



October 17, 2018

Responses to Questions for the Record  
House Committee on Energy and Commerce  
Subcommittee on Health  
“Examining Barriers to Expanding Innovative, Value-Based Care in Medicare”

The Honorable Gregg Harper

1. Throughout 2017 and 2018, we have seen significant advancement in federal telehealth policy, both from the legislative and regulatory standpoints, which you outlined in your testimony. We are pleased that four provisions of the CONNECT for Health Act (HR 2556), of which I am an original cosponsor, were signed into law earlier in 2018; and we appreciate that CMS has been supportive of utilizing available authorities to pay for Remote Patient Monitoring and other technology-enabled platforms.
  - a. Given this progress, what do you see as the next legislative and regulatory priorities for telehealth practitioners and advocates?
- The Connected Health Initiative (CHI) applauds and thanks you for your leadership on the CONNECT for Health Act (HR 2556) and as a champion of connected health reforms. Without your work in Congress, the legislative branch may not have made the significant gains it accomplished over the last two years. Going forward, we have several legislative and regulatory priorities.
- *Regulatory priorities:*
  - The Centers for Medicare and Medicaid Services (CMS) should approve the proposed current procedural terminology (CPT) codes 990X0, 990X1, and 994X9 in its final Physician Fee Schedule (PFS) rule. These three codes would reimburse for various activities and devices used to perform physiologic monitoring of patients.
  - CMS should finalize its proposal to adopt and pay for virtual check-ins and remote evaluation of recorded patient information. We also believe CMS should adopt its own proposal to pay for interprofessional consultations performed via communications technology including telephone or internet.
  - CMS should finalize its proposal to recognize “communication technology-based services” separately from Medicare telehealth services, as defined in Section 1834(m). This recognition would further enable CMS to support remote patient monitoring activities while continuing to apply 1834(m) restrictions to the narrow set of uses that meet the Medicare telehealth services definition.
  - CHI understands that the Department of Health and Human Services’ (HHS’) Office of Civil Rights (OCR) may be interested in suggestions for modernization of Health

Insurance Portability and Accountability Act (HIPAA) rules. We expect to provide commentary based on the experience of our member companies. For example, some of our member companies, in forming relationships with health systems, encounter conflicting interpretations of HIPAA's requirements—some health systems believe the rules require several Business Association Agreements (BAAs) to be entered into for various parts of the business, while other health systems insist on only one. In addition to that instance of confusion, CHI has heard from other members who have encountered confusion around other parts of HIPAA, and CHI plans to relay those issues as helpful examples for how requirements could be clarified either by regulation or guidance.

- CHI awaits the Office of the National Coordinator's (ONC's) report on "information blocking" as required by the 21<sup>st</sup> Century Cures Act. We hope that ONC's report provides further definition to the set of activities that are "reasonable and necessary," and which do not constitute information blocking. Clarity is essential to the adoption of interoperability measures like information formatting and entry standards.
- *Legislative priorities:*
  - The centerpiece of the CONNECT for Health Act is a provision that would ensure that CMS recognizes and provides financial support for the use of remote patient monitoring for certain individuals. We believe Congress should pass this measure, as well as the other provisions of the CONNECT for Health Act that have not yet been enacted, as soon as possible. Under its existing authority, CMS has begun to lay the groundwork for reimbursement of remote patient monitoring in the PFS and to some extent has mitigated the disincentive for providers to use remote monitoring in the Quality Payments Program (QPP) rulemaking, but a mandate and authorization from Congress requiring these strides to be made at an accelerated pace would be game changing.
  - Flexible and Health Spending Accounts (FSAs/HSAs) provide tax incentives for the purchase of items used for preventive care and medical treatment. But while the tax code currently covers items like lip balm, cold packs, shoe insoles, and magnifiers, FSAs fail to cover state-of-the-art devices and software platforms that can provide care teams with actionable, clinically relevant patient-generated health data (PGHD). Sensors and software have advanced to the point where physicians can benefit from a wide range of indicators from accurate electrocardiogram data to medication adherence information from ingestible transmitters. Congress should pass legislation that includes amounts spent on the purchase of connected health technologies as eligible FSA/HSA expenses to provide critical incentives for consumers to invest in software platforms and connected devices that enable them to engage with care teams and manage their health for prevention and treatment.
  - As the Medicare system continues its long evolution from fee-for-service to value-based care, the Congressional Budget Office's (CBO's) modeling restraints will harm Congress' ability to enact the commonsense measures necessary to keep apace of the state of the art in patient care. One way Congress could address this issue is by passing the Preventive Health Savings Act (HR 2953).

- Unfortunately, bills introduced this Congress that amend Medicare authorities have also included definitions of “telehealth” that include “remote patient monitoring.” We urge you to avoid legislation that includes any definition of “telehealth” that includes “remote patient monitoring.” Such a definition could reverse the work CMS has done to distinguish communications technology-based services from Medicare telehealth services. Moreover, definitions that lump remote monitoring in with telehealth could inadvertently cause originating site and other 1834(m) restrictions to apply to remote patient monitoring services.

**b. How do you propose we overcome CBO’s modeling challenges (i.e., is analyzing beyond CBO’s 10-year window, as proposed in the Preventive Health Savings Act, the best approach)?**

- Generally, new dynamic scoring approaches offer opportunities for CBO to improve its modeling in recognizing the value of connected health innovations. However, we believe that CBO continues to face constraints in developing its scoring methodologies that only Congress can address. For example, we support the Preventive Health Savings Act because some of the benefits of telehealth and other connected health modalities may not be fully recognized until after the 10-year window has elapsed. However, we note that studies of the use of remote patient monitoring, telehealth, and other means of engagement—whether preventive or for treatment purposes—produce cognizable benefits within just a couple of years. The University of Mississippi Medical Center case study from our testimony is perhaps the most dramatic example of savings to Medicaid within a short period of time, directly attributable to the use of remote monitoring and telehealth. In the past, CBO has been reluctant to use some of these studies because they are localized, involve populations with specific characteristics, or for other reasons. To ameliorate this perceived lack of research, CHI is currently proposing for the Agency for Healthcare Research and Quality (AHRQ) to conduct studies on (1) “the role of both synchronous and asynchronous remote monitoring of patient-generated health data as an essential element of advanced healthcare systems and a necessary aid in chronic condition treatment and prevention”; and (2) the use of cutting-edge hardware/software tools for medication adherence.

**c. Do you believe there are opportunities to replicate the approach taken in the Reducing Unnecessary Senior Hospitalizations (RUSH) Act of 2018 (HR 6502) for the use of telehealth in various settings and for other medical specialties? Are there merits or challenges with this bill?**

- While we note the limited scope of Medicare telehealth services and the incredible potential of the wide range of connected health innovations, the RUSH Act would alleviate unnecessary restrictions imposed on Medicare telehealth services in certain scenarios. Challenges facing the RUSH Act include its narrow scope. The RUSH Act’s merits are in its removal of Medicare telehealth restrictions in Section 1834(m) which we support across all use cases, including those that the RUSH Act would address.

The Honorable Anna G. Eshoo

1. Ten years ago, I authored legislation to improve the utilization of electronic health records and require their interoperability however, I still hear from physicians in my District about the challenges of EHR interoperability. Over the past decade there has been an increased adoption of electronic health records but there is still room for improvement when it comes to how consumers and providers utilize E.H.R.s. For example, consumers often don't have the ability to easily access their records and providers can't easily share records. This lack of interoperability diminishes the potential value of E.H.R.s.

**a. Why is interoperability important for value-based care?**

- The success of value-based care models depends heavily on bidirectional interoperability of healthcare data. To reward better outcomes and cost-effective approaches to care, providers must be able to utilize two-way application programming interfaces (APIs) to access, share, and make meaningful use of data about their patients. True interoperability involves not just the ability to access data but also the ability to use it and manipulate it for the user's purposes and to benefit the patient. Knowing the whole story is important for providers and payers to understand the best treatment plan or prevention measures for patients, as well as for patients who seek greater engagement in their own care. Data from previous care settings becomes more important in value-based care because the viability of the provider depends on outcomes—which are arrived at more efficiently with care plans tailored to patients' medical history, genetics, and other factors.
- This is especially true for providers in rural areas, where there are fewer physicians serving people who live further away from care. Rural providers especially need data that shows which care plans or prevention and treatment measures are likely to work—and which don't—for the patients they see. Physicians spend about half their time doing paperwork and grappling with electronic health records (EHRs) that create friction in their workflow. With fewer caregivers per capita and greater distances to care in less urban parts of the country, a system that traps physicians in endless stretches of administrative busywork is even more costly to rural patients. Caregivers simply don't have the time. Value-based care models enable providers in rural areas to divert resources to where and when they are needed most, and the ability to access and analyze data on patients and populations is central to the ability to deliver cost-effective, high-quality care.

**b. From your perspective, what is the state of interoperability today?**

- As a nation, we are not realizing interoperability in health data today. Our members continue to face barriers between systems, as well as exorbitant fees in order to access health data. Interoperability is a moving target because as technologies evolve, the interoperability of the data that fuels them will shift over time. Therefore, interoperability must be iterative, and it must evolve along with the tools it supports. Government's role should be to ensure that this evolution is possible and remains a pillar of healthcare policy in the United States. That is why we applaud you and your colleagues for the bipartisan 21<sup>st</sup>

Century Cures Act, which requires HHS to give definition to and prohibit “information blocking.”

- As CHI awaits the report from ONC on “information blocking,” we expect that it will give definition to “reasonable and necessary” activities that do not constitute information blocking. Guidance from ONC on how HHS will enforce interoperability under 21<sup>st</sup> Century Cures is a crucial component to making it a reality. Interoperability between EHRs, vendors, population health data sets, etc., remains difficult without enforcement guidance from ONC.
- The private sector is making strides to assist with the interoperability of data across EHRs and other platforms. For example, Health Level Seven International (HL7) is a standards-setting organization comprised of stakeholders from across the healthcare spectrum that has developed the Fast Healthcare Interoperability Resources (FHIR) standard. This is a “light, thin” standard that attempts to homogenize a relatively small subset of data formats and elements across different data users in the healthcare system. The FHIR standard also comes with an API to facilitate the exchange of EHRs. To effectuate adoption of FHIR, HL7 launched the Argonaut Project, which is also working on standardizing more granular aspects of data formatting and field entries.
- Public policy should encourage the adoption of data field and format standards like FHIR, without strict mandates that could lock in standards that fail to keep pace with innovation. Data field and format standardization is likely to change as better data set management develops. Eventually, EHRs and other vendors should provide for two-way APIs that allow software developers to both download data from large sets held by the EHR *and* upload that data into the system. This two-way capability will be central to ensuring that 1) patients will benefit from newer innovations as quickly as possible and 2) interoperability will evolve more naturally with developments in software and hardware. Healthcare providers usually work with a wide variety of vendors, from device makers to software companies, and ensuring they all work together to paint an accurate and seamless picture for caregivers is critical, especially for value-based care models.
- Importantly, not only should data fields and formats should be standardized, but also the data contained therein must also be consistent, understandable, and usable. For this to occur, data must be in a recognizable electronic package (data structure or syntax) and maintain a consistent meaning (data semantics). Just as the English language is built from words and grammar, the translation from data to knowledge can only occur if the meaning of data is consistent. However, levels of semantic interoperability vary greatly in the health care system. Physicians agree that the current level of interoperability is inadequate to support the necessary changes, reforms, and innovations desired in health care.<sup>1</sup> As a practical matter, the more data exchanged that lacks both semantic and syntactic interoperability, the less useful it is to physicians and patients.
- This leads to another piece of the interoperability puzzle that the industry must address: data mapping. Mapping is needed so transmitted data can be used by the receiving EHR rather than just viewed. For example, if a patient has a problem identified as “hypertension,”

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<sup>1</sup> Stanford Medical, How Doctors Feel About Electronic Health Records National Physician Poll by The Harris Poll, (June 2018), Available at <http://med.stanford.edu/content/dam/sm/ehr/documents/EHR-Poll-Presentation.pdf> (last visited Oct. 16, 2018).

a simple interface can move this text to another system where it can be viewed. However, to be useful in automated alerts and care planning, mapping must translate this information so that it has the same “meaning” in the receiving system. To create the appropriate meaning, the “hypertension” text typically must be put into the correct part of the receiving EHR’s database so that EHR “knows” the patient has this condition. Additionally, problems like hypertension often are comprised of many different attributes, all of which should be captured, stored and transmitted in a common format. While this example may seem simple, the proprietary nature of EHRs, and the lack of an agreed upon medical data model, makes this difficult—even with the increased use of standardized codes.

- Furthermore, EHRs typically do not identify components of the office note in the same manner. For instance, when a physician sees a note drafted in a Cerner EHR shown in an Epic EHR the information gets rearranged, misconstrued, or lost. This is because information stored in Cerner’s terminologies and logic is not machine-readable by Epic’s technology. For the information to interoperate between the two systems, the information must be translated into a standard terminology while, at the same time, preserving all the exchanged information’s content and context. Providers spend hours documenting and searching for needed information when they lack access to interoperable and usable digital information. The federal government needs to do more to recognize and support clinician-led activities, organizations, and collaboratives working to address these issues.
- Beyond standards, health information exchanges (HIEs) are another piece of the interoperability puzzle that exists today. HIEs help facilitate the transfer of patient records between health systems within a given geographic region. Without HIEs, health systems might be negotiating over the cost of transferring each patient’s records, whether the data at issue is test results, images, prescriptions, physician notes, or allergies. The pending regulatory actions at HHS, including the information blocking report and Trusted Exchange Framework and Common Agreement (TEFCA) proceeding, are important for the effective functioning of the HIEs. These regulatory processes should result in more clarity for HIEs and the providers that use them to understand how all stakeholders can most efficiently make healthcare information interoperable without incurring liability.
- However, EHR vendors still do not agree on a consistent approach to implement technology to support health information exchange. For instance, an EHR may still be certified by ONC without actually proving it will send, receive, and incorporate medical information with another certified EHR technology (CEHRT). Since EHR certification and testing is done in a controlled laboratory environment, products will be designated as “interoperable” by the federal government without even actually connecting to other certified EHR products. In fact, there is little assurance that two CEHRT products from the same vendor will be interoperable—this will still hold true for 2015 Edition products. This is further complicated by data intermediaries, other third-party products, Health Information Exchanges (HIE), patient matching issues, and the unique ways EHR vendors handle data.
- ONC should establish more robust reporting requirements for EHR vendors as part of the product certification, testing and surveillance processes. ONC must also implement more robust conditions and maintenance of certification, testing and surveillance processes to ensure that EHR vendors demonstrate and attest to their systems’/ platforms’ interoperability (ability to send data to and receive data from other EHRs and data sources) and conformance to standards (i.e., explicit conformance to FHIR versioning, resources).