Testimony of

Mary R. Grealy
President
Healthcare Leadership Council

Hearing on

21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication

United States House of Representatives
Committee on Energy and Commerce Subcommittee on Health

Tuesday, July 22, 2014
3:00 p.m.
2123 Rayburn House Office Building

Mr. Chairman and members of the subcommittee. Thank you for the opportunity to testify today on the importance of communication and evidence development in our drive to continually improve the quality of American healthcare and in the shared quest to develop 21st century cures for the diseases and illnesses that continue to exact an unacceptable toll on our society in both lives and resources.

My name is Mary R. Grealy and I am president of the Healthcare Leadership Council (HLC). The HLC is a coalition of chief executives representing virtually every sector of American healthcare. Our members are leaders of hospitals, insurers, pharmaceutical companies, medical device manufacturers, distributors, pharmacies, health information technology companies and other health disciplines. HLC members are united by our belief that American healthcare can be more affordable and accessible, that it can reach higher levels of quality, that it can achieve improved health outcomes and an unprecedented success in improving population health. We believe that these objectives can and must be attained through data-driven innovation, the kind of innovation that has defined private sector healthcare for generations.

The topic of this hearing goes to the heart of the challenges we face in maximizing healthcare's potential. Each year, millions of patients and consumers in the United States interact with the healthcare system. Those interactions lead to literally trillions of decisions, communications, interventions, consultations, treatments and therapies. We have a constant, never-ending cascade of real-time data that contains the secrets to entering the next era of high-quality healthcare and developing the 21st century cures that the Energy and Commerce Committee has outlined so clearly and compellingly.

The key to capturing this potential lies in putting the policies and practices in place that will allow us to harness this data. By utilizing and analyzing this massive trove of information we will catalyze more rapid progress in medical research and design the kind of health delivery improvements that will make our healthcare system more quality-driven and cost-effective.

The Healthcare Leadership Council has been engaged in this challenge for some time. Our individual members are among the early adopters and innovators in using data to enhance the entire continuum of healthcare – from treatment protocols to payment systems to the manufacturing of drugs and devices – and, cumulatively, they provide a broad-based perspective on the challenges that currently exist in the accessibility and usability of data to make further strides in healthcare advancements. As you articulated so well in the meeting notice for this hearing, "We need to make sure that patients, providers, researchers, and drug and device companies are able to communicate and collaborate in the most productive and transparent manner possible."

Because HLC represents these various sectors, we are able to provide you today with our members' broad perspectives and experiences on issues related to data accessibility and data sharing. I will divide my testimony into three areas: (1) The role of the HIPAA privacy law; (2) The need for federal data policies that strengthen access to information and enable improved care, greater healthcare value and accelerated research; and (3) The need to examine the impact of Sunshine Act laws on physician-industry collaboration and the patient-focused benefits that result from those collaborations.

Health Insurance Portability and Accountability Act (HIPAA)

In addition to bringing together the expertise of its various members, HLC also leads a multi-organizational Confidentiality Coalition, which has played an important role for more than a decade in advising policymakers on the steps needed to protect confidential health information while also making data appropriately accessible under HIPAA to strengthen care quality, improve healthcare systems and advance research.

We believe that the HIPAA privacy and security laws are, generally, serving patients and the healthcare system well and that it should continue to be the guiding rule wherever HIPAA-covered entities are involved. As healthcare payment and delivery systems evolve, and even as 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.

In order to achieve more rapid healthcare advancement, while still protecting patient confidentiality, there are certain aspects of HIPAA and privacy laws in general that warrant policymaker review and discussion, specifically:

- As medical research itself evolves, we must be cognizant of the limitations HIPAA imposes on research into new cures and technologies. HIPAA was created at a time when policymakers were not thinking about the knowledge that could be gained by accessing data residing in large databases. We now are in an era where researchers can harness vast amounts of data to learn at a rapid pace unlike we have ever seen. Policymakers should be aware of the need to adjust the authorization components of HIPAA as necessary to ensure that data can be used effectively in a research setting.

- Currently, in most research environments, patient data must be de-identified before it can be utilized. In general, we promote the HIPAA de-identification standard as a strong model for making data anonymous and believe this standard should be applied in appropriate circumstances to health data, inside or outside of the HIPAA schema, to effectively protect patient and consumer health data. Policymakers, however, need to be aware of circumstances in which de-identified data is not sufficiently useful to achieve particular research objectives.

- The presence of 50 separate sets of state privacy laws and regulations represents an impediment that slows down medical and scientific progress. It makes little sense and does not serve the public interest for healthcare entities and research to try to untangle inconsistent, overlapping laws. In today's world, information must be transmitted across state lines and laws should enable this data sharing, not obstruct it.

We believe strongly that progress toward 21st century cures would be aided by the presence of a national privacy framework to replace the complex and burdensome patchwork quilt of current state laws. This national framework should be modeled upon the current HIPAA structure which is, again, working well in protecting patients and enabling healthcare improvement.

Federal Data Policy

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's Health Data Initiative led to the

sharing of valuable information from agencies like the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration.

However, the hands-on experience of our HLC member companies in multiple health sectors informs us that much more needs to be done in the area of data accessibility and quality. Toward that end, HLC members collaborated in the development of consensus, multi-sector principles on data policy. I am submitting this full set of principles as an addendum to my testimony (Attachment 1). Some of these relevant principles include:

- **As taxpayer-funded entities, it is the responsibility of government health agencies to maximize public benefit from data collected through their operations.** By allowing regular access to data at minimal cost to organizations that are subject to consumer protection laws, organizations throughout the country can develop novel ways to fight disease, improve the quality of care, reduce costs and accelerate innovation. We encourage increased coordination among federal government agencies to reduce data "silos."

- **Timeliness, format and regulatory flexibility are critical for organizations serving consumers to make the most of data held by the federal government's health programs.** Federal 'data use agreement' restrictions keep many healthcare organizations from gaining access to data that would allow them to improve care and reduce costs. These agreements should be revised to allow organizations to get preapproval for real-time access to CMS data for appropriate uses. The current practice of precluding some organizations from purchasing data at all and substantial lag time in the availability of key information slows progress that could benefit everyone.

- **Federal health data should no longer be denied to entities perceived to have a commercial interest.** Healthcare organizations are using advanced data analytics to improve healthcare quality, better manage population health and address consumer health needs using private-sector patient-level data. These organizations can enhance their work with appropriate access to federal program data. Commercial entities could easily be held to the same Data Use Agreement standards as noncommercial entities.

HLC has also collaborated with stakeholders outside our own membership to discuss the issue of access to federal government health data. Participants in these discussions include individuals representing the health sectors in our own membership, along with think tanks and academic organizations. Those we have worked with have shared insights on data exchange, current barriers to access and policies that can broaden medical and healthcare knowledge, engage patients and support essential research.

Important data policy themes have emerged from these discussions:

- **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.

- **The federal government should convene all stakeholders for a broad discussion of situations in which there should be restrictions on data access.** This would enable government to establish a more consistent rationale for restrictions on health

data that continue to exist. It could also include reexamining the feasibility of regulating access by usage of health data instead of by type of user.

- **Federal policymakers should broaden efforts to share most federally-held health data, when appropriate.** 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. As partners to the federal government in national efforts to improve care while lowering costs, private sector organizations should have access to the tools needed for success.

On the issue of private entity access to federally-held health data, I am also attaching to my testimony a March 7, 2014 letter to CMS Administrator Marilyn Tavenner from the Healthcare Leadership Council and the National Pharmaceutical Council. In this letter, we applaud CMS, in its proposed rule affecting the Medicare Part D and Medicare Advantage programs, for opening up the topic of access to Prescription Drug Event data by entities with commercial interests**.** We recommend expanding the discussion to include the long-standing HHS policy that denies access by commercial entities to data from the Medicare Part A, B, D and Medicaid programs as well as other program datasets (Attachment 2).

In the letter, we note that the profit status of the organization in question should not take precedence over the larger question of whether the research in which the organization is engaging is of high quality and has the potential to improve population health. Further, by excluding certain organizations from access to federal health data, federal policy is also excluding the deep scientific and analytic expertise that can bring improvements to the entire healthcare spectrum. Any standard that essentially bars access to this critical data is, in fact, detrimental to the larger goals of our healthcare system and our shared societal goals.

The Physician Payments Sunshine Act

The Physician Payments Sunshine Act (referred to hereafter as "Sunshine Act") requires manufacturers of drugs, medical devices and biologics that participate in federal health programs to report payments and transfers of value to physicians and teaching hospitals. This reporting of payments is already taking place and a website is expected to be launched this fall making this data available to the public.

We believe it will be essential for Congress to closely monitor the implementation and impact of the Sunshine Act to ensure that it does not have an adverse impact on physician-industry collaboration and, as a consequence, innovative healthcare progress.

Many of the most important medical developments of the past half-century have come as a result of physicians and researchers sharing their insights and expertise with product manufacturers. These lifesaving and life-transforming innovations include CAT scans, cervical disc replacements, coronary stents, deep brain stimulation, the heart and lung bypass machine, laser eye surgery, mumps and measles vaccines, penicillin, statins, total knee replacements, artificial heart valves and ultrasound diagnostic technologies. And these are just a few examples of a much longer list of benefits yielded from physician-industry collaborations. I have included a list of some of these as an attachment to my testimony (Attachment 3). This interaction between physicians, researchers and manufacturers is the inception point for so many of our cures, treatments and medical technologies – in the past, the present and, hopefully, the future.

Our concern with the Sunshine Act should not be construed as opposition to transparency. In fact, HLC launched an initiative under our National Dialogue for Healthcare Innovation (NDHI)

platform which brought together leaders from multiple health sectors, government, academia and patient organizations to thoroughly discuss the issues surrounding physician-industry collaboration. That effort led to the development of a consensus set of principles on the issue, endorsed by organizations from many of the aforementioned sectors, which emphasize transparency, research independence and patient-centeredness. I have attached those principles and additional information regarding NDHI and physician-industry collaboration to my testimony (Attachment 4).

Rather, our concern is with the possibility of transparency without proper context. If the only information conveyed to the public and media regarding transfers of value between manufacturers and physicians involves dollar amounts – without a full, adequate explanation of the benefits generated for the public as a result of those interactions – there are legitimate concerns on the part of physicians that they will be unfairly stigmatized and lose the faith and confidence of their patients and the public at large. One only has to look at the controversies surrounding the recent release of Medicare physician payment data to see that information can be easily misconstrued if not presented with full context.

We have, in fact, already heard from some of our HLC member companies that physicians who have worked with them in the past to ensure the efficacy and safety of products are now reluctant to continue doing so because they are concerned about how these interactions will be reported and interpreted. When this collaboration is discouraged, those hurt the most are current patients as well as those who will suffer from diseases and illnesses in the future because new cures and treatments were delayed or never developed. This concern is amplified by the recent decision by CMS in the proposed Physician Fee Schedule for 2015 to include the reporting of continuing medical education (CME) funding, a move that will only have a

dampening effect on physicians learning new medical science because of a perceived stigma associated with industry support of CME activities.

Again, we encourage Congress to closely monitor the implementation of the Sunshine Act and seek the input of those in the physician community as well as pharmaceutical and medical device manufacturers to get a comprehensive perspective on whether the law, in its current form, is having an adverse impact on the innovation that is critical to 21st century cures. Transparency and innovation are not and should not be viewed as mutually exclusive and we stand ready to work with Congress to ensure that both goals are achieved.

Chairman Pitts and members of the subcommittee, thank you again for the opportunity to present testimony on this important issue. The Healthcare Leadership Council and its individual members believe strongly that the diseases and illnesses that diminish and shorten too many lives can be conquered within the foreseeable future as long as we enable and incentivize the healthcare innovation that has generated countless medical miracles over the past several decades. We look forward to working with you to make this vision for 21st century cures a reality. Thank you.

Attachments (7)

HEALTHCARE LEADERSHIP COUNCIL

HLC Principles on Data Policy

HLC envisions a future in which public and private sector healthcare organizations securely share information in an efficient, effective manner that is accessible and useful for all stakeholders. HLC members have already proven that they can harness data to improve care and value in healthcare. Improved accessibility and quality of health data can accelerate progress in medicines, improve the quality of care delivery, reduce costs, and will lead to other benefits that we cannot yet imagine.

Access to Data

- **As taxpayer-funded entities, it is the responsibility of government health agencies to maximize public benefit from data collected through their operations.** We applaud current work by HHS to reduce the time lag and improve compatibility of data released by the agency, but there is still significant room for improvement. By allowing regular access to data at minimal cost to organizations that are subject to consumer protection laws, organizations throughout the country can develop novel ways to fight disease, improve the quality of care, reduce costs, and accelerate innovation. Increased coordination among federal government agencies to reduce data "silos" and support for crossagency data access by private sector organizations will allow innovative new research that benefits consumers.

- **Timeliness, format, and regulatory flexibility are critical for organizations serving consumers to make the most of data held by the federal government's health programs.** Federal "data use agreement" restrictions keep many healthcare organizations from gaining access to data that would allow them to improve care and reduce costs. These agreements should be revised to allow organizations to get preapproval for real-time access to Centers for Medicare and Medicaid Services (CMS) data for appropriate uses. While many restrictions are important and necessary to protect patient confidentiality, others, such as restrictions on combining data sets, inhibit the true potential of data analysis in healthcare. The current practice of precluding some organizations from purchasing data at all and substantive lag time in the availability of key information slows progress that could benefit everyone.

- **Federal health data should no longer be denied to entities perceived to have a commercial interest.** All entities should be allowed access to federal data to conduct research of interest to federal programs, such as provider and product performance improvement activities. Healthcare organizations are using advanced data analytics to

improve healthcare quality, better manage population health, and address consumer health needs using private-sector patient-level data. Healthcare organizations can do even better with appropriate access to federal program data. At the same time, healthcare organizations have a responsibility to abide by consumer protection laws, such as the Health Insurance Portability and Accountability Act (HIPAA), when handling federal health data. In the era of value-based healthcare and performance-driven reimbursement, all entities arguably have a "commercial interest" in federal program data. These data are important for all healthcare sectors to drive toward value. Commercial entities could be held to the same Data Use Agreement standards as noncommercial entities, including, for example, that the research be relevant to public programs.

Consensus Standards

- **Voluntary, consensus-based standards for observational research must be established that are broadly agreed upon among all healthcare stakeholders and healthcare sectors.** As it becomes technically easier and less costly to use real world heathcare data to establish treatment guidelines and protocols, to make coverage decisions, and to set reimbursement rates, it becomes increasingly important that we work together to ensure that the research is robust. To that end, we need to understand and agree upon the limitations of various data sources and data sets – establish consensus ideas of which data are fit for what purpose. We need consensus on appropriate research methods for nonexperimental observational research, including dataset management. We also need to agree that once research is conducted and findings released, all interested stakeholders should be able to review detailed information about the data set(s) used, how the data were curated, and the research methods employed. The research process should be documented and transparent so that another researcher could replicate a given study.

- **As health data increasingly flow among organizations to improve care, standards for the ownership of health data should be established.** These standards would serve to reduce legal uncertainty and facilitate important information flows.

Secondary Use of Data

- **Efforts to provide consumer transparency of healthcare prices must provide practical, consumer-friendly information that facilitates decisionmaking.** Consumer-accessible data should not include "input prices" but rather prices at the point of service. The price a hospital pays for equipment is not helpful to consumers, but the cost paid by patients for an intervention could be important. In fact, transparency of input prices could cause those prices to regress to the mean over time while still not helping the consumer make informed choices.

- **Any collection and publication of provider price or payment data should be released alongside information on quality in order to drive value in healthcare.** HLC members are continually innovating to drive higher quality and better value in healthcare. There is a significant risk that consumers, when given provider payment information, will make erroneous assumptions about quality based on reimbursement – defeating our efforts to drive toward better value. We urge policymakers to take a thoughtful approach to the release of any cost data to ensure that consumers make a judgment based on value.

- **Electronic Health Records (EHRs)/Electronic Medical Records (EMRs) data should be made available for research and other healthcare innovation.** Despite the fact that the installation of EHRs nationally has been dramatically subsidized by the federal government, it is not yet clear if data collected by the federal government from EHRs as part of the Meaningful Use, Medicare Shared Savings Programs and others will be accessible. Government policy should encourage and foster efforts to use this data to broaden knowledge, improve provider performance, engage patients, and conduct health outcomes research. With appropriate protections for privacy and proprietary information, government policy should support the development of applications that connect various government data sources for approved purposes.

- **Common approaches to risk-adjusting data must be developed to ensure consumer decisionmaking is based on accurate comparisons.** The impact of multiple factors, such as socioeconomic status, on clinical outcomes is well documented. Adjusting for these factors is necessary if data are to be used accurately for comparisons.

<u>Governance and Data Privacy Protections</u>

- **The information protection framework established by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule should be maintained.** HIPAA established a framework for acceptable uses and disclosures of individually identifiable health information within healthcare delivery and payment systems for the privacy and security of medical information. Confidentiality of patient medical data is of the utmost importance in the delivery of medical care. We must maintain the trust of the patient as we strive to improve healthcare quality. At the same time, providers should have as complete a patient history as is necessary to treat patients. Having access to a complete and timely medical record allows providers to remain confident that they are well informed in the clinical decisionmaking process.

- **A privacy framework should be consistent nationally so that providers, health plans, and researchers working across state lines may exchange patient health data efficiently and effectively to provide treatment, extend coverage, and advance medical knowledge,** whether through a national health information network or another

means of health information exchange. To the extent not already provided under HIPAA, simple, uniform confidentiality rules should apply to all individuals and organizations that create, compile, store, transmit, or use personal health information. Patients' private medical information should have the strictest protection from others outside the medical delivery system and should be supplied only to those necessary for the provision of safe and high-quality care.

- **In order to improve safety and quality, healthcare organizations must have a safe and legal way to match the right patient to his or her own medical record across time and place.** The privacy of individuals in a modern health system must be respected and privacy laws should be vigorously enforced. It is critical that health organizations have a means to gain access to the correct individual patient's medical record in order to provide the right treatment to the right patient at the right time.

- **The timely and accurate flow of deidentified data, with appropriate protections for consumer privacy, is crucial to achieving the true potential of data analytics in healthcare.** Federal privacy policy should abide by HIPAA regulations for the deidentification and/or aggregation of data to allow access to properly deidentified information. This allows researchers, public health officials, and others to assess quality of care, investigate threats to the public's health, respond quickly in emergency situations, and collect information vital to improving healthcare safety and quality.

March 7, 2014

The Honorable Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4159-P, P.O. Box 8013,
Baltimore, MD 21244-8013

Dear Administrator Tavenner:

We write in response to the Proposed Rule of January 10, 2014 (CMS-4159-P) – specifically in regard to the request for comment on the proposal to expand access to Part D Data. We applaud CMS for soliciting comments on this important topic. Expanding access to health data is a necessary component of CMS's mission of "strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost."[1]

The Healthcare Leadership Council (HLC), a coalition of chief executives from all disciplines within American healthcare, 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 system that makes affordable, high-quality care accessible to all Americans. HLC members advocate measures to increase the cost-effectiveness of American healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to elevate value. HLC works to provide access to health coverage for the uninsured, accelerate the growth of health information technology, reform healthcare payment systems, promote quality improvement, advance patient safety, address workforce challenges, reform medical liability, and improve care through patient information sharing while also protecting patient confidentiality.

The National Pharmaceutical Council (NPC) is a health policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment in the United States that supports medical innovation. Founded in 1953 and supported by the nation's major research-based biopharmaceutical companies, NPC focuses on research development, information dissemination, education and communication of the critical issues of evidence, innovation and the value of medicines for patients. Our research helps inform critical healthcare policy debates and supports the achievement of the best patient outcomes in the most efficient way possible.

[1] CMS Strategy: The Road Forward 2013-2017. Accessed 2/27/14 from cms.gov

CMS invites comments on whether its current ban on access to Part D Drug Event data for commercial purposes should be revised to allow access for research with a commercial purpose. Currently, access to Research Identifiable Files (RIFs), which include the Medicare Part D data, is not allowed under a variety of situations—either because the research could have commercial implications, or the researcher is associated with a commercial enterprise.

We support continued examination of data access policies by CMS and believe it is appropriate to continue restriction of commercially and financially sensitive data. With that understanding, we would like to expand the discussion of appropriate access to Prescription Drug Event (PDE) data by entities with commercial interests to the broader, long-standing HHS policy that denies access by commercial entities to federal Medicare A, B, D, Medicaid, and possibly other program datasets. For reasons discussed below, we believe it is time to re-consider this overarching policy that affects access to federal program RIFs in Medicare, including Part D, and in other federal health programs.

In Our Changing Healthcare System, When Should Data Access Be Prohibited?

CMS has been at the forefront of moving the US healthcare system to the next level—to a system that values and rewards quality, good health outcomes, effectiveness, and efficiency. We strongly support those goals.

In order to achieve our shared goal of a high performing, value- and evidence-based healthcare system, greater alignment of stakeholder incentives is required. Alignment means that all stakeholders are rewarded for new and different behaviors focused on quality not quantity. CMS is keenly aware of this pivotal requirement for success. Indeed, the challenge of quantifying greater efficiency and evidence of improvement as part of overall health reform requires more access to federal data.

Consider these scenarios involving data access, health system improvement for patients, and commercial interest:

- A multi-specialty provider group that uses Medicare Protected Health Information (PHI) beyond their patient base to determine more effective ways to case manage high-risk patients resulting in better patient outcomes as well as savings to the Medicare program, beneficiaries, and providers under a bundled payment or Accountable Care Organization-type arrangement.
- A hospital that uses data to identify high-risk patients and discern the key factors that reduce re-admission rates and thus reduce their financial penalties while improving quality of patient care.
- A pharmaceutical company that uses data to look for factors that improve medication treatment adherence to improve health.
- A diagnostic company that uses predictors of patient response to existing treatments and therefore identifies a diagnostic test to better stratify patient populations who are likely to respond.
- A device company that uses data to identify types of patients who are not optimally managed with medical care and develops a patient decision-aid to help patients and their providers determine which treatment (including a device) is needed.

- A consumer group that uses data to determine which wellness programs work best for whom so that individuals or groups of individuals can maximize their financial rewards under various wellness programs.

In addition to producing better patient outcomes, each of these scenarios also could produce clear benefit to the particular stakeholder. Each of these scenarios, if successful, will benefit the healthcare system overall as the results are published and as best practice diffuses through a competitive system. There are commercial interests as well as positive developments for patients and potentially the Medicare Trust Funds. In an aligned, high functioning healthcare system, everyone should be able to benefit financially from effective use of data to improve quality and efficiency in the healthcare system. We know that CMS shares these goals, and has sought to encourage data access specifically for research that will benefit CMS in its effort to monitor, manage, and improve the Medicare and Medicaid programs or the services provided to beneficiaries. We believe that broadening this interpretation will create further benefit to both CMS programs and patients by dramatically increasing the bandwidth for research leading to increased care quality, system efficiency, and consumer satisfaction.

Financial benefit and profit status of the organization should not overlay the criteria by which a research proposal is evaluated. The standard should be: Is the research proposed high quality and does the research have the potential to improve program administration or the health of the covered population?

CMS Interpretation of "Commercial Interest"

There is standing Department policy that prohibits the sharing of certain federal program data with entities that have a commercial interest. Entities with commercial interest can access public use files and limited dataset files. However, direct access to Research Identifiable Files (which includes the Part D Prescription Drug Event data) is generally prohibited for these entities. Entities that are presumed or determined to have a commercial interest are denied access to RIFs that contain person-level, protected health information (PHI). This policy is referenced in different department documents, including the proposed rule.

We applaud CMS for reopening discussion of this important distinction in the proposed rule. In our rapidly evolving healthcare sector, the way in which data are being used has changed dramatically. Patient level information is needed to achieve the very care transformation CMS seeks. The lines are blurred with respect to which types of entities have commercial interest – commercial purposes could encompass much more than just a product or tool. Because the quality and efficiency of all physician groups, health plans, hospital systems and suppliers can be enhanced using data, any notion that commercial interest is limited and discrete is outdated.

Within organizations currently excluded, there is deep scientific and analytic expertise which enables a broader understanding and knowledge of public health issues across the entire healthcare ecosystem. Ultimately, any standard that essentially bars access to important data is detrimental to the larger goals of our healthcare system and our common goals for the evolution of that system.

Does the CMS Ban Affect New Data Infrastructure and Multi-Payor Datasets?

The current CMS policy gives rise to another important issue or question. When CMS data is included in the Food and Drug Administration Sentinel system, the Patient-Centered Outcomes Research Institute Clinical Data Research Networks, and other multi-payor, multi-source data networks, does the CMS prohibition persist? Will entities that CMS deems to have a commercial interest be prohibited from accessing these large, innovative sources that seek to improve infrastructure and patient health? If a commercial entity is contributing data to one of these databases, would that entity not be permitted to access these multi-source data files?

CMS Access Criteria Should Apply to All Research Requests, Without Regard to Profit Status or Commercial Interest.

All researchers should be subject to the same rules of data access for PHI Medicare data. The criteria[2] for access are currently:

- Strong research design
- Research question must assist CMS in managing programs/improving services[3]
- Researcher must have expertise and experience
- Researcher must sign a Data Use Agreement generally concerning handling and use of the data
- Researcher will not disclose research findings if such findings can be linked with other data where an individual's identity can be deduced
- Researcher will adhere to CMS cell size policy

There are a host of important public policy considerations that should lead to a revision in how CMS and HHS view access to RIF by a broad range of researcher requestors. The goal is a high-functioning, efficient, quality healthcare system. It will take all stakeholders in that system to reach that very important goal within the foreseeable future.

Conclusion

We applaud CMS for requesting public comments on this important topic, however, we urge you to expand your examination of data access beyond just the Medicare Part D program. Patient-level data held by federal agencies is key in allowing stakeholders to improve quality and create efficiencies needed to meet ambitious health goals in the coming years. CMS facilitation of greater data access would be a positive development that aligns with federal policy goals. The question of access and commercial interest is larger, more important, and more urgent than CMS has considered thus far.

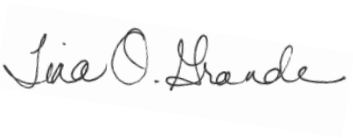
---

[2] For the complete list of criteria, see CMS information for researchers. Accessed 2/7/2014. http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Researchers.html

[3] In other places on the CMS website, it states that research proposals are evaluated on the potential of the research to improve the quality of life of Medicare beneficiaries in addition to improving services or program administration.

We would be pleased to meet to discuss these issues. Please contact Tina Olson Grande, Senior Vice President for Policy at the Healthcare Leadership Council (tgrande@hlc.org), or Robert Dubois, MD, PhD, Chief Science Officer at the National Pharmaceutical Council (rdubois@npcnow.org), for further information.

Sincerely,



Tina Olson Grande
Senior Vice President for Policy
Healthcare Leadership Council

Robert W. Dubois, MD, PhD
Chief Science Officer
National Pharmaceutical Council

NATIONAL DIALOGUE FOR Healthcare Innovation

A Sample List of Physician Collaboration Case Studies

Please visit www.ndhi.org for more information about NDHI and each of the innovation case studies referenced in this document.

ACE Inhibitors

- Snake venom played a critical role in creating ACE inhibitors, which now stand among the most successful and widely used drugs in the world. ACE inhibitors have transformed the treatment of congestive heart failure and high blood pressure.

Benzodiazepines

- A chance discovery led to the development of benzodiazepines, some of the most widely prescribed drugs for the treatment of anxiety disorder and other mental health conditions.

CAT Scan

- Refusing to take “no” for an answer leads to a Nobel Prize for the creator of the CAT scan, a life-saving diagnostic tool now used 52 million times a year around the world.

Cervical disc

- A neurosurgeon imagined a device that could be implanted in the neck to replace a deteriorated disc while still allowing for normal movement between the vertebrae.

Chickenpox vaccine

- A workshop of scientists was the catalyst for the creation of a vaccine for chickenpox.

Childhood pneumococcal Vaccine

- A doctor and two colleagues set out to find a new approach for vaccine creation that eventually led to a childhood pneumococcal vaccine that saves the lives of an estimated one million children worldwide every year.

Coronary stent

- Millions of Americans who suffered from heart disease had no alternative to open heart bypass surgery until a garage experiment with metal wires resulted in a less invasive, more effective treatment for coronary artery disease.

Cortisone

- A doctor and professor from Mayo Clinic develop a compound to battle severe inflammation, a discovery The New York Times hailed at the time as a “modern miracle.”

Cystic fibrosis diagnostic test strips

- A childhood fascination with a Life magazine cover featuring an image of DNA’s double helix structure led to a career in genetics and a test for cystic fibrosis that has significantly lowered the incidence of cystic fibrosis among newborns.

Deep brain stimulation

- A French neurosurgeon and a neurologist were treating patients for tremors one day when their "Eureka moment" led to a therapy known as Deep Brain Stimulation. DBS therapy represents one of the best stories of a medical discovery that led to a unique physician-industry collaboration that benefits patients suffering from neurological diseases such as Parkinson's disease.

EEG (electroencephalogram)

- A German physician began working on ways to measure brain electricity to better understand mental processes. His work led to the electroencephalogram, which remains the standard and most important non-invasive device for diagnosing epilepsy.

Fluorouracil

- A University of Wisconsin researcher teams up with Hoffman-LaRoche to develop fluorouracil, an important weapon in fighting cancer, particularly pre- and post-surgery for colon cancer, as well as in other cancers, including breast and certain head and neck cancers.

Gleevec

- As recently as a decade ago, chronic myelogenous leukemia patients had no good options to treat their disease – either a highly risky bone marrow transplant for which few patients qualified, or chemotherapy treatment that prolongs survival only by an average of two years, with debilitating side effects. That changed with the development of Gleevec, a pill which targets cancer cells and leaves healthy cells alone.

Haemophilus Influenza Type B vaccine

- Before a vaccine was developed, Hib was the leading cause of acquired mental retardation nationally, and the treatment of Hib-related illnesses cost the U.S. health care system over $2 billion each year. In the United States alone, the instance of Hib-related meningitis and other diseases has been reduced by 99%, such that Hib-related infections are rarely seen today.

Heart and lung bypass machine

- In 1930, after witnessing the death of a patient from a pulmonary embolectomy, a young physician conceived the idea of a machine that could support cardiac and respiratory functions during surgical procedures to repair defects in the heart and lungs. He eventually persuaded IBM to provide him with the technical expertise needed to produce a sophisticated device.

Hepatitis B vaccine

- An accidental discovery revealed an elusive virus and led to a vaccine for Heptatitis B, a virus estimated to be 100 times more infectious than HIV. This vaccine is believed to have saved tens of millions of lives in the 30 years since its creation.

Herceptin

- A concept initially greeted with skepticism led to the novel approach of targeting a specific form of breast cancer with a genetic compound. Herceptin kills the cancer cells and decreases the risk of reoccurrence, with a 49 percent improvement in overall survival.

Integrated insulin pump therapy

- The idea for an automatic insulin pump that would replace manual insulin injections circulated among diabetes specialists for years before the first version was created in the late 1970s. The CEO of Pacesetter Systems then formed a team in 1980 to develop a wearable insulin pump in conjunction with NASA and the Applied Physics Laboratory at Johns Hopkins University.

Laser eye surgery

- A laser originally used for etching silicone computer chips in the 1970s became a tool to restore sight for over five million people worldwide. Two doctors and an IBM researcher found that the laser could remove biologic material without causing heat damage to the neighboring material.

Measles vaccine

- A vaccine against one of the most contagious diseases known to man is created in a partnership between a celebrated virologist and researchers at Merck. An estimated 110 million lives have been saved in the 50 years since the measles vaccine.

Mumps vaccine

- A researcher developed a vaccine for mumps from the illness of his own five-year-old daughter. The vaccine has become one of the most widely used in the world, with over 500 million doses distributed worldwide.

Negative wound pressure therapy

- Two plastic surgeons discovered that treating hard-to-heal wounds with sub-atmospheric pressure in a localized vacuum showed promising results. They teamed up with a leader in wound management therapies to create new technologies that have dramatically improved chronic wound care and healing.

Neupogen

- Researchers cracked the code of white blood cell production and developed a compound that allows cancer patients to better withstand chemotherapy treatments. Neupogen has revolutionized the way cancer patients are treated.

Oral Contraceptives

- A pioneer and activist team up with a renowned biologist to achieve one of the 10 greatest public health accomplishments of the 20th century.

Pacemaker

- In the 1950's, external heart pacemakers existed to help regulate heart rhythm, however they were bulky, relied on external electrodes, and had to be plugged into a wall outlet. The co-founder of medical device manufacturer Medtronic, collaborated with a pioneer in open heart surgery at the University of Minnesota Medical School to develop a wearable, external, battery-powered pacemaker.

Penicillin

- A professor of bacteriology in London returned from a holiday to find an unusual mold growing in a petri dish. The zone immediately around the mold was clear, as if the mold had secreted something that inhibited bacterial growth. Researchers at Oxford University helped turn the discovery from a laboratory curiosity into a life-saving drug, and launch the age of antibiotics.

Polio Vaccine

- Polio had been around since the beginning of human history as a source of childhood paralysis. But it wasn't until the 1950's that two March of Dimes grantees took separates routes to find the cure that has all but eliminated polio in the United States and most of the world.

Prostate specific antigen (PSA) screening test

- Scarcely a quarter century ago, the diagnosis of prostate cancer was the equivalent of a death sentence, since only 4% of prostate cancers diagnosed were curable, and there was no easy way to detect the disease in an early state in men. A team of 20 scientists successfully located a prostate-specific antigen, and in partnership with the biomedical industry testing kits were developed that have now been administered more than 1 billion times worldwide.

Recombinant Factor VIII

- In the early 1980s, a small group of scientists in the San Francisco Bay Area teamed up with the young biotechnology company Genentech with the aim of discovering a way to make a blood treatment without using donated blood plasma. They were motivated by the added urgency of the recent discovery of a deadly new disease called HIV-AIDS that could be transmitted through contaminated blood plasma. Recombinant Factor VIII has virtually eliminated the transmission of HIV-AIDS and hepatitis through blood donations.

Starr Edwards Heart Valve

- A retired engineer with a passion and a garage-laboratory collaborated with a young surgeon to develop a mechanical device to replace the heart's natural valves. Once considered a "mystery killer," heart valve disease, which affects more than five million Americans, is now routinely treatable.

Statins

- Building on the earlier work of a Japanese biochemist, the chief scientist and later CEO of Merck developed the first cholesterol-lowering statins from a fungus. In the quarter-century since they were developed, statins have lowered the cholesterol and extended the lives of millions of people around the world.

Swan-Ganz Catheter

- Watching sailboats off the coast of California led a doctor to begin work with a medical device company to eventually create a catheter that for the first time allowed doctors to determine exactly how much blood to give trauma patients, monitor their overall blood flow, and confirm other diagnoses such as heart failure.

Total Knee Replacement

- Little more than a quarter-century ago, people suffering from arthritis of the knee and other debilitating joint conditions were forced to accept a difficult truth: for the remainder of their lives the best any doctor could do was minimize their pain. Today, through the work of pioneering orthopedic surgeons and a leading medical device maker, new knee replacement technology has transformed the lives of millions of people, who are up and walking hours after surgery.

Transcatheter Aortic Valve Implantation

- A pioneering cardiologist teamed up with a small company to invent a device that was "nothing less than transformational," by providing a therapeutic solution for a very large number of elderly patients with aortic stenosis who were not good candidates for traditional open-heart surgery, due to their age and condition.

Ultrasound/Echocardiogram

- Researchers harnessed a military technology to develop a simple diagnostic device that is used painlessly to detect and analyze not only diseases of the heart, but just about every major medical condition involving soft tissue.

Vacuum-Assisted Breast Biopsy

- While breast mammograms have significantly lowered the death rate from breast cancer, mammograms don't always give a complete picture. Biopsies required an invasive surgical procedure several hours in length, involving high costs and often producing substantial physical scars. That changed when a doctor and inventor founded a company to develop a device that allows for quick, multiple captures of breast tissue for biopsies through a very small incision, leaving women with hardly a scar and almost immediate recovery.

NATIONAL DIALOGUE FOR
Healthcare Innovation

Physician-Industry Collaboration Facts and Statistics

10% reduction
in all cause mortality over
30 years has a value of over
$18.5 trillion

From 1970 to 2000,
gains in life expectancy added about
$3.2 trillion per year to national wealth

Patient Benefits

Economic Benefits

INNOVATION=
Earlier detection
+
Advanced technology
+
Better treatment protocols

40% decline in mortality resulting from coronary heart disease (1980 and 2000)

30% decline in the overall hospitalization rate for heart failure (1998-2008)

50% reduction in U.S. AIDS deaths (1995-1996)

55% reduction in hospital mortality from acute myocardial infarction (1975-1995)

90% reduction in Hib-related meningitis and other diseases in the U.S. from 1975-1995

Prostate cancer screening has reduced mortality rates **saving $4,500 per life**

30-year gain in life expectancy worth over **$1.2m per person** in the current population

Gains in life expectancy added **$3.2 trillion per year to national wealth,** with half due to gains against **heart disease**

NATIONAL DIALOGUE FOR
Healthcare Innovation

A Joint Statement on 21st Century Collaboration for Healthcare Advancement

Collaboration between industry, healthcare professionals, and scientists has been at the heart of most of the advances in U.S. healthcare over the past several decades. Appropriate collaboration between non-industry healthcare professionals and scientists and industry -- guided by clear principles and conducted for the benefit of patients -- drives medical innovation, meaningful health outcome improvements, and economic growth for our nation.

For the past few years, concerns about undue influence of industry on healthcare have presented an increasingly complex challenge to medical research, education, communication, and innovation efforts. With this in mind, the National Dialogue for Healthcare Innovation (NDHI) has brought together varying perspectives to discuss issues that affect innovation and patient care. NDHI has identified four principles to guide collaborations designed to advance medical technology, innovation, and patient care. These principles do not replace or subsume the important existing guidelines and codes that have already been developed by professional societies, trade associations, government agencies, academic medical centers, or individual companies. They do, however, provide a basic framework to help guide collaborative efforts and maintain the confidence and trust of all participants in our healthcare system, including patients, providers, payers, industry, researchers, academia, and government.

1. **The benefit of patients:** Collaborations at any level, from the research lab to the doctor's office, must aim to benefit patients and put patients' interests first.

2. **The autonomy of healthcare professionals:** Healthcare professionals and scientists must be free to assess independently multiple sources of information and treat each patient in a manner consistent with the patient's needs and best medical practice. This is vital to preserve the public's trust in the innovation process and in our healthcare system.

3. **Transparency:** Patients and all those involved in healthcare should have reasonable access to relevant and meaningful information about how academic institutions, researchers, healthcare professionals, and medical products companies engage in collaborative relationships. Transparency builds trust between patients and the healthcare professionals who serve them.

4. **Accountability:** All participants across healthcare must be responsible for their actions. External regulation is important here, but internal self-regulation with recurrent training and communication is essential to this effort.

The organizations agreeing to this statement and participating in the National Dialogue for Healthcare Innovation comprise a diversity of voices, but share a common goal – to promote the American innovative spirit so that new advances in medicine and medical technology can continue to make the journey from concept to the practice of medicine for the benefit of patients. In order to do this, we seek to preserve and enhance an environment that fosters innovation of new products, practices, and ideas. This must happen with the participants in these collaborative activities understanding the importance of principles such as patients' best interests, autonomy of healthcare professionals, transparency, and accountability. Such principles will help achieve the dual goals of encouraging medical innovations that save, extend, and improve lives, while maintaining the trust in the collaboration process.

Developed and endorsed by the following organizations:

AAMC · AdvaMed · AOA American Osteopathic Association · Cleveland Clinic · Council of Medical Specialty Societies · Friends of Cancer Research · Healthcare Leadership Council · Lahey Clinic · Lilly · Medtronic · PhRMA

NATIONAL DIALOGUE FOR Healthcare Innovation

Additional endorsements:
Alliance for Aging Research
American Association of Colleges of Osteopathic Medicine
American Association of Neurological Surgeons
American College of Cardiology
American College of Osteopathic Neurologists and Psychiatrists
American College of Osteopathic Surgeons
Association of Clinical Research Organizations
Federation of State Medical Boards
Johnson & Johnson
Kansas Association of Osteopathic Medicine
Men's Health Network
Merck
Osteopathic Physicians and Surgeons of Oregon
Pfizer
Stryker
Society for Women's Health Research
South Carolina Osteopathic Medical Society
The Congress of Neurological Surgeons
Vanderbilt University School of Nursing
WomenHeart: The National Coalition for Women with Heart Disease

Individual endorsements:
Dennis Ausiello, M.D. (Harvard Medical School & the Massachusetts General Hospital)
Eugene Braunwald, M.D. (Harvard University School of Medicine and Brigham & Women's Hospital)
William N. Kelley, M.D. (University of Pennsylvania School of Medicine)
Ralph Snyderman, M.D. (Duke University School of Medicine)
Bruce Wilkoff, M.D. (Cleveland Clinic)

October 26, 2011

Jerry Menikoff, M.D., J.D.
Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway
Suite 200
Rockville, MD 20852

Re: HHS-OPHS-2011-0005 (Advanced Notice of Proposed Rulemaking on Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators)

Dear Dr. Menikoff:

The Confidentiality Coalition respectfully submits these comments in connection with the Advanced Notice of Proposed Rulemaking related to Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, published in the Federal Register on July 26, 2011 (the "ANPRM"). In this response, we (i) provide background on the Confidentiality Coalition; and (ii) offer comments on certain limited aspects of the ANPRM that relate to the privacy and security of patient information.

Background

The Confidentiality Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, clinical laboratories, patient groups, and others[1] founded to advance effective patient confidentiality protections.

The Coalition's mission is to advocate policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, enable the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions. The Confidentiality Coalition is committed to ensuring that consumers and thought leaders are aware of the privacy protections that are currently in place. And, as healthcare providers make the transition to a nationwide, interoperable system of electronic health information, the Confidentiality Coalition members believe it is essential to replace the

[1] A list of the Confidentiality Coalition members who have signed on to this letter is attached.

current mosaic of sometimes conflicting state healthcare privacy laws, rules, and guidelines with a strong, comprehensive national confidentiality standard for healthcare information.

Comments

- **The Coalition supports the premise of matching HIPAA's protections to the IRB/Human Subject Research Environment.**

Rather than mandate that Institutional Review Boards (IRBs) assess informational privacy risks each time a research project is proposed, the Department through this ANPRM is proposing to standardize privacy and security protections in the research environment, using the HIPAA privacy and security rules as the baseline standard. We wholeheartedly support this approach.

There are two aspects of this approach that are important to recognize. First, the HIPAA Privacy and Security Rules provide significant privacy and security protections to all protected health information. These safeguards – even with the upcoming regulatory changes from the HITECH Act – are well understood in the healthcare industry and have provided substantial protections to all patient information.

Second, there have been concerns throughout the healthcare industry and among our members that some of the interpretations (and misinterpretations) of the HIPAA Rules – including how they have been applied by IRBs and others in the research context – have sometimes created material impediments to effective research. We are aware of repeated instances where a lack of understanding of some of the provisions of the HIPAA rules and the protections they provide have resulted in unnecessary burdens that have not created additional or meaningful new privacy protection. Therefore, we also support the idea of removing the obligation from IRBs to address these informational privacy risks, by applying a common privacy standard across these research projects. We believe this will permit IRBs to focus on the healthcare risks that are the primary focus of their attention and their expertise, while providing meaningful privacy protections to research subjects consistent with other areas of the healthcare industry.

Therefore, we support the intent of the ANPRM – to align the definitions and requirements of HIPAA and the Common Rule, and to impose consistent privacy and security standards. We believe this is a "win-win" approach. Patient privacy and security will be protected in a consistent fashion. IRBs can focus their attention on areas that are more appropriate to their expertise. And researchers and others involved in research projects can follow a consistent approach throughout their activities.

- **We have strong concerns about adding new patient consent requirements.**

While we support the overall approach of the ANPRM, we also have strong concerns with the primary exception to this approach – the effort to impose a new patient consent requirement in certain situations related to the use and disclosure of de-identified data in connection with research studies.

The ANPRM proposes new requirements for individual consent for the research use of data, including for the use of limited data sets, and even de-identified data – that would go far beyond

HIPAA requirements. We do not believe that this step is necessary or appropriate. Instead – contrary to the overall approach taken in the remainder of the ANPRM – this step would provide new impediments to research and a different set of legal rules, in situations where the patient privacy interests are limited at best. In fact, the ANPRM purports to require new patient consent in situations where the HIPAA Rules have deemed the patient privacy concerns to essentially have been eliminated through the de-identification of healthcare data. We see no significant advantage to patients in this situation, and believe that this new requirement will create significant burdens on research projects. In fact, to obtain this consent, the provision may force research entities and others to re-identify patient data simply in order to try to obtain consent – where no such re-identification would have been permitted or appropriate in the normal course of business. Unlike the remainder of the ANPRM, we view this approach as a "lose-lose" situation. Patient privacy interests (a) could actually be harmed by forcing re-identification of patient data and (b) no significant new protection will be provided through a new and burdensome consent requirement. At the same time, this new requirement will create substantial (and perhaps insurmountable) new obligations on research entities, with significant detrimental effects on research projects. We do not believe that this is a step that makes sense in any way.

Accordingly, we believe that extending the overall approach of HIPAA's privacy and security protections to the research environment should be applied consistently.

Conclusion

The Confidentiality Coalition appreciates the Department's efforts to revise the Common Rule standards to make the requirements consistent with HIPAA. We believe that this approach will benefit the public, by improving overall healthcare research, without creating any material privacy or security concerns for patients.

The Confidentiality Coalition appreciates this opportunity to comment on this ANPRM. Please let Tina Grande at tgrande@hlc.org know if there are any comments or questions about the comments in this letter.

Sincerely,

Mary R. Grealy
President, Healthcare Leadership Council
On Behalf of the Confidentiality Coalition

Enclosure

Attachment 6

HLC MEMBERS 2014

(Alphabetized by Company)

HLC Chairman
Greg Irace
President & CEO
Sanofi US

Mark Bertolini
Chair, President & CEO
Aetna

Todd Ebert
CEO
Amerinet

Steven Collis
President & CEO
AmerisourceBergen

Rolf Hoffmann
SVP, U.S. Commercial Operations
Amgen

Anthony Tersigni, EdD, FACHE
President & CEO
Ascension

Jonathan Bush
President & CEO
athenahealth, Inc.

Joel Allison
CEO
Baylor Scott & White Health

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

William Gracey
President & CEO
BlueCross BlueShield of Tennessee

Greg Behar
President & CEO
Boehringer Ingelheim Pharmaceuticals

George Barrett
Chairman & CEO
Cardinal Health

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

Tim Ring
Chairman & CEO
C. R. Bard

Michael A. Mussallem
Chairman & CEO
Edwards Lifesciences

Alex Azar
President, Lilly USA
Eli Lilly and Company

Neil de Crescenzo
CEO
Emdeon

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

Patricia Hemingway Hall
President & CEO
Health Care Service Corporation

Robert Mandel, M.D.
CEO
Health Dialog

Daniel Tassé
Chairman & CEO
Ikaria

Daniel Evans, Jr.
President & CEO
Indiana University Health

Paul Meister
Chairman & CEO
inVentiv Health

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

Brian Ewert, M.D.
President
Marshfield Clinic

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

John Hammergren
Chairman & CEO
McKesson Corporation

Chris O'Connell
EVP & President, Restorative Therapies Group
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

Mark Neaman
President & CEO
NorthShore University HealthSystem

Christi Shaw
U.S. Country President and President, Novartis Pharmaceuticals Corporation
Novartis

Jesper Hoiland
President
Novo Nordisk, Inc.

Craig Smith
President & CEO
Owens & Minor

Susan DeVore
President & CEO
Premier healthcare alliance

Chris Wing
President & CEO
SCAN Health Plan

Tim Scannell
Group President, MedSurg & Neurotechnology
Stryker

Paul Uhrig
Acting CEO
Surescripts

Doug Cole
President
Takeda Pharmaceuticals U.S.A.

Douglas Hawthorne, FACHE
CEO
Texas Health Resources

Frank Tarallo
CEO
Theragenics

Curt Nonomaque
President & CEO
VHA Inc.

Gregory Wasson
President & CEO
Walgreens

James Chambers
President & CEO
Weight Watchers International

Jaideep Bajaj
Chairman
ZS Associates

CONFIDENTIALITY COALITION

MEMBERSHIP

Aetna
Amerinet
Amgen
AmerisourceBergen
American Clinical Laboratory Association
American Hospital Association
American Pharmacists Association
American Society for Radiation Oncology
America's Health Insurance Plans
Ascension Health
Association of American Medical Colleges
Association of Clinical Research Organizations
Athenahealth, Inc.
Baylor Scott & White Health
Bio-Reference Laboratories, Inc.
Blue Cross Blue Shield Association
BlueCross BlueShield of Tennessee
Boeringer Ingelheim Pharmaceuticals
Cardinal Health
CIGNA Corporation
Cleveland Clinic
College of American Pathologists
C.R. Bard
CVS Caremark
Edwards Lifesciences
Eli Lilly
Express Scripts
Federation of American Hospitals
Franciscan Missionaries of Our Lady Health System
Genetic Alliance
Health Care Service Corporation
Health Dialog
Healthcare Leadership Council
Healthways
Ikaria
IMS Health
Indiana University Health
Intermountain Healthcare
inVentiv Health
Johnson & Johnson
Kaiser Permanente
Marshfield Clinic
Mayo Clinic
McKesson Corporation
Medical Group Management Association
Medtronic
MemorialCare Health System
Merck
MetLife
National Association of Chain Drug Stores
National Association of Health Underwriters
National Association of Psychiatric Health Systems
National Community Pharmacists Association
NewYork-Presbyterian Hospital
NorthShore University HealthSystem
Novartis
Novo Nordisk
Owens & Minor
Pharmaceutical Care Management Association
Premier healthcare alliance
Quest Diagnostics Incorporated
Sanofi US
SCAN Health Plan
Siemens Corporation
State Farm
Stryker
Surescripts
Takeda Pharmaceuticals North America
Texas Health Resources
Theragenics
Vanderbilt University School of Nursing
VHA
U.S. Chamber of Commerce
Walgreens
Weight Watchers International
WellPoint
Workgroup for Electronic Data Interchange
ZS Associates