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October 4, 2024

Micky Tripathi, Ph.D.
National Coordinator
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW
Floor 7
Washington, DC 20201

Dear Mr. Tripathi,

The Children's Hospital Association (CHA) appreciates the opportunity to comment on the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) proposed rule, Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2). We support the rule's advancement of the exchange of safe and timely information among providers, payers, and public health authorities to empower patients and ensure they receive quality care, and want to work with you to ensure that the health information technology (HIT) infrastructure meets the needs of children and their specialized providers.

The appropriate exchange of health information enables pediatric patients, their families/caregivers, and their providers to have timely access to needed health care information to ensure the best possible health outcomes. These types of communications are particularly important for families of children with medical complexity as they empower them to address changes in their child's condition and help avoid frequent visits to the emergency department, reducing costs and stress for the family.

The 200+ children's hospitals across the country are dedicated to the health and well-being of our nation's children and the advancement of child health through innovations in the quality, cost and delivery of pediatric care. We are regional centers for children's health, providing highly specialized pediatric care across large geographic areas, and as such, are especially attuned to the value and need of strong interoperability and HIT infrastructure to support high-quality care across pediatric settings.

Children are not little adults, and their health care delivery system is designed to meet their unique needs. Therefore, there is a subset of issues in HIT that are especially impactful for pediatric health care and important to consider as you pursue efforts to improve information-sharing among, providers, payers, and public health authorities to support enhanced communication with pediatric patients and their families. We recommend that:

- Public health interoperability standards incorporate the needs of children and their families so they can more readily get the information they need to facilitate their access to child-appropriate physical and mental health care during an emergency.
- Pediatric-specific certification criteria be developed and required for application program interfaces to assure that the HIT products used by patients, providers and payers meet the unique needs of child patients and their families.
- Information blocking exceptions be expanded to reflect the unique needs of pediatric patients and the pediatric health care delivery system.

Our detailed comments are below.

Champions for Children's Health

Public Health: New and Revised Public Health Data Exchange Certification Criteria

We applaud your proposal to improve public health data interoperability by enhancing the exchange of immunization data and improving population-based surveillance from emergency departments, clinical, and non-clinical sources. To strengthen these provisions, we urge that interoperability standards incorporate strategies that ensure the exchange of pediatric-focused information that can help enable children and their families to readily access child-appropriate physical and mental health care during an emergency. It is critical that children have timely and seamless access to physical and mental health care services during an emergency, including natural disasters and pandemics. The impact of multiple challenges during an emergency, including disruptions in health care, food or housing insecurity, trauma or grief, can be cumulative, putting children at higher risk for both physical and mental illnesses well into adulthood.

We recommend that the ASTP/ONC collaborate and confer with a range of pediatric expert stakeholders to build out a national data infrastructure capable of efficiently sharing important public health information (e.g. number of available hospital beds), including pediatric-specific information, among providers and federal, state, and local agencies. Public health data should be stratified by age and socioeconomic status. Further, we ask you to establish specific guidelines to ensure responsible data sharing and storage, with the clear intention that data use will help facilitate the provision of child-appropriate care during an emergency. During a public health crisis, pediatric-specific information is needed to appropriately account for differences between the way health care delivery and support systems are structured to meet the unique physical, mental, developmental and social needs of all children, including those with complex medical conditions.

Furthermore, we urge you to address the unique needs of children and the pediatric health care system in relation to the exchange of immunization data. We encourage you to consult pediatric experts on how to balance the need for adolescent privacy with the goal of reducing disparities in access to immunization services. It is critical that the ongoing input from pediatric health care providers and emergency preparedness experts guide these efforts to reduce inconsistent access to immunization records across care settings that could lead to delays in access to needed vaccines. It's also important to consider the possible safety issues for children, such as sharing information with a family member who may not have custody of the patient, or in child abuse cases.

In addition, a real-time surveillance data network that includes already available pediatric data (from hospital inpatient, outpatient and emergency departments, as well as school settings) is needed. It is important that you build upon and strengthen existing systems that collect this data to avoid imposing additional administrative burdens on pediatric health care providers. That network must have the capability to connect data with other already existing resources for better insight into pediatric cases and to provide an accurate representation of pediatric capacity and continued service needs.

Patient, Provider and Payer Application Program Interfaces

We appreciate the ASTP/ONC's proposed certification criteria aimed at enhancing and standardizing information exchange between health care payers, providers, and patients to facilitate the sharing of clinical, prior authorization and coverage data. As we have recommended previously, it is critical that the ASTP/ONC require the development of pediatric-specific criteria to assure that the HIT products meet the unique needs of pediatric health care providers and their patients.

Due to the lack of standardized electronic health record (EHR) elements intended for a pediatric setting, children's hospitals still may need to customize their pediatric clinical content if their IT vendor has not adopted the current voluntary pediatric standards. These "workarounds" are burdensome for the hospital and detrimental to interoperability initiatives and strategies as they lead to a lack of uniformity between institutions.

Patient Access API

We support the intent of the Patient Access API proposal to improve access to health and administrative information, including information on drug formularies and clinical information through patients' preferred health applications. However, we urge the ASTP/ONC to strengthen these provisions to address issues unique to children and adolescents. 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—that meet federal, state and local standards—to manage parent/guardian access to a minor’s records when situations arise that require that access to be discontinued, such as some circumstances related to alternative guardian and other child welfare situations. We encourage you to work with pediatric providers and privacy experts on the specific pediatric criteria for the APIs.

Payer-to-Payer API

We support your proposal to facilitate the electronic data exchange between payer systems when a patient switches insurance plans. This information exchange is a critical tool to help ensure that ongoing care is not disrupted when a pediatric patient changes plans or moves between a qualified health plan, and Medicaid and/or Children’s Health Insurance Program (CHIP). Payer-to-payer electronic exchange of pediatric patient claims, encounter data, and pending and active prior authorization decisions when a patient newly enrolls in a plan is key to pediatric care coordination and continuity.

Prior Authorization API

We support your proposal to ensure the ability of payers and providers to request and populate prior authorization information and to submit and respond to prior authorization requests through a prior authorization API. The seamless sharing of this information is key to care coordination and continuity in pediatric health care so that children receive the care they need in a timely manner.

Payers’ burdensome prior authorization processes create stress for patients’ families, administrative burdens for the children’s hospitals where they receive their care and can impede timely care and increase costs. For example, one hospital has reported that most of its payers take up to 14 days to render a decision for the authorizations they submit for approval. Findings from another children’s hospital’s internal analysis of prior authorization denial adjudications showed a 33% increase in frontline prior authorization staff over the course of four years to keep up with those denials, at a cost of \$4 million. According to that analysis, the final denial rate for cases that went through a prior authorization process was only .006%; 99% of denials were ultimately overturned because the payer agreed with medical staff that the denied services were appropriate. The delays in care that result from these types of complicated, and ultimately unwarranted, denial adjudications can have serious implications for children’s long-term health and well-being and can drive up health care costs.

Information Blocking

We appreciate that the proposed rule expands upon exceptions for information blocking, but note that there are issues unique to pediatric health care that must be addressed to ensure that these provisions do not have unintended consequences for the children and adolescents cared for by children’s hospitals. For example, it is critical that the information blocking exceptions allow for the appropriate protection of adolescent confidentiality and the management of access to minors’ health information. They must also ensure that the inability to transfer health information due to incompatible EHR systems is not considered information blocking. Furthermore, it is crucial that pediatric-specific solutions to information blocking are appropriately funded, electronic medical record vendor agreements are secured, and data sharing agreements are implemented in a reasonable time frame. Therefore, we recommend additional refinements to the information blocking exceptions below.

Patient Confidentiality

We urge the ASTP/ONC to address the privacy and proxy issues that are unique to pediatrics. Information blocking exceptions must ensure that pediatric providers have the flexibility to adapt to the confidentiality needs of a pediatric patient’s particular situation when developing and implementing new digital technologies and to modify record accessibility to reflect specific state or local requirements.

We note that there are varying federal and state rules and regulations about parent/guardian access to sensitive adolescent data, and the potential significant harm in parents/guardians inadvertently being given access to that data. We especially highlight state confidentiality compliance requirements regarding adolescents, which are in accordance with the Health Insurance Portability and Accountability Act (HIPAA) privacy rules that establish national standards to protect the privacy of health information. HIPAA does not override state law provisions that are at least as protective as the federal safeguards. For

example, most states allow adolescent patients to seek consent for medical care for certain conditions on their own (e.g. mental health services) without permission or awareness of their parents or legal guardians, and many prohibit this information from being shared with parents/guardians without the adolescent's consent. Additionally, a provider might be justified in withholding a drug test result from the health record of an adolescent patient because the patient does not want his/her parents to see that result. Under these circumstances, the provider's actions should not be considered information blocking.

In addition, there are unique safeguards needed to protect the privacy of minors' genetic data, such as obtaining informed consent from both minors and their legal guardians, to ensure that genetic data is only used for specific, authorized purposes. Sharing genetic information of minors can reveal predispositions to diseases and conditions, which could lead to discrimination or stigmatization and pose significant risks to a child's future health and well-being. Requiring specific consent before sharing this type of information should not be considered information blocking.

Finally, we seek clarification that this exception would apply to proxy consent situations where the provider must confirm proxy authority in the interest of the child patient's safety. Children's hospitals regularly work with—and obtain proxy consent from—parents, legal guardians, or other authorized representatives when providing care to minor children and before extending an invitation for portal access. It is not unusual for a hospital to receive a request from a parent, non-guardian, foster parent, or temporary court-ordered care provider—i.e., extended family, friends, etc.—who does not have authority to receive the child's protected health information (PHI). Providing electronic health information (EHI) access to the person with parental rights for an at-risk child who may have been subjected to abuse or neglect could cause further harm to the child and would be inappropriate. Again, these situations should not be considered information blocking.

Preventing Harm

We ask the ASTP/ONC to apply the “Preventing Harm” exception to certain situations where a minor's immediate access to their EHI via their online portal may be blocked. In particular, the exception should take into account pediatric providers' need to review and interpret the results and then communicate with their patients and patient families. To that end, we recommend engaging with pediatric providers to identify which electronic medical records (EMR) fields, including discrete fields outside of clinical notes, may pose harm to a pediatric patient and should be filtered from an online portal. It is critical that access to this data does not result in unintended harmful consequences.

For example, there may be circumstances when a provider would want to decline the download of pediatric data unless the portal has a safe way to present clinical notes, so a young patient is protected from potentially distressing and/or confusing information. A teen patients' immediate access to clinical notes in the absence of appropriate supervision from an adult (parent and/or provider) may lead to significant distress and confusion upon first seeing a troubling diagnosis.

In addition, the preventing harm exception must accommodate situations where the provider may need to prevent a parent or guardian from receiving certain information to protect the safety of the child. As noted above, there are occasions where a children's hospital will receive a request from a parent, non-guardian, foster parents or temporary court-ordered care providers (i.e., extended family, friends, etc.) who do not have authority to receive the child's information or face other complicated family situations. Providing EHI access to the person with parental rights for an at-risk child who may have been subjected to abuse or neglect would be inappropriate and could cause further harm to the child.

Incompatible EHR Systems

Finally, we ask you to clarify that the inability of a provider to communicate with another health care entity due to incompatible HIT systems or one provider's lack of certified EHR technology would not constitute information blocking and would fall under the “Infeasibility” exception.

As we note above, incompatibility among systems is especially prevalent in pediatrics given the lack of standardized EHR elements for the pediatric setting, even with the adoption by ONC of voluntary pediatric certification standards. It is not uncommon for there to be different systems in use between differing types of children's hospitals and community-based

providers or for there to be no EHR systems at all in use by some community providers with which families interact. This is especially problematic in the care of children with medical complexity who are typically cared for by a number of pediatric specialists and subspecialists affiliated with one or more children's hospitals, as well as numerous community providers.

Interactions with legacy medical records systems or with providers with incompatible systems may pose a key barrier to interoperable information exchange and may appear to be information blocking. For example, one children's hospital formed a care network comprised of nearly 200 community-based practices, including practices across state lines, that use a variety of EHR systems. Each practice is responsible for their own EHR configuration, which leads to numerous barriers to information exchange, including the use of different vendor platforms, the lack of standardization among pediatric systems and across states, and challenges related to patient identification in the absence of standard patient naming conventions. Furthermore, while the hospital provides the latest guidance on information blocking regulations to those community providers, each provider controls the type and timeliness of the information that is shared with patients and families.

In conclusion, we appreciate your work to improve the electronic information exchange processes between patients, providers, payers, and public health authorities. We look forward to working with you to further reduce the complexity of these systems to improve pediatric patient care and outcomes. Please contact Natalie Torentinos at natalie.torentinos@childrenshospitals.org or (202) 753-5372 should you need more information.

Sincerely,

A handwritten signature in black ink that reads "Aimee C. Ossman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Aimee Ossman
Vice President, Policy
Children's Hospital Association