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

HEALTHCARE LEADERSHIP COUNCIL

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.

Roundtable Participants

Stephanie Zaremba,
athenahealth

Meg McElroy,
Ascension Health

Mary Ella Payne,
Ascension Health

David Liss,
Bio-Reference Laboratories, Inc.

Janet Marchibroda,
Bipartisan Policy Center

Niall Brennan,
Centers for Medicare and Medicaid Services

Allison Oelschaeger,
Centers for Medicare and Medicaid Services

Elizabeth Sump,
Cleveland Clinic

Matt Krupnick,
Dell

Chris Adamec,
Healthcare Leadership Council

Tina Grande,
Healthcare Leadership Council

Mary R. Grealy,
Healthcare Leadership Council

Kim Gray,
IMS Health

Jody Hoffman,
IMS Health

Victoria Zagaria,
Intel

Danielle DeForge,
inVentiv Health Inc.

Steve Phillips,
Johnson & Johnson

Kathleen Harrington,
Mayo Clinic

Jen Mallard,
Mayo Clinic

John Hopkins,
McKesson Corporation

Scott Devine,
Merck & Company, Inc.

Angela Stewart,
Merck & Company, Inc.

Jim Cimino,
National Institutes of Health

Jane Horvath,
National Pharmaceutical Council

Joe Selby,
Patient Centered Outcomes Research Institute

Kristen Axelsen,
Pfizer

Robert Popovian,
Pfizer

Danielle Lloyd,
Premier Healthcare Alliance

Jeremy Leffler,
Sanofi US

Lana Skirboll,
Sanofi US

Max Sow,
Surescripts

Christine Dang Vu,
The Brookings Institution

Amy Kilbourne,
U.S. Department of Veterans Affairs

Tomas J. Philipson,
University of Chicago

Jason Doctor,
University of Southern California Center for Health Policy and Economics

Erin Trish,
University of Southern California Center for Health Policy and Economics

Nandini Selvam,
Wellpoint

Marcus Wilson,
Wellpoint

BIPARTISAN POLICY CENTER

1225 Eye Street NW, Suite 1000
Washington, DC 20005
(202) 204-2400

WWW.BIPARTISANPOLICY.ORG

HEALTHCARE LEADERSHIP COUNCIL

750 9th Street, NW, Suite 500
Washington, DC 20001
(202) 452-8700

WWW.HLC.ORG