ConnectedHealthInitiative

March 25, 2022

Micky Tripathi, PhD MPP
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Mary E. Switzer Building
330 C Street Southwest, 7th Floor
Washington, District of Columbia 20201

RE: ***Connected Health Initiative Comments on the Office of the National Coordinator for Health IT's Request for Information on Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria [Docket No. HHS-ONC-2022-0001; 87 FR 3475]***

Dear National Coordinator Tripathi:

The Connected Health Initiative (CHI) writes to provide input to the Department of Health and Human Services (HHS) Office of the National Coordinator for Health IT (ONC) on electronic prior authorization standards, implementation specifications, and certification criteria that could be adopted within the ONC Health IT Certification Program.[1]

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly encourage the use of digital health innovations and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled American healthcare system. The efficacy of precision medicine, population health, clinical decision support—and artificial intelligence (AI)-driven tools in particular—is dependent in large part on the availability of massive data sets. Interference with interoperability and patient access to health information prevent timely and informed care coordination and decision-making.

Electronic health information and educational resources are critical tools that empower and engage patients in their own care. A truly interoperable eCare system includes patient engagement facilitated by store-and-forward technologies (ranging from connected medical devices to general wellness products) with open application programming interfaces (APIs) that allow the safe and secure introduction of patient-

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[1] 87 FR 3475.

generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized and structured formats with interoperability facilitated by APIs provides analytics as well as near real-time alerting capabilities. Interoperability must not only happen between providers, but also between remote patient monitoring (RPM) products, medical devices, and EHRs. The use of platforms for data streams from multiple and diverse sources will improve the healthcare sector, helping to eliminate information silos, data blocking, and deficient patient engagement.

The harms of the existing prior authorization system are widely recognized today, and it is widely agreed that significant reforms to the prior authorization system are needed to protect patient safety.[2] Streamlining processes related to prior authorization is essential to advancing health data interoperability throughout the continuum of care. Moving prior authorizations from a paper-based approach to an automated and electronic approach can enable timely adjudication, is a critical step towards realizing a connected care continuum, and may enable more informed, accurate, and timely coverage eligibility and medical decisions to be made. CHI notes that, while ONC's exploration of electronic prior authorization in this matter does not consider prescription drug management, electronic prior authorization functionalities can and should be applied to this key use case as well.

Generally, we support ONC's efforts to encourage the voluntary implementation of industry standards to ensure interoperability between EHR systems, medical devices, and healthcare products. This practice can also gauge the interoperability of EHR products. A system demonstrating "widespread interoperability" will provide useable data from various sources, not just from certified EHR technology (CEHRT) and CEHRT systems. A good example of industry-led efforts to establish standardized implementation is the Argonaut project, which helps standardize the implementation of the Fast Healthcare Interoperability Resources (FHIR) standard. But even private sector efforts like Argonaut can focus too much on compliance-driven efforts to meet perceived regulatory requirements. There must also be an incentive to communicate and pass information from one party to another. We note that the Medicare and CHIP Reauthorization Act of 2015 provides that incentive in a value-based healthcare environment—one which engages patients, reduces costs, and documents quality metrics.

To reward better outcomes and cost-effective approaches to care, providers must be able to utilize two-way 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 success of the provider depends on

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[2] https://www.healthit.gov/sites/default/files/page/2021-02/2020-11-17_ICAD_TF_FINAL_Report_HITAC_508_0.pdf.

outcomes. Arriving at these outcomes is more efficient when care plans tailor 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 healthcare facilities. Rural providers especially need data that shows which care, prevention, and treatment measures are likely to work—and which won't. Healthcare providers spend about half their time doing paperwork and grappling with EHRs that create friction in their workflow. With fewer caregivers per capita and greater distances to care in rural areas, a system that traps those caregivers in endless stretches of administrative busywork is costly to patients.

We believe ONC (and the Centers for Medicare and Medicaid Services [CMS]) share CHI's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD, and we strongly encourage the federal government's interoperability efforts to prioritize data generated by patients outside of the traditional care setting. There is now an expectation throughout the healthcare value chain of seamless and secure patient data across the care continuum, where individuals can easily integrate and compile longitudinal electronic health information across online tools, mobile platforms, and devices to participate in shared decision-making with their care, support, and service terms. Moreover, we support efforts to incentivize software developers and patients to make use of Medicare claims data. This Administration's Blue Button 2.0 initiative, which would help make this claims data usable via APIs to developers, should supplement those efforts by ensuring that Medicare covers tools that enable patients to use, analyze, and share their claims data. A diversity of APIs are emerging to assist in bringing PGHD into the continuum of care, but we stress that not all of these are necessarily well integrated with EHRs. While CEHRT will be required to support APIs, many vendors will enable "read only" access, allowing for data to only flow out of the EHR rather than both in and out. Additionally, we are aware that CEHRT vendors have not implemented a common approach to API development and lack a consistent implementation of API technical standards. CHI reiterates our concern with, and lack of confidence in, any presumption that the 2015 ONC CEHRT standards will facilitate seamless interoperability.

Building on the above views, CHI supports ONC putting rules into place that will create an effective electronic prior authorization system that interfaces well with EHRs, provides access to payer's coverage data and guidance, and is welcomed and adopted by the provider community:

- Consistent with the above, ONC, along with CMS, must leverage standards like FHIR to unlock third-party tools to access the data needed to enable real-time (or near-real-time) resolution of prior authorization requests. Such standards need to be evaluated for adequacy (i.e., tested in real-world environments and across a diverse range of setting and scenarios, not just in select connectathons) before being included in a certification program. ONC should also safeguard that Implementation Guides (IGs) and standards are certifiable and that technology is able to be tested to a level of conformance that ensures end-to-end interoperability.

- ONC should take steps in its prior authorization rules to require that any future certification program ensure sufficient data (e.g., National Provider Identifier numbers, health insurance policy information, and clinically relevant data) needed to make electronic prior authorization decisions rapidly is securely available via APIs. CHI shares ONC's goal of providing patients with information about their prior authorization decisions, and supports requiring making information available to patients about any pending and active prior authorization decisions (and related clinical documentation and forms) for items and services via the Patient Access API conformant with the HL7 PDex IG no later than one (1) business day after a provider initiates a prior authorization request or there is a change of status for the prior authorization. Further, tools such as HL7's CDS Hooks, which allows acting on prior authorization obligations within the EHR (rather than in a separate program or screen) would streamline the process if adopted and should be championed by ONC. However, more testing and CDS Hooks maturity is required before it is ready for tight integration within an electronic prior authorization process.

  ONC (and CMS) are encouraged to work with all affected stakeholders to educate and ease compliance burdens. For example, we support ONC and CMS testing and vetting standards of data transfer in the leadup to requiring their implementation as some proposed protocols have not been fully implemented into health level 7 (HL7). Further, ONC and CMS should take all steps possible to limit burdens on providers and other stakeholders including fees charged by EHR vendors for integration of their APIs into technology solutions that will further compliance with these new rules. CHI urges ONC and CMS to understand and test, through a feedback loop to the technology developer community, how new standards will affect the healthcare ecosystem before altering relevant Health Insurance Portability and Accountability Act (HIPAA) requirements. CHI encourages ONC and CMS to provide financial or other positive incentives, in alignment with the BlueButton 2.0 initiative, to drive the development of technologies that will support priorities to encourage interoperability widely.

- Privacy and security issues should be adequately addressed in standards and IGs that would be certified to before requiring electronic prior authorization uses (and we support ONC's collaboration in identifying and addressing existing gaps in such standards and IGs). To increase security and transparency, CHI supports the collection of third-party app developers' attestations of privacy practices when such developers are accessing patient data via an API. CHI has long supported measures to increase transparency into data management and privacy practices to enable patients to make informed decisions about their own health data, which the ONC Model Privacy Notice, among other solutions, will advance. We support such information being made easily available to patients, which will require consolidation in a single resource (which should pull in necessary data from other entities such as private third-party certifiers). As we have previously expressed to CMS, CHI supports payers reporting the names of the unique apps that access the payer's API and recommend that this information be reported on a quarterly basis, including an app developer's response to privacy attestations.

- Additionally, CMS should, in coordination with ONC, take action to safeguard that support for electronic prior authorization is adequately provided by commercial health plans and payers that participate in government programs.[3] We urge CMS to move forward with requirements for commercial health plans and payers that participate in government programs to support electronic prior authorization via standard APIs as soon as possible, and to extend such obligations to Medicare Advantage (MA) plans as MA beneficiaries would immensely benefit from a streamlined prior authorization processes. Data provided by payers electronically under this rule should include the payer's list of covered items and services that require prior authorization as well as related documentation requirements.

- To advance provider use of electronic prior authorization capabilities (consistent with the above recommendations) in value-based care environments, CMS could, in coordination with ONC, consider leveraging electronic prior authorization tools in its Quality Payment Program's Merit-based Incentive Payment System (MIPS). Any effort to integrate electronic prior authorization within CMS MIPS must, however, first evaluate the readiness of electronic prior authorization technology and standards across medical facilities of various sizes and specialties. Furthermore, any MIPS measure should leverage positive incentives and guard against further burdening providers. We reiterate that the goals for electronic prior authorization are the reduction of provider burden, addressing systematic prior authorization process deficiencies, and the removal of prior authorization-initiated harms to patients.[4]

In addition, CHI urges ONC and CMS to take action to support real-time benefit checks to inform timely medical and prescription drug decisions and understand costs. Currently, CMS requires that that each Medicare Part D plan sponsor must have real-time benefit check capabilities that can work with at least one provider's EHR system and will put a requirement on Medicare Part D plans in 2023 to create pharmacy real-time benefit check functionality that enables cost and prior authorization as part of patient access. ONC and CMS should help develop and leverage standards for automated benefit information and real-time benefit check capabilities through EHR certifications, access to patient-level APIs, and by providing financial incentives to providers for using real-time benefit check capabilities. In particular, Medicare plans should integrate the National Council for Prescription Drug Programs N1 and N2 claims standard, which will permit providers/pharmacies to run accurate and efficient benefit verification processes. ONC can take significant steps forward by including real-time benefit check capabilities in its list of functionalities required in electronic prior authorization rules.

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[3] CHI has provided supportive comments, consistent with its views expressed here, to CMS in response to its proposed rulemaking that would place new requirements on state Medicaid and CHIP fee-for-service programs; Medicaid managed care plans; CHIP managed care entities; and Qualified Health Plan issuers on the Federally-facilitated Exchanges to improve the electronic exchange of health care data and streamline processes related to prior authorization, which are available at https://www.regulations.gov/comment/CMS-2020-0157-0178.

[4] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

CHI appreciates the opportunity to submit its comments to ONC and urges its thoughtful consideration of the above input.

Sincerely,

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