June 3, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-9115-P. Interoperability and Patient Access for MA Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of QHPs in the Federally-facilitated Exchanges and Health Care Providers

Dear Administrator Verma,

On behalf of the more than 220 children’s hospitals across the country, the Children’s Hospital Association (CHA) is pleased to provide comments on the Centers for Medicare & Medicaid (CMS) proposed rule to advance interoperability and patient access to health data. We share the goal articulated in this proposed rule of creating a nationwide infrastructure that can give patients and their families/caregivers, as well as their providers, timely access to needed information to ensure the best possible health outcomes. At the same time, we believe there are aspects of the proposed rule that could hinder, rather than advance, that goal in pediatrics.

Although they account for less than 5 percent of hospitals in the United States, children’s hospitals care for almost one-half of children admitted to hospitals. Children’s hospitals are regional centers for children’s health, providing care across large geographic area, and as such, are especially attuned to the value and need of a strong interoperability and health information technology (HIT) infrastructure to support high-quality care across pediatric settings. Children’s hospitals serve the majority of children with serious illnesses and complex chronic conditions and most children in need of major surgical services. As leaders in local and regional pediatric health care, we are committed to HIT as a means to advance high-quality children’s health care and health outcomes.

As we noted in an April 11 letter to the Office of the National Coordinator (ONC) with our recommendations for voluntary pediatric electronic health record (EHR) certification guidelines, there are a critically important subset of HIT issues unique to pediatric hospital care. Our comments focus on the aspects of the proposed rule that pertain to those pediatric concerns, but also touch on a few other key aspects of the proposed interoperability requirements with implications for the care we provide and the patients we serve. These include:

- Recommendations for changes to the proposed requirement that providers give patient’s access to their health information through open Application Programming Interfaces (APIs) to better advance the health care needs and outcome goals of child patients, families and caregivers and appropriately protect the pediatric patient’s privacy.
- Our opposition to the use of the Medicare and Medicaid Conditions of Participation (CoPs) as a mechanism to advance data sharing and interoperability. Instead we recommend that CMS focus,

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1 See Children’s Hospital Association letter to Donald Rucker, April 11, 2018.

Champions for Children’s Health
instead, on reducing the existing barriers to health information exchange and using currently available enforcement levers to expand opportunities for exchange.

- Recommendations that CMS work with the ONC to develop a more robust set of data elements for the USCDI that include social determinants of health (SDOH), which are critical components of any effective care coordination effort, particularly in pediatrics.

In addition, we provide our feedback on the Requests for Information related to Advancing Interoperability in Innovative Models and Patient Matching. Our detailed comments are below.

**Patient Access Through Application Programming Interfaces (APIs)**

We agree with CMS that patients should have access to their health records in an easy-to-use format and should be able to share those records as they choose. However, we believe that the scope of this requirement is too broad to be practical for providers, payers and developers or useful to patients and their families or caregivers in terms of the nature of the information that would be available via the open API and the degree of privacy and security risks that could result. Therefore, we recommend several changes that better advance the health care needs and outcome goals of child patients, families and caregivers and appropriately protect the pediatric patient’s privacy.

First, we recommend that the scope of the data that can be downloaded with APIs be limited to the data elements included in the proposed U.S. Core Data for Interoperability (USCDI) – the core baseline of data classes that must be commonly available for interoperable exchange and serve as foundational components of care coordination, which is the primary goal of preventing information blocking. We also encourage CMS to consider the feasibility of requiring APIs related to pediatric care to incorporate educational content for families on specific pediatric conditions. That content would include post-hospital care and concerns, as well as social services and school-related issues – information that is vital to ensuring positive child health outcomes. In addition, API developers should be encouraged to include Direct Messaging capabilities in the APIs to facilitate ongoing real time communications between providers, patients and their caregivers. Timely communication can help reduce preventable emergency department visits when there is a change in the child's condition. For families of a child with medical complexity these types of communications can help empower families to address changes in their child’s condition and avoid frequent visits to the emergency department, thus reducing costs and stress on the family.

At the same time, we caution that there are privacy issues specific to children and adolescents that need to be addressed by API developers. For example, proxy access to a minor child’s record must be incorporated into the API for both parents and guardians. There also must be privacy protections available to manage parent/guardian access to the records when situations arise that require their access to be discontinued, such as some circumstances related to the care of adolescents (e.g. reproductive health, gender identity, drug use, and genetic issues) and alternative guardian situations. The APIs should include functionality that allows for the flagging of individual record components as confidential and for modifications of record accessibility to adapt to the confidentiality needs of a patient’s particular situation and specific state or local requirements. States may have differing requirements and procedures related to the degree of confidentiality documentation (i.e. which types of information can or cannot be shared with family members) and the point of care when an item is labeled as such.
Revisions to Conditions of Participation (CoPs) to Include Electronic Notification Standards For Providers

We applaud the agency’s commitment to improving interoperability among providers during transitions of care, but do not support the proposed revision to the CoPs to require hospitals to send electronic notifications when a patient is admitted, discharged, or transferred to other facilities, providers, or community care providers with an established patient relationship. We believe that a focus on improving the EHR infrastructure is a much more effective way to meet our shared objective of an interoperable health information system, not the imposition of new requirements on providers.

We urge CMS to focus, instead, on reducing the existing barriers to health information exchange to expand opportunities for exchange. Barriers include the ability to exchange information across different vendor platforms, to identify the correct patient when information is exchanged between systems, and the lack of standardization among pediatric systems and across states. The proposed pediatric EHR certification guidelines are a vitally important and promising first step towards that barrier reduction and we hope that CMS will collaborate with the ONC to achieve optimal operationalization across the health care system.

In pediatric care, the ability to easily share patient information among providers and facilities can be compromised by a number of challenges that may be out of the provider’s control, even though timely communications among a child’s provider (primary care through quaternary care) are critically important. In particular, children with medical complexity are typically cared for by a number of pediatric specialists and subspecialists who may be affiliated with one or more children’s hospitals or practices in the community. Furthermore, it is not uncommon for a child with multiple health issues to need care from several different children’s hospitals and even across state lines, given the regionalization of children’s specialty care. The effectiveness of care coordination efforts between a variety of institutions and providers depends on the ability of those providers to communicate with each other.

However, the current lack of standardization in pediatric HIT systems and low pediatric EHR system adoption by community providers can pose challenges to large children’s hospitals trying to share information about a child among themselves if they use different or customized electronic systems or none at all. While the new voluntary EHR certification guidelines proposed by the ONC will help advance better standardization in the future, they will require time to operationalize. Furthermore, given the fact that they are voluntary certification criteria, rather than required, it is too soon to tell whether they will actually have a substantial impact on system alignment.

Moreover, even if standardization occurred to enable timely communication among all of a patient’s providers, there remain unique needs, challenges and sensitivities in transmitting information about a child patient’s status with providers. These include the need to acquire the appropriate authorization of parent/guardian proxies for child patients, adolescent confidentiality issues and requirements, and potential family and legal dynamics.

We also note that CMS already has mechanisms to hold hospitals accountable for information exchange outside of the CoPs, including the Promoting Interoperability Program. The agency also requires hospitals to attest that they have not taken steps to limit or restrict health information exchange. The attestations
achieve the purpose of requiring health information exchange without the administrative burden that a new CoP would initiate. Additionally, ONC has initiatives underway to advance the health information exchange infrastructure including the recently released Trusted Exchange Framework and Common Agreement Draft 2. We believe these efforts are better suited to effectively advance the goal of information sharing in a consistent and transparent manner.

In the event that CMS chooses to adopt its proposed revision to the CoPs, despite the above concerns and compliance barriers, we seek clarification regarding:

- The identification and parameters of the “patient’s care team.” The proposed rule requires notifications to be sent to “practitioners and providers that have an established care relationship with the patient relevant to his or her care” and gives hospitals some leeway in how to identify care team members. We request greater specificity regarding what constitutes “an established care relationship” and the extent of the specialization of the care team members. In addition, we seek clarification regarding the timeline for an “active care relationship” (e.g. “last seen within 12 months”).
- The ability of patients to opt out of transition notifications to all or specific providers when there are unique confidentiality concerns related to the care of an adolescent and/or specific family dynamics (e.g. contested guardianship situations). We recommend that the rule also clarify that, under circumstances where a patient opts out of transition notifications, the relevant providers should be made aware that event information has been withheld.
- The role of vendors, existing HIEs and states in facilitating, and cooperating with, providers to comply with the requirements. For example, HIEs and states might be allowed to identify preferred vendors and intermediaries and could work with providers to facilitate common data elements. At the same time, we remind CMS that it is not uncommon for children to cross state lines to receive care from physicians or a children’s hospital with specific expertise, given the regionalization of pediatric specialty care. For an electronic notification infrastructure to work effectively, the cross-state common functionality must also exist.
- The metrics that will be used to assess compliance with the CoP requirement. We recommend a minimum standard consisting of notification of the patient’s primary care provider, with an incentive structure for additional provider notifications.

Coordination of Care: Transactions to Communicate Between Plan

We generally support the proposed requirement that an enrollee’s USCDI data be sent from one plan to another or to a recipient upon request as this data exchange can be a useful tool in care coordination. However, we note that the proposed data elements of the USCDI (Version 1) do not include any social health factors and urge CMS to work with the ONC to develop a more robust set of data elements that consider SDOH. A child’s socioeconomic background, social history and related information related to living arrangements, family, pets, grade in school, and other environmental and social issues are critical components of an effective care coordination effort, particularly in pediatrics. Optimal care coordination for children with chronic or complex health conditions happens in the home, school, and broader community, as well as within the walls of the hospital. Knowledge of the life of the child – and the ability to share this information with others involved in the care continuum – is integral to the child’s health and well-being, particularly post-discharge when learning needs, housing or food instability, and personal psycho-social stressors must be addressed.
Request for Information: Advancing Interoperability in Innovative Models

We are pleased that CMS requests information on ways the Innovation Center can promote interoperability as part of the design and testing of innovative payment and service delivery models. We agree that innovative approaches to data exchange across providers may improve care coordination, enhance the quality and safety of care and eliminate duplication to reduce costs. We suggest that the Innovation Center consider ways to promote standard nomenclature and data mapping as part of any future delivery and payment reform models. A major challenge to advancing interoperability and data exchange is the difficulty organizations have in appropriately managing, organizing and mapping incoming data. Data reconciliation, mapping and de-duplication is a massive undertaking that can result in large pools of data sitting in queues for entry into a hospital’s EHR. Until entered into the HIT system, the information cannot be integrated and, therefore, is not useful or accessible to providers/patients.

In addition, we encourage CMS to pursue models that include standards for the capture of data related to social determinants of health (SDOH). As noted above, socioeconomic/social history and related SDOH data elements, such as housing or food instability, and personal psycho-social stressors, that impact children’s health, should be captured and recorded in a consistent way. This standardization could trigger referrals to social and ancillary services and inform others involved in the care of the child, leading to more optimal care and outcomes. In addition to capturing SDOH at the point of care, CMMI could examine the use of neighborhood-level data and risk indicators to inform clinical care.

Request for Information: Patient Matching

We agree with CMS regarding the importance of patient matching and the serious safety, quality and cost implications of ineffective matching and are pleased that the agency is examining the issue to determine its appropriate role in advancing solutions. In pediatrics, it is vital that documentation capabilities of the pediatric EHR system allow for a standard patient identifier methodology that can match patients with their family/guardian but is not reliant on a social security number. The EHR should be able to capture parents’/guardians’ legal names, along with additional demographic data, including telephone number, e-mail address, and gender. Family structure is changing and technology must be dynamic enough to capture less traditional identifiers. For example, not all children who receive care at a children’s hospital will have a social security number. In addition, records must be capable of capturing preferred names, which may be different from legal names in the case of transgender individuals or due to dynamic family situations.

We believe that a unique patient identifier for each child beginning at birth is the optimal long-term solution to patient matching. Names can change if children transition into different familial circumstances (i.e. adoption or blended families) and duplicate entries for the same child may be entered into immunization and other registries, for example. Furthermore, leaving data entry up to the individual typing the name allows for potential human error in spacing, punctuation, etc. At the same time, we caution that biometrics could be a solution for adults, but it is complicated in pediatrics as children’s fingerprints change size as they grow.
Furthermore, patient matching conventions should enable the linking or matching of EHRs and organizations related in any way to the care of newborns. For example, there currently is not a recognized newborn naming convention that assures that seriously ill newborns who are transferred to a children’s hospital from the birth hospital are correctly identified and that their records are appropriately transferred between the institutions. Technology should allow for queries, utilizing newborn naming conventions (e.g. mother’s first name), of the birth hospital to identify and verify a newborn’s records prior to their import into the EHR. In addition, technology should be able to capture multiple birth status, including birth order, for use in patient identification. Finally, the EHRs should capture the mother’s name in discrete fields and without punctuation (e.g. Jamir rather than J’amir).

In conclusion, while we share CMS’ interest in advancing interoperability as a key component of care coordination and quality health care, we urge the agency to rescind its proposal to use CoPs to achieve those goals. Instead, we look forward to working with you to collaboratively advance a pediatric HIT infrastructure that can efficiently and effectively allow for health information exchange that supports child patients and their families and caregivers. Please contact Jan Kaplan at 202-753-5384 with any questions.

Sincerely,

M. James Kaufman, PhD
Vice President, Public Policy