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June 5, 2019

The Honorable Lamar Alexander
Chairman
Senate Committee in Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate Committee in Health, Education, Labor and Pensions
404 Senate Hart Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray,

Thank you for the opportunity to provide comments on the discussion draft of the Lower Health Care Costs Act, and for working on a bipartisan basis to reduce health care spending while improving patient outcomes. Several aspects of the proposed legislation would use health data—including health insurance claims—to meet those goals. However, gaps remain to fully realize the intent of the legislation to gather better data on health outcomes and equip patients with information about their care.

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products and reducing costs. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of electronic health records.

This draft bill builds on bipartisan efforts from the committee to improve the availability of health data, increase transparency in health care, and allow patients to be active participants in their care. The 21st Century Cures Act (Cures) took major steps toward those aims by equipping patients and clinicians with better information to inform care decisions. This bill contiunes that work, with several aspects of the package geared towards improving access to patient data while protecting privacy. Pew is pleased to provide analysis of the policies proposed in this legisaltion based on our research into these important areas.

Access to claims data can improve care, but gaps remain

Two parts of the discussion draft bill emphasize the importance of claims data to give patients and clinicians the information they need to make informed medical decisions.

Section 303 of the draft legislation would create a nationwide claims database, which would aggregate medical information on millions of patients—while protecting privacy—to help identify factors that influence the costs and quality of care. This section would also authorize grants to states so they can create and maintain similar claims-based transparency initiatives.

Section 501 of the draft bill would require commercial health insurers to grant patients access to their health insurance claims data, a list of in-network providers, and expected out-of-pocket

costs via application programming interfaces, or APIs, which are software tools that allow different systems to communicate. APIs are the backbone of the modern internet. These tools allow websites to aggregate flight information, track personal financial habits, and display social media posts in real time. APIs operate in the background, connecting and transferring information between different systems. Previously through the Blue Button 2.0 program, the Centers for Medicare & Medicaid Services (CMS) ensured that patients can download their Medicare claims data via APIs. Now, in this proposal, Congress proposes to extend that capability for patients with insurance coverage by private health plans, thus giving them a holistic understanding of the services and treatments that they have received from different health care providers.

In tandem, these provisions represent another action by Congress that emphasizes the value of claims data to improve patient care. Claims contain a wealth of data, that when centralized will help patients, clinicians, health plans, and researchers understand patient outcome trends. Claims are especially useful for this purpose because, unlike other information sources, they contain data for nearly every encounter with the health care system for a specific individual. For example, claims information collected over many years may contain data showing that a patient received a specific prescription drug, had surgery, and visited the emergency department. As claims transmissions from health care providers to payers are already standardized, they are more easily aggregated from different sources and over time. It is precisely this characteristic of claims that has made them a valuable source of information for researchers to evaluate the correlation between different medical interventions and patient outcomes. Health care providers, health plans, and policymakers can then use those findings to improve the quality and safety of care, and reduce spending.

Congress's efforts to provide researchers and patients with this information, while laudable, omit a critical element highlighted by Pew's research on ways to improve patient safety. Currently, claims only indicate that a particular procedure was performed—for example, a total knee replacement—but not the brand and model of implant used. In parallel, the unique device identifier system developed by the Food and Drug Administration (FDA) provides each medical device with a code corresponding to its brand and model. Adding the device identifier (a portion of the unique device identifier that indicates the product brand and model) to claims can fill the gap, and will enable the same benefits for patients with implants as Congress intends for health care writ large.[1] Pew has conducted research on how to leverage the new unique device identifier system to improve patient care, and worked with many organizations—including hospitals, clinicians, and patients—to advance private sector actions to support the addition of device identifiers to claims.[2]

Adding device identifiers to claims data will let researchers use the nationwide claims database proposed in Section 303 of the discussion draft to study safety associated with different types of implants. FDA or researchers could identify devices that are likely to fail prematurely, and prevent patient harm—even death—associated with faulty products.[3] Detection of safety issues sooner would also reduce costs; the Office of the Inspector General of the Department of Health and Human Services found that the recall or premature failure of just seven cardiac device types cost the Medicare program $1.5 billion and patients an additional $140 million in out-of-pocket expenses.[4]

Similarly, patient access to claims data with detailed information about their implants would allow them to better know if they have a recalled device or seek brand-specific follow up care from clinicians. Adding device identifiers to claims data would enable patients to get the device identifiers of implants they have when requesting information from health plans.

Adding device information to claims has bipartisan support, including from Senate Finance Committee Chairman Chuck Grassley and Senator Elizabeth Warren, who have been calling for the inclusion of medical device unique identifiers on claims forms since 2014.[5] In addition, many health plans, hospitals, and providers representing clinicians that implant these devices support this commonsense change.[6] Research conducted by experts at Brigham and Women's Hospital has also shown that adding device identifiers to claims is "straightforward" and does not introduce an undue burden on clinicians.

As your Committee evaluates ways to leverage claims data and reduce costs, Congress should support efforts to incorporate device identifiers in claims. X12—the organization that oversees claims transactions standards—has issued preliminary recommendations to add device identifiers for implants to the next iteration of health insurace claims transactions. We urge the Committee to express support for this bipartisan change, and work with CMS to ensure that the agency updates claims transactions to include medical device identifiers.

Standards-based APIs can advance Congress' goals
Section 501 of the discussion draft would build on efforts from CMS—in recently proposed rulemaking—to secure patient access to their claims data. CMS achieves this by supporting the use of APIs built on a common standard, called the Fast Interoperability Healthcare Resources. Use of this standard will help different applications—such as on smartphones—more easily interpret the data request by patients from health plans.

We urge Congress to support CMS in the use of standards-based APIs, and to continue to work with CMS and the Office of the National Coordinator for Health Information Technology (ONC)—which oversees extraction of data from electronic health records—to ensure that more data elements are made available to patients and clinicians.

Taking steps to address gaps in privacy
Section 503 of the discussion draft tasks the Government Accountability Office (GAO) with studying gaps in privacy and security protections when patients gain access to their health information on their phones via applications, and to identify opportunities to improve privacy.

This provision would build on previous efforts from Congress to support patient use of mobile applications to improve their care. Congress in Cures required ONC to develop new criteria for EHRs to make "all data elements" available via APIs, which would allow patients to download their health records more easily into the applications of their choice. Pew's research on data standardization and exchange has indicated that use of APIs could represent a significant turning point in the interoperability of health information. Recent draft regulations from ONC implementing this provision have the potential to improve the effectiveness and use of health information technology by equipping patients and clinicians with better information to inform

care decisions. In Cures, Congress also instructed GAO to conduct a study on patient access to health data.

These efforts from Cures—which, among other advances, provide patients data on their phones—can help give patients the information they need; however, they could also introduce privacy concerns if not addressed. Once data is in the patient's possession in a smartphone application, protections from the Health Insurance Portability and Accountability may no longer apply. Instead, the terms and service conditions of the application would govern how the data are used (such as whether the information can be made available for research purposes). Congress should work with ONC and CMS to ensure that patients are informed about how their data are being used so that the API provision from Cures is not undermined.

In parallel, Pew is conducting focus groups with patients across the country to understand how they want to access their data, and how it should be used and shared. Pew is also conducting interviews with EHR developers and health care providers on the current state of APIs. We look forward to sharing our research findings with the Committee.

Conclusion

The bipartisan passage of Cures launched a new era for improving the use of health data and equipping patients with access to their information. Policymakers' focus on ways to better leverage claims data and support secure patient access to their information will help build on those provisions to further improve the quality and coordination of care.

Thank you for the opportunity to provide comments on this discussion draft of the Lower Health Care Costs Act. Should you have any questions or if we can be of assistance, please contact me at 202-540-6333 or bmoscovitch@pewtrusts.org.

Ben Moscovitch
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The Pew Charitable Trusts

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[1] The Pew Charitable Trusts, "Unique Device Identifiers Improve Safety and Quality," (2016), https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/07/unique-device-identifiers-improve-safety-and-quality.

[2] The Pew Charitable Trusts, "Implementing Unique Device Identification," (2015), https://www.pewtrusts.org/-/media/assets/2015/09/udiimplementation-report.pdf.

[3] Associated Press, "Medical devices for pain, other conditions have caused more than 80,000 deaths since 2008," Stat News (blog), November 25, 2018, https://www.statnews.com/2018/11/25/medical-devices-pain-other-conditions-more-than-80000-deaths-since-2008/.

[4] Department of Health and Human Services, Office of the Inspector General, "Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices," (2017), https://oig.hhs.gov/oas/reports/region1/11500504.asp.

[5] Chuck Grassley, "Grassley, Warren Call for Inclusion of Medical Device Identifiers on Medicare Claim Forms," press release, June 18, 2018, https://www.grassley.senate.gov/news/news-releases/grassley-warren-call-inclusion-medical-device-identifiers-medicare-claim-forms.

[6] The Pew Charitable Trusts, "Unique Device Identifiers Improve Safety and Quality," (2016), https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/07/unique-device-identifiers-improve-safety-and-quality.