Charges

As a public service on this web page we list the various state statutes that control the amount of money doctors, hospitals, and other health care providers can charge for copies of **medical records provided to the patient or the patient's attorney for use in personal injury or wrongful death civil cases**. Note that there may be other statutes which pertain to workers' compensation claims, Social Security disability matters, etc.

We update this page when we learn of new statutes or revisions to statutes already posted; as such, there is no regular time point at which we do this. **We cannot and do not represent that all statutes are up-to-date.** One type of revision which is especially hard for us to keep track of has to do with **cost changes** allowed annually by a statute and based on some indexed inflation rate.

Please always **view the actual statute when there is a link available** and always **check any "UPDATE" link** which you may see for a particular state because these items could contain cost information that is more current than the summary text which appears on this web page.

If you are aware of an additional statute which should be posted on this web page, please send a link to the relevant statute to Tom Lamb.

Likewise, any clarifications, corrections, or updates regarding the statutes listed on this web page should be submitted to Tom Lamb.

Under the Health Insurance Portability and Accountability Act (HIPAA) a covered entity can only charge "reasonable" cost-based fees for providing the medical records to patients. See 45 CFR 164.524(c). Arguably, fees that are not cost-based, even if permitted by a state statute, may be contrary to the HIPAA regulation and therefore preempted by this federal regulation.

Lastly, state and federal regulations require hospitals and certain other institutional health care providers to maintain medical records for specified periods, but those laws usually do not apply directly to physicians or physician groups. See this 50 state survey of record retention requirements list found on the www.HealthIT.gov website (note, list appears to have been created in 2008).

Please understand that the materials on this web page are for general information purposes only, and is **not intended as legal advice**.

- [Read more about the Law Offices of Thomas J. Lamb, P.A. >>](#)
- [Go to this Request Form in order to receive a Firm Brochure >>](#)
- [Here you can see a list of our many Case Evaluation Forms >>](#)

AL | AK | AZ | AR | CA | CO | CT | DE | DC | FL | GA | HI | ID | IL | IN | IA | KS | KY | LA | ME | MD | MA | MI | MN | MS | MO | MT | NE | NV | NH | NJ | NM | NY | NC | ND | OH | OK | OR | PA | RI | SC | SD | TN | TX | UT | VT | VA | WA | WV | WI | WY |

Alabama

Section 12-21-6:1 Alabama Code Reproduction

The reasonable costs of reproducing copies of written or typed documents, or reports shall not be more than:

- One dollar (\$1) for each page of the first 25 pages
- Not more than 50 cents (\$.50) for each page in excess of 25 pages
- A search fee of five dollars (\$5)
- If the medical records are mailed to the person making the request, reasonable costs shall include the actual costs of mailing the medical records
- A person may charge in addition to the above fees, the actual cost of reproducing X-rays and other special medical records

Alaska

Arizona

A.R.S. 12-2205

Except as otherwise provided by law, a health care provider or contractor may charge a person who requests copies of medical records a reasonable fee for the production of the records. Except as necessary for continuity of care, a health care provider or contractor may require the payment of any fees in advance.

Arkansas

Arkansas Code Annotated [A.C.A.] Sec. 16-46-106

Medical Clinics and Doctors' Offices

- May charge no more than \$0.50 for the first twenty-five (25) pages
- No more than \$0.25 per page thereafter for existing records
- A labor charge not exceeding \$15.00 may be added or a reasonable retrieval fee for off-site stored records
- Actual cost of any required postage may also be charged

Hospitals and Ambulance Providers

- May charge a "reasonable amount" for records retrieval and re-storage, in addition to the photocopy charges

California

California Evidence Code Section 1560-1567

- Not more than \$.10 per page for 8 5x14 inches or less
- \$.20 per page for microfilm copies
- actual costs for the reproduction of oversize documents or the reproduction of documents requiring special processing which are made in response to a subpoena
- reasonable clerical costs incurred in locating and making the records available to be billed at the maximum rate of twenty-four dollars (\$24) per hour per person, computed on the basis of six dollars (\$6) per quarter hour or fraction thereof
- actual postage charges

Evidence Code Section 1153

If a patient's attorney requests the medical records:

- Ten cents (\$.10) per page for documents 8 5x14 inches or less
- Twenty cents (\$.20) per page for document copies from microfilm
- Actual costs for oversize documents or special processing
- Reasonable clerical costs to retrieve records: \$4.00 per quarter hour or less
- Actual postage charges

UPDATE: California Health & Safety Code Section 123100

Colorado

C.R.S. 25-1-802. Patient records in custody of individual health care providers

Colorado law establishes the following reasonable fees that a health care facility may charge a third party. The fees may not exceed the following:

- For the first ten pages: \$18.53
- For the next thirty pages (pages 11 through 40): 85 cents per page
- Each additional page after page 40: 57 cents per page (all records except those stored on microfilm) or \$1.50 per page (records stored on microfilm)
- Actual reproduction costs for each copy of a radiograph
- Certification of medical records, if requested: \$10.00 fee
- Actual postage and electronic media costs if applicable
- Applicable taxes

Connecticut

Title 20 §20-70(b)

Upon a written request of a patient, his attorney or authorized representative, or pursuant to a written authorization, a provider, except as provided in section 4-194, shall furnish to the person making such request a copy of the patient's health record, including but not limited to: bills, x-rays and copies of laboratory reports, contact lens specifications based on examinations and final contact lens fittings given within the preceding three months or such longer period of time as determined by the provider but no longer than six months; records of prescriptions and other technical information used in assessing the patient's health condition. No provider shall charge more than:

- Sixty-five cents per page, including any research fees, handling fees or related costs, and the cost of first class postage, if applicable.
- Except such provider may charge a patient the amount necessary to cover the cost of materials for furnishing a copy of an x-ray, provided no such charge shall be made for furnishing a health record or part thereof to a patient, his attorney or authorized representative, if the record or part thereof is necessary for the purpose of supporting a claim or appeal under any provision of the Social Security Act and the request is accompanied by documentation of the claim or appeal.
- A provider shall furnish a health record requested pursuant to this section within thirty days of the request.

Section 19a-490b

Upon the written request of a patient or the patient's attorney or authorized representative, or pursuant to a written authorization, an institution licensed pursuant to this chapter shall furnish to the person making such request a copy of the patient's health record, including but not limited to: copies of bills, laboratory reports, prescriptions, and other technical information used in assessing the patient's health condition:

- No institution shall charge more than sixty-five cents per page, including any research fees, clerical fees, handling fees, or related costs, and the cost of first class postage.

Delaware

Delaware Administrative Code, Title 24, 24 Del. Code, Chapter 1700, Section 29

A new rule, effective November 11, 2009, limits the fees a practice may charge Delaware patients for copies of the patient's medical records that it provides either directly to the patient or to another physician. These fee limits apply to both electronic and paper copies:

- \$2.00 per page for pages 1-10
- \$1.00 per page for pages 11-20
- \$0.50 per page for pages 21-60
- \$0.50 per page for pages 61 and above

In addition to the fees above, practices may charge the following:

- When the records are mailed, practices may charge the actual cost of postage or shipping.
- When the type of record requested cannot be photocopied (such as radiology films or fetal monitoring strips), practices may charge the cost of reproducing the records.

Practices may require payment of all costs in advance of releasing the records except for records related to an application for a disability benefits program.

District of Columbia

Florida

Florida Statutes 395.3025

Regarding records from hospitals:

- Exclusive charge for copies may include sales tax and actual postage
- Non-paper records not to exceed \$2.00 per page
- Paper records not to exceed \$1.00 per page
- An additional \$1.00 may be charged for each year of records requested

Florida Statutes 395.301, Itemized Patient Bill

- The facility may not charge the patient for making such verification records available; however, the facility may charge its usual fee for providing copies of records as specified in s. 395.3025.

Rule 64B8-10.003, Florida Administrative Code

Regarding records from physicians:

- No more than \$1.00 per page for the first 25 pages of written material
- \$.25 for each additional page
- Actual cost of reproducing nonwritten records such as x-rays
- "Recognizing that patient access to medical records is important and necessary to assure continuity of patient care, the Board of Medicine urges physicians to provide their patients a copy of their medical records, upon request, without cost, especially when the patient is economically disadvantaged."

Georgia
Georgia General Assembly Unannotated Code §31-33-3

- A charge of up to \$25.65 may be collected for search, retrieval, and other direct administrative costs
- A fee for certifying the medical records may also be charged not to exceed \$9.70 for each record certified
- The actual cost of postage incurred in mailing the requested records may also be charged
- Copying costs for a record which is in paper form shall not exceed:
 - \$0.97 per page for the first 20 pages of the patient's records which are copied
 - \$0.63 per page for pages 21 through 100
 - \$0.66 for each page copied in excess of 100 pages
 - These numbers reflect July 1, 2011 increase for inflation.
- For medical records which are not in paper form, including but not limited to radiology films, the provider shall be entitled to recover the full reasonable cost of such reproduction

UPDATE: July 2014

Hawaii
Hawaii Revised Statute Section 622-67(g)

- Reasonable costs incurred by a health care provider in making copies of medical records shall be borne by the requesting person.

Idaho

Illinois

IL ST CH 735 §5-5-2006

The practitioner shall be reimbursed by the person requesting such records at the time of such copying, for all reasonable expenses, including the costs of independent copy service companies, incurred by the practitioner in connection with such copying not to exceed:

- a \$24.81 handling charge for processing the request for copies
- \$0.53 cents per page for the first through 25th pages
- \$0.62 cents per page for the 26th through 50th pages
- \$0.11 cents per page for all pages in excess of 50
- the charge shall not exceed \$1.55 per page for any copies made from microfiche or microfilm
- and actual shipping costs

These rates shall be automatically adjusted as set forth in Section 5-2006. The physician or other practitioner may, however, charge for the reasonable cost of all duplication of record material or information that cannot routinely be copied or duplicated on a standard commercial photocopy machine such as x-ray films or pictures.

UPDATE: 2014 Annual Adjustment

Indiana

760 IAC 1-71-3

- First 10 pages - \$1.00 per page; no per page charge is allowed for the first 10 pages if a labor fee is charged
- Pages 11 through 50 - \$0.50 per page
- Pages 51 and higher - \$0.25 per page
- Labor fee - \$20.00
- Actual costs of mailing

Iowa

45 CFR (Code of Federal Regulations) 164.524(c)(4)

If the individual requests a copy of the PHI [protected health information] or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

- Copying, including the cost of supplies for and labor of copying, the PHI requested by the individual.
- Postage, when the individual has requested the copy, or the summary or explanation be mailed; and
- Preparing an explanation or summary of the PHI, if agreed to by the individual as required by paragraph (c)(2)(ii) of this section.

UPDATE: Charges associated with litigation and Worker's Compensation, July 2008

Kansas

K.S.A. 65-4971(b) which required the Secretary of Labor to annually adjust the maximum fees that may be charged for non-workers compensation medical records copying, was repealed by the 2011 Kansas Legislature. Without any state guidelines, federal law governs the establishment of copying charges.

See "Allowable charges for copying records" (from the Kansas Medical Society)

Kentucky
KRS 422.317

Upon a patient's written request, a hospital licensed under KRS Chapter 216B or a health care provider shall provide, without charge to the patient, a copy of the patient's medical record. A copying fee, not to exceed one dollar (\$1) per page, may be charged by the health care provider for furnishing a second copy of the patient's medical record upon request either by the patient or the patient's attorney or the patient's authorized representative.

Louisiana

Louisiana Revised Statutes 40:1299-96

For records, a reasonable charge not to exceed:

- \$1.00 per page for first 25 pages
- \$0.50 per page for pages 26-100
- \$0.25 per page thereafter
- Plus handling charge of \$26.00
- Plus actual postage

For x-rays, microfilm, electronic, and imaging media:

- Reasonable reproduction costs.
- Plus handling charge of \$20.00 for hospitals, \$10.00 for other health care providers

Maine

Title 22 Section 1711

- \$5 for the first page
- \$ 45 for additional pages
- Up to a maximum of \$250

Maryland

Health-General Article Section 4-304(c)(3)

- Health care provider may charge a fee for copying and mailing not exceeding 50 cents for each page of the medical record. In addition to the fee charged under subparagraph (i) of this paragraph, a hospital or a health care provider may charge:
 - A preparation fee not to exceed \$15 for medical record retrieval and preparation
 - The actual cost for postage and handling of the medical record
- This law, originally established in 1964, states that these fees may be adjusted annually for inflation in accordance with the Consumer Price Index

UPDATE: 2012 Annual Adjustment

Massachusetts

243 CMR 2.07(13)(c)

- A fee for copying in excess of \$.25/page or a fee for clerical work in excess of \$20.00/hour is presumptively unreasonable.
- Charges for copies of x-rays and similar documents not reproducible by ordinary photocopying shall be at the licensee's actual cost, plus reasonable clerical fees not in excess of \$20.00/hour.

MEDICAL RECORD COPYING FEE: 2013 UPDATE

Chapter 111, Section 70 Records of hospitals or clinics: custody; inspection; copies; fees

Michigan

Medical Records Access Act 47 of 2004 333.26269 Section 5 Fee:

- Initial fee of \$20.00 per request for a copy of the record
- Paper copies:
 - One dollar per page for the first 20 pages
 - Fifty cents per page for pages 21 through 50
 - Twenty cents for pages 51 and over
- For mediums other than paper, the actual cost of copying
- Postage or shipping costs
- Actual costs incurred for records older than seven years

UPDATE: 2014

Minnesota

Minnesota Statute 144.395, Subdivision 5

When a provider or its representative makes copies of patient records upon a patient's request under this section, the provider or its representative may charge the patient or the patient's representative no more than:

- 75 cents per page, plus \$10 for time spent retrieving and copying the records, unless other law or a rule or contract provide for a lower maximum charge
- This limitation does not apply to x-rays
- The provider may charge a patient no more than the actual cost of reproducing x-rays
- Plus no more than \$10 for the time spent retrieving and copying the x-rays
- The respective maximum charges of 75 cents per page and \$10 for time provided in this subdivision are in effect for calendar year 1992 and may be adjusted annually each calendar year as provided in this subdivision

UPDATE: 2014 Annual Adjustment

Mississippi

Section 11-1-52, Mississippi Code of 1972

- Maximum copying charge is \$20.00 for up to 20 pages
- \$1.00 per page for the next 30 pages
- \$.50 per page for all pages thereafter
- 10 percent of the total charge may be added for postage and handling
- \$15.00 may be recovered by the medical provider or hospital or nursing home for retrieving medical records in archives at a location off the premises where the facility is located
- Actual cost of reproducing x-rays or other special records

Missouri

Missouri Revised Statutes §191.227

- A handling fee of \$17.05
- Plus a fee of \$ 40 per page for copies of documents made on a standard photocopy machine
- Providers may charge for the reasonable cost of all duplications of medical record material or information which cannot routinely be copied or duplicated on a standard copy machine.

Provides that effective February 1st of each year, the handling fee and per page fee will be increased or decreased based on the annual percentage change in the unadjusted U.S. city average, annual average inflation rate of the medical care component of the Consumer Price Index for all urban consumers (CPI-U).

UPDATE: 2015 Annual Adjustment

Montana

Montana Code Annotated 50-15-540

- A reasonable fee for providing health care information may not exceed 50 cents for each page for a paper copy or photocopy
- A reasonable fee may include an administrative fee that may not exceed \$15 for searching and handling recorded health care information

Montana

Montana Code Annotated 50-16-640

- A reasonable fee for providing health care information may not exceed 50 cents for each page for a paper copy or photocopy
- A reasonable fee may include an administrative fee that may not exceed \$15 for searching and handling recorded health care information

Nebraska

71-8404

- A provider may charge no more than twenty dollars as a handling fee
- No more than fifty cents per page as a copying fee.
- A provider may charge for the reasonable cost of all duplications of medical records which cannot routinely be copied or duplicated on a standard photocopy machine.
- A provider may charge an amount necessary to cover the cost of labor and materials for furnishing a copy of an X-ray or similar special medical record. If the provider does not have the ability to reproduce X-rays or other records requested, the person making the request may arrange, at his or her expense, for the reproduction of such records.

Source: Laws 1999, LB 17, § 4, Effective date August 28, 1999.

Nevada

NRS 629.061

- Actual cost of postage
- Costs of making the copy not to exceed 60 cents per page for photocopies and a reasonable cost for copies of x-ray photographs and other health care records produced by similar processes
- No administrative fee or additional service fee of any kind may be charged for furnishing a copy

New Hampshire

Title XXX Occupations and Professions Chapter 332-H Medical Records

- The charge for the copying of a patient's medical records shall not exceed \$15 for the first 30 pages or \$.50 per page, whichever is greater
- Copies of filmed records such as radiograms, x-rays, and sonograms shall be copied at a reasonable cost.

New Jersey

New Jersey Administrative Code §8-43G-15.3(d)

Hospitals

- \$1.00 per page for first 100 pages
- \$.25 per page thereafter to a maximum charge of \$200.00 for the entire record

2004 Update

2005 Reabsorption from NJ Dept. of Health and Senior Services

New Jersey Administrative Code §13-35-6.5(c)(4)

Doctors

- \$1.00 per page or \$100.00 for the whole record, whichever is less

UPDATE: 2012 Copying Charges

New Mexico

16-10-7 NMAC

- \$30.00 for the first 15 pages
- \$.25 per page thereafter
- The actual cost of reproduction for electronic records and record formats other than paper, such as x-rays

UPDATE: 2009 Adjustment

New York

Sections 17 and 18 of Public Health Law (PHL), Laws of 1991, Chapter 165, sections 43 and 49

The cost can be no more than Seventy-Five cents (\$.75) per page for paper copies and a reasonable charge for diagnostic images, plus postage.

North Carolina

North Carolina General Statutes §90-411

Inclusive of searching, handling, copying, and mailing costs:

- \$.75 for first 25 pages
- \$.60 for pages 26-100
- \$.25 for pages over 100
- Minimum fee of \$10.00 permitted

North Dakota

N.D. Cent. Code Section 23-12-14

Upon the request for medical records with the signed authorization of the patient, the health care provider shall provide medical records at a charge of no more than:

- \$20 for the first 25 pages
- \$.75 per page after 25
- This charge includes any administration fee, retrieval fee, and postage expense

Ohio
§ 3701.741

Except as provided in divisions (C) and (E) of this section, a health care provider or medical records company that receives a request for a copy of a patient's medical record from the patient or patient's personal representative may charge not more than the amounts set forth in this section. Total costs for copies and all services related to those copies shall not exceed the sum of the following:

- \$2.50 per page for the first ten pages
- \$.50 per page for pages eleven through fifty
- \$.50 per page for pages fifty-one and higher
- With respect to data recorded other than on paper, \$1.70 per page
- The actual cost of any related postage incurred by the health care provider or medical records company

UPDATE: 2014 Adjustment

Oklahoma
76 Okla. Stat. Sec. 19

Any person who is or has been a patient of a doctor, hospital, or other medical institution shall be entitled, upon request, to obtain access to the information contained in the patient's medical records, including any x-ray or other photograph or image.

- The cost of each copy, not including any x-ray or other photograph or image, shall not exceed One Dollar (\$1.00) for the first page and fifty cents (\$.50) for each subsequent page.
- May produce the records in digital form at a cost not to exceed twelve cents (\$.12) per digital page.
- The cost of each x-ray or other photograph or image shall not exceed Five Dollars (\$5.00) or the actual cost of reproduction, whichever is less.
- The physician, hospital, or other medical professionals and institutions may charge a patient for the actual cost of mailing the patient's requested medical records, but may not charge a fee for searching, retrieving, reviewing, and preparing medical records of the person.

UPDATE: Revised 11/2013

Oregon
ORS 192.821 Health care provider and state health plan charges

A health care provider or state health plan that receives an authorization to disclose protected health information may charge:

- No more than \$30 for copying 10 or fewer pages of written material and no more than \$.50 per page for pages 11 through 50 and no more than \$.25 for each additional page.
- Bonus charge of \$.50 if request for records is processed and records are mailed by first class mail to the requester within seven business days after the date of the request.
- Postage costs to mail copies of protected health information or an explanation or summary of protected health information, if requested by an individual or a personal representative of the individual.
- Actual costs of preparing an explanation or summary of protected health information, if requested by an individual or a personal representative of the individual.

Pennsylvania

Act 26 sets the maximum fees that can be charged for medical records. These fees are updated yearly through the Department of Health. With a few exceptions, the maximum fees for a record request from a patient or attorney for 2007 are as follows:

- searching and retrieving the record - \$19.80
- pages 1 through 20 - \$1.33 per page
- pages 21 through 50 - \$.98 per page
- pages 51 and after - \$.33 per page
- actual mailing or delivery fees

UPDATE: 2015 Adjustment

Rhode Island
Rules and Regulations [for Medical Records]
(see Section 11.2, at pages 11-12)

- Not more than \$0.25 per page for the first 100 pages
- After 100 pages, not more than \$0.10 per page
- Maximum fee of \$15.00 for retrieval regardless of time spent retrieving
- Special handling fee of an additional \$10.00 if records must be delivered within 48 hours of request
- Copying of x-rays or other documents not reproducible by photocopy at physician's actual cost plus clerical fees not to exceed \$15.00

South Carolina
SC ST SEC 44-115-80 for Doctors

A physician or other owner of medical records may charge a fee for the search and duplication of a medical record, but the fee may not exceed:

- Sixty-five cents per page for the first thirty pages
- Fifty cents per page for all other pages
- A clerical fee for searching and handling not to exceed fifteen dollars per request
- Plus actual postage and applicable sales tax
- The physician may charge no more than the actual cost of reproduction of an x-ray

SC ST SEC 44-7-325 for Hospitals

- \$.65 per page for the first 30 pages
- \$.50 per page for all other pages
- Clerical fee not to exceed \$15.00
- Plus actual postage

2014 Update for both Doctors and Hospitals Statutes

South Dakota

South Dakota Codified Laws 36-2-16

Medical records released to patient or designee on request. Licensee may require before delivery that the patient pay the actual reproduction and mailing expense.

Tennessee

Tennessee Code/Title 63 Professions Of The Healing Arts/Chapter 2 Medical Records/63-2-102.

- For other than records involving workers' compensation cases, such reasonable costs shall not exceed twenty dollars (\$20.00) for medical records forty (40) pages or less in length.
- Twenty-five cents (\$.25) per page for each page copied after the first forty (40) pages.
- the actual cost of mailing.

Tennessee Code Annotated 68-11-304

Fees that hospitals can charge patients, their lawyers, or their authorized representatives for hospital records.

- Generally, a hospital may require a "reasonable charge" for copying. The law interprets "reasonable" not to exceed a \$18 retrieval fee for the first 5 pages of the record.
- \$.25 for pages 6-50.
- \$.60 for pages 51-250.
- \$.35 for page 251 and thereafter.

UPDATE: 2010

Texas

Texas Health and Safety Code §241.154

MAXIMUM FEES ALLOWED FOR PROVIDING HEALTH CARE INFORMATION EFFECTIVE OCTOBER 2013: <http://www.dhs.state.tx.us/WorkArea/DownloadAsset.aspx?id=59668> (PDF)

Hospitals

A basic retrieval or processing fee not to exceed \$45.00 for first 10 pages of records, then,

- \$1.51 per page for pages 11-40
- \$.75 per page for pages 51-400
- \$.40 per page for any remaining pages.
- Plus actual cost of mailing or shipping.

If the requested records are stored on any microform or other electronic medium, a retrieval or processing fee, which must include the fee for providing the first 10 pages of the copies and which may not exceed \$66.66, and

- \$1.51 per page thereafter.
- Actual cost of mailing, shipping, or otherwise delivering the provided copies.

If the requested records are provided on a digital or other electronic medium and the requesting party requests delivery in a digital or electronic medium, including electronic mail,

- a retrieval or processing fee, which may not exceed \$51.57, and
- the actual cost of mailing, shipping, or otherwise delivering the provided copies.

Title 22 Part 9 Chapter 165 Rule 165.2

Posters

No more than \$25.00 for the first 20 pages, then,

- \$.50 per page for every copy thereafter.
- In addition, actual cost of mailing or shipping.
- Also, a reasonable fee not to exceed \$15.00 for executing affidavit.

22 Texas Administrative Code §165.3

Doctors

- Maximum charge for x-rays and diagnostic imaging studies \$8.00 per copy.

Utah

Utah Code

Title 78B Chapter 5, Section 610: Patient access to medical records

- A health care provider who provides a copy of a patient's records to the patient or the patient's personal representative may charge a reasonable fee to cover the health care provider's costs.

Vermont

16 V.S.A. § 9419: Charges for access to medical records

- A custodian may impose a charge that is no more than a flat \$5.00 fee or no more than \$0.50 per page, whichever is greater, for providing copies of an individual's health care record.
- A custodian may charge an individual a fee, reasonably related to the associated costs, for providing copies of x-rays, films, models, disks, tapes, or other health care record information maintained in other formats.

Virginia

VA Code § 32.1-127.1.03: Health records privacy.

If an individual or his agent / attorney requests a copy of his own medical records, the health care entity may impose a reasonable cost-based fee, which shall include the cost of supplies for and labor of copying the requested information, as well as postage where applicable.

NOTE: As to what may be regarded as "reasonable" in connection with the above statute, see:

Va. Code Section R 61-413 (2003)

A reasonable charge may be made for the service of maintaining, retrieving, reviewing and preparing such copies. Except for copies of X-ray photographs, however, such charges shall not exceed:

- fifty cents per page for up to fifty pages
- twenty-five cents a page thereafter for copies from paper or other hard copy generated from computerized or other electronic storage, or other photographic, mechanical, electronic, imaging or chemical storage process.
- one dollar per page for copies from microfilm or other micrographic process plus all postage and shipping costs and a search and handling fee not to exceed ten dollars.
- Copies of hospital, nursing facility, physician's, or other health care provider's records or papers shall be furnished within fifteen days of such request.

Washington
WAC 245-06-400

- No more than ninety-six cents per page for the first thirty pages
- No more than seventy-three cents per page for all other pages
- The provider can charge a twenty-two dollar clerical fee for searching and handling records
- If the provider personally edits confidential information from the record, as required by statute, the provider can charge the usual fee for a basic office visit

UPDATE: July 2013 through June 2015

West Virginia
West Virginia Code §16-29-2(a)

- \$10.00 maximum search fee plus "reasonable expenses" provided that the cost may not exceed \$.75 per page for copying of records already reduced to written form

Wisconsin
Section 145.83

If a patient or if the personal representative of the patient requests copies of the patient's health care records, the health care provider may charge no more than the following fees:

1. For paper copies: \$1 per page for the first 25 pages; 75 cents per page for pages 26 to 50; 50 cents per page for pages 51 to 100; and 30 cents per page for pages 101 and above.
2. For microfiche or microfilm copies: \$1.50 per page.
3. For a print of an X-ray, \$10 per image.
4. If the requester is not the patient or a person authorized by the patient, for certification of copies, a single \$8 charge.
5. If the requester is not the patient or a person authorized by the patient, a single retrieval fee of \$20 for all copies requested.
6. Actual shipping costs and any applicable taxes.

Wyoming

Wyoming Statutes Title 35, Chapter 2, Article 6, Section 35-2-611(b)

The hospital may charge a reasonable fee, not to exceed the hospital's actual cost, for providing the health care information and is not required to permit examination or copying until the fee is paid.

Law Offices of Thomas J. Lamb, P.A.
1616 Eastwood Road, Suite 225
Carmichael, NC 28413
Tel: (888) 428-9038 • Fax: (704) 296-2872
Email: info@LambLawOffice.com
© Webster and Copyright

Available at <http://www.lamblawoffice.com/medical-records-copying-charges.html>

