Senate Committee on Health, Education, Labor and Pensions

Implementing the 21st Century Cures Act: Making Electronic Health Information Available to Patients and Providers

Tuesday, March 26, 2019

10 am, 430 Dirksen

Purpose

Purpose of the hearing was to review HHS rules relating to interoperability and improving access to electronic health records.

Members Present

Chairman Alexander, Ranking Member Murray, Senators Cassidy, Braun, Baldwin, Rosen, Romney

Witnesses

Mr. Ben Moscovitch, Project Director, Health Information Technology, the Pew Charitable Trusts

Ms. Lucia Savage, Chief Privacy and Regulatory Officer, Omada Health

Mr. Christopher R. Rehm, Chief Medical Informatics Officer, Lifepoint Health

Ms. Mary Grealy, President, Healthcare Leadership Council

Opening Statements

Chairman Alexander said that Reid Blackwelder, a family physician, remarked to the New York Times that the electronic health record provider for his clinic and a nearby hospital do not communicate. Dr. Blackwelder could pay for his patients' EHRs to be sent to the hospital, but it would cost $26,400 every month. For many doctors, record-keeping is more burdensome as a result of EHRs. EHRs got a boost in 2009 when the federal government began the bipartisan Meaningful Use Program to incentivize doctors and hospitals to use these systems. At the hearing last summer, Dr. Brent James said that up to 50 percent of healthcare spending is unnecessary, so there is bipartisan focus on reducing healthcare costs, such as reducing unnecessary care and administrative tasks. This can be done through increasing interoperability. This committee realized that EHRs increase healthcare spending due to information blocking and lack of interoperability. This hearing is about two rules that lay out a path towards interoperability through the following ways: defining information blocking; by January 2020, insurers must share a patient's healthcare data with the patient so the data follows the patient; all EHRs must adopt the same API; hospitals are required to send health information to a patient's doctor immediately after intake or discharge. Kaiser found that emergency room doctors make up to 4,000 clicks per shift to access EHR data. Interoperability will greatly reduce that administrative burden, saving up to $3.3 billion per year.

Ranking Member Murray said today, one in 20 hospitals have not adopted EHRs. EHRs play an important role in understanding how the water in Flint was endangering families. They help avoid duplicative tests or medication errors and identify counterproductive medical treatments. The HITECH Act was good progress, but there must be continued oversight, especially after the ONC Health IT office published a report on the issue of information blocking. The ONC report found substantial evidence that some organizations were setting up barriers between systems, like exorbitant fees, restrictive contracts and

needlessly complicated systems. Bad actors cannot prioritize their bottom line over patients' best interests. Health IT cannot get better when vendors include gag clauses. It should be easy for providers to learn about potential issues and for medical professionals to speak out when they see something that jeopardizes people's health. A man in California suffered brain damage after a software problem did not allow the hospital to interface with a testing lab, and a woman in Vermont died of a brain aneurysm due to a similar issue. In the Cures provision, it is made clear that patients and their care providers should not be stopped by unreasonable barriers while seeking care. ONC is tasked with strengthening its certification program beyond technical criteria for EHR so they can ensure that if vendors what the government seal of approval, they cannot use gag clauses or information blocking. The uniform application programming interface (API) clause will also allow systems to speak to each other even if developed independently. Security and data stewardship must be prioritized to protect against the cybersecurity threats. That will become more important as tech companies introduce additional platforms like health-related mobile apps for consumers. Tech companies must put patients in the driver's seat.

Testimony

Mr. Moscovitch said EHRs have revolutionized modern medicine, but gaps remain that keep EHRs from reaching their full potential. First, interoperability requires patients and clinicians to be able to access and extract information from EHRs. To address that, Congress directly ONC to develop new criteria for EHRs for systems to communicate: APIs. For APIs to be effectively used, different system need to exchange data in the same way, so ONC identified a standard system called FHIR. Congress should ensure the agency maintains its commitment to these standards. Interoperability also requires patient matching. Pew has identified concrete steps for ONC to take, including better standardization of patient data. ONC should standardize use of the postal standard address and email address for patient matching. Congress also recognized that EHR usability should be increased. Pew collaborated with MedStar health to find that HER usability contributed to more than a third of the 9,000 adverse events examined in pediatric care. The agency should better focus on safety and usability. For example, ONC should clarify that developers seeking certification involve pediatric doctors and nurses to test the system. The agency should embed safety in the usability program, as recommended by clinicians and technology professionals. Congress should support secure, standard API access to a wide range of health data, encourage ONC to address patient matching through better standards, and pressing ONC to focus on patient safety throughout the implementation of Cures.

Ms. Savage said that Omada is just like a doctor's office under federal law, so all the HIPAA data privacy laws apply. Among the most impactful rules proposed by ONC is that information blocking rules apply to business-to-business transactions. This is a logical next step. **Ms. Savage** referred to an article she co-authored yesterday in the ABA Antitrust Law Journal about the anticompetitive effect of the B to B exchange space absent ONC's proposed rule. There are three areas where ONC may want to consider unintended consequences or pursue its vision more aggressively. First, the ONC rule does strike a good balance between privacy and security, but the rule proposes ongoing deference to organization policy that may be at odds with democratically developed privacy laws. There should be a sunset period for systems to adapt to app-enabled health info exchange and to

eliminate organizational policy that blocks appropriate flow of health facts. Second, 21CC applies the prohibition against info blocking to developers of health IT, but only applies it to certified EHRs. This limitation leaves out many times of health IT, such as connected devices or Software as a Medical Device, or uncertified EHRs like uncertified pharmacy systems. Third, ONC proposes to allow technology developers to license interoperability elements. Licenses cannot stifle innovation or create barriers to new entrants. As ONC finalizes interoperability elements, it must clarify that the health facts within a software are never to be licensed.

Dr. Rehm said providers and patients are impacted by a lack of interoperability daily. HER, patient monitors and medical devices are supposed to help with care, but they frequently add to the complexity and burdens felt by providers. First, providers do not bill the technologies, they purchase from vendors. Many vendors release technologies that reach the ONC minimum standard for certified technology; their contracts do not cover maintenance or updating and it's up to the provider organization to cover the cost and burden of implementing the add-ons. Second, upgrades takes time: it can take up for 12 months for provider organizations to deploy vendor technologies to ensure not breaking custom interfaces, but are only given 6 months by CMS. Healthcare software technologies must work in real-life settings. Third, the HITECH Act did not address the underlying issue of interoperability to enable digital liquidity. Providers have been left to bridge the gap with interface engines, workarounds and manual processes with varying degrees of success. This lack of infrastructure is troubling. The CMS proposed rule would require hospitals to send electronic notification when a patient is admitted or discharged or transferred. Providers must clearly understand the requirement and objective compliance measure, which the proposal lacks. The Administration should focus on its current activities to advance interoperability, including vendor accountability. Additionally, the entrance of non-healthcare actors who do not fall under HIPAA into the healthcare market necessitates strong principles of trust and security. One proposal is an industry-backed process to vet these applications to ensure they use data appropriately and meet all security standards. And the groups that offer medical advice must be evaluated to determine if the information is medically sound.

Ms. Grealy said academic health centers, hospitals, pharmaceutical companies, laboratories, biotech firms, health product distributors, and IT companies, among others, advocate for measures to improve healthcare through a patient-centered approach. Full nationwide interoperability must be achieved, including seamless access to data for consumers, patients and providers. Patients interact with specialists, clinical labs, pharmacies, insurers and more, yet these entities often don't talk to each other electronically. Interoperability is absolutely necessary. The Healthcare Leadership Council (HLC) set out to determine what needs to be done to achieve this. The research and recommendations are in the written testimony, but there are some highlights. First, it is significant that leaders across the entire healthcare continuum have agreed upon mechanisms to accelerate nationwide operability. These private sector entities are placing the responsibility among themselves. Second, there must be common standards utilized to improve patient matching. Third, there must be the rapid adoption and implementation of open standards-based APIs. There is a great deal of alignment with the proposed rules

discussed today with the HLC's recommendations. Both proposed rules incorporate new, innovative products such as third party applications that are not covered by HIPAA. There must be a thoughtful evaluation of how current HIPAA entities share PHI with these entities to ensure the safeguarding of identifiable health information. Given the significant impact of these rules, including the heavy enforcement penalties, HLC is requesting that ONC and CMS grant a 30-day extension of the comment period for these proposed rules.

Questions and Answers

Sen. Cassidy said that in his state, the patient does not own their own data, and he asked Ms. Grealy if Healthcare Leadership Council has a position on whether the patient should own their data. **Ms. Grealy** said that is important that patients own their data and have access to that data. **Sen. Cassidy** asked Ms. Savage if the patient owns the data that the health plan has. **Ms. Savage** said that it is a matter of state law. It is ambiguous. **Sen. Cassidy** asked if there is legal access to the data. **Ms. Savage** replied yes, but the in practice the issue of patients getting their own data is a top five complaint at OCR. **Sen. Cassidy** asked if there should be standardization of how patients can access data and what comprises patient data. **Ms. Grealy** said that using an app and standard API is a good idea. Additionally, the Association of Health Information Management is working on a standardized form. But it is not enough. **Sen. Cassidy** said that he read of technically companies and insurers partnering to put smart watches being on the wrist of the insured. He questioned if that data provided through the watch should be protected health data since it is going to the insurer. **Dr. Rehm** said yes, that should be protected. **Ms. Savage** said that the health plan is a covered entity, and when data flows into its entity, it is covered by HIPAA. Collection by the app is covered by HIPAA when the covered entity pays for it. OCR does not reach to app or data in app that is not paid for by a covered entity.

Ranking Member Murray asked if patients who share their information with third party apps have their information covered by HIPAA. **Ms. Savage** said that all HIPAA rules apply within the app for Omada, but people can't be stopped from blurting information out. **Ranking Member Murray** asked what patients should know if they use an app that isn't covered by HIPAA. **Ms. Savage** said that it is too much information for consumers to understand. People think that rules apply when they don't. **Ranking Member Murray** asked if data can be sold. **Ms. Savage** said outside of HIPAA yes, inside HIPAA only in an unidentifiable way. Social media apps could sell digital records. **Ranking Member Murray** asked for policy recommendations to better protect patient privacy. **Ms. Savage** said that digital life is no longer sliced into economic sectors and policies must converge. There should be a uniform policy that consumers can understand that extends past HIPAA. **Ranking Member Murray** asked Mr. Moscovitch why it is key that the EHRs developers publish business and technical documentation associated with their APIs. **Mr. Moscovitch** said that in other industries the documentation is publicly available to spur innovation since it is essentially an instruction manual. **Ranking Member Murray** asked if this requirement would impose a burden**. Mr. Moscovitch** said that many EHR developers are already implementing these standards and reaching these levels of documentation on FHIR standards. **Ranking Member Murray** said that if health organizations are hoarding data, there are consequences if the department takes too long to implement these policies. She asked Ms. Savage what the risks are of delaying the prohibition of information blocking. **Ms. Savage** said that there documented savings associated with avoiding redundant costs and an increase in productivity for consumers.

Chairman Alexander asked Dr. Rehm if these are the right standards that it is correct to insist that the same standards apply to everyone and if the rules are moving too fast to implement these rules. **Dr. Rehm** said that this is the correct direction. The industry will take advantage of standards that are too broad, leaving providers to do all the work because it is not interoperable. Being prescriptive and precise in the standard will accelerate interoperability. On being too fast, the provider is always months behind of the technology that is being developed. **Chairman Alexander** clarified that he meant that the new rules must be implemented at a pace that gets to the goal but doesn't it do it so rapidly that it makes it more difficult to get to the goal. **Dr. Rehm** said that there are 24 months for the tech orgs to come alongside the final rule and implement it, but time must be added to that for provider organizations to react/understand the technology that is released. **Chairman Alexander** asked the same question to Ms. Grealy. **Ms. Grealy** said that innovation is a shared concern and that many parties will ask for more time. Standards like open APIs and the FHIR standards have broad, deep agreement and are not viewed as stifling innovation.

Sen. Baldwin said that the proposed rules released by the Administration to advance implement of 21st Century Cures are critical steps to achieving interoperability and achieving patient access to health data. Several provisions would allow patients to become more engaged with their own care by making data available to be exported and available through third-party apps. The proposal may expose new vulnerabilities for patient confidentiality. **Sen. Baldwin** asked Dr. Rehm if this could lead to breaches in patient privacy and how to best balance patient access and confidentiality. **Dr. Rehm** said that there is risk with third-party applications, especially since there is no current organization vetting the technology security of those applications. Patients must be protected when using the open API to pull their health information. **Sen. Baldwin** said she has heard concerns from her constituents about the lack of clarity and standards in the rule concerning what constitutes electronic health information. There is currently no standard for this broader group of data, which may create risks to vendor compliance and protection of patience protection. **Mr. Moscovitch** said that for many data elements, standards don't exist, so as ONC finalizes regulations it should clarify which information needs to be available to patients in an easy way.

Sen. Braun said it is concerning that the healthcare industry needs to be nudged to act in this area. The intentional cloaking and shrouding of the healthcare industry leads to this discussion. **Sen. Braun** asked where Congress should spend the resources to speed the process of interoperability and information sharing. **Mr. Moscovitch** said that Congress had a lot of foresight in leveraging APIs in 21st Century Cures and ONC implemented these provisions with a lot of foresight. **Sen. Braun** asked if the industry would be pushing forward on its own without this hearing. **Mr. Moscovitch** said that Congress has accelerated the adoption of APIs in a meaningful way. **Ms. Savage** agrees that the HITECH and Cures nudges have been crucial, citing the "Ax the Fax" hashtag on Twitter. **Dr. Rehm** said that the focus should be on forcing the technology side of the industry for the interoperability piece. **Ms. Grealy** said that these proposed rules have been very welcome, with great alignment between what the government is offering and the private sector's desires. There should be a private-public campaign on educating people on how to use this information and how to access it. **Sen. Braun** said transparency is

needed for that to be accomplished. He urged the industry to be more proactive in embracing transparency and competition.

Sen. Rosen said that 88 percent of medical providers do use EHRs but the biggest concern is privacy. She asked Ms. Savage who is ultimately responsible for patient data protection. **Ms. Savage** said that each covered entity is responsible for what is in their custody. Similarly, outside of that system, the individual is responsible, such as how they are responsible for their own banking. **Sen. Rosen** said that medical devices do upload to medical health records, which can give a doorway into the system for cyber-attacks or hacking. She asked which measures are preventing those security risks. **Ms. Savage** said that the FDA is hard at work helping device manufacturers understand how to upgrade the security of their equipment, but the FDA doesn't enforce security standards except on those devices. The legal authority falls on OCR, who enforces it at the doctor's office or hospital level. The policy question for all the Senators is how to bring those things together that was previously living in distinct silos. **Sen. Rosen** asked how do patients get a correction. **Ms. Savage** said that patients have the right to ask record holders to correct data at physicians or hospitals, but this kludgy process could be automated. **Dr. Rehm** said that the open API is potentially opening electronic health data to a segment that is not currently covered by HIPAA. **Sen. Rosen** asked what the burden is to hire more people to take care of this data and information. **Dr. Rehm** said that the provider burden today due to lack of interoperability is huge. Small practices lack the workforce to handle that burden, which puts them at risk for unintentionally conducting data blocking. Not everyone has the expertise.

Chairman Alexander asked what data interoperability has to do with devices and the data that comes from those devices. **Ms. Savage** said that her written testimony contains an example of a patient whose medical device feeds information to the brace manufacturer's servers and may or may not feed to a physicians practice. It is health IT with information such as gait that is not subject to this rule. **Mr. Moscovitch** said that the CMS rule focuses on getting patients their claims data. Claims today for patients with implants lack key info, such as the device identifier of the implant in their body. So when they get their claims data, they won't now which brand or model of their device is, and CMS can close that gap by adding device data to claims. **Dr. Rehm** said that interoperability between devices like a ventilator machine or blood pressure cuff is just as key as interoperability between systems. **Chairman Alexander** asked the witnesses what they would like Congress to do to encourage interoperability as they consider the two rules. **Mr. Muscovitch** said that patient matching needs to be discussed, especially given the research on how better demographic data can improve match rates. ONC should finalize these rules with this in mind. **Ms. Savage** said that the best thing is to figure out what is working in healthcare and migrate it elsewhere, to ensure consumer confidence. **Dr. Rehm** said real-world testing that is working across vendors. **Ms. Grealy** said that the committee should maintain oversight on the implementation of this and the time necessary to do it the right way. There may be more time required, especially with the challenges faced by providers doing this.

Sen. Romney said that he is pleased that the healthcare providers in his state such as LifePoint, Mayo and Intermountain have interoperability within their own systems. The interoperability is having a very significant impact on the cost and quality in the enterprise. He asked if this information informs the choice of doctors to guide the type of treatment they provide, and if the EHR data is being used to allow the patient to inform their life choices, such as if the data

indicates that an individual may be at risk for diabetes. **Ms. Savage** said that a diabetes prevention program is offered to Intermountain employees and expanded to applicable patient populations, where EHR is leveraged to offer useful information to participants. When business relations and data relationships are fully understood, that magic alchemy occurs. **Mr. Moscovitch** said that better APIs and better patient matching can meet that end. **Dr. Rehm** said that physicians frequently cannot access outside information when meeting patients and thus cannot leverage it. So usability and interoperability go hand in hand. **Ms. Grealy** described an anecdote involving her husband receiving successful treatment for a stroke through an unusual treatment that was provided only by the cardiologist looking through cutting-edge research. This needs to happen nationwide and not only within closed healthcare systems.

Chairman Alexander said that 21st Century Cures is the most important bill passed in that Congress and there is determination for it to be implemented correctly. These two rules are important steps towards interoperability.

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