December 16, 2019

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Reps. DeGette and Upton,

On behalf of over 220 children’s hospitals across the country, the Children’s Hospital Association (CHA) appreciates the opportunity to provide comments as you draft Cures 2.0. We also applaud your work in ensuring the passage of the 21st Century Cures Act, which played a vital role in bringing new innovations to the health care market that will benefit children. Children’s hospitals are well-positioned to provide feedback on the four requested focus areas—digital health, coverage of new cures, the utilization of data to empower patients, and caregiver literacy/education. Included within some of the sections are specific policy suggestions, while others highlight the uniqueness of kids that should be considered during the development of this legislation.

Children’s hospitals are a vital safety net for all children. We work hard to deliver state-of-the-art care to children and their families. Children’s hospitals play an active role in helping with the development of new technologies and cures. We are committed to developing the next generation of cures while ensuring our patients and caregivers have the tools they need to make informed care decisions.

DIGITAL HEALTH

- Implement the proposed pediatric electronic health record (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

As regional centers for children’s health, children’s hospitals are especially attuned to the value and need for a strong digital health infrastructure to support high-quality care across pediatric settings. We share the goal of enabling patients and their families/caregivers, as well as their providers, to have timely access to needed information to ensure the best possible health outcomes. In particular, there is a critically important subset of digital health/health information technology (HIT) issues unique to pediatric hospital care crucial to advancing children’s health and health care. It is particularly important that the advances in digital health/HIT promote care coordination and information exchange between patients, families and providers; among providers; and with local, state, and federal agencies.

Children’s hospitals are working hard to preserve a balance between delivering better quality patient care and gauging the risk profile of each new technology. We also note that—as hospitals shift to the utilization of digital tools that help patients and their families manage care outside of the hospital and the tracking of population health data that assists us in managing entire populations—we have encountered some pediatrics-specific barriers. These include dependency on a strong pediatric-appropriate EHR system, physician training/burnout, difficulties in controlling proxies in a pediatric setting, and the adaptation of telemedicine.

Champions for Children’s Health
Dependency on Strong EHR Systems
Children’s hospitals were pleased that the Office of the National Coordinator (ONC) proposed 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program rule included guidelines for pediatric HIT certification. Those guidelines and clinical priority certification recommendations represent a positive step forward for the improvement of EHRs used in the care of children. However, children’s hospitals believe Congress could further delineate the certification parameters to require pediatric-specific testing and EHR technologies to comply with the full package of certification standards. Congress also will have a key oversight role to play as adoption of the new standards moves forward.

Analytical platforms that house EHR typically serve as the foundation for these new technologies to ensure care coordination. Pediatric EHR platforms come at a high cost and require constant updating and reworking to ensure compliance with federal and state requirements and to meet the unique needs of pediatric providers—particularly in the hospital setting. The lack of standardized pediatric EHR elements leads to 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 customizing available EHR systems or use niche pediatric products that are then integrated into the children’s hospital EHR. For example, existing major EHR systems do not typically recognize the differences between adult cardiac care—which is focused on coronary artery and/or structural valve disease—and pediatric care, where providers must manage a wide array of anatomical and physiological abnormalities primarily related to birth defects and genetic syndromes. This absence of appropriate EHR systems leads to customizations for clinical content, as well as parent education and other content, which can be burdensome for the hospital and detrimental to interoperability initiatives and strategies. The proposed guidelines for pediatric HIT certification from the ONC represent a strong, positive step forward for improving EHRs in the care of children, but could use further refinements—as noted in the CHA comments to the ONC on its proposed 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program rule.

Children’s hospitals’ adoption of new digital health tools will rely on a strong pediatric EHR system that can serve as the connector for patients, families, providers and community partners. As these new technologies hit the market, there will be a constant need to balance replacing technologies with augmentation/refinements to meet pediatric needs. Any policy changes regarding new technologies must factor in the unique needs of the pediatric setting, and the challenges of assuring interconnectedness of large HIT systems.

Provider Training and Burnout
As federal policies are being considered to advance digital health, it is critically important to provide training resources and funding, and to include appropriate timelines for compliance to accommodate training and implementation needs. The need for provider training and the potential for burnout as a result of workflows is a common barrier to the adoption of digital health technologies across all settings, but particularly so in pediatrics. A lack of standardization is common across pediatric settings and workarounds may be needed. Each new system requires significant amounts of training that takes the provider away from directly caring for patients. CHA outlines a number of these challenges and solutions related to workflow in a letter to the ONC on pediatric HIT certification.

Proxy Considerations
Any new federal HIT policies must accommodate the role that parent/guardian proxies and adolescent confidentiality concerns play in pediatrics. Federal policies must ensure providers have the flexibility to adapt to the confidentiality needs of a patient’s particular situation, including restricting access to some personal health information (PHI) without running afoul of information blocking requirements. In addition, any new federal policies should be reflective of specific state or local requirements.
A unique aspect of HIT in pediatrics is the use of parent/guardian proxies for care-related decisions as well as for authorization to access health records. In addition, privacy and confidentiality are critically important aspects of EHRs and digital health innovations, particularly in relation to the care of adolescents. Therefore, for example, 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.

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 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). Pediatric providers who serve large Medicaid populations, including children’s hospitals, often run into a disproportionately higher number of difficult-to-address guardianship disputes, non-traditional family structures, primary caregivers who have not received formal legal authorizations, undocumented children, or other related situations. This can make proxy identification more complicated. Furthermore, providing PHI 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.

In addition, there are certain adolescent privacy issues—such as reproductive health, gender identity, drug use, and genetic issues—where parents’ involvement may need to be addressed. Digital tools and other patient and family-facing tools should allow for the ability to flag individual EHR components as confidential.

There are also privacy issues specific to children and adolescents that need to be addressed by developers of application programming interfaces (APIs). As we note in our comment letters to CMS and ONC, there are numerous privacy areas to address in APIs—including those related to proxy access to a minor child’s record for both parents and guardians in the API and safety of information downloaded to the API. In particular, APIs must have functionality allowing 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.

In addition, the safety and security of downloaded health records can be a concern in pediatrics when minors do not fully understand the implications of downloading and sharing PHI. In addition, 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.

**Telemedicine Barriers**

Telemedicine is an increasingly important care delivery tool, especially for families that do not live near a children’s hospital. However, providers continue to run into barriers regarding reimbursement and policies restricting sites of care and the delivery of services across state lines. Patients want to use virtual health tools to improve their care; however, payments and procedures are not keeping up with technological advances. Additionally, special consideration should be given to technology at the non-host site. Many of the sites that we need to serve do not have access to high-speed internet tools. This becomes a barrier when regulations require specific updates to these technologies that might not be ideal for the non-host sites.
There is also uncertainty around liability and responsibility for the different types of information. An example of this is devices that patients use within a home setting. In this setting, it is often a parent delivering the care, not a provider. Hospitals are sometimes hesitant to explore these technologies because it requires the hiring of additional staff to monitor and respond to the data that comes from these devices. It should also be noted that many of these in-home tools are not being reimbursed within a fee for service environment.

**COVERAGE OF NEW CURES**

- Improve coordination between payers, manufacturers, patients, specialty pharmacies and the Food and Drug Administration (FDA) to ensure timely patient access
- Consider ways to use technology to improve prior authorization processes
- Examine ways to measure patient access to new curative drugs and therapies
- Recognize delivery barriers that can sometimes come with these drugs

Children’s hospitals are at the forefront in delivering new cures to patients. Diseases and conditions that were once seen as untreatable are now being cured or greatly improved. Many of the new curative drugs that recently entered the market target small pediatric populations. While the science of these drugs progresses rapidly, barriers continue to arise when delivering these curative drugs to patients. These barriers include the need for earlier communication among the different players—i.e. payers, pharmacy benefit managers, manufacturers, specialty pharmacies, patient/caregivers, providers, hospital care teams and reimbursement teams—prior authorization processes, patient access concerns and dictation by payers of delivery method. While these barriers have existed for some time, they are being exacerbated by the increase of new high-cost therapies (HCT) coming to market. We encourage Congress to examine the impact these barriers have on patient access. Often, the focus is on getting these drugs to market, but there are several steps that must take place prior to administering the drug. These steps should be examined by Congress and considered as part of the drug development process.

It should be noted that while the RFI requests feedback on Medicare policies, children’s hospitals wish to provide comments pertaining to Medicaid and private payers, due to our low Medicare volumes. More than half of the care provided at children’s hospitals is covered by Medicaid.

**Earlier Alignment between the FDA, Manufacturers and Payers**

As new HCTs come to market, it is important to look at improving coordination between payers, manufacturers, patients, specialty pharmacies and the FDA. Payment and billing policies are falling behind the release of these drugs. Congress and federal agencies should look beyond drug development when discussing cures. There needs to be an additional focus on patient access and payment barriers as part of the development discussion. A drug is of little value if it cannot be accessed by patients.

When a new curative drug enters the market, it gives families hope—but it can take months for payer procedures to be developed. Often the delay is even longer with state Medicaid programs. Medicaid programs have a great deal of flexibility and discretion on covering specific interventions. Additionally, while federal and state laws require broad categories of benefits, they allow a high degree of discretion over specific coverage determinations. These delays are extremely harmful when the drug is approved for a limited age range. Kids can age out of the label approval while waiting for payer procedures to be developed. Families are the ones being put in middle of this delay and breakdown. Congress should look for ways to create outlets that allow payers the ability to communicate earlier with manufactures and the FDA. This is especially important for state Medicaid agencies. States are being caught off guard with each new market introduction.
Prior Authorization and Labeling Indications
Many of these new HCTs come with prior payment steps. Hospitals spend hours navigating these prior approval processes. These processes may include prior authorization, step therapy, and peer to peer reviews. Children’s hospitals have been forced to hire additional FTEs to handle the time it takes to get approval and acquisition management for these medications. Appealing denial letters multiple times has become the norm. Each payer has a different policy, so hospitals also must manage and navigate each of them differently. Families are caught in the middle of this, having to wait with their medically complex child who is in and out of our hospitals. Hospitals are also starting to see payers place additional clinical monitoring requirements before the drug can be given. For example, a patient may be denied a disease modifying therapy because they have a pulmonary function that is too high. We encourage Congress to consider how technology could be used to improve these processes—many involve actual paper and rest the burden solely on hospitals. It is important to note that hospitals understand the need for approval processes to ensure eligibility. However, these processes have grown extreme and put enormous stress on the families and patients.

Patient Access
Policymakers must examine the impact these new HCTs have on patient access. There are concerns that some hospitals could potentially face challenges in administering a million-dollar drug without guarantee of payment, as this shortfall could have a major impact on the ability to care for the thousands of patients treated at each institution. As a result, some hospitals are forced to weigh their ability to administer these HCTs. This means that the administering of these treatments could fall disproportionately on a small number of providers. Questions regarding network adequacy also start to arise when there is a lack of providers who can fulfill these services. These same barriers bubble over into Medicaid. States are struggling as curative drugs and therapies continue to enter the market. Similar to hospitals, these are expensive products to be at-risk for when state budgets are tight. It is critical that we start to look at these access issues now, as we know drugs for diseases that impact much larger populations—such as sickle cell disease—are coming up in the pipeline. Public payers may not be able to handle the pressure this puts on budgets. As these new drugs enter the market, Congress should look for ways to measure patient access, particularly with public payers.

Payers Dictating Delivery Method
These curative drugs and therapies come at a high cost resulting in a trend of payers dictating specific distribution methods for products. While congressional action is likely limited within this realm children’s hospitals want to highlight this growing barrier—it can lead to delayed access. Ultimately, the dictation of the delivery method takes away a hospital’s ability to pick what works best for their patients and their facility.

There are often two methods used to receive a drug: “buy and bill” and “white bagging.” For buy and bill, hospitals purchase, stock and prepare the drug. Then the hospital seeks reimbursement for the drug and the administering fees. Under a white bagging method, plans contract with a specialty pharmacy to purchase the drug and ship it to the hospital. Often this results in a hospital not being reimbursed for the cost of acquiring, storing, compounding/manipulating for dose, and delivering the drug. This has a big impact when the drug requires special handling instructions. For example, one popular drug in pediatrics requires a pharmacy to shut down one of their hoods for at least 30 minutes to ensure patient and staff safety. This means drugs meant for other patients must be put on hold while this drug is compounded, as well as for a period afterwards. White bagging can also result in issues pertaining to delivery site and timing, including significant delays in care for a variety of reasons outside the control of the patient or hospital.

Additionally, some payers are beginning to dictate coverage through a white bagging only method. The limitations sometimes imposed through these practices lead to hospitals not being compensated appropriately for care. This is further complicated for states and hospitals that do not allow white bagging due to concerns around guaranteed
quality control. Children’s hospitals support innovative, value-based approaches that limit the cost of drugs and are concerned that other factors are being weighed more heavily than patient care.

UTILIZATION OF DATA TO EMPOWER PATIENTS

- Take into account potential HIPAA violations that could occur when converting data into a patient-friendly format
- Consider policies that promote efforts to connect information throughout the U.S., and not simply on a state-to-state basis

Children’s hospitals are exploring the utilization of data to empower patients. Methods currently being used include patient portals, family care conferences, whiteboards in patients’ rooms and discharge instructions. Many barriers can arise when utilizing this health data, including privacy issues, sensitivities around adolescent care, care being received at different locations, and systems that do not interact easily with each other.

Accessing Data

Children’s hospitals encourage Congress to weigh the barriers highlighted above when developing policies that involve sharing data with families. What is good for a small child might not be as applicable to an adolescent. Hospitals are working to build tools that optimize this data for patients and their families. Privacy and legal issues must be weighed when utilizing any sort of tool. This is especially true for situations that involve behavioral health diagnoses or ongoing custodial issues. Children’s hospitals would also like to highlight that data extracted from EHR systems typically do not produce patient-friendly formats. Any new policy aimed at converting this data to a patient-friendly format must consider HIPAA rules. If part of this care is being delivered in a school setting, FERPA must also be thought about when developing a full care picture for the patient.

Children’s hospitals also encounter several data barriers when caring for medically complex kids. These kids see several specialists and travel to different states to receive their care. Often, the caregiver serves as the data collector. It is hard to develop a complete care picture when data systems are not built to connect and communicate with each other. Children’s hospitals encourage Congress to look at policies promote efforts to connect information throughout the U.S. and not simply on a state-to-state basis.

CAREGIVER LITERACY, EDUCATION AND TRAINING

- Consider children’s hospitals an ally in the field of caregiver training and education

Children’s hospitals are uniquely positioned to educate and work with caregivers. Since the majority of patients seen at children’s hospitals rely on caregivers, these special facilities work hard to develop resources and tools that ensure continuance of care. Hospitals often view these caregivers as the voice of the patient, particularly when infants are involved. While we do not have specific policy requests for this section, children’s hospitals want to highlight some of the steps they take to ensure successful caregiver training.

Children’s hospitals use a variety of tools to increase health literacy, train caregivers and provide them with knowledge to make informed care decisions. For these tools to be successful, careful consideration toward their development must be emphasized along with patient involvement and provider training. It should be noted that common barriers can arise pertaining to varying reading levels, language/cultural differences and unsuitable timing.

Development of Tools

At the center of successful caregiver tool development is the use of plain language, defining of medical terms, inclusion of images, and listing of important information up front. Children’s hospitals work hard to develop tools
families can easily understand. When developing these tools, hospitals often use members of their family councils to review them and provide feedback. At the heart of these tools is the understanding that most caregivers are coming from non-medical backgrounds. What’s more, they are caring for their own child—often an extremely emotional process.

It is also important to have staff from different departments within the hospital provide feedback, as they will view the tool from different perspectives. Hospitals also often depend on federal tools, including the Agency for Healthcare Research and Quality (AHRQ) Pediatric Education Material Assessment Tool (PEMAT) and CDC’s Clear Communication Index (Index) to evaluate understandability and actionability of the tool.

Finally, a focus should be given to developing tools that can be used in different mediums and continually evaluated. Simply giving caretakers handouts is seen as an unsuccessful approach within a children’s setting. Instead, children’s hospitals use a variety of tools like videos, handbooks, infographics, photobooks, handouts and apps.

**Patient Training and Documentation**

The development of caregiver tools is seen as the first step of the education process. Once the tools are developed, children’s hospitals utilize a variety of methods to ensure caregivers have a full understanding. One common method is the teach-back method. The teach-back method involves the caregiver explaining and re-teaching the information in order to identify gaps and reinforce the material. Another method used at children’s hospitals is simulation. Simulation provides a safe zone for learners to immerse themselves in near-real stressful situations, helping them build confidence. This approach is especially useful when caring for technology-dependent infants. Many children’s hospitals also have health libraries onsite and staff trained to help caregivers. The ultimate goal is to provide the information in as many forms as possible and to be cognizant of timing. These tools should not be used during a time when the caregiver is not ready to receive the training.

Once a training has been completed, it is important to document this completion within the hospital’s EHR system. It is critical to have a history of what has been shared and when. This documentation helps with follow-up prior to and after discharge.

**Provider Training**

Provider training is another critical step in ensuring the success of caregiver training and education. It is essential that clinicians know about the tools and can easily find them. Many hospitals utilize their EHR systems to house training documents. This education must be constantly reinforced. Some hospitals also provide training around caregivers during new employee orientation to serve as a foundation. Another method of training is intensive courses for selected clinicians. These courses immerse staff in ongoing caregiver initiatives and often lead to the development of new resources. An additional popular tool for provider training is the use of patient stories that have the identifying data removed. These stories highlight worst case scenarios and remind staff of these tools’ importance. This training ensures that educating caregivers is seen as the responsibility of all the clinicians in the hospital.
CONCLUSION
Again, children’s hospitals appreciate your willingness to consider feedback on Cures 2.0 and look forward to continuing work with you both and your staffs.

If you have any questions or comments, please contact Amanda Major at:
Amanda.Major@childrenshospitals.org.

Sincerely,

M. James Kaufman, PhD
Vice President, Public Policy