June 3, 2019

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Floor 7
Washington, DC 20201


Dear Dr. Rucker,

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 Office of the National Coordinator for Health Information Technology (ONC) notice of proposed rulemaking to improve the interoperability of health information. We share the goals articulated in this proposed rule of creating a nationwide infrastructure needed to ensure that patients, their caregivers and their providers have 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 areas, 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. They serve the majority of children with serious illnesses and complex chronic conditions and most children in need of major surgical service. They are committed to the meaningful adoption of HIT as a means to improve the quality and safety of pediatric health care.

The nation’s children’s hospitals greatly appreciate the opportunity to share their expertise through national pediatric HIT improvement efforts and commend the ONC for this proposed rule. The rule is a significant step in implementing the interoperability and health information blocking requirements of the 21st Century Cures Act (Cures Act) and will help advance pediatric functionality in electronic health records (EHRs) and data sharing to improve children’s health and health care. At the same time, we remind the ONC that there are a critically important subset of HIT issues unique to pediatric hospital care that are important to consider, as we noted in our April 11, 2018 letter regarding our recommendations for voluntary pediatric EHR certification guidelines.¹

Our comments below focus on the aspects of the proposed rule that pertain to those pediatric concerns and touch on a few other key aspects of the proposed rule with implications for the care we provide and the patients we serve.

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

Champions for Children’s Health
In particular, our comments encourage the ONC to:

- Modify the certification requirements contained in the proposed United States Core Data for Interoperability Standard (UCSDI) to better meet the unique functionality and data sharing needs of pediatric providers.
- Implement the proposed pediatric EHR certification program with some additional refinements to best meet the needs of pediatric providers and their child patients and to improve pediatric quality and patient safety.
- Address the safety, security, and confidentiality considerations that are unique to pediatrics, including the care of adolescents and children in unique family situations.

We also urge the ONC to reformulate the definition of electronic health information (EHI) to meet congressional intent of the information blocking provisions of the Cures Act by limiting its scope to the proposed components of the USCDI. As proposed, the USCDI will serve as the core baseline of data classes that must be commonly available for interoperable exchange and will be foundational to care coordination, which is the primary goal of preventing information blocking.

Finally, we appreciate the ONC’s interest in ways to: capitalize on HIT functionalities to address opioid use disorder (OUD), including care for infants with neonatal abstinence syndrome (NAS); ensure that patients receive meaningful information about their health care costs to help guide their care decisions; clarify the disincentives that should be applied to discourage information blocking; and determine its appropriate role in advancing solutions to patient matching. We respectfully offer our recommendations of approaches that the ONC can use to advance these various policies to support and not impede high-quality pediatric health care across the spectrum of settings and subspecialties.

Our detailed comments on provisions in the proposed rule with implications for children’s hospitals and the children and families they serve are below.

**IV. Updates to the 2015 Edition Certification Criteria**


We support the adoption of the USCDI and the inclusion of the new “Pediatric Vital Signs” elements. Our comments below focus on some key elements of particular importance to children’s health care.

- **Pediatric Vital Signs**
  
  We strongly support the addition of “pediatric vital signs” in the proposed USCDI, as we believe that their inclusion would enable more precise care for children by allowing different applications to model the growth of a patient according to biologic reference ranges, and prescribe the proper dosing of drugs based on weight and age. However, we recommend more specificity in the included elements to go beyond the proposed three elements. In particular, at a minimum, the ONC should assess the feasibility of including elements such as height and weight rather than solely the derived calculation of BMI, as well as blood pressure and pulse.

  In addition, we urge the ONC to prohibit the usage of EHR systems that do not have the pediatric vital sign capabilities. Systems that do not support this functionality could pose serious harm if they are used in pediatric-related care, given the importance of accurate recording of these key elements for children’s health and safety, particularly related to accurate dosing of drugs and other treatments.

- **Patient Demographics**
  
  We support the addition of address and phone number, but seek clarification that the address would include postal information, such as zip code. The inclusion of zip codes and standardized postal service addresses can improve the accuracy of patient matching. In addition, zip code information can be an important tool in
population health measurement and management and can be used to determine service needs and gaps related to social determinants of health.

- Clinical Notes
  We applaud the addition of the Clinical Notes and recommend that Emergency Department and Urgent Care Notes be added as required elements.

- Medications
  The ONC requests comments on whether to expand the “medication allergies” element to also encompass reactions for other substances, such as food. We encourage the ONC to adopt an expanded definition, as it could facilitate clinical decision support tools that would alert clinicians when patients are allergic to substances from which medications are made, as well as to nutritional supplements. The list should also be expanded to include substances used in medical equipment and devices, such as latex or other materials.

In addition, we are very concerned that the proposed USCDI does not appear to capture social health needs information. It is absolutely critical that the required data classes and elements capture socioeconomic/social history items related to living arrangements, family, pets, grade in school, and other environmental and social issues that impact children’s health, in addition to the medical history. Knowledge of the life of the child is integral to the child’s health and well-being.

The system should also allow providers to clearly flag children with special health care needs, complex conditions and/or behavioral health needs who may benefit from care management, tailored decision support tools, or social services. It should also allow the charting of children’s behavioral health visits and visits with other non-clinical service providers within the health care setting.

The ONC requests input on whether to only allow the patient and his or her authorized representative to be the requestor of their EHI. We do not believe that the EHI access criteria should be strictly limited and, instead, recommend that the ONC require vendors to supply both options: patient/proxy as requestor through the portal, and patient utilizing the provider or office staff as requestor on the patient’s behalf. These options would be especially important for adolescents who usually share portal access with a proxy, but for whom the generic EHI export without the identification of sensitive data could result in privacy concerns. For example, there are some adolescent privacy issues (such as reproductive health, gender identity, drug use, and genetic issues) where parents’ involvement may need to be addressed in the best interest of promoting the adolescent’s health and health care.

We recommend that the ONC consider pediatric use cases in the adoption of the HL7® Fast Healthcare Interoperability Resources (FHIR) standard related to the consent resource. The Consent2Share model was designed to allow patients to provide consent for sharing data with providers and allows them to delegate management of their privacy and consent to a caregiver. However, it does not currently support a use case for consent to proxy access, which is key for the pediatric population. In addition, the model may need to address state-specific laws governing pediatric patients’ ability to consent to data sharing/non-disclosure among care team members.

In addition, we are pleased that the ONC seeks comment on how the availability of this proposed certification criterion might support care coordination and privacy priorities in pediatric care. There are unique privacy and confidentiality issues in children's health care that must be addressed when sharing a minor’s health data or seeking consent to share their data and urge the agency to address those issues in any future policies or standards. As noted
above, there are varying state rules and regulations about parent or guardian access to sensitive adolescent data (e.g. substance use, behavioral health, reproductive health), as well as their ability to give consent to share that information. In addition, there is potential significant harm in parents or guardians inadvertently being given proxy responsibility for the sharing of that data, particularly in families with custody disputes or concerns about abuse.

Clear policies and processes that address these concerns can facilitate the data sharing between providers that is foundational to care collaboration and coordination, improved outcomes and overall quality of life for a child with special health care needs or a complex medical condition. 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. In fact, it is not uncommon for a child with multiple health issues to need care from several different children’s hospitals even across state lines, given the regionalization of children’s specialty care. The child’s medical team must be able to access the data that is gathered in the home facility and by external providers and community organizations throughout the continuum of care in order to make more informed clinical and post-acute care decisions. However, they must be able to do so without putting the child patient’s privacy, confidentiality and safety at risk.

Section VI – Health IT for the Care Continuum

A. 2. Health IT for Pediatric Setting – Recommendations for the Voluntary Certification of Health IT for Use in Pediatric Care

We applaud the ONC for releasing the proposed guidelines for pediatric HIT certification and provide some suggestions for ways to refine and strengthen those guidelines to ensure that they help advance high-quality pediatric care. The guidelines and clinical priority certification recommendations represent a positive step forward for the improvement of EHRs that are used in the care of children.

It is critical that pediatric EHRs focus on children’s health and strengthen and advance pediatric clinical care; care coordination; information exchange between patients, families and providers, among providers, and with local, state, and federal agencies; and the overall quality and safety of health care for children and their families. However, as we noted in our April 11 letter, the current lack of standardized EHR elements for the pediatric setting has resulted in resource-intensive “work-arounds” by children’s hospitals. Currently, it is not uncommon for a children’s hospital to have to spend time and resources to customize available EHR systems or use niche pediatric products that are then integrated into the children’s hospital EHR.

Therefore, we are pleased that the 10 recommended clinical priorities selected by the ONC from the Children’s Format, with the input of pediatric experts, represent a strong, positive step forward for improving EHRs used in the care of children. The priorities and their technical worksheets provide an opportunity to address usability and safety in a thoughtful and deliberate way. At the same time, we offer the following refinements to several of the ONC recommendations for the voluntary certification criteria, which we believe would further improve the usability and safety of EHRs in the pediatric setting.

- **Recommendation 1: Use biometric-specific norms for growth curves and support growth charts for children.** Condition-specific norms should be included in the EHR, if available and validated. Examples include Down Syndrome growth curves; gestational age-adjusted norms (i.e. growth curves for infants who are born preterm); and norms/curves for blood pressure, if possible. Currently, hospital-based clinicians who care for a child with a complex condition often must rely on paper growth charts because these children do not always fall into the set growth charts that are available in existing EHRs.

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2 See [Letter to Donald Rucker](https://www.fh患儿.com), April 11, 2018
• **Recommendation 3: Ability to document all guardians and caregivers.** The listing of care providers should explicitly include and identify the medical home provider, if appropriate, which may be a pediatric specialist in the case of a child with medical complexity. It is also critical that the documentation capability includes security features to protect the confidentiality and safety of the child patient in accordance with any applicable state and federal laws. These include protections to prevent the sharing of this information with unauthorized individuals or entities in order to protect the safety of the child in situations of abuse or other threatening situations, and a mechanism to flag an EHR to indicate a complex family situation. It is not unusual for a hospital to 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 access a child’s information. Furthermore, providing access to a 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.

• **Recommendation 4: Segmented access to information.** There should be a default mechanism that prevents parental access to an adolescent’s information without proper authorization, as allowed under applicable state or federal law. Privacy and confidentiality functions are critically important in relation to the care of adolescents, particularly related to issues such as behavioral health, reproductive health, gender identity, drug use, and genetic issues. In that same vein, there should be a mechanism that allows the provider to tag certain medications as confidential in the care of adolescents. There should also be a mechanism that allows providers to grant proxy information access to parents/guardians under certain circumstances, such as parents/guardians of an adolescent with a developmental delay or cognitive or health condition for whom lack of parental access could jeopardize health outcomes. State-based differences in minor’s right to consent and to assent to services, particularly mental health services, will need to be considered, as well as guardianship for patients 21 years of age or over being cared for in a pediatric setting.

• **Recommendation 8: Associate maternal health information and demographics with newborn.** The methodology that matches newborns with maternal health information should be able to capture legal names, along with additional demographic data, including telephone number, e-mail address, and social security number if available. It should also be able to associate and capture key health and demographic information about parents/guardians, other than the mother. Family structure is changing and technology must be dynamic enough to capture less traditional identifiers. In addition, the EHR should have the capability to capture the newborn’s socioeconomic/social history items related to living arrangements, family, and other environmental and social issues that could have implications for their health and well-being once they leave the care setting. It is also critical that the EHR includes safeguards that allow for a record to be flagged if there are family dynamics that could be of concern, such as disputed guardianship, domestic violence or other issues that may pose a risk to the newborn.

• **Recommendation 10: Flag special health care needs.** We agree that complex medical conditions should be included among the conditions that are flagged under this critically important recommended criteria. We also suggest that this capability include behavioral health needs. In addition, we suggest the incorporation of a standard set of definitions of special health care needs, coupled with some flexibility in the flagging structure to allow the provider to flag unique situations.

In addition, we believe that there are a number of ways that the ONC could further tailor the pediatric certification program to best meet the needs of pediatric providers and their patients and to improve quality and patient safety. In particular, we recommend that the ONC develop pediatric-specific EHR testing requirements and guidance as described below.

• **Require pediatric-focused EHR testing/use of simulated pediatric data scenarios.** The ONC should clarify that some of the testing scenarios used by developers to secure pediatric certification must involve pediatric patients and pediatric-specific factors. EHR developers currently use different testing scenarios – which mimic real clinic events and workflows – to demonstrate the functionality of their systems. The ONC should clarify that some of the testing scenarios must focus on situations involving children as patients to obtain
certification for pediatric functionality. The ONC should also clarify that the test data that is used by developers must involve simulated data of children and consider providing test data for simulated pediatric patients to developers as it currently does for developers demonstrating that their technologies comply with the 2015 Edition.

Include pediatric end-users in testing. The ONC should require EHR developers to involve pediatric clinician end-users, such as pediatric nurses or specialists, who work in a variety of health care settings (e.g., hospital, community practice, etc.) in the testing of products for pediatric-focused certification. We recommend that, at a minimum, 50 percent of the testers should be pediatric clinicians. Under current regulations, EHR developers must use testing scenarios that mirror real clinical events and workflows to demonstrate the functionality of their systems and compliance with the ONC’s criteria. However, under the proposed rule, pediatric end-users are not necessarily required to be included within the minimum 10 end-users that are involved in (the testing of a product under consideration for pediatric-focused certification. We recommend that at least five of all the end-users testing for a pediatric product should be clinicians who care for pediatric patients to obtain robust input from end-users with experience caring for children.

• Develop specific guidance on implementation and use of the pediatric clinical priorities. The ONC should involve pediatric and usability experts (including pediatric clinicians) in the development of detailed implementation guides and test procedures for the 10 pediatric clinical priorities. This type of guidance, which the ONC has developed in the past for certification under the 2015 Edition (e.g., the Certification Companion Guide), would assist EHR developers and testing organizations in assessing conformance with the pediatric clinical priorities. For example, “Recommendation 2: Compute Weight-Based Drug Dosage” requires the appropriate computation of drug dosages, display of the dosing weight, and the weight-based dosing strategy on the prescription. The development of pediatric-specific certification criteria to meet this recommendation, along with certification companion guides and formal test procedures that include testing usability and safety, will provide needed information to help guide implementation.

Finally, the ONC should clarify that only those EHR technologies that meet all of the pediatric certification criteria can obtain the pediatric certification. Otherwise, technologies may receive certification for some of the clinical priorities and health care facilities may inadvertently believe that the system supports all 10 clinical priorities.

B.4. Health IT and Opioid Use Disorder Prevention and Treatment – Request for Information
We are pleased that the ONC is considering ways to capitalize on HIT functionalities to address opioid use disorder (OUD), including care for infants with NAS. We support strategies that can assist with innovative treatment approaches and strongly urge the ONC to address the unique nature of health care for infants, children and adolescents as the agency moves forward to advance and implement those strategies.

First, the proposed rule highlights stakeholder interest in the new opioid measures in the CMS Promoting Interoperability Program and the alignment of new 15 Edition certification criteria with those measures. As we noted in our comments to CMS on the new measures3, they may not be appropriate for pediatric patients. In particular, the measure “Verify Opioid Treatment Agreement” does not reflect the role of the parent in overseeing and participating actively in the care of children who may be prescribed opioids for long or short-term pain relief. We encourage the ONC to work closely with CMS on modifications to these standards to ensure their suitability for hospitals that predominantly serve patients under the age of 18. The refined standards should incorporate the parental/guardian role as proxy and address adolescent confidentiality protections.

In addition, we are very pleased that the ONC is seeking input on the effective use of HIT in support of interventions for NAS, including issues related to provider training, establishing workflow, and other related safety

3 See June 25, 2018 Letter from CHA to Seema Verma.
and usability considerations. However, we encourage the ONC to expand its focus beyond NAS to also include children and adolescents with OUD. These core HIT issues are critically important in the effective care of specific subsets of children and youth who may suffer from, or be at risk of, OUD because they have special health care needs or serious health conditions. These may include pediatric patients discharged from pediatric critical care services with oral opioid withdrawal medications; children and youth who are post-operatively discharged with an opioid pain control plan; pediatric patients on the hematology/oncology service line who are discharged with opioids for pain control secondary to malignancy; and children and youth in end-of-life care who are discharged home with high-dose opioids for pain control.

VII. Conditions and Maintenance of Certification


We agree that there could be significant patient engagement and care coordination benefits from efforts to use Application Programming Interfaces (APIs) to facilitate more seamless access to health information by patients, authorized caregivers and providers. However, the safety and security of downloaded EHI is a particular concern in pediatrics for several reasons. First, minors may not fully understand the implications of downloading and sharing their EHI. Second, there are varying state rules and regulations about parent or guardian access to sensitive adolescent data (e.g. substance use, reproductive health care, etc.), and there is potential significant harm in parents or guardians inadvertently being given access to that data without the adolescent patient’s consent. Furthermore, there are limited apps available with the ability to safely host multiple patients’ data (i.e. parent and child) in a single app. If the apps are not set up to safely handle multiple patients, there is significant risk that data from multiple patients could be mixed and confused, creating a potential for serious harm in how those data are interpreted.

Therefore, we believe there are additional requirements needed for API developers to strengthen data safety and security, particularly related to pediatric patients’ EHI. We also recommend that related safety and security issues be treated as Information Blocking exceptions, as described in our comments on those provisions of the proposed rule. First, the ONC should establish a system to verify the authenticity of app developers seeking to be registered, such as a certification process for third-party apps that have the capability of directly downloading EHI. In addition, the third-party app must have a safe way to partition data from multiple patients and health care systems must be able to determine which sensitive adolescent data they can exclude from download through an API. The proposed rule does not specify how an API Technology Supplier would verify the authenticity of app developers seeking to be registered, which raises concerns regarding the safety and security of the EHI once it is downloaded into a third-party application. Because third-party apps are not subject to HIPAA regulations, there are limited assurances for a patient or family that their data is protected once downloaded.

Finally, the ONC requests comment on which version of the FHIR standard is most appropriate to adopt as the baseline for HIT and interoperability standards. We believe that FHIR Release 4 (R4) is the “normative” version that should be adopted across the industry as the baseline standard, coupled with appropriate implementation guidance. FHIR R4 will already have been available for a few years by the time these ONC regulations take effect and the ONC should leverage its capabilities, which reflect the input of stakeholders with implementation and quality review experience.

VIII. Information Blocking

C.3. Relevant Statutory Terms and Provisions – Electronic Health Information

We appreciate the ONC’s attempt to align the definitions of EHI under the proposed rule with the definition of “protected health information” under HIPAA. However, we believe the proposed definition exceeds congressional intent under the Cures Act and respectfully request the ONC reformulate the definition of EHI to reflect the
Therefore, we welcome the opportunity to work with HHS to develop best practices that help our patients and their families navigate that information. We also note the challenges of gathering the most appropriate information in a timely manner. In order for providers to furnish the most meaningful aspects of price information—the deductible, copay, and out-of-pocket limits—to families/guardians they must work closely with them and their insurer to access the necessary information as quickly as possible. Furthermore, the uncertain nature of medicine, especially as it pertains to the care of developing and growing children and adolescents, combined with the fragmentation of the health care industry and the regionalization of pediatric specialty care which can result in children receiving care from hospitals across state lines, add to the challenge of providing meaningful price information.

Therefore, we welcome the opportunity to work with HHS to develop best practices that help our patients and their families/guardians understand their financial obligations and make the best care decision. We also appreciate the opportunity to provide the following responses to the questions on price information that are posed in the proposed rule.

- **Should prices that are included in EHI:**
  - Reflect the amount to be charged to and paid for by the patient’s health plan (if the patient is insured) and the amount to be charged to and collected from the patient (as permitted by the provider’s agreement with the patient’s health plan), including for drugs or medical devices? The family’s/guardian’s ultimate concern is the out-of-pocket cost; additional information that is not meaningful may confuse and potentially deter the family/guardian from seeking timely care for the child. Furthermore, there are legal barriers to providing negotiated rates as agreements with insurers often prohibit the disclosure of such rates.
  - Include various pricing information such as charge master price, negotiated prices, pricing based on CPT codes or DRGs, bundled prices, and price to payer? We believe that out-of-pocket cost information should be shared with the patient’s family or guardian to the extent that it can be estimated, as that is their foremost concern. Other information, such as the chargemaster price or the negotiated price, does not provide patients’ families/guardians with meaningful information. Furthermore, there are contractual barriers that prohibit the disclosure of negotiated prices. However, we also note that, though we do not believe it is meaningful to share chargemaster information, the FY 2019 Medicare IPPS final rule already requires hospitals to post chargemaster prices on the internet.
  - Be reasonably available in advance and at the point of sale? As you know, the provision of health care is complex and difficult to predict, which makes it extremely difficult to provide a meaningful estimate of total out-of-pocket costs in advance. For example, a seemingly minor physical discomfort may mask significant medical issues that are revealed only after thorough examination and testing. In addition, it is difficult to determine in advance the total out-of-pocket obligations for a patient for whom the exact medical condition has not been diagnosed. Even after a condition is diagnosed, complications may occur that require unanticipated intervention that may increase the total cost of care. For instance, there are different severity...
levels within the same diagnosis-related group (DRG), which will determine the ultimate reimbursement amount.

- Reflect all out-of-pocket costs such as deductibles, copayments and coinsurance (for insured patients)? Children’s hospitals are committed to helping families understand their out-of-pocket obligations, including through financial counseling. While hospitals may be able to provide some information, they require input and timely cooperation from the insurer, as well as the patient’s family/guardian. Insurers are responsible for the design and nuances of their products, including patients’ out-of-pocket costs and, thus, are the ultimate source of such information. However, health plans range in size and sophistication, and smaller plans may not have the infrastructure to provide the necessary information in a timely manner. Without accurate information from all the necessary parties, it is not possible for hospitals to provide accurate and individualized price information.

- Include a reference price as a comparison tool such as the Medicare rate and, if so, what is the most meaningful reference? We do not believe that reference prices, such as Medicare rates, are meaningful to our patient families/guardians, given that, on average, more than half of our patients are covered by Medicaid or CHIP, while only about 8,000 children in the entire country with end-stage renal disease are generally covered by Medicare. Therefore, a requirement that we provide Medicare rates as a reference comparison price would be both administratively burdensome and largely meaningless for the majority of our patient families/guardians. Furthermore, Medicare is designed to serve the elderly population and pediatric conditions and procedures performed in children’s hospitals may not have analogous counterparts under Medicare.

- To the extent that patients have a right to price information within a reasonable time in advance of care, how would such reasonableness be defined for:
  - Scheduled care, including how far in advance should such pricing be available for patients still shopping for care, in addition to those who have already scheduled care? We respectfully note a number of operational challenges to the provision of price information in advance, in addition to those that are posed by the complexity of the practice of pediatric specialty medicine. First, as we noted above, insurers establish and calculate deductibles, copays and coinsurance. Hospitals need cooperation from the insurer as well as the family/guardian to furnish meaningful price information to patients’ families/guardians. Therefore, considerations would need to be made to allow for the time necessary for hospitals to secure the relevant information from both parties. In addition, as noted above, insurance plans range widely in size and sophistication, and smaller plans may not have the infrastructure to provide the necessary information in a timely manner. Finally, nonprofit hospitals have charity policies that offer financial assistance based on income level. For such families, time must be budgeted to allow for the review and application of those policies.

Furthermore, any proposal on advance price information must carefully balance the technical challenges to furnishing such information. First, insurance status or income levels may change after price information is provided to the patients’ families or guardians, which could affect the validity of that information. For instance, a patient’s family may change employers and gain different insurance coverage, which would require a new determination. Alternatively, a patient’s family might exceed the deductible or reach the annual out-of-pocket limit, or the medical service could be delayed subsequent to the information being provided. In those circumstances, the family may be subject to a different cost-sharing amount than was originally provided. In addition, hospitals may not have access to price information for certain physician services, pharmaceuticals, or medical devices furnished in the hospitals due to the fragmentation of the health care industry. Physicians providing services inside a hospital, for instance, may not be employees of the hospital as physicians frequently are employed by separate legal entities that independently contract with insurers and have separate billing arrangements from the hospital.
Finally, we note that insurers have started implementing a practice in recent years commonly referred to as “white bagging” due to the high prices of certain drugs and biologicals. In white bagging, insurers pay for the high-priced product itself and have the product delivered to the hospital to be administered by the hospital. Although administered by the hospital, the hospital does not control the cost of the product, and may not be able to provide meaningful price information.

- **Emergency care, including how and when transparent prices should be disclosed to patients and what sort of exceptions might be appropriate, such as for patients in need of immediate stabilization?** We respectfully highlight the complicated nature of disclosing pricing to pediatric patients and their families/guardians when the patient receives emergency care. First, most pediatric patients are not likely to have the health insurance literacy necessary to provide the necessary insurance information, particularly during an emergency. This is a concern because the families/guardians of pediatric patients receiving care in a children’s hospital emergency department may not be readily available to answer insurance-related questions or receive the information.

In addition, we emphasize that the most urgent task in such situations is to stabilize the patient and minimize unnecessary distraction or stress. The families/guardians of pediatric patients who need immediate stabilization, by definition, would not be able to receive advance information prior to that care. Furthermore, patients who need emergency care have undiagnosed medical conditions and health care providers cannot determine the type or the level of care necessary in advance. Therefore, price information cannot be determined since neither the condition nor the intervention has been identified. Finally, we are concerned that efforts necessary to obtain relevant information from the patient, and the discussion of price information with the patient’s family, could distract or intimidate them and prevent the patient from accepting proper care.

- **Ambulance services, including air ambulance services?** Similar to emergency care, it is difficult to provide patients and their families/guardians with price information for ambulance services as the patients who need ambulance services often require immediate stabilization. In addition, ambulance services might be provided by an entity unaffiliated with the hospital as ambulance services may deliver patients based on factors such as need, proximity, and availability. Hospitals cannot provide price information for ambulance services furnished by a different legal entity.

- **Unscheduled inpatient care, such as admissions subsequent to an emergency visit?** Similar to emergency care, patients in unscheduled inpatient care may have unidentified medical conditions that require further consultation and diagnostic testing. The uncertainty of the diagnosis creates uncertainty in care plans, and makes advance price information unfeasible.

- **How would price information vary based on the type of health insurance and/or payment structure being utilized, and what, if any, challenges would such variation create to identifying the price information that should be made available for access, exchange, or use?** Health care providers must gather the necessary information from the patient or the patient’s family to correctly identify their insurance coverage and then must separately contact and obtain the necessary benefit information from the insurer to estimate the price information. However, this process can be exceedingly complicated given the wide range of health insurance types and payment structures, which increase the complexity and challenge of providing meaningful price information. For patients with private insurance, there is a dizzying array of benefit design permutations. Even the same insurer may offer different products that provide different benefit levels, benefit carve-outs, negotiated rates, provider network coverage, utilization management, pharmaceutical formulary design, or patient cost-sharing, just to name a few variables. These variables may also change from year-to-year as insurers update the plans. In addition, the process of accessing patient’s insurance coverage and status is currently not yet fully automated and the administrative burden varies according to insurer. Insurers have differing levels of infrastructure and smaller plans may not be able to transmit the necessary information to providers in a timely manner, thus jeopardizing the provision of meaningful price information to patients.
Children’s hospitals also face a unique challenge as some pediatric patients have more than one form of health insurance coverage. For instance, children of working families with employer-sponsored insurance may, in some cases, also have Medicaid coverage. The process to provide meaningful price information to patients and their families/guardians with multiple forms of health insurance about their out-of-pocket obligations is significantly more administratively complex.

In addition, as you know, most states do not have out-of-pocket requirements for children covered by Medicaid. Therefore, we recommend that those services for a child that are covered by Medicaid be explicitly exempted from any price information disclosure requirements. Families of children covered by Medicaid that receive meaningless and irrelevant pricing information could be confused and avoid seeking needed care for their children because they believe they might be charged for that care.

- **Would updates to the CMS-managed HIPAA transactions standards and code sets be necessary to address the movement of price information in a standardized way?** We recommend that CMS consider more robust requirements to the HIPAA 270/271 eligibility inquiry & response code set as one way to streamline and facilitate the provision of necessary information from insurers to enable providers to share meaningful price information. To provide meaningful price information to the patient’s family, health care providers need insurers to confirm benefit information, such as deductibles, copays, co-insurance, and annual out-of-pocket limits, along with a patient’s insurance eligibility. However, currently not all payers provide all the necessary information when requested. The transmission of this information between insurers and providers should be automated and available from all payers upon request to help improve the provision of meaningful price information to patients’ families and guardians.

**D. Proposed Exceptions to the Information Blocking Provision**

We are generally supportive of the information blocking exceptions in the proposed rule, but seek more specificity in several areas to address the unique confidentiality issues related to the care of adolescents and other minors with unique family situations.

**D.1. Proposed Exceptions to the Information Blocking Provision – Preventing Harm**

We believe that this exception should explicitly address minors’ access to their EHI to ensure that the access does not have unintended harmful consequences. First, we propose an exception that allows a health care system to decline the download of pediatric data unless the third-party app has a safe way to partition data from multiple patients. As we noted earlier, to date there are very few apps available that have the ability to safely host multiple patients’ data (i.e. parent and child) in a single app. For example, Apple Health Record is currently confronted with this challenge. If the apps are not set up to safely handle multiple patients, there is significant risk that data from multiple patients could be mixed together and confused, creating a potential for serious harm in how those data are interpreted. We also remind the ONC that minors may not fully understand the implications of downloading and sharing their EHI. Therefore, providers may want to impose some restrictions to unemancipated minors’ direct access to downloaded EHI through an API. This practice should not be considered information blocking.

In addition, 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 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 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 proxy situations. Providing 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.
D.2. Proposed Exceptions to the Information Blocking Provision – Promoting the Privacy of EHI
We recommend that the rule clarify that there are situations where a provider may withhold certain information from a parent based on a minor child's wishes without it constituting information blocking. In addition, we note the 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 confidentiality compliance requirements regarding adolescents in accordance with HIPAA laws. For example, 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 that circumstance, the provider’s actions should not be considered information blocking.

D.5. Proposed Exceptions to the Information Blocking Provision – Responding to Requests That are Infeasible
We urge the ONC to clarify that circumstances in which a provider communicates with another healthcare entity that either has an incompatible HIT system or does not yet have certified EHR technology in place are not considered information blocking. 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, children’s hospitals work with many community-based providers that are often quite small and may not have adopted EHR systems or have compatible pediatric-specific systems.

In addition, in the event that the ONC finalizes its problematic proposal to include pricing information in the definition of EHI, we recommend an additional exception that addresses the inability of the health care provider to make that information available to patients in a timely manner. As we noted previously, for health care providers to furnish individualized out-of-pocket cost, health care providers must have cooperation from multiple parties – families/caregivers must provide timely and accurate insurance information to the provider and insurers must provide timely and accurate benefit information. If any of these parties does not provide the necessary information to the provider, that provider's inability to provide the appropriate pricing information should not be considered information blocking.

G. Disincentives for Health Care Providers – Request for Information
CHA appreciates the ONC’s request for information to assist it in clarifying the disincentives that should apply to information blocking. Given the complexity of the various interactions between developers, payors, providers, and patients, as well as the additional concerns related to pediatric health care that we have highlighted, we urge the ONC to move with deliberation on any further definition of disincentives. We recommend that the agency convene relevant stakeholders, including pediatric health care providers, to consider the information gleaned through this RFI and assist in the development of a set of evidence-based recommendations. Any penalty for health care provider information blocking should be moderate and gradual to accommodate the inevitable legal, technical, and operational challenges that will arise. In particular, unreasonable penalties could stifle the discussion and cooperation necessary to lead to better and more meaningful practices that foster care coordination, and ultimately better outcomes.

X. Patient Matching Request for Information
We are pleased that the ONC recognizes the importance of patient matching, as well as the serious safety, quality and cost implications of ineffective matching and 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 changes in family structure or transgender individuals.

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. We also 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, we are pleased that the ONC has released the voluntary pediatric EHR certification guidelines in this proposed rule. However, we note that there are a number of aspects of the rule that need modifications and refinements to appropriately address the unique nature of pediatric health care, regardless of the setting of care. We look forward to working with you to collaboratively advance an HIT infrastructure that can efficiently and effectively allow for health information exchange that supports child patients and their families and leads to improved outcomes and long-term productivity. Please contact Jan Kaplan at 202-753-5384 with any questions.

Sincerely,

M. James Kaufman, PhD
Vice President, Public Policy