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Submitted electronically via email to: InnovationCaucus@mail.house.gov

The Honorable Mike Kelly
United States House of Representatives
1707 Longworth House Office Building
Washington, DC 20515

The Honorable Ron Kind
United States House of Representatives
1502 Longworth House Office Building
Washington, DC 20515

The Honorable Markwayne Mullin
United States House of Representatives
1113 Longworth House Office Building
Washington, DC 20515

The Honorable Ami Bera, M.D.
United States House of Representatives
1431 Longworth House Office Building
Washington, DC 20515

RE: Request for Information: Health Care Innovation Caucus

Dear Representatives Kelly, Kind, Mullin and Bera,

The Pew Charitable Trusts is pleased to respond to the Health Care Innovation Caucus' request for information (RFI) regarding improved quality of care and lower costs for consumers across the United States. Pew is a non-profit research and policy organization with a number of initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products and reducing costs.

Attached please find responses from two of our projects, the Antibiotic Resistance Project (ARP) and the Health Information Technology project (HIT). Below please find brief descriptions of these projects:

1. ARP—Pew's antibiotic resistance project supports policies that would spur the creation of new antibiotics by removing the regulatory, economic, and scientific obstacles that impede antibiotic discovery and development; and establish stewardship programs to ensure that antibiotics are prescribed only when necessary in human health care settings. For more information on our work on antibiotic resistance please visit <http://www.pewtrusts.org/en/projects/antibiotic-resistance-project>
2. HIT—Pew's HIT project seeks to enhance interoperability among electronic health record (EHR) systems through improved patient matching and use of standards, and incorporate specific data on the type of medical implants used in procedures to better evaluate the quality and safety of devices. For more information on our work on HIT please visit <http://www.pewtrusts.org/en/projects/health-information-technology>

Thank you for the opportunity to respond to the Health Care Innovation Caucus RFI. If you need additional information please contact Sarah Despres at (202) 540-6601 or sdespres@pewtrusts.org

Sincerely,

Allan Coukell
Senior Director, Health Programs
The Pew Charitable Trusts

ANTIBIOTIC RESISTANCE

Antibiotic overuse poses a public health threat by contributing to antibiotic resistance. Antibiotic stewardship programs will promote appropriate use of antibiotics, and will improve patient outcomes and healthcare quality and should be integrated into innovative, value-based healthcare programs.

Antibiotics underpin modern medicine and are critical to treating a wide range of conditions. At the same time, antibiotic use drives the development of resistance, which can make these important drugs ineffective. And antibiotics can have significant adverse effects, including *Clostridium difficile* infection, a potentially fatal diarrheal disease. The Centers for Disease Control and Prevention (CDC) estimate that about one third of antibiotics used in hospitals are inappropriate and previous analyses by the Pew Charitable Trusts and the CDC found that approximately 30 percent of antibiotics prescribed in the outpatient setting are unnecessary. Antibiotic stewardship efforts – which aim to ensure that antibiotics are only prescribed when needed and that the right antibiotic, at the right dose, for the right duration is given to the patient – have been shown to improve patient safety, reduce cost, and slow the development of antibiotic resistance by reducing inappropriate antibiotic use.¹ Pew recently completed a [case series](#) which highlights how hospitals of varying sizes and resource levels across the US have been able to implement antibiotic stewardship programs that successfully demonstrated favorable economic and patient outcomes. Pew and CDC also created a guide for critical access hospitals to help these facilities implement stewardship programs using available resources.

Given the clear benefits to improving health care quality and public health, antibiotic stewardship should be included as part of value-based health care programs. Both the private and public sectors have already taken steps to include antibiotic stewardship as part of quality improvement activities. For example, Anthem recently included [standards](#) for antibiotic stewardship programs in the Quality-In-Sights Hospital Incentive Program, a performance-based reimbursement program for hospitals. In addition, the Federal Office of Rural Health Policy also recently began requiring critical access hospitals that participate in the Medicare Beneficiary Quality Improvement Project to have an antibiotic stewardship program as part of the Medicare Rural Hospital Flexibility Grant Program. These and other efforts to create incentives for stewardship have great promise to improve patient safety, reduce cost, and slow the development of antibiotic resistance.

HEALTH INFORMATION TECHNOLOGY

Advancing high quality, value-based care relies on clinicians having the data they need to provide the right care for each patient. As patients often obtain healthcare services at many different facilities, clinicians may lack key information to inform care delivery. Improving the coordination of care across multiple locations can lead to better outcomes and lower costs, but requires sharing critical health data.¹

Two overarching changes to how information is gathered and used would improve clinicians' ability to provide value-based care: enhanced interoperability among electronic health record (EHR) systems through improved patient matching and use of application programming interfaces (APIs); and better data on the type of medical implants used in procedures to improve the evaluation of the quality and safety of devices.

Interoperability

Several key barriers inhibit the ability to exchange clinical data stored within EHRs including: challenges linking individuals with their records (referred to as patient matching); and difficulties effectively accessing medical information contained in these records. The Health Care Innovation Caucus has recognized the important role that interoperability plays in transforming from a volume-driven to a value-driven system in asking how health technologies can improve interoperability and data sharing.

¹ Tamar F. Barlam et al. "Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America," *Clinical Infectious Diseases*, 62, no. 10 (2016):e55-e77, <https://doi.org/10.1093/cid/ciw118>.

Improvements to patient matching are essential to interoperability

Patient matching is the ability to link a patient to his or her health records that may be held at multiple locations. Researchers have found match rates as low as 50 percent when matching across healthcare facilities.² This challenge in correctly linking an individual with his or her records may make it difficult to coordinate between different facilities and thus could affect care quality. Improving patient matching is a necessary step in creating a healthcare system that provides high-quality care at affordable prices.

Pew is conducting research to better understand challenges with patient matching and to evaluate solutions to this interoperability problem. For example, we are assessing whether the use of more detailed standards for demographic data—such as address and date of birth—could help enhance match rates, or whether individuals can be involved in matching their records—such as by using a smartphone application.

The Office of the National Coordinator for Health Information Technology (ONC), the federal agency that oversees EHRs, has opportunities to improve patient matching. As required by the 21st Century Cures Act (Cures) passed in 2016, ONC is developing a framework to support nation-wide interoperability. As part of that framework, Congress should ensure that the agency takes steps to improve patient matching—such as by encouraging better standards for the data elements that must be exchanged—so that data transmitted can be matched to the right patients.

Effective use of APIs critical to interoperability

APIs are tools that allow two systems or software applications to communicate with each other. Although APIs could improve the communication of clinical data across different systems, they have not yet been widely used to do so. Through Cures, Congress directed ONC to develop regulations for patients and clinicians to receive greater access to information through APIs, and make documentation and terms of use open and available to the public. These APIs must allow access, exchange, and use of “all data elements in a patient’s electronic health record to the extent permissible under applicable privacy laws” without “special effort.”³ This API functionality could not only allow patients easier access to information from their own health record, but also facilitate many other uses, including fostering interoperability among facilities and development of new clinical decision tools for care providers.

While Cures requires health IT developers to make “all data elements” in the EHR available, it does not provide details on what information specifically should be included as part of defining that term. As ONC develops regulations to implement this provision, the agency should define “all data elements” for availability via APIs to encompass information beyond what is currently required in the Common Clinical Data Set (CCDS).⁴ Although the CCDS includes medications, allergies and other information that EHRs must exchange, it lacks some clinically relevant data, such as written notes, information from medical devices, social determinants of health data, or genomic test results that patients and clinicians may need. Establishing transparent and open APIs to allow data extraction from EHRs will better ensure that patients and their care providers can access health record information to support coordination and improve outcomes.

Once ONC establishes criteria for these APIs, the Centers for Medicare & Medicaid Services (CMS) could encourage hospital adoption of EHRs with this functionality through their payment programs.

Better data on device performance can save lives, reduce costs

In addition to interoperability, better access to information on the quality and safety of medical devices can support value-based care.

To provide better data on medical devices, Congress required the Food and Drug Administration (FDA) to develop a unique device identifier (UDI) system, which provides each product with a code corresponding to its brand and model. Once added to real-world data sources—such as EHRs and insurance claims forms—UDIs can provide patients and clinicians additional information on the medical devices they use. While ONC

has advanced the addition of UDIs to EHRs, the incorporation of device identifiers—particularly for implants, such as cardiac stents and artificial joints—to claims data still requires support from CMS.

Adding UDIs to claims can better equip clinicians with enhanced data on the performance of different implants, and better guide decisions on which devices to use to optimize quality. Claims, unlike other data sources, contain data for nearly every encounter with the healthcare system for a specific individual, and are standardized across providers and payers to make it easier to aggregate the information. 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, even if those events had all occurred at different health systems. Adding UDI to claims would allow researchers to use claims to evaluate devices in the same way they already evaluate drugs and procedures—to identify whether certain products provide better value than others.

Incorporating UDIs in claims can also generate savings. The Office of the Inspector General (OIG) of the Department of Health and Human Services has found that the failures of just seven cardiac implants cost Medicare \$1.5 billion to treat affected patients, and an additional \$140 million directly to beneficiaries in out-of-pocket costs.⁵ OIG recommended the addition of device identifiers to claims to detect these problems sooner, saving lives and money.

The policy also has support from the Medicare Payment Advisory Commission and other groups from across the healthcare system—including health plans, large hospital systems, clinical societies that represent physicians who implant these products, patient groups, and many other organizations.⁶ Adding device identifiers to claims has also generated bipartisan support in Congress.

Congress could help further advance this commonsense policy by supporting efforts to add device identifiers to claims to advance the development of better data that can improve care quality, safety, and value. As the Health Care Innovation Caucus works to promote alternative payment models based on value rather than utilization, we urge you to consider the importance of interoperability and robust data on device performance in reaching those goals. Interoperability is essential to care coordination as patients travel throughout the health system and can help maintain high quality of care while reducing costs. Additionally, as procedures involving medical devices can vary significantly in quality and cost, better data on implant performance can enhance clinician and patient decisions on the products to use. By prioritizing these topics, the Health Care Innovation Caucus can help ensure the success of value and outcomes based payment systems.

¹ “Care Coordination,” Agency for Healthcare Research and Quality, last modified July 2016, <https://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html>.

² Genevieve Morris et al., “Patient Identification and Matching Final Report,” Feb. 7, 2014, https://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf.

³ 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

⁴ 2015 Edition Certification Companion Guide, Office of the National Coordinator for Health Information Technology, last modified Feb. 2018, https://www.healthit.gov/sites/default/files/2015Ed_CCG_CCDS.pdf.

⁵ Daniel R. Levinson, “Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices,” Department of Health and Human Services Office of Inspector General, Sept. 2017, <https://oig.hhs.gov/oas/reports/region1/11500504.pdf>.

⁶ “Report to Congress: Medicare and the Health Care Delivery System,” Medicare Payment Advisory Commission, June 2017, http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.