May 29, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3310-P
Submitted electronically to: http://www.regulations.gov

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3

Dear Mr. Slavitt,

On behalf of children’s hospitals across the country, the Children’s Hospital Association (CHA) thanks you for the opportunity to provide comments on the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program – Stage 3 proposed rule published by the Centers for Medicare and Medicaid Services (CMS). CHA shares the federal government’s commitment to utilizing health information technology (HIT) to improve clinical care, care coordination, information provided to patients, and the overall quality of health care for children and their families in our country.

CHA would also like to express our appreciation to CMS for your willingness to work with us to ensure that this incentive program works for children’s hospitals and the unique health needs of children. Children are not little adults; they require services and care specifically suited to their unique development and growth needs. We urge CMS to consider the unique health needs of the pediatric population as they develop and implement policies for Stage 3 of meaningful use (MU). Policies that are developed for the adult population and adult providers may not work for children and pediatric providers.

Before outlining our specific comments and recommendations for Stage 3 of meaningful use (MU), CHA would like to express our general concern about the readiness of HIT infrastructure to support the successful achievement of the proposed Stage 3 requirements of the EHR Incentive Program in 2018. We believe the creation of an efficient and effective infrastructure of health information exchange (HIE) is essential and is a precursor to many of the proposed advances for Stage 3. At this point, we believe that the Department of Health and Human Services should prioritize activities that accelerate the availability of the necessary infrastructure for HIE and refrain from finalizing a Stage 3 MU rule in 2015. Additional time for maturation of implemented technology and optimization to support meaningful use and other regulatory requirements is critical to the success of the program. We urge CMS to not only delay finalizing the Stage 3 MU rule, but also delay the start of Stage 3 until there has been an opportunity to assess and build upon the lessons learned from Stage 2.

In addition, we request that CMS consider including a hardship exception for providers who change vendors. Safe and effective implementation of a new EHR system requires extraordinary care and attention and must not be rushed. Installation of a new EHR system in a health system is a phased endeavor. Installation of a new system can take approximately 19 months or more (3 months for software assessment and testing interfaces, 8 months for installation, implementation and training, 5 months building to MU requirements and at least 3 months for the required MU reporting period). Installation system-wide is a multi-year process. CMS should recognize this reality and not force providers to choose between keeping a system that they would prefer to replace or incurring MU penalties. In lieu of a hardship exception for changing EHR
systems, CMS could afford providers the opportunity to take one hardship exception from the program’s requirements for any reason.

Below are our specific comments on the proposed rule.

**Meaningful Use Stages and Reporting and Aligning with Calendar Year**
CHA has concerns with the proposal that all EPs, EHs, and CAHs regardless of prior participation in the EHR Incentive Program must satisfy the requirements, objectives, and measures for Stage 3. We believe that regardless of when an EP or EH begins the MU program, they should be able to phase into the EHR Incentive Program by meeting the requirements in Stage 1 and Stage 2.

Overall, CHA supports aligning the reporting period with the calendar year. However, CHA has concerns about eliminating the 90-day EHR reporting period for new meaningful EHR users beginning in 2017. Reporting on a full year would be difficult to achieve, especially for the first year. Therefore, we recommend that the first year of Stage 3 attestations be a continuous 90-day reporting period. This would be especially beneficial for organizations that have a significant number of EPs by allowing them time to prepare for all EPs to meet the Stage 3.

**Clinical Quality Measures**
CMS needs to ensure that measures included in the Physician Fee Schedule and Inpatient Prospective Payment Schedule rules will be appropriate for pediatric organizations. Since these rules focus on the Medicare program, we are concerned that the unique needs of pediatrics will be overlooked. There could be a significant negative impact if these measures are not well researched with regards to pediatrics. This includes ensuring that the thresholds are suitable. Thresholds that were defined in the MU rule related to CQM exclusions must be maintained going forward in the appropriate rules.

In addition, CMS should increase the number of pediatric focused high-priority health conditions. Implementing the systems to report on health conditions that do not impact the pediatric population is ineffective for children’s hospitals and other pediatric providers.

CHA would like to take this opportunity to provide comment on the specifications used for quality measure reporting. While there may not be certification burden to vendors in providing updated quality measure specification packages, for some hospitals, there has been significant testing burden with the organizations validating CQM reporting. Children’s hospitals and other pediatric providers are not always using the higher volume quality measures used by Medicare organizations, and some hospitals have found significant reporting concerns with the less frequently used quality measures in testing. It is costly to continue to update where there is very little value or perceived change in the measures. At a children’s hospital (non-newborn location), very few measures pertain and even few give results that are beneficial and useful. Having to purchase upgrades and support to address these measure upgrades on an annual basis seems overkill. CHA requests that CMS consider allowing submission of quality measures for at least two versions for electronic and manual reporting.

**Topped Out, Redundant, and Duplicative Measures**
CHA appreciates CMS’s efforts to ensure that EHs, CAHs, and EPs are not required to report on duplicative or “topped out” measures. However, we urge CMS to consider both the pediatric population as well as the adult population before they determine that a measure is topped out.

**Electronic Versus Paper-based Objectives and Measures**
CHA applauds CMS’s goal of minimizing the submission of paper. However, CHA believes that there must be a focus on standards to ensure that EHRs are collecting the appropriate and relevant clinical data. For example, in some settings, the electronic version of the summary of care is printed with limited attention to the human readability of the electronic output. If printed, the electronic versions of visit summaries should be
presented in a clinically relevant manner. In addition, since the commercial payer community is not impacted by MU, many providers continue to prefer a paper-based information format with electronic formats limited to practice management software. This can create difficulties when transitioning patients to this community, and there is no way to send information electronically.

Below are CHA’s comments regarding the specific objectives and measures.
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<tr>
<th>Stage 3 Proposed Measure</th>
<th>CHA Comments</th>
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<td><strong>Objective 1: Protect Patient Health Information</strong></td>
<td>We request that CMS provide clarification on how this proposed policy relates to FAQ 10754, which indicates completion of the risk analysis once a year continues. With Medicaid first year providers reporting a 90-day period, for organizations that have multiple EPs with multiple reporting periods in a year, requiring a risk assessment by that organization for each of the EPs’ reporting periods creates administrative inefficiencies for the organization. Repeating the risk analysis within a short period of time does not change the nature of the risk being analyzed or the effectiveness of addressing the risk. We request that the final rule continue to support previous clarification that not all security deficiencies need to be corrected within the reporting period.</td>
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| Conduct or review a security risk analysis, including addressing the security (including encryption) of data stored in Certified EHR Technology (CEHRT), implement security updates as necessary, and correct identified security deficiencies as part of the provider’s risk management process. The timing or review of the analysis must be as follows:  
  - EPs, Eligible Hospitals, and CAHs must conduct the analysis upon installation of the CEHRT or upon upgrade to a new Edition of CEHRT.  
  - In subsequent years, a provider must review the analysis of the CEHRT and the administrative, physical, and technical safeguards implemented, and make updates as necessary, but at least once per EHR reporting period. | |
| **Objective 2: Electronic Prescribing** | Generally, clinicians support e-prescribing if it is efficient. However, there are situations when e-prescribing is problematic:  
  - There is no standard for pediatricians transmitting compounded medications.  
  - There is also poor adaptability to transmitting doses that are different at varied times of day (a frequent occurrence for seizure medications for children).  
  - There are also instances when insurance companies require paper-based information, which leads to double the work. |
| EPs, EHs, and CAHs must generate and transmit permissible prescriptions electronically, (eRx). | CHA believes the 80 percent threshold for all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT is too high. With current workflow challenges and some of the aforementioned issues, some providers are hesitant to do two-way prescribing and default to printing if they are prescribing controlled substances and other medications. This makes it hard to achieve this measure. This threshold is also particularly difficult. |
| **Proposed EP Measure for Stage 3:** More than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT. This is up from 50 percent in Stage 2. | |
| **Proposed EH/CAH Measure for Stage 3:** More than 25 percent of hospital discharge orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT. | |
This is up from 10 percent in Stage 2.

For Stage 2, this measure included new, changed, and refill prescriptions ordered during the course of treatment while the patient is in the hospital. For Stage 3, CMS is proposing to limit this to only new and changed prescriptions.

to meet for providers who primarily serve populations outside of national HIE networks, such as international patients. In addition, some children’s hospitals have issues with inclusion of state specific controlled substances being included in reporting (e.g. growth hormone is a controlled substance in at least one state).

Therefore CHA recommends the following thresholds for EPs and EH/CAH. In addition, there should be a way to exclude patients that fall outside of the HIE networks from the denominator.

**Proposed EP Measure**
We recommend 70 percent as a reasonable threshold. This will lessen provider burden as it requires a less dramatic increase from the thresholds for Stages 1 and 2.

**Proposed EH/CAH Measure**
We recommend keeping the 25 percent threshold for hospitals.

CHA agrees with CMS’s proposal to continue to exclude over-the-counter medicines from the definition of a prescription.

We support the exclusion for EPs who write fewer than 100 permissible prescriptions.

CHA would also like to raise a concern related to transmission of patient weight, which is not part of the standard transaction for eRx. This is impacting the workflow of eRx as pharmacy follow-up is required since most pediatric dosing is based on weight.

### Objective 3: Clinical Decision Support (CDS)
Implement CDS interventions focused on improving performance on high-priority health conditions.

**Proposed Measures:** EPs, EHs, and CAHs must satisfy both measures in order to meet the objective:

**Measure 1:** Implement five CDS interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to scope of practice or patient population, the CDS intervention must be related to high-priority health conditions.

Since there are few CQMs that pertain to pediatrics, the value of aligning CDS with these measures is not significant. Therefore, we recommend that the “related to four or more CQMs” be removed. We also believe this will allow a hospital more flexibility to align the CDS with its internal quality goals.

However, we do recognize that CMS notes in the proposed rule that absent four CQMs to the provider’s scope of practice or patient population, the CDS intervention must be related to high-priority health conditions. CHA is supportive of this.

If CMS plans to specify which drug-drug interaction checks, we urge CMS to consider a minimum approved set for pediatric drug-drug interaction-checking. We recommend referencing The “Core Drug-Drug Interaction Alerts for Inclusion in Pediatric Electronic Health Records with
**Measure 2:** The EP, EH, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Computerized Prescriber Order Entry (CPOE)” that appeared in the *Journal of Patient Safety* in March 2014. This article outlines a core list of 19 high value pairs for electronic drug-drug interaction alerts to be recommended as high value alerts in prescriber order entry software used with a pediatric patient population. For example, such drug-drug interactions between amiodarone and digoxin, methadone or warfarin; amitriptyline and sertraline or trazodone; ciprofloxacin and theophylline; among others.

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<th>Measure 4: CPOE</th>
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<td>Use CPOE for medication, laboratory, and diagnostic imaging orders directly entered by any licensed health care professional, credentialed medical assistant, or medical staff member.</td>
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| Proposed Measures: EPs, EHs, and CAHs must meet all three measures. |

| Proposed Measure 1: More than 80 percent of medication orders created by the EP or authorized providers of the EH’s or CAH’s inpatient or ED during the EHR reporting period are recorded using CPOE. |

**Proposed Measure 2:** More than 60 percent of laboratory orders created by the EP or authorized providers of the EH’s or CAH’s inpatient or ED during the EHR reporting period are recorded using CPOE.

**Proposed Measure 3:** More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the EH’s or CAH’s inpatient or ED during the EHR reporting period are recorded using CPOE.

**Objective 5: Electronic Access to Protected Health Information (PHI):**

**Proposed Objective:** The EP, EH, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through application-program interfaces (API), within 24 hours of its availability.

CHA appreciates that CMS no longer requires patient action in order for EPs, EHs, and CAHs to meet the threshold. However, we do want to express that there is continued concern by hospitals and providers that by holding EHs and EPs responsible for patient engagement, EHs and EPs will struggle.
to meet all measures under patient electronic access, coordination of care, and health information exchange. Organizations can only create the availability and awareness that PHI is available. They cannot require patients to access it.

We also ask that CMS address the challenge for pediatric institutions to meet all measures under patient electronic access, coordination of care, and health information exchange due to the complexities surrounding pediatric patient populations, such as patient proxies and pediatric/adolescent privacy laws.

**Proposed Measures:** EPs, EHs, and CAHs must satisfy both measures in order to meet the objective.

**Proposed Measure 1:** For more than 80 percent of all unique patients seen by EP or discharged from the EH or CAH inpatient or ED:

- The patient (or authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or
- The patient (or authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or authorized representatives) access to their health information within 24 hours of its availability to the provider.

**Proposed Measure 2:** The EP, EH, or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the EH or CAH inpatient or ED during the reporting period.

**Proposed Measure 1**
CHA supports the flexibility of offering both the portal and API as options. However, children’s hospitals have a number of concerns with raising the threshold to 80 percent:

- Children who are under 13 years of age are not allowed direct access to their PHI. As a result their guardian must be present to be given proxy access to their child’s PHI. Non-guardians – such as children with foster parents, temporary court ordered care providers (i.e., extended family, friends, etc...), even a parent designated care provider – do not qualify as the guardian to be given such access.
- Similarly, pediatric providers that work with high Medicaid populations may run into a disproportionately higher number of difficult-to-address guardianship disputes, non-traditional family structures, primary caregivers that have not received formal legal authorizations, undocumented children, or other related situations.
- Organizations serving lower socioeconomic groups may also have difficulties meeting this threshold if patients and their families are not able to access the information electronically.
- Some children’s hospitals have non-English speaking limitations in the portal product that could impact meeting this threshold. The portal would have to offer multiple languages to make the 80 percent threshold more realistic.

Given these concerns, CHA recommends keeping the threshold at the current level or increasing it to no more than 60 percent. In addition, CHA believes an exclusion should be available to providers giving care to patients at risk (e.g. patients subjected to sexual abuse, neglect, drug abuse, court involvement, etc...). For children at risk, providing PHI access to the person with parental rights could cause further harm to the child and therefore would be inappropriate.

We recommend that everyone associated with the patient should receive “credit” for all aspects of electronic communication. A patient viewing the information should be considered as the contribution. Questions related to billing, scheduling of appointments, or administrative subjects should also count towards meeting this measure. Since the goal is to actively engage the patient in their health care via access to information, administrative functions are a part of healthcare delivery. Having patients and their families engage in these functions demonstrates that the clinical community is working to engage the patient electronically.
In addition, while the 24 hour deadline might be doable in some situations, we urge CMS to consider the specific needs and sensitivities in transmitting information for pediatric populations. For instance, certain types of information may require proper communication from a provider to a parent, guardian, or authorized representative before being made available online. Thus, this deadline might not be realistic in all circumstances.

CHA also requests clarification on a couple of items:

- “Providing access” when patient or family have opted-out. In pediatrics, access to the patient portal needs intervention to clarify legal guardianship before an invitation can be extended for portal access.
- That the numerator and denominator include documentation of opt-out as well as opt-in. Please clarify that a provider would not be penalized for an opt-out decision by a patient’s family.
- The proposed rule states: “[a]dditionally, this objective should not require the provider to make extraordinary efforts to assist patients in use or access of the information, but the provider must inform patients of these options, and provide sufficient guidance so that all patients could leverage this access.” We request greater clarity on the definition of “extraordinary efforts.” Hospitals can only create the availability and awareness.

Proposed Measure 2

CHA believes the recommended threshold of 35 percent is too high and too much of an increase from the current 5 percent. Patient-specific education printed and given to the patient is a functional method for providing education, especially for organizations treating patients in an urban or inner-city setting. Eliminating paper-based patient education will have a negative effect on such patient populations. The threshold also fails to consider the availability and use of pre-made, patient-specific educational tools that may be paper-based.

CMS should consider EHs that have a high percentage of critical care patients that have complex or specific educational requirements which would not be included in a standard content offering and which could be shared electronically via the portal.

CMS must also take into consideration the fact that electronic sources of patient information do not exist for highly specialized pediatric conditions. For example, children’s hospitals are able to easily access electronic handouts for otitis media or scoliosis, but it is much harder to get electronic sources for conditions such as graft-versus-host disease or recessive dystrophic epidermolysis bullosa.
We recommend keeping the threshold the same as Stage 2 (5 percent) or raising it to no more than 20 percent.

**Objective 6: Coordination of Care through Patient Engagement**

Use communication functions of certified EHR technology to engage with patients or their authorized representative about the patient’s care.

**Proposed Measures:** CMS proposes that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures in this objective.

**Proposed Measure 1:** During the EHR reporting period, more than 25 percent of all unique patients seen by the EP or discharged from the EH or CAH inpatient or ED actively engage with the EHR made accessible by the provider. This measure may be met by either:

- More than 25 percent of all unique patients (or authorized representatives) seen during the EHR reporting period view, download, or transmit to a third party their health information; or
- More than 25 percent of all unique patients (or authorized representatives) seen during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

**Proposed Measure 2:** For more than 35 percent of all unique patients seen during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or authorized representative), or in response to a secure message sent by the patient (or authorized representative). CMS asked for comments on whether any provider who contributes to a message during the...
Proposed Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 15 percent of all unique patients seen by the EP or discharged by the EH or CAH inpatient or ED during the EHR reporting period.

For this measure only, CMS proposes that “non-clinical setting” is defined as a setting with any provider who is not an EP, EH, or CAH as specified for the Medicare and Medicaid EHR Incentive Programs and where the care provider does not have shared access to the EP, EH, or CAH’s certified EHR.

We ask that CMS clarify the definition of “Care Team Members.” Would this include social workers, dietitians, school nurses, physical therapists, community case managers, etc.? If so, this would require secure methods for messaging these providers, which is not standard. If these types of providers are not included, we would urge CMS to consider a lower threshold.

Proposed Measure 3
This measure should only require that the provider has the capability to receive generated data as discrete, structured data, whether via interface upload or via entry into the patient portal. In addition, this measure is applicable to providers that have an ongoing provider-patient relationship. There are many instances where a patient may have only one encounter with a provider/hospital admission for which there is no indication for patient-generated health data or data from a non-clinical setting. There are many scenarios where certain specialties or treatment models simply do not rely on the type of clinical interaction that would benefit from patient-generated data. Since this functionality is not required for Stage 2, establishing such a high threshold for Stage 3 is an unproven and impractical expectation. As a result, establishing a threshold is unrealistic in many circumstances.

Therefore, we recommend measuring that the functionality is fully enabled for patients to input their data if it is appropriate for their personal management of their health status. The other option would be to exclude this requirement for specialists who do not feel this fits within their scope of practice.

We also request that CMS clarify “patient-generated health data or data from a non-clinical setting is incorporated into the CHERT…” If the expectation is that clinical data – such as blood pressure, weight, or blood sugar readings – be entered into the record by patients, it is unreasonable to expect that 15 percent of the patient population of a general pediatric EP would have relevant data to enter. There are not many opportunities for pediatric patients to enter clinical data into the record. Unlike adults, most pediatric patients are healthy and free of chronic disease. Not all clinicians incorporate patient-generated data into their EMR so this could be an issue if providers do not have the workflow in place. Moreover, patient-generated or non-clinical generated information for EH does not make sense. The patient is in the hospital and the hospital is collecting information with our systems in place.

In the proposed rule, CMS asked several specific questions regarding this measure. Below are the
questions and CHA’s responses.

- Should the data require verification by an authorized provider?
  No, if it is reported by the patient/other, how can a provider verify it?

- Should the incorporation of the data be automated?
  It should be accessible within the EHR, but not required to be incorporated into the EHR.

- Should there be structured data elements available for this data as fields in an EHR?
  This should not be a requirement. Patients/families may document on a log, and that should count.

- Should the data be incorporated in the CEHRT with or without provider verification?
  It should be accessible via the CEHRT, but not incorporated unless verified.

- Should the provenance of data be recorded in all cases and for all types of data?
  Yes.

Finally, we do not feel this measure should be split into two separate measures. On its own, it will be very difficult for certain specialties to meet, and separating it into two separate measures with two separate thresholds would add additional complexity and difficulty.

**Objective 7: Health Information Exchange**

**Proposed Objective:** The EP, EH, or CAH provides a summary of care record when transitioning or referring their patients to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology. CMS is also proposing that the receipt of the summary of care document (CCDA) may be passive (provider is sent the CCDA and incorporates it) or active (provider requests a direct transfer of the CCDA or provider queries an HIE for the CCDA).

CMS proposes that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures.

**Proposed Measure 1:** For more than 50 percent of transitions of care and referrals, the EP, EH, or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using CEHRT and (2) electronically exchanges the summary of care record.

We heard from some children’s hospitals that their technology does not currently allow them to count for this measure. Communication of transition of care requires Direct, not HIE. In these situations, it would be more beneficial to utilize the query/retrieve functionality of an HIE instead of transition of care.

**Proposed Measure 1**
CHA believes that the 50 percent threshold is too high.
CMS is maintaining the requirements established in the Stage 2 final rule, which requires that all summary of care documents must include the following information to meet the objective:

- Patient name
- Referring or transitioning provider’s name and office contact information (EPs only)
- Procedures
- Encounter diagnosis
- Immunizations
- Laboratory test results
- Vital signs (height, weight, blood pressure, BMI)
- Smoking status
- Functional status, including activities of daily living, cognitive and disability status
- Demographic information (preferred language, sex, race, ethnicity, date of birth)
- Care plan field, including goals and instructions
- Care team, including the primary care provider of record and any additional known care team members beyond the referring or transitioning provider and the receiving provider
- Discharge instructions (hospital only)
- Reason for referral (EP only)

**Proposed Measure 2:** For more than 40 percent of transitions of care and referrals received and patient encounters in which the provider has never before encountered the patient, the EP, EH, or CAH incorporates into the patient’s EHR and electronic summary of care document.

To achieve the 50 percent threshold, the summary of care would require significant enhancements of current Health Information Service Provider (HISP). This would need to include common data elements that are required and improve interoperability between existing HISPs.

The sending of electronic summary of care documents for transitions of care and referrals measure relies on external providers. External providers, such as smaller physician practices, may not have the capability to implement the functionality necessary to receive electronic summary of care documents. Moreover, EHs and EPs should not be held accountable for the inactions or inabilitys of external providers to receive electronic summary of care documents. Some children’s hospitals reported that they often bear the financial burden of establishing mailboxes for external providers to receive the transmitted information. Thus, the threshold should account for the fact that the infrastructures (or lack of infrastructure) used by external providers are outside of the referring provider or hospital’s control.

For these reasons, CHA recommends that the threshold for this measure remains at 20 percent.

**Proposed Measure 2**

This measure is dependent on the referring provider having the capability to send a summary of care electronically. As an organization, hospitals receive a number of referrals, yet they have no control over the technologic capabilities of the providers who are referring the patients.

Furthermore, this measure is dependent on having an interoperability infrastructure in place to facilitate the electronic exchange of information. This infrastructure is only partially available and the timeline for its completion is currently unknown. Consequently, some children’s hospitals have reported difficulty meeting even a 10 percent threshold. Since this proposed measure is totally dependent upon the referring provider’s ability to send the CCDA to an organization or for each individual EP and this was not a Stage 2 requirement, we believe establishing a threshold is unrealistic at this time. We propose that a more realistic measure would capture whether the EP, EH, or CAH has enabled the functionality to incorporate the electronic summary of care document from a source other than their own EHR system. Since this will be the first time some hospitals have to meet the threshold, it will take time to ensure the referring providers are prepared to send CCDAs.

In addition, patients are given the flexibility to transition their care to whomever they select, which may or may not be known at the time of the referral. With this unknown, having the document electronically submitted as a requirement would create a hardship on both the patient and the
Proposed Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, EH, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

- Medication
- Medication allergy
- Current problem list

CMS sought comment on whether “electronic alerts received by EPs from hospitals when a patient is admitted, seen in the emergency room or discharged from the hospital—so called ‘utilization alerts’—should be included in measure two, or as a separate measure.” We recommend that CMS not include electronic alerts because the receiving provider would be accountable for processing such alerts and health information exchanges are not mature enough for this yet.

Proposed Measure 3
CHA believes the 80 percent threshold is too high. Given that there are many pediatric practices that are paper-based whose clientele is commercial insurance and do not take Medicaid, these providers have no reason to convert to an electronic medical record. This places the burden on the hospital/provider, who can only control what they send—not what they receive. We believe a 50 percent threshold—as required for Stage 2—is more reasonable and should be retained. At the same time, we support the overall movement of the industry towards supporting clinical information reconciliation, and propose that EPs, EHs, and CAHs put the necessary workflows in place to move towards this general goal.

Objective 8: Public Health and Clinical Data Registry Reporting
Proposed Objective: The EP, EH, or CAH is in active engagement with public health agencies (PHA) or clinical data registries (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

For Stage 3, CMS proposes to remove the prior “ongoing submission” requirement and replace it with an “active engagement” requirement. Active engagement means that the provider is in the process of moving towards sending “production data” to a PHA or CDR, or is sending production data to a PHA or CDR. CMS proposes that “active engagement” may be demonstrated by any of the following options:

- **Active Engagement Option 1 – Completed Registration to Submit Data** – The EP, EH, or CAH registered to submit data with the PHA or, where applicable, the CDR to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP, EH, or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation.

- **Active Engagement 2 – Testing and Validation** – The EP, EH, or CAH is in the process of testing and validation of the electronic submission of data. Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

- **Active Engagement Option 3 – Production** – The EP, EH, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR. CMS also proposes to create a centralized repository of national, state, and local PHA and CDR readiness.

Proposed Measures: CMS is proposing six possible measures. EPs would be required to choose from measures one through five, and the proposal to provide support to providers seeking to meet the requirements by creating a centralized repository of national, state, and local PHA and CDR will be helpful to those providers in states that are not pursuing Syndromic Surveillance electronic submission.
would be required to successfully attest to any combination of three measures. EHs or CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures.

**Measure 1 – Immunization Registry Reporting:** To successfully meet this requirement, bidirectional data exchange between the provider’s certified EHR technology and the immunization registry/IIS is required.

**Measure 2 – Syndromic Surveillance Reporting:** The EP, EH, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs or an emergency or urgent care department for EHs or CAHs.

**Measure 3 – Case Reporting:** The EP, EH, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions. This is a new reporting option.

**Measure 4 – Public Health Registry Reporting:** The EP, EH, or CAH is in active engagement with a public health agency to submit data to public health registries.

**Measure 5 – Clinical Data Registry Reporting:** The EP, EH, or CAH is in active engagement to submit data to a clinical data registry (e.g., The National Quality Registry

We request that definitions of standards for data sharing be clarified as well as source of data. Could a provider use a data warehouse, which receives its data from the CEHRT, but is not certified to submit electronic case reporting or registry data?

For the proposed objectives, CHA recommends:

- EHs and EPs should be allowed to utilize transmission methods that are supported by the registries accepting the data. The methods for registries to accept data varies greatly. As a result, the EH or EP should have the flexibility to determine the appropriate method of transmission to the registries accepting the data.

- There needs to be exclusions for providers that do not have access to and/or organizational decisions have been made that limit participation in existing registries. Not all EPs — particularly specialists — have a relevant registry available to which they can submit data. An organization’s strategic plan may impact participation in certain registries. EPs should have the ability to align with their organization’s initiative.

- Similarly, not all hospitals have the capability to integrate or communicate with existing registries. There should be an exclusion for these hospitals.

- CMS provides (with updates) a list of nationally-identified registries. CMS could serve as a resource for identifying available registries.

CHA has some concerns with CMS’s proposal that an exclusion for the Public Health and Clinical Data Registry Reporting measure does not to count toward the total of the measure. Similar to the other proposed objective measures, if any of the Public Health and Clinical Data Registry Reporting measures include an option for exclusion, an EH or EP should be permitted to attest to the exclusion and have it count toward the total of four EH measures or three EP measures. For example, if an EP is actively engaged with an immunization registry, but has not administered any immunizations during the EHR reporting period, then the EP should be permitted to take the exclusion option for the immunization measure and it should count towards their total of three EP measures. In this example, the provider has met the CMS goal to “further advance communication between providers and PHAs or CDRs, as well as strengthen the capture and transmission of such health information within the care continuum.” The EP should not be penalized for attesting to the appropriate exclusion. Furthermore, this exclusion scenario may be seen often in the 90-day reporting periods in 2015 and in first year MU providers under the Medicaid EHR incentive program.

In addition, there may not be a public health registry and/or the clinical registry for specialists. If registries are not available then there should be an exclusion for them.
<table>
<thead>
<tr>
<th>Measure 6 – Electronic Reportable Laboratory Result Reporting: The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.</th>
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<tbody>
<tr>
<td><strong>Proposed Measure 1</strong></td>
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<td>In general, CHA supports bi-directionality but CMS must address standardization and capacity needs. Currently, many states are unable to conduct bi-directional exchange of information. This is a result of the lack of standard formatting requirements and a required set of data elements.</td>
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With respect to the reporting and attestation timeline, CMS requested comments on the following options:

**Whether the flexible option to attest to Stages 1 or 2 should be limited to only those providers who could not fully implement EHR technology certified to the 2015 Edition in 2017.**

Regarding flexible options related to Stage and Certification level in 2017, we agree with the rule as proposed which would allow providers to report at either Stage 1 or 2 (or potential Stage 2 modified) in 2017 regardless of whether they have fully implemented 2015 CEHRT. Implementing the technology is one step, but often requires additional time for process and workflow to be implemented to support. Limiting the flexibility in these years leading up to 2018 could present some of the same issues we realized in 2014 with technology availability/testing/implementation and measurement.

**Whether those providers with fully implemented EHR technology certified to the 2015 Edition in 2017 should be required to attest to Stage 3 in 2017.**

For the same reason as the point above, there still needs to be time for process and workflow implementation or reporting validation. Providers should be allowed the flexibility to be ready for 2018.

**Whether providers should not have the option to attest to Stage 3 regardless of an upgrade to EHR technology certified to the 2015 Edition in 2017, and should instead be required to delay demonstrating Stage 3 until 2018 using EHR technology certified to the 2015 Edition.**

This could indeed make everything a bit more synergistic for support, issue identification/resolution, and sharing of knowledge in preparation for Stage 3. With the proposed modification rule, everyone would be at Modified Stage 2 for 2016 and 2017, and working toward full Stage 3 implementation.

We appreciate the opportunity to provide comments on the proposed regulation and partnering with CMS to ensure the successful implementation of the Medicaid EHR incentive payment program. We believe implementation of this program will result in improved health care outcomes for the nation’s children. If you have any questions on our comments, please contact Liz Parry at 202-753-5392 or liz.parry@childrenshospitals.org.

Sincerely,

M. James Kaufman, PhD
Vice President, Public Policy