THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700 215.575.9050 Phone
Philadelphia, PA 19103-7077 215.575.4939 Fax

901 E Street NW, 10th Floor 202.552.2000 Phone
Washington, DC 20004 202.552.2299 Fax
www.pewtrusts.org

February 2, 2016

The Honorable Lamar Alexander, Chair
The Honorable Patty Murray, Ranking Member
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Senators Alexander and Murray,

Thank you for the opportunity to comment on your draft legislation to improve patient safety, care quality and efficiency through the use of health information technology (IT).

The Pew Charitable Trusts is an independent, non-profit research and public policy organization with a number of drug and medical device initiatives focused on improving quality of care, safety and innovation.

Our comments on the draft legislation are informed by our work on clinical data registries and ways to use electronic health records (EHRs) to improve patient safety. These comments will focus on:

- Adopting better patient matching methods;
- Promoting data integration to enhance interoperability; and
- Improving the safety and usability of EHRs.

Adopting better patient matching methods

Many health data systems—including registries—obtain information from EHRs and other clinical sources, but often face difficulties determining whether the same individual's data exists in multiple locations. Similarly, patients' own medical histories are distributed in EHRs located in different healthcare facilities, or even in multiple entries within a single hospital or other institution. These challenges associating patients with records contained in various data sources—known as matching—hinder registries' ability to conduct robust analyses and impair care coordination by clinicians. The draft legislation would take a key next step to address these challenges by commissioning a study from the Government Accountability Office on current methods of patient matching across these data sources and EHRs, and how they could be improved.

In addition to that study, there may be other approaches to help expedite solutions to patient matching challenges. One such solution entails the creation of a system to uniquely identify patients in different data sources to help them access their own medical information and support analyses of health outcomes. This system would not need to be government run; in fact, the private sector could develop and implement a solution that includes appropriate privacy safeguards and that preserves patient choice regarding their participation. Congress initially approved the creation of a national health ID solution in 1996 but has since restricted the federal government's ability to participate in such a system.[1]

Another alternative is to improve mathematical algorithms used to locate and identify individuals' health records in different databases. These algorithms often use demographic information, such as name and date of birth, but still often fail to correctly locate individuals' health records for one in five patients.[2] Therefore, policies to enhance these algorithms could also help resolve this challenge.

Promoting data integration to enhance interoperability

Even once registries and EHRs can locate medical information, they also face challenges exchanging data because of coding differences. The draft legislation requires that certified health IT and clinical registries be able to transmit, receive and accept data from each other. Additionally, it would establish a process for the evaluation and adoption of common data standards by the Office of the National Coordinator for Health Information Technology (ONC) to improve the ability for electronic data systems to share information.

Through health IT certification criteria regulations, ONC has already adopted some standards for key data elements—particularly information in patients' medical summaries, such as medication lists. However, these standards often do not fully enable the exchange of information because the standards are not specific enough and include flexibility in the depiction of different data elements. This flexibility—also known as optionality—means that two data systems could use the same standard, but still code information in different ways. Therefore, new policies to adopt standards could improve upon existing programs by explicitly requiring the removal of unnecessary optionality.

Another approach that may help resolve data standardization challenges involves incorporating more transparency in how each system codes information via publicly available—or open—application programming interfaces (APIs). Through these open APIs, with sufficient privacy and data protections, registries and other health information systems could more easily access data in EHRs, regardless of the standards used. Registries and others in the private sector would then be able to develop technologies and solutions to extract and exchange the needed information.

Improving the safety and usability of electronic health records

Last summer, Pew, in conjunction with the Armstrong Institute for Patient Safety and Quality at Johns Hopkins University, hosted a conference with 70 clinical and health information technology experts to identify solutions that would improve patient safety and generate health system efficiencies by enhancing the usability of EHRs.

While the draft legislation includes several provisions intended to prioritize EHR safety and usability, attendees at the Pew conference identified several other policy opportunities.

The draft legislation would extend legal protections to developers of health information technology when they report safety problems identified with their products to patient safety organizations (PSOs). While this provision may encourage some safety reporting to PSOs, many experts at the Pew conference recommended the creation of a single, designated entity to collect, analyze and share findings from all safety events related to health information technology products. Such an organization may be a single PSO or a public-private partnership that could require congressional funding or authorization.

The legislation would also establish measures as part of the proposed health IT rating system to evaluate the usability and user-centered design of health information technology, along with other elements. The experts convened by Pew emphasized that usability measures should also assess safety issues—such as the rate at which EHRs contributed to medication errors. To encourage reporting on these measures, they could be embedded in the next update of the ONC EHR certification criteria or the Centers for Medicare & Medicaid Services' Merit-based Incentive Payment System.

Finally, better testing of EHRs could also detect design problems that cause safety and usability problems. Current EHR testing requirements from ONC only assess whether certain functions work as intended but not whether they introduce inefficiencies that cause unintended safety problems. Expanding these requirements to also evaluate how different EHR functions affect patient safety would help prevent design problems that cause harm. The experts convened by Pew indicated that such testing should occur during the initial development of an EHR, upon the completion of the system and after integration into a healthcare setting where additional modifications can occur.

Conclusion

We look forward to working with you on this draft legislation to support the development of better data on care quality and enhance patient safety. Should you have any questions, please contact me at jrising@pewtrusts.org.

Sincerely,

Josh Rising, MD
Director, Healthcare Programs

---

[1] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

[2] Bernie Monegain, "Unique patient ID problem must be solved: Need to improve accuracy called a matter of patient safety," Healthcare IT News, April 12, 2015, http://www.healthcareitnews.com/news/unique-patient-id-problem-must-be-solved.