



August 29, 2014

The Honorable Joseph R. Pitts
Chairman
House Energy and Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts:

Thank you again for inviting me to appear before the House Energy and Commerce Subcommittee on Health on July 22, 2014 to testify at the hearing entitled, "21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication." I welcome your additional questions for the record, and I have attached my responses.

I have also included, for your reference, a recent publication by the Healthcare Leadership Council and the Bipartisan Policy Center addressing the challenges of federal health data access. This publication builds upon a roundtable discussion of experts the two organizations convened this spring.

Thank you for your continued leadership on these important topics. We look forward to continuing our work with you and your staff to identify existing barriers to allowing healthcare data to drive better care quality and value. Please feel free to reach out to Tina Grande, Senior Vice President, at tgrande@hlc.org or (202) 449-3433, with any additional questions or for clarifications on any of the responses detailed in this letter.

Sincerely,

A handwritten signature in black ink that reads "Mary R. Grealy". The signature is written in a cursive, flowing style.

Mary R. Grealy
President

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health
The Honorable Renee Ellmers

Attachment(s)

Additional Questions for the Record

1. **Ms. Grealy, you mention in your testimony that 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. How does HIPAA need to change in order to ensure that data can be used effectively for this vital research?**

The HIPAA Privacy and Security Rules generally work well for the covered entities and their business associates who are under its jurisdiction. We see no reason for significant change in these rules based on new developments in technology or otherwise. These rules – particularly the Security Rule – have been drafted to accommodate technological change on an ongoing basis.

At the same time, there are details of the HIPAA research rules that can be modified to improve the overall ability of the health care system to benefit from health information in the research context. The Department of Health and Human Services (HHS) already has begun a proceeding to modify the existing HIPAA rules related to research. HHS published an “Advance Notice of Proposed Rulemaking” in July of 2011. We attach the comment letter prepared by the Confidentiality Coalition (convened by HLC) on the advance notice. We have encouraged HHS to move forward with a proposed rule that will streamline the existing HIPAA research processes to permit a broader and easier use of health information in connection with research.

Furthermore, HIPAA establishes a perverse disincentive for covered entities to use health data to pursue “generalizable knowledge” – that is, for research. The HIPAA Privacy Rule defines “health care operations” to include, for example:

*“conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, **provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities;** patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment” (emphasis added).*

Pursuant to this provision, covered entities (such as hospitals and medical practices) can use patient information for “internal research,” to improve their own protocols and develop appropriate standards, but are limited in their ability to then publish or disseminate these results to others for broader public purposes, even if no patient information whatsoever is disclosed during that publication. We believe that, in line with the current effort to streamline the research requirements, covered entities who engage

in permitted “health care operations” activities should then be permitted to publish results “for generalizable knowledge,” so long as no patient identifiable information is disclosed during the publication. This goal could be accomplished through a revised HIPAA Privacy Rule provision or, more directly, through guidance from HHS that addresses this idea of “primary purpose” and makes clear that a health care provider that develops useful information from its patient data may then disclose the results to others.

- 2. You stated that in most research environments, patient data must be de-identified before it can be utilized but note that there are circumstances in which de-identified data is not sufficiently useful to achieve particular objectives. Would you expound upon this a little farther and explain how we should take this into account in any policy changes we consider as part of this initiative?**

While there are various processes by which patient information can be used for research purposes, one option involves the “de-identification” of “protected health information” or “PHI,” using a defined HIPAA standard, so that this “PHI” is no longer identifiable to a particular patient. At that time, the data can be used for research purposes without the need for patient permission or any other HIPAA compliance steps. However, data that has been “de-identified” according to the HIPAA standard also may not be particularly useful in a research context, because so many identifiers have been eliminated. For example, de-identified data does not contain dates associated with the individual, which makes any sort of longitudinal or chronological research nearly impossible. There are other mechanisms whereby patient data can be used for research purposes, such as the “limited data set” that can include dates in data that otherwise has been de-identified. We encourage HHS to develop additional rules and/or guidance that permits a broad use of this data where primary identifiers have been removed, either through a broader “limited data set” provision or by encouraging privacy review boards to permit disclosure of a broader range of data for research purposes without the need for additional and burdensome patient authorizations. Where appropriate procedures have been implemented (such as those required in connection with a limited data set), and where research entities have developed appropriate security procedures and means of ensuring that patient identities are not disclosed, we believe that patient privacy can be protected while still permitting more effective research. Privacy Review Boards (who have authority under HIPAA to approve research projects without the need for specific patient authorization) should be given broader guidance and additional encouragement to approve research projects where appropriate protections for patient data are in effect.

- 3. You note that there are 50 separate sets of state privacy laws and regulations that can be incredibly difficult to navigate. You believe strongly that a national privacy framework should replace this current patchwork of state laws. Would you explain what you mean by a national privacy framework and why you think it is necessary?**

The complexity of the legal structure regulating privacy is a monumental barrier. Even where HIPAA applies, it is not the only rule to abide by. States have hundreds of different, inconsistent, and overlapping laws that create meaningful compliance and operational challenges. This complexity, by itself, works against appropriate use and disclosure of information, as health care providers and others do not know how to act in many circumstances. Most of these laws (although not all) were passed before the HIPAA rules went into effect. Many of these state laws do not appropriately address any kind of electronic technology or the broader levels of cooperation and information-sharing that are common and beneficial component of the current health care system today. Many of these laws do not clearly permit the use of any vendors to assist an entity in performing services. Interpreting how these states laws compare to HIPAA is exceedingly difficult, confusing and time consuming. There is virtually no guidance on these laws, and little enforcement of these provisions. In fact, this patchwork of laws has made it extremely difficult, if not impossible, for organizations such as Health Information Exchanges (HIEs), to share data across state borders. I do not think I am exaggerating in saying that this unaligned patchwork of state privacy laws is a reason that HIEs have failed to flourish. While the HIPAA rules create a federal baseline for privacy protection, we encourage Congress to make this baseline the applicable standard nationwide, by preempting these other state laws. The HIPAA standard should be the governing standard for any entities (covered entities and business associates) that are covered by the HIPAA rules. A national standard would facilitate nationwide information exchange, interoperability, and help patients by allowing the right information to reach their providers whenever and wherever they need it.

- 4. You state in your testimony that federal health data should no longer be denied to entities perceived to have a commercial interest. What is preventing agencies from making this data available now?**
 - a. How would clarifying and modernizing any such laws and policies benefit federal public health agencies?**
 - b. Are there operational or organizational changes that could help enhance collaboration within and between federal public health agencies?**

There is standing HHS 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 (RIFs, 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). The exact origin of this policy is unclear, however it is referenced in various CMS documents.

The Centers for Medicare and Medicaid Services (CMS) recently reopened discussion of this important distinction in the January proposed rule on Medicare parts C and D (Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2015). 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.

It is not fair nor does it make sense in an era when all stakeholders, regardless of their tax status, are vital partners in improving the healthcare system. We believe that 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 needs using private-sector patient-level data. These organizations can enhance their work with appropriate access to federal program data.

HLC believes that all researchers should be subject to the same rules of data access for PHI. Current rules for access include:

- Strong research design*
- Research question must assist CMS in managing programs/improving services*
- 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.*

These rules are sufficient to ensure quality, patient-serving research and should be applied to all organizations, regardless of “commercial interest.”

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 important goal within the foreseeable future.

- 5. Would you explain what is current federal policy with respect to allowing innovative companies to access such data and why this is an impediment to additional discovery and development?**

Please see the attached publication by HLC and the Bipartisan Policy Center for details on current data access requirements and how changes in these restrictions could lead to innovative new healthcare options for consumers.

- 6. Are there more collaborative data sharing policies or initiatives in place in other countries that we could learn from?**

This is a great question, but is outside our area of expertise. The question is very complicated due to the significant structural differences between how various nations deliver healthcare.

- 7. You attach a number of examples in your testimony about lifesaving and life-transforming innovations that are the direct result of collaboration between physicians and drug and device companies. How could misinterpretation of the Sunshine Act impact this critical type of interaction and how can we proactively avoid any such unintended consequences?**

Two points. One, I think people give short shrift to the importance of educating physicians on the purpose, impact and potential side effects of new pharmaceuticals and medical devices so that they can safely and effectively make the right decisions for their patients. What some pejoratively describe as enticing physicians to use a drug or device is actually this essential education. But, second, we are seeing no indication that the Sunshine Act will explain the purposes for these transactions between physicians and manufacturers. Maybe a payment is for education on the proper uses of a new product, maybe another is for the hands-on insights that lead to new innovations in organ transplantation. This is the importance of context, to which I referred in my testimony. Less important than the dollars involved in these interactions is the impact on patient care and medical progress. Information without context can have a chilling effect on the willingness of providers to engage in collaboration and, in fact, we're already receiving reports of physicians disengaging from their prior working relationships with manufacturers. We believe it is imperative that Congress as well as all sectors of the healthcare community insist that the Centers for Medicare and Medicaid Services fully explain the nature and patient benefits of the transactions of value between physicians and innovative healthcare companies. Congress must make it clear that it will not abide any action that slows or halts medical progress that is vital to millions of patients and consumers.

- 8. Data analytics of huge bodies of data holds the potential to spur innovation and development in disease areas that haven't seen a new drug in 50 years. In your testimony, you state that "we are now in an era where researchers can harness vast amounts of data to learn at a rapid pace unlike we have ever seen." We all support the need to protect patient data: is the potential you see in big data spurring development of new treatments limited by HIPAA?**

As discussed above, we encourage a streamlining of the HIPAA rules related to research to permit a broader ability to take advantage of the broad range of health care data that can be available for research purposes. We believe strongly that these improved research practices will result in improved quality of care delivery, reduction of costs, and will lead to other benefits that we cannot yet imagine. The ongoing HHS regulatory process addressing these potential changes may be the appropriate vehicle for this effort, and we encourage HHS to move forward with this activity. We are not implying that researchers have carte blanche access to all identifiable information without any oversight, but rather, to thoughtfully develop an approach through HIPAA that makes it easier to access data to do research that improves individual and population health, benefiting society for this and future generations. We also encourage appropriate development of rules and/or guidance to govern research proceedings that relate to useful data that is outside the current structure. Researchers within the healthcare industry can utilize data from other sources where there are appropriate protections for this data.

- 9. We are entering an age where technological innovation and data have the potential to reinvigorate cures discovery and development in this country, but only so far as the regulation of these technologies allow us to go. In your opinion, do we need to review the current HIPAA and privacy paradigm in this country to ensure it is truly protecting patients – both from a privacy but also from an accessibility perspective?**

As discussed above, the current HIPAA structure strikes the appropriate balance between data sharing and the protection of patient confidentiality where it applies. At the same time, there has been a substantial growth in the volume of health related data that is available outside of the HIPAA structure (and other data that is not considered "health data" but that may be useful or relevant to appropriate research). Much of this information can be valuable for research and innovation purposes. There are various ongoing efforts to review potential regulation of this "non-HIPAA" healthcare data. While we encourage development of appropriate standards related to this "non-HIPAA" healthcare data, we must be vigilant that new laws and regulation do not stifle data-driven innovation, which is dependent on the ability to access and share data.

Question from the Honorable Renee Elmers

- 1. Ms. Grealy, in North Carolina we have academic medical centers like Duke and UNC, and joint-partnerships between the individual physicians, the bio-pharma companies and the teaching hospitals are crucial for innovation. Therefore, I'd like to know, what is the role that academic medical centers play in supporting innovation?**

Academic medical centers play a vital role in finding new treatments and cures. Nearly 85% of NIH's budget is awarded to medical schools and universities, which has resulted in many medical advances, such as in the treatment of leukemia. At one time 80% of children diagnosed with leukemia died. Today, the survival rate stands at 90% thanks to research funded by NIH and conducted in academic medical centers. Also, Mr. Mussallem mentioned in his testimony the Transcatheter Aortic Valve Replacement. The development of this lifesaving device came about due to a partnership between Edwards Lifesciences and New York Presbyterian hospital, another HLC member and premier academic medical institution.



Health Program

Health Innovation Initiative

Access to Federal Health Data: A Key Imperative for Improving Health and Health Care

Meeting Proceedings

On April 3, 2014, the Healthcare Leadership Council (HLC) convened a roundtable of public- and private-sector leaders in collaboration with the Bipartisan Policy Center's (BPC) Health Innovation Initiative to explore the benefits of federal health data, current challenges associated with access and use, and the policy changes needed to support both the availability and utility of such data, while effectively managing and maintaining privacy.

The roundtable included more than 35 leaders representing numerous sectors of the health care industry, including academic and research institutions, hospitals and health systems, health plans, life sciences organizations, technology companies, and the federal government.

To lay the foundation for the discussion, representatives from the Centers for Medicare and Medicaid Services (CMS), the National Institutes of Health (NIH), and the Department of Veterans Affairs (VA) provided an overview of current agency policies and procedures governing data-sharing and access.

Insights offered by participants in the roundtable discussion are summarized in this report.

Key Take-Aways

Benefits of Federal Data Access

Access to federal health data helps clinicians and other providers make better clinical decisions. It also supports emerging delivery system and payment models that have been shown to improve health and health care. Access also plays a key role in supporting consumer decision-making and improving population health.

Key Challenges

Challenges associated with federal health data identified by participants fall into three primary categories:

- Limitations on access to Medicare data
- Lack of flexibility in Data Use Agreements
- Restrictions associated with those who have a commercial interest

Policy Considerations

1. Further explore and encourage government-wide policies and standards for health data-sharing
2. Engage in a broad public discussion regarding situations where restrictions on health data access are appropriate
3. Expand access to federal data sets for health and health care improvements, with appropriate protections



BIPARTISAN POLICY CENTER





Benefits of Federal Data Access

American health care is moving at an unprecedented pace toward a data-driven, information-based system that will improve health outcomes, increase efficiency in health care delivery, and improve the quality of care. Health care data plays a critical role in these transformation efforts.

The use of health data:

- Helps clinicians and other providers make better decisions, leading to higher-quality, more cost-effective care;
- Powers rapidly emerging delivery system and payment models that have been shown to improve both health and health care;
- Supports efforts to improve population health, including clinical and comparative effectiveness research, monitoring and responding to public health and safety threats, and measuring outcomes to support improvements;
- Empowers consumers by helping them make better health care decisions as well as understand and manage their own health.

Given the promise of big data, the federal government has begun to promote new levels of data transparency and access for public and private entities. However, these current efforts are not robust enough to address the significant barriers that remain in appropriately accessing data that will allow these goals to be achieved.

Current Federal Policies Associated with Federal Data Access

The “open government initiative” was created in 2009 by the federal government to establish a system of transparency, public participation, and openness in government.¹ Aimed at addressing multiple broad issues, its impact on health care is tangible. As part of this effort, several health-related federal agencies are currently engaged in increasing access to federal health data, including the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), CMS, the Food and Drug Administration (FDA), NIH, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the VA. An overview of a subset of these efforts is provided below.

Centers for Medicare and Medicaid Services

As the nation’s largest payer of fee-for-service claims, representing 35 percent of total national health expenditures, CMS is the largest source of data that could be used to improve the quality and cost-effectiveness of care.² According to CMS, it already shares “more data in more formats” than any similar organization. With respect to questions about data reuse, CMS clarified that it allows reuse of data on a frequent basis, despite public misconceptions.

CMS has specific rules and procedures governing the release of Medicare and Medicaid data, summarized in more detail below. Access restrictions vary depending upon the type and cost of data, the applicability of certain

privacy-related laws and regulations, and availability of CMS resources.

The agency only allows access to data after applicable legal procedures are followed, regardless of the type or urgency of request. However, legal procedures have evolved and will continue to evolve over time to make data more accessible for legitimate needs. CMS has specified that research using certain data must benefit CMS in its effort to monitor, manage, and improve the Medicare and Medicaid programs or the services provided to beneficiaries.

CMS maintains a list of all the data that is collected within the Systems of Records (SOR).³ Any data with specific personal health identifiers is subject to the Privacy Act of 1974, the Health Insurance Portability and Accountability Act (HIPAA), and other federal government rules and regulations.^{4,5}

CMS data falls into one of the three categories listed below:

- *Research Identifiable Files (RIFs)* contain protected health information (PHI). RIF requests are subject to review by CMS' Privacy Board to ensure that the beneficiary's privacy is protected and the need for identifiable data is justified. CMS requires all RIF requestors to sign a Data Use Agreement (DUA).⁶
- *Limited Data Sets (LDS)*, which contain PHI from which certain specified direct identifiers of individuals and their relatives, household members, and employers have been removed. LDSs also require DUAs.⁷
- *Public Use Files (PUFs)*, which have been stripped of any personal identifying information.⁸

Embracing the administration's open government initiative, CMS engages in the following key efforts:

- *Qualified Entity (QE) Program*: Created under the Affordable Care Act, the QE program provides a framework for improved access to Medicare Part A, Part B, and Part D data wherein compliant QEs are expected to combine Medicare data with data from other payers to create more accurate provider performance reports.⁹
- *CMS' Virtual Research Data Center (VRDC)*: A subscription-based tool for conducting research using CMS data. The VRDC offers researchers several advantages, such as less costly data and access to more timely data.¹⁰
- *Proposed Rulemaking*: In January 2014, CMS issued a proposed rule that invited comments on a number

of aspects of Part D data access, including 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.¹¹ The agency will review the comments received as it contemplates reforms to data access policies.

The Department of Veterans Affairs

The VA participates in the Open Data Initiative which is intended to make information easier for the public to find and to facilitate its reuse by developers, non-profits, and other third parties to improve the quality and cost of health care.¹² By serving as both a payer and provider for a high number of individuals with mental health or behavioral disorders, the VA operates amid heightened concerns about record privacy and consent. Also, data from veterans' health records carry a higher risk for being re-identified (after de-identification) than other records because, in part, veterans are a smaller population. Due to such sensitivities, the VA generally releases data only to investigators with a VA affiliation, rather than entities outside of the VA.

The VA does have an interest in facilitating greater data-sharing, particularly for the purposes of collecting more data on the care that veterans seek outside the VA system.

National Institutes of Health

NIH has taken steps to increase access to federal data. For example, it funds research that generates a greater volume and wide range of data in genome wide association studies (GWAS) and has extended the current policy to encompass data from a broader spectrum of human and non-human genomic research as part of this effort.¹³ In 2014, NIH developed an online database of genotypes and phenotypes to which researchers have access.¹⁴ The White House Office of Science and Technology Policy's (OSTP) request to formalize policies on data-sharing sparked NIH's current process of drafting internal policies governing different types of data.¹⁵ Such policies are expected to be released soon.

NIH notes that future policies on data-sharing regarding genomic data will allow researchers to access sensitive data for legitimate uses.

Discussion Summary

Access to Medicare Data

Ensuring adequate access to Medicare data is a widely held concern. CMS has specified that research using certain



data must benefit CMS in its effort to monitor, manage, and improve the Medicare and Medicaid programs or the services provided to beneficiaries. Many roundtable participants believe that broadening this interpretation will create further benefits to both CMS programs and patients by dramatically increasing the bandwidth for research leading to increased care quality, system efficiency, and consumer satisfaction. While many restrictions are important and necessary, other current restrictions inhibit the true potential of data analysis in health care.

For example, access to Medicare Part D Program data must be considered differently than Part A and Part B data because CMS placed new and significant restrictions on the use of Part D data when implementing the program. Under the Part D Program, private prescription drug plan sponsors must submit to CMS a Prescription Drug Event (PDE) record that contains comprehensive information for every prescription filled under a Part D plan, which includes more than 25 million Medicare Part D beneficiaries. When linked to other Medicare claims for hospitalizations and physician services, these data are a rich source of information about patterns of drug treatment, health outcomes, and adverse events among the elderly and disabled that, to date, have not been available. Currently, access to RIFs, which include the Medicare Part D data, is not allowed under a variety of situations—including when the researcher is associated with a commercial enterprise. CMS will consider reforming the program after it reviews comments received in response to its January 2014 Proposed Rule.¹⁶ In addition, the forthcoming proposed rule on accountable care organizations (ACOs) may be another opportunity to address access to federal data for Medicare Shared Savings Program participants.

Data Use Agreements

CMS requires external researchers to sign a DUA that outlines certain restrictions placed on the data. Several challenges are created by DUAs required by CMS. First, in ACOs, DUAs prohibit data-sharing outside of the requesting organization. In an ACO, this might restrict the appropriate sharing of health data among a beneficiary's multiple providers.

Second, DUAs generally require that the data be destroyed at CMS' request, which can interfere with HIPAA tracking and compliance requirements. CMS is currently assessing ways to facilitate data access while preserving CMS control of its data.

Restrictions Imposed on Those With Commercial Interest

Currently, restrictions to federal health care data access are imposed on organizations with a "commercial interest." Entities with commercial interest can access public use files and limited dataset files.¹⁷ However, direct access to RIFs, which includes the Part D PDE data, is generally prohibited for these entities. The genesis and rationale for restricting commercial entities' access to data is not well documented. Data access restrictions on commercial entities prevent these entities from using data for research that benefits the public, such as improving clinical trial design or studying the use and effectiveness of a treatment. Academic organizations have greater access to federal data because historically these organizations have tools in place—such as peer review procedures—that create limits on their use of the data. CMS acknowledges that academic organizations can also use data for commercial purposes rather than purely academic purposes and that the distinction between commercial and academic entities for the purposes of data access may need to be reconsidered.

A more structured definition of commercial interest that focuses on the use of the data as opposed to the organization that uses the data may be more appropriate. Roundtable participants encouraged CMS to expand the discussion of appropriate access to PDE data by entities with commercial interests to the broader, long-standing Department of Health and Human Services policy that denies access by commercial entities to federal Medicare A, B, D, Medicaid, and possibly other program datasets. Many believe it is time to reconsider this overarching policy that affects access to federal program RIFs in Medicare, including Part D, and in other federal health programs.

These concerns are relevant for more than just government and commercial entities. Other efforts to leverage health data for system-wide improvement, such as those through the Patient Centered Outcomes Research Institute (PCORI), face possible challenges due to restrictions on data access and use. PCORNet—PCORI’s large, widely representative, national network for conducting clinical outcomes research—is designed to help a wider audience access health data in order to perform comparative effective research studies.¹⁸

Several potential approaches to improve the current data restrictions imposed on commercial entities and other users were proposed during the HLC-BPC roundtable discussion, including:

- Improving and expanding the current peer-review process used for academic research to commercial research;
- Educating patients about the benefits of data-sharing and expanded data access to facilitate higher levels of patient consent and cooperation;
- Issuing requests for information and holding future roundtable meetings to explore revisions to current data-sharing restrictions in a way that balances research needs and privacy protections; and
- Basing data access on considerations such as whether the entity is using data for the public good and whether the entity has appropriate data security measures in place.

Policy Considerations

Based on insights shared by meeting participants and previous policy work, HLC and BPC offer the following policy considerations.

1. As part of the administration’s open government initiative, the government 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. Consistency across federal agencies could reduce confusion among data users and allow third parties to more efficiently analyze the U.S. health care system.

2. The federal government should convene all stakeholders for a broad discussion of situations where restrictions on data access are appropriate.

As a product of this discussion, government could establish a more consistent rationale for restrictions on health data that continue to exist. This discussion should revisit the feasibility of regulating access by intent of the researcher, rather than by the type of organization involved.

3. 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. Private-sector organizations should have access to information on programs and services they deliver—particularly when this information supports decision-making. 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.

Conclusion

Discussions during the HLC and BPC roundtable shed new light on key policy issues surrounding increased access to federal health data for improving health and health care in the United States. This meeting report touches briefly on the role of federal data and current strategies for increased access and sharing, and also offers crucial insights into some of the greatest challenges to future progress. Ultimately, it is clear that the federal government, along with additional public- and private-sector leaders and policymakers, must continue to foster and engage in the kind of rich dialogue that occurred during this roundtable discussion in order to move the nation forward toward better care and better health for all citizens.

Endnotes

1. "Memorandum for the Heads of Executive Departments and Agencies," The White House, <http://www.whitehouse.gov/open/documents/open-government-directive>
2. "National Health Expenditures Projections 2012-2022," Centers for Medicare and Medicaid Services, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/proj2012.pdf>
3. "Systems of Records," Centers for Medicare and Medicaid Services, last modified March 2, 2013, <http://www.cms.gov/Regulations-and-Guidance/Guidance/PrivacyActSystemofRecords/Systems-of-Records.html>
4. "Privacy Act of 1974," Centers for Medicare and Medicaid Services, last modified June 3, 2013, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/PrivacyActof1974.html>
5. "Summary of the HIPAA Privacy Rule," Department of Health and Human Services, <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>
6. "Federal Regulations Relating to the Release of CMS Data," Research Data Assistance Center (RESDAC) Centers for Medicare and Medicaid Services, last modified August 9, 2012, <http://www.resdac.org/resconnect/articles/147>
7. "Federal Regulations Relating to the Release of CMS Data," Research Data Assistance Center (RESDAC) Centers for Medicare and Medicaid Services, last modified August 9, 2012, <http://www.resdac.org/resconnect/articles/147>
8. "Federal Regulations Relating to the Release of CMS Data," Research Data Assistance Center (RESDAC) Centers for Medicare and Medicaid Services, last modified August 9, 2012, <http://www.resdac.org/resconnect/articles/147>
9. "Qualified Entity Program," Centers for Medicare and Medicaid Services, last modified June 18, 2014, <http://www.cms.gov/QEMedicareData>
10. "CMS Virtual Research Data Center (VRDC)," Research Data Assistance Center (ResDAC) Centers for Medicare and Medicaid Services, 2013, <http://www.resdac.org/cms-data/request/cms-virtual-research-data-center>
11. "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs." *Federal Register: A Proposed Rule by the Centers for Medicare and Medicaid Services*. January 10, 2014., 1917 -2073. <https://www.federalregister.gov/articles/2014/01/10>
12. "FY 2013-2015 Information Resources Management Strategic Plan." *Department of Veteran Affairs, Office of Information and Technology*. March 24, 2014., 34-35. http://www.ea.oit.va.gov/docs/VA_IRM_Strategic_Plan_Final_Signed_20140424.pdf
13. "Genomic Data Sharing Policy," The National Institutes of Health, <http://gds.nih.gov/03policy2.html>
14. "Database of Genotypes and Phenotypes (dbGaP)," The National Institutes of Health, <http://www.ncbi.nlm.nih.gov/gap>
15. "Memorandum for the Heads of Executive Departments and Agencies," Executive Office of the President: Office of Science and Technology Policy, http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf
16. "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs." *Federal Register: A Proposed Rule by the Centers for Medicare and Medicaid Services*. January 10, 2014., 1917 -2073. <https://www.federalregister.gov/articles/2014/01/10>
17. "Guidance Materials for Consumers," US Department of Health and Human Services: Health Information Privacy, <http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html>
18. "PCORnet: The National Patient-Centered Clinical Research Network," <http://pcornet.org/>



About the Healthcare Leadership Council

The Healthcare Leadership Council (HLC), a coalition of chief executives from all disciplines within American health care, is the exclusive forum for the nation's health care leaders jointly to 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 health care 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 accelerate the growth of health information technology in order to promote quality improvement and improve care through patient information-sharing while also protecting important patient privacies.

Based on the interest of its member CEOs, HLC has convened leaders from all disciplines within American health care to consider the challenges and opportunities of "big data" health policy. HLC envisions a future in which public- and private-sector health care organizations securely share information in an efficient, effective manner that is accessible and useful for all stakeholders. HLC members have already proved that they can harness data to improve care and value in health care. 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 cannot yet be imagined. See www.hlc.org.

About the Bipartisan Policy Center

Established in 2007 by former Senate Majority Leaders Howard Baker, Tom Daschle, Bob Dole, and George Mitchell, BPC is a nonprofit organization that drives principled solutions through rigorous analysis, reasoned negotiation, and respectful dialogue. With projects in multiple issue areas—such as democracy, economic policy, energy, housing, immigration, national security, and health care—BPC combines politically balanced policymaking with strong, proactive advocacy and outreach.

The BPC Health Innovation Initiative conducts research and collaborates with experts and stakeholders to advance recommendations that promote innovation and drive improvements in the cost, quality, and patient experience of care. BPC's work in supporting the use of data to improve health and health care includes convening leaders and releasing numerous reports that address the electronic information sharing needs of both individuals and new models of care and the policies and strategies required to accelerate information sharing. See www.bipartisanpolicy.org.

Acknowledgements

HLC and BPC would like to thank and acknowledge the roundtable participants for contributing their time and expertise to the interactive policy discussion. HLC and BPC would also like to acknowledge Chris Adamec, health policy manager, HLC; John Michael DeCarlo, policy analyst, BPC; Tina Grande, senior vice president, policy, HLC; Janet Marchibroda, director, Health Innovation Initiative and executive director, CEO Council on Health and Innovation, BPC; and Ann Gordon, editor, for their contributions to this report.

Disclaimer

This report is a product of the HLC and BPC. This meeting summary was prepared by HLC and BPC staff as a factual summary of discussions that occurred during the meeting hosted by HLC in collaboration with the BPC Health Innovation Initiative on April 3, 2014. The statements made are those of the authors or individual meeting participants and do not necessarily represent the views of all of the meeting participants. Also, the findings and recommendations expressed herein do not necessarily represent the views or opinions of the Bipartisan Policy Center, its founders, or its board of directors.

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athenahealth

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Ascension Health

Mary Ella Payne,
Ascension Health

David Liss,
Bio-Reference Laboratories, Inc.

Janet Marchibroda,
Bipartisan Policy Center

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Elizabeth Sump,
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Matt Krupnick,
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Healthcare Leadership Council

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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 others¹ 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

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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,

A handwritten signature in cursive script, appearing to read "Mary R. Gentry". The signature is written in black ink and is positioned below the word "Sincerely,".

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

Enclosure



Steering Committee Signatories

Aetna	National Association of Chain Drug Stores
American Hospital Association	Pharmaceutical Care Management Association
America's Health Insurance Plans	Pharmaceutical Research and Manufacturers of America
Association of Clinical Research Organizations	Premier healthcare alliance
Blue Cross Blue Shield Association	Surescripts
CVS Caremark	Texas Health Resources
Federation of American Hospitals	VHA
Healthcare Leadership Council	Walgreens
Health Dialog	WellPoint
IMS Health	Wolters Kluwer Pharma Solutions
Marshfield Clinic	
Mayo Clinic	
McKesson Corporation	

General Membership Signatories

Abbott	Genentech, Inc.	National Community Pharmacists Association
Adheris	Genetic Alliance	NewYork-Presbyterian Hospital
American Academy of Nurse Practitioners	Health Care Service Corporation	NorthShore University HealthSystem
Amerinet	Health Industry Distributors Association	Novartis
AmerisourceBergen	Healthways	Novo Nordisk
American Pharmacists Association	Humana, Inc.	Pfizer
Ascension Health	Ikaria	Press Ganey
AstraZeneca	Intermountain Healthcare	ResMed
Baylor Health Care System	Johnson & Johnson	SAS
BlueCross BlueShield of Tennessee	Kaiser Permanente	sanofi-aventis
Cardinal Health	Lahey Clinic	SCAN Health Plan
CareFusion	Medical Group Management Association	SCHOTT
Caris Life Sciences	MedAssets	Siemens Corporation
Catalina Health Resources	Medtronic	Society for Human Resource Management
CIGNA Corporation	MemorialCare Health System	State Farm
Cleveland Clinic	Merck	Theragenics
Care Continuum Alliance	MetLife	Vanderbilt University School of Nursing
College of American Pathologists	National Association of Health Underwriters	U.S. Chamber of Commerce
Covidien	National Association of Manufacturers	Wal-Mart
C.R. Bard	National Association of Psychiatric Health Systems	Weight Watchers International
Eli Lilly		
Franciscan Missionaries of Our Lady Health System		
Fresenius Medical Care		