May 29, 2015

The Honorable Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3310-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-3310-P Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3

Dear Administrator Slavitt:

The American Academy of Pediatrics (AAP), a non-profit professional organization of more than 64,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children, adolescents, and young adults, appreciates the opportunity to comment on the Electronic Health Record (EHR) Incentive Program, Notice for Proposed Rule Making for Stage 3 of Meaningful Use.

The AAP is committed to the meaningful adoption of health information technology (HIT) for improving the quality of care for children and commends the comprehensive approach being taken by the Centers for Medicare and Medicaid Services (CMS) to streamline and improve the Meaningful Use reporting requirements for Medicare and Medicaid EHR incentive programs. There is tremendous potential for HIT to facilitate patient safety, quality improvement, quality measurement and better reporting through efficient data collection, analysis and information exchange.

The AAP has been involved in programmatic activities aimed to improve pediatric functionality in EHRs over the course of the last decade. We are one of the founding organizations of the Continuity of Care Record (CCR) effort that was the original way that interoperability was achieved. We have also published pediatric specific requirements for ePrescribing as well as inpatient and outpatient HIT systems. The AAP also worked with Agency for Healthcare Research and Quality (AHRQ) and CMS as a subcontractor to develop the Model Pediatric EHR Format. We continue to be involved in subsequent ongoing work to identify and enhance critical pediatric EHR functionality outlined within the original format. Finally, the AAP is also working closely with the Centers for Disease Control and Prevention (CDC) on how to best incorporate immunizations into EHRs.
Pediatricians have been early and ambitious adopters of health information technology. As the AAP has stressed in all of our prior comments and communications with CMS, children have different needs than adults, and therefore, pediatricians also have specific needs when it comes to health information technology. This is particularly true for pediatric data collection, reporting and functionality. The AAP would like to provide the following suggestions on the Notice for Proposed Rule Making for Stage 3 Meaningful Use:

**AAP/ONC Collaboration on Meaningful Use for Pediatrics**

Although vendors, insurers, and the federal government each have important roles to play in setting standards for the Meaningful Use of health information technology for children, the American Academy of Pediatrics is best suited to coordinate and fulfill this role. According to a recent study published in *Pediatrics*¹, pediatricians’ adoption of electronic health records lags behind other groups of physicians, despite initially being early and ambitious adopters. In addition, data from the Office of the National Coordinator of Health IT (ONC) revealed that pediatricians’ participation rates in the Medicaid EHR Incentive Program are also quite low, with only 17.2% of eligible pediatricians participating nationally. Concerns about cost and loss of productivity and lack of pediatric specificity and design are preventing pediatricians from adoption of currently available EHRs. The AAP and ONC should continue their collaborative efforts to improve EHR usability for pediatricians.

Additional barriers to use exist; for example, a recent editorial in *Pediatrics*² pointed out how Meaningful Use participation is much more challenging for pediatricians than for other specialists. Unlike most other specialists, pediatricians are eligible for Meaningful Use through the Medicaid program. Barriers to Meaningful Use include low Medicaid panels due to low and unreliable Medicaid payments, exclusion of CHIP patients in the Medicaid threshold requirement in several states (those with separate CHIP programs), varying reporting requirements by state and territory burdening pediatric vendors, delayed opening of incentive programs in some states, and a brief but arbitrary non-payment of Meaningful Use monies by Florida. For more than a year, the AAP has been warning that pediatricians will fall behind in the adoption of Meaningful Use unless some changes are made to the program.

At the April 7, 2015 HIT Policy Committee meeting new federal data showed that the AAP warning is becoming reality. Dawn Heisey-Grove, Public Health Analyst at the Office of the National Coordinator for Health IT, presented the most recent registration and attestation data. Registration to Meaningful Use indicates the intent to participate. After receiving the Adopt-Implement-Upgrade (AIU) payments, which are paid once a provider implements a fully certified Electronic Health Record (EHR), the next step to more Meaningful Use incentive payments requires attestation of Meaningful Use.

With 176,000 registrants, more providers have registered for Medicaid than anticipated; however Medicaid eligible providers (pediatricians) have a lower Meaningful Use attestation rate than

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providers eligible under Medicare (Figure 1 below). Less than half of Medicaid eligible providers (EPs) attest to Meaningful Use in the year following AIU payment. More than half (56%) of all Medicare-registered providers were scheduled for stage 2 in 2014 compared to eight percent of all Medicaid-registered EPs. While providers eligible under Medicaid have more time to implement (Table 1 below), this delay is more than can be explained by the schedule differences. Of all providers scheduled to attest to Stage 2 of Meaningful use, 93% are eligible under Medicare.

This data shows pediatricians are falling behind in the attestation of Meaningful Use and in the advancement of higher levels of adoption. If this trend is not reversed pediatricians will forfeit billions in dollars intended to incentivize the use of certified EHRs in pediatric offices. These funds could be used to improve EHRs to serve pediatricians and children better by providing pediatric functionalities currently found in only 8% of office based EHRs.

Figure 1: Attestation rates of eligible providers (Source ONC)

<table>
<thead>
<tr>
<th>Program</th>
<th>Last year to begin program and receive incentive payments</th>
<th>Final year incentives may be paid</th>
<th>Max. number of years of incentive payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>2014</td>
<td>2016</td>
<td>5</td>
</tr>
<tr>
<td>Medicaid</td>
<td>2016</td>
<td>2021</td>
<td>6</td>
</tr>
</tbody>
</table>

Children are not just little adults, and their providers are responsible for ensuring that they are receiving appropriate care; care that is at times quite different from the adult standards set by Medicare. The AAP is experienced in pediatric functionality of EHRs and stands to improve the overall processes and level of care for pediatric health information technology. The AAP can work with ONC and CMS to better tailor the Meaningful Use program to pediatrics, thereby improving the lives of children everywhere. As such, the AAP strongly recommends a robust and formal collaboration between AAP and ONC to significantly improve the levels of participation and attestation by pediatricians in the Medicaid EHR Incentive Program.
Expanding Meaningful Use
The AAP believes the Meaningful Use should be expanded to include all pediatricians, regardless of their Medicaid threshold. The current threshold disenfranchises children on Medicaid who receive care from providers who do not meet Meaningful Use eligibility criteria. Expanding Meaningful Use would benefit the health and well-being of all children. The AAP believes that, at the very least, the Children’s Health Insurance Program (CHIP) should count toward the threshold in all states, not just Medicaid expansion or combination programs.

Length of Reporting Period Each Year
The AAP strongly advocates for a 90 day reporting period for all reporting years. Although we appreciate CMS’ intent to create a less burdensome reporting structure, it is important to remember that meeting requirements throughout an entire 365 day reporting period without any tolerance for downtime, system upgrades, personnel interruptions, and other workflow challenges sets a bar that simply will discourage providers from participating in the Meaningful Use program. We believe that a 90 day, or at least a reporting period much shorter than 365 days, provides the flexibility for providers to be able to manage these types of challenges. For example, a 90 day reporting period will allow time for providers to improve their performance after a vendor upgrade, which typically causes declines in performance, without having to meet higher levels of requirements for the remainder of the year in order for the average to meet the Meaningful Use requirement. This concept is much more in line with the “Learning Healthcare System” that enhances the development and application of evidence in health care decision making that we are trying to create.

II.F.2.b. State Reporting on Meaningful EHR Users
The AAP is firmly against the proposal of penalizing providers who do not meet Medicaid thresholds by reducing their funding. The AAP does not support penalizing pediatricians who do not meet Medicaid thresholds and suggests removing the language regarding downward payment adjustments.

Additionally, the AAP requests that CMS further clarify who is exempt from the state reporting. We are concerned that exempting some providers and not others would create an incomplete and inaccurate picture of the landscape. This would also cause difficulty for providers looking to benchmark themselves against their other peers.

Objective 1: Protect Patient Health Information
Protecting patient health information is crucial to ensuring patient and public trust in electronic health records. While many institutions have protocols in place to protect information, the vendors must also be held accountable for their products’ ability to ensure the security of this data.

This objective would require an eligible provider (EP) to conduct or review a security risk analysis, including addressing the security (including encryption) of data stored in Health IT Certification Criterion (CEHRT), implement security updates as necessary, and correct identified security deficiencies as part of the provider’s risk management process.
The AAP is concerned, however, that an annual formal risk assessment can be a burden on small practices unless there is an easy to use, fast-track tool. Anecdotal data from AAP members indicates this is already the case. For example, the AAP has been made aware of one physician who failed her risk assessment on an audit because she did not use her state’s official contractor to perform the risk analysis. She was then told it would not have cost her anything to do the analysis through the contractor, but she had already used the AAP’s tools to perform the assessment. Unfortunately there are many places where risk assessments are not free, and it can be burdensome on small practices to hire a company to come and perform one. There are also wide variations between states on requirements to fulfill the risk assessment. The AAP suggests that security assessments be done every 3 years, or that they be done with a major upgrade of the system. This will allow smaller practices some financial flexibility, and ensure that they do not unnecessarily fail the assessment, or fail to have one performed.

Additionally, it is important to recognize that it is nearly impossible to switch EMRs and run at best capacity for 365 days in a row. The AAP suggests that there be a 90-day reporting period as providers are switching EMRs.

**Objective 2: E-Prescribing**

This electronic prescribing goal in the Proposed Rule that more than 80 percent of all permissible prescriptions written by the eligible provider are queried for a drug formulary and transmitted electronically using CEHRT, is aggressive and ambitious, and the AAP feels that it will not be easy to achieve for pediatric providers. Current vendor solutions, both in EMRs and retail pharmacies, lack the tools to assure safe electronic prescribing for many medications used in children. Commonly used tools to transmit an ePrescription from pediatric offices to pharmacies do not reliably transmit weight and body surface area and thus put the safety of pediatric patients at risk. Pediatricians will have difficulty meeting the timeline in the Proposed Rule until these gaps in safety, such as the ability to transmit patient weight, the verification of receipt, and the availability of certain less common suspensions, are addressed.

The AAP also urges CMS to ensure that there is adequate language differentiating between renewals and refills of prescriptions. Different systems count renewals and refills differently, and thus could under- or over-inflate the number of e-prescriptions.

**Objective 3: Clinical Decision Support (CDS)**

Objective 3 is designed to help implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions. The AAP strongly urges CMS to include immunization forecasting as a measure of CDS as it is one of the most important things that pediatricians do and has an especially strong evidence base.

Also of importance is determining what constitutes a CDS intervention. The language around this implies that an order set or template can be considered to be a CDS intervention. The AAP suggests that it should remain that way.

Additionally, data mining in Clinical Quality Measures (CQMs) is not standardized. This means that the data is not always accurate, and it is difficult to do true continuous quality improvement.
Finally, the AAP would like to stress that CMS must develop CQMs for all programs for every payer. Pediatricians who use adult CQMs do not meet these measurements. Therefore it is important that pediatricians have a model CQM program, and that it is harmonized against all payers and recognition. This also supports our recommendation above that CMS should delegate Meaningful Use requirements to the AAP.

**Objective 4: Computerized Provider Order Entry**

Though there are benefits for Computerized Provider Order Entry (CPOE) in the inpatient setting, which Objective 4 is attempting to promote, the AAP would like to stress that in outpatient settings, this requirement does not apply. Outpatient providers are simply not able to put their orders in a particular place and meet this requirement at 100 percent. The real challenge in this scenario is the management of the orders. Some pediatricians use the term Computerized Physician Order Management (CPOM) instead of CPOE because “management” is what is of importance.

In the outpatient setting, providers must track orders to make sure that they are getting results. Some labs require that providers use their individual forms, and this requires duplication of effort as both the lab’s form and the form required by the provider’s EMR is necessary. Many patients do identify a lab prior to the order or know the date the lab testing will be completed. Small but routine gaps in data increase the time and effort required by the outpatient office in addition to likely duplication of requirements. The clinical value for providers is not multiple data entry demands, but rather the successful creation and fulfillment of the order.

The AAP suggests that the CPOE requirement be sunset and a requirement to follow up and complete orders should be put in its place. The AAP is a strong proponent of the medical home, and feels that this requirement would be an opportunity to create continuous quality improvement on how a practice is monitoring outside labs and incorporating them as part of the medical home.

**Objective 5: Patient Electronic Access to Health Information**

In regard to Measure 1 of Objective 5, the AAP is concerned that the 24 hour-period at the conclusion of which patients must have access to their data is unworkable. For example, providers could simply make incomplete data available to the patient without completing clinical notes for several days or longer. Some practices and systems might also choose to delay the availability of information in order to give time for appropriate physician review and thus measuring the availability of this information within 24 hours is impracticable.

Additionally, we are concerned with the requirement in Measure 1 that, “the patient is provided access to view online, download, and transmit their health information” or “the patient is provided access to an ONC-certified API.” We feel that the definition of “access” needs to be further defined. For example: is simply setting up a patient portal considered to be access? Or does CMS intend that the provider has to go further in ensuring this such as providing Internet access?
Also of concern is that many patients still desire communications in paper format. Many patients still prefer to have information physically handed to them upon leaving the office, and therefore, providers should not face penalties for patient-centered communications approaches. For this reason, we suggest that Measure 1 reads that, “>80% of patients have access to information in the format that they desire.”

Measure 1 is also completely silent regarding the unique needs of adolescent patients. Some practices report discontinuing their portal for their patient’s period of adolescence because assuring necessary confidentiality becomes extremely difficult. There should be an exception for providers whose portals are unable to provide appropriate adolescent confidentiality functionality. Furthermore, though many vendors are presently building solutions, none have developed a solution that adheres to published policy by the AAP or Society for Adolescent Health and Medicine (SAHM) regarding issues of adolescent privacy. It is essential that CEHRT, at a minimum, provide reliable mechanisms for adolescents to have their privacy, and may share parts of their health information with their parents, and other proxies as they deem fit.

For Objective 5, CMS is also seeking input as to whether Measure 1 should place greater or exclusive emphasis on application-program interfaces (API). As the Proposed Rule states, an API is a set of programming protocols established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current "patient portals." While promising, the AAP believes that there should not be an exclusive emphasis placed on APIs. If CMS changes this measure to place greater emphasis on API, many vendors will have to completely rewrite their technology. This method is untested, and while it shows great promise, it is unclear that it is the right path. Instead, the AAP suggests that CMS make the API approach optional. If it is the right technology, the marketplace will support it in the future. The AAP feels strongly that CMS should not be trying to push particular technologies as a part of the MU program.

In Measure 2, the AAP feels that CMS has overemphasized the Health IT Certification Criterion (CEHRT) as the appropriate way to provide all resources, which effectively makes the EHR the center of all patient and provider interactions. AAP feels strongly that the patient, not the EHR, should be the center of interactions. For example, pediatricians often supply educational materials to patients outside of the EHR. Also, outside materials are often necessary for individuals whose first language is not English. Many providers find themselves supplying web links or supplementary materials in the patient’s language of choice. Accordingly, AAP support attestation that this is done rather than CEHRT reporting.

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

Measure 1 of Objective 6, which would require that, during the EHR reporting period, more than 25 percent of all unique patients seen by the eligible provider (EP) or discharged from the eligible hospital or critical access hospital (CAH) inpatient or emergency department actively engage with the electronic health record made accessible by the provider, makes the assumption that most patients want electronic access to their patient record, which may not be the case. Some patients still prefer paper records. In addition, the proposed measure also places a large burden on the provider for patient behavior. While providers can encourage patients to access their
records electronically, it is unreasonable to expect providers to become the enforcers of patients “actively engaging” with their personal health information. We also feel that CMS has gone too far in increasing the thresholds of this measure, from 5 percent to 25 percent.

Measure 3 of Objective 6, which requires that patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or emergency department during the EHR reporting period, may not be effective in terms of being able to use accurate data, patient safety, and technological security. Providers need guidance and structure for how patient data is displayed in the EHR, so that they may vet the quality and accuracy of the data. Currently there are no standards for displaying or identifying the source of patient data. If providers are working from inaccurate or incomplete data, patient safety is at risk. Additionally, providers need to be assured that when they access patient-entered data, they are not introducing damaging viruses or malware into their system.

Overall, the AAP believes that CMS should remove the numerical thresholds from each of the three measures, thus maintaining Objective 6’s status as a capability measure until at least 2020. They should read as follows:

Measure 1: Unique patients **can** actively engage with the accessible EHR.
Measure 2: Unique patients **can** receive a secure message
Measure 3: Unique patients **can** have patient-generated health data or data from a non-clinical setting incorporated into the CEHRT

**Objective 7: Health Information Exchange**

The AAP suggests that this objective, which is designed to improve communication between providers caring for the same patient by ensuring a summary of care record is transmitted or captured electronically and incorporated into the EHR for patients seeking care among different providers in the care continuum, be measured by capability only until 2020, and then, in 2020, that it impose thresholds lower than those outlined in the document. Although EHRs and the electronic exchange of health information, either directly or through health information exchanges, can reduce the burden of such communication, providers are struggling to find other practices who want to exchange data. Additionally, DIRECT messaging, which has been created through the Direct Project as part of the Nationwide Health Information Network, has not been effective at the practice level. Though the AAP agrees that this capability is important, the thresholds set forth in this goal will be difficult if not impossible for many providers to meet through no fault of their own.

The AAP also objects to the inclusion of summary of care documents in the case of a referral within a system where all practices are on the same instantiation of an HER, in the numerator to calculate the Measures 1 and 2 in Objective 7 since it unfairly provides an advantage to large referral systems over small individual practices or group settings.

Measure 3 of Objective 7, which would require more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH, to perform a clinical information reconciliation, is particularly
concerning because reconciling the problem lists in EHRs is impractical given the current state of the art. The nomenclature between EHRs can be vastly different, and lists of problems and conditions can be practically impossible to reconcile. For example, some providers record allergies as problems and some record them appropriately in the allergy section of the EHR. EHRs differ significantly on what constitutes an allergy, with some using a concept of “intolerances.” Beyond medications, this information must be better standardized before clinical reconciliation is possible.

**Objective 8: Public Health and Data Clinical Data Registry Reporting**
The AAP is concerned with each of the measures in Objective 8—which is designed to ensure that the EP, eligible hospital, or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology—because the only measure that applies to pediatrics in the outpatient setting is Measure 1: Immunization Registries. Additionally, these measures are problematic because public health officials and clinical data registries frequently do not accept pediatric data. In Stage 2, CMS ruled the pediatricians would get credit for at least attempting to share this data, and the AAP would prefer that Stage 3 include this as well. We also believe that Stage 2 modification logic should be applied in order for this to be acceptable and realistic for pediatricians. Furthermore, any reporting to Accountable Care Organizations (ACOs), etc. should count toward this requirement, as was proposed in the Stage 2 wording. Finally, sharing data with a research registry, such as the electronic Pediatric Research in Office Settings (ePROS) database, the larger Comparative Effectiveness Research through Collaborative Electronic Reporting (CER) database (both overseen by the Pediatrics Research in Office Settings group at the AAP) or with other research registries, should count toward this threshold. Participation in such registries is one way to use EHR data to meaningfully improve care.

AAP appreciates the opportunity to provide comments on CMS’ proposed rule for the Electronic Health Record Incentive Program – Stage 3. The Academy is committed to the meaningful adoption of HIT for improving the quality of care for children and looks forward to continuing to work with CMS to ensure that Meaningful Use is implemented in a way that promotes the goals of improving the quality, safety and cost-effectiveness of care. If we may provide further information or assistance, please contact Patrick Johnson in our Washington, DC office at (202) 347-8600 or pjohnson@aap.org.

Sincerely,

Sandra G. Hassink, MD, FAAP
President

SGH/arp