May 29, 2015

311 Arsenal Street
Watertown, MA 02472

Marilyn Tavenner, R.N.
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted via www.regulations.gov

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

Dear Administrator Tavenner,

athenahealth, Inc. ("athenahealth") appreciates the opportunity to provide comments on the Electronic Health Record Incentive Program—Stage 3 Proposed Rule ("Proposed Rule").

As you know athenahealth provides electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to physician practices, working with a network of more than 60,000 healthcare professionals who serve over 60 million patients in all 50 states. We envision and work to establish a nationwide health information backbone that makes healthcare work as it should by connecting patients and care providers with the information they need to seek and provide high-quality, cost-effective, efficient care. All of our providers access our services on the same instance of continuously-updated, cloud-based software. Our clients' successes, exemplified by a Meaningful Use ("MU") attestation rate more than double the national average, underscore the very real potential of health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs.

General Remarks

Subject to the suggestions below athenahealth generally supports this Proposed Rule, which in our view is a significant improvement over previous MU stages. The Center for Medicare and Medicaid Services ("CMS") has incorporated stakeholder calls for flexibility, simplification, and focus on the key areas that make use of certified EHR technology ("CEHRT") truly meaningful in the colloquial sense. We hope that CMS will continue to build on this progress to address two areas that continue to threaten the success of the MU program: the lack of interoperation among disparate CEHRT systems and the certification and use of systems that simply cannot keep up with program requirements.

In our view the MU program should drive toward for "interoperation" (an activity) in MU, not mere "interoperability" (a capability). Much of the confusion and dysfunction that exists in this area of health IT policy, and in the health IT marketplace, arises from the fact that vendors of closed information systems and their clients are able with straight faces to claim that their systems are interoperable, often citing MU certification as a proof point, while in practice they

erect financial, operational, and technological barriers to actual, systemic interoperation. The recently-passed MACRA law (Medicare Access and CHIP Reauthorization Act of 2015 and Consolidated and Further Continuing Appropriations Act, 2015) is appropriately-focused on dismantling these barriers, which are impeding progress toward the goal of widespread interoperability and, by extension, impeding the broad-based care coordination necessary for the MACRA framework to succeed. We urge CMS to join Congress in investigating and addressing the sources of these barriers. Simply put, CMS cannot continue to subsidize the use of CEHRT systems that cannot or intentionally do not freely exchange information with other systems.

Because many care providers are currently burdened by the failings of such systems, it is crucial that the final rule enables and encourages providers to transition from one CEHRT system to another. A staggering number of providers either received a penalty for failing to meet MU program requirements or applied for a hardship exemption in the past year. Many of these providers were let down by their EHR vendors. They should not in future years have to choose between continued participation in the MU program using inferior technology, or transitioning to CEHRT that can meet the expectations of the 21st century information economy.

Requirements for a full-year reporting period and for certain functionality, such as clinical decision support tools, to be in place consistently for the entire reporting period appropriately raise the bar for the majority of providers. However, the full-year reporting period leaves not a single day for providers switching to a new EHR to make their transition, let alone any time for ramping up on the new system. We urge CMS to consider a policy that would allow for a shorter reporting period for providers switching to a new CEHRT system. The difficulty of switching systems is so significant that we think the risk of abuse of such a policy is incredibly low, and the leniency would prevent providers from being "locked in" with vendors that fail to deliver on promises of success under the MU program.

Specific Comments

With the above context in mind, we provide the following specific comments on the proposed Stage 3 objectives and measures:

Objective 2: Electronic Prescribing

We support the increase in the threshold for electronic prescribing, but we are concerned that some of the proposed restrictions from the numerator are unreasonable. Over-the-counter medications and prescriptions to on-site pharmacies, if entered electronically, should be sent electronically and counted toward this measure. There are patient safety benefits to encouraging these prescriptions to be made electronically, especially when this measure is considered in conjunction with the requirements for medication reconciliation under Objective 7. With respect to on-site pharmacies, we support efforts by CMS to encourage the transmission of information outside of organizational and CEHRT walls, but we do not think excluding prescriptions electronically sent within an organization furthers this goal.

Objective 3: Clinical Decision Support

We applaud CMS for incorporating flexibility in providers' choice of clinical decision support (CDS) tool. However, the requirement the same CDS tools to be in place for an entire reporting period will be an unreasonable requirement for providers who choose to change CEHRT mid-year. Because of the flexibility in choosing CDS tools that meet this requirement, if is very unlikely that two different CEHRT products would have the exact same CDS options available, making it impossible for providers switching CEHRT to have the same CDS tools in place for the entire year. Therefore, we suggest that CMS revise this measure so that providers may switch CEHRT and the CDS tools included in CEHRT during a reporting period.

We are also concerned that the guidance provided by CMS in the Proposed Rule regarding who should receive CDS alerts and when those alerts are appropriate is confusing. In this instance, too much flexibility in measure specifications will lead to ambiguity. This will make it difficult for vendors to prove that their CEHRT meets the CDS requirements, and it will be difficult for providers to prove, in the event of an audit, that they met the requirements for who received a particular intervention. While we support the flexibility, we implore CMS to ensure that CEHRT and auditing requirements will also support this flexibility.

Objective 4: Computerized Provider Order Entry

athenahealth supports the increase of the thresholds for measures under this objective. Based on the experience of our clients, providers should be able to easily meet these thresholds by 2017.

Objective 5: Patient Electronic Access to Health Information

athena is fully supportive of the goal to ensure patients have timely access to their full health record. Additionally we support offering choices to patients as there is not one-size-fits-all model of a patient and how that patient wishes to access/interact with his/her health information. As such, we support the direction that requires EHRs and providers to offer both methods (portal or API) – Alternative A. However, for the purposes of MU measurement, we recommend that there be a single numerator and denominator measure that counts unique patients that have seen the EP, and the numerator is satisfied if the patient was given timely access to EITHER the portal or the API (or both). We ask ONC to recognize that it is more likely the patient's choice of which option makes the most sense for them and their health needs and technology comfort. Neither option is inherently better than the other for all patients. We would not support the option that relies solely on APIs as that more heavily relies on the patient to take initiative with a third party tool which simply would be too complicated for some portion of users.

A crude parallel can be drawn to a bank's website and intuit's Mint® application. Mint® is a free independent platform that lets consumers pull data in from their multiple financial accounts across companies. But each bank's website is still heavily used and often is the onramp for a user to feel comfortable with the concept of electronic data access and communication in general. And even in Mint's® case, they are still using the authentication of each bank's website to enable secure access so the user must have a user account active on the bank's website account before he/she can use the API to consolidate information within Mint®. It is the more advanced user who after being comfortable with the individual website who then wants to try to find a solution to the "see everything in one place" problem. As that natural progression

occurs, the API option should be available at the beginning of Stage 3 for early adopters and should remain available as individual patients progress through their health engagement journey over time.

athenahealth is excited to move forward with API options for patient access and patient care team communications. As part of our commitment to ensuring success of this approach, we offer the following comments to help inform the final rule relating to APIs:

- Overall, we support openness and are supportive of the idea of introducing APIs to the MU3 standards. We believe that standards are important to have successful APIs. We believe that the best way to create standards is by a consortium of the top Healthcare IT companies, similar to CommonWell, rather than by a government agency.
- While APIs are all that is needed for the ability to interoperate, the true goal is actual interoperation which will be very difficult to succeed without standards. Without a standard, each third-party looking to connect with each other must custom build to each other's proprietary APIs. This makes it possible but not easy.
- Critical for APIs to work is an understanding of how patient identity is established. Specifically, who is accessing a particular patient record, and what level of access should they have? Granting and maintaining access to health information is currently very tightly coupled with whoever owns the EHR for security reasons surrounding the protection of PHI. Therefore, part of the API should include granting and revoking access.
- Because the person accessing the patient record is not necessarily the patient, and not even necessarily a patient at a given EP or Hospital, we feel strongly that the notion of a portal user or API consumer should be an entity separate from the patient. This is important for a few of reasons:
    - Age of Majority: In the case of a young child whose parent is granted access to their medical record. When that child reaches the age of majority, access to that record should by default be revoked. If the parent had been logging in as the child (meaning there is no way to distinguish a parent accessing the record from a young adult accessing the record) then PHI might be inappropriately revealed to the parent.
    - Shared access to a patient record: For example, two parents might have access to a child's record. After a divorce, the parent with custody might wish to revoke the other parent's access to the child's health information. If both parents have been given the same "password" to the child's account, it will be difficult to revoke access for one of them, or even know if both of them have access. Furthermore, being able to uniquely identify who is accessing health information is an important part of HIPAA.
    - Being able to uniquely identify who is accessing the information will make it easier to count access as part of the MU stage 3 measures.
- In order to properly measure API use more easily, it would likely be good to require that each API include a way to identify who is accessing the information.

Additionally, athenahealth requests that ONC reconsider the proposed time period for providing access of information to the patient is within 24 hours of its availability to the provider. Prior stages of MU relied on 'x' number of business days. We support the definition that relies on business days and on our provider's behalf, ask CMS to change this from '24 hours' to 1 business

day. Requiring patient access within 24 hours either requires providers or their staff to work off hours or weekends/holidays or essentially requires the immediate availability to the patient.

Related to the measure calculation which evaluates the varying data to ensure each component is made available within the appropriate time window, we request clarification on how a single failure to meet the time window should affect satisfaction of a unique patient in the numerator. For example, a patient could have been sent for several sessions of lab tests over the course of the year-long reporting period. If the provider successfully reviews and approves the results for viewing by the patient within the time window for 50 lab results, but misses the deadline on a single result for that same patient (maybe the provider was on vacation that day or had a family emergency), is it truly the intention to have that unique patient count as failing the numerator? This highlights the difficulty in calculating and explaining measure when the denominator is unique patients but the numerator is that the patient must do something EVERY time as opposed to once. We would recommend defining this numerator similar to Secure Messaging, where the unique patient satisfies if the provider meets the numerator conditions at least once during the reporting period. Either way, please clarify in the final rule whether a single instance failure for a patient over the course of an entire year automatically fails that patient for the Electronic Access measure.

Obj*e*ctive 6: Coordination of Care Through Patient Engagement

Measure 1 – For reasons explained in our comments for Objective 5, we recommend that providers be able to satisfy this measure by using either option and adding the numerators together to capture unique patients who accessed their health information regardless of technical channel.

Measure 2 –We appreciate the proposed change in stage 3 to allow inclusion of provider-generated messages in the measure numerator and in general, support increasing the threshold for secure messaging, but we encourage CMS to consider adding a component to the requirement which considers limiting the denominator to only include patients seen 2 or more times within the reporting period. This threshold for multiple encounters is similar to your ask for comments in regards to Part 3 of this measure. While some types of providers, such as PCPs or OB may have on-going relationship with the patient, many other types of providers may not provide ongoing care. In situations that do not require ongoing patient care, the likelihood of clinical need to communicate with the provider decreases, therefore a higher threshold may result in an unintended consequence of the policy of having messages without clinical need sent just to meet the threshold. This is neither in the provider nor the patient's best interest.

We support including other care team members in secure messaging calculation. Given the goal to encourage appropriate use and adoption of technology which will lead to better care, we recommend that CMS defines success as viewing the communication and does not require creation of response or content. Requiring contribution will likely lead to unnecessary or over-communication in order to meet this program requirement, adding a burden to the provider, their care team and the patient. In combination with our above comment of further limiting the use of secure messaging to patients the provider has an on-going relationship with, viewing the communication is most likely to encourage use of this capability in ways that improves care delivery.

Patient Access via ONC-certified API – A con of measuring number of patients who access it is that this then relies on a 3rd party to develop an app that patients want, for providers to figure out what that app is and for patients to have some intrinsic incentive to set that connection up and use it. We believe capability should be made available to patients but that providers should not be required to have patients adopt this type of capability.

Measure 3 – On the question of patient-generated health data, the denominator is the whole population, but patients for whom this matters is a much smaller subset. It would be good to find a way to limit the denominator to those who really need closer monitoring. We applaud the objective to promote patient-generated information to become part of their health record and we support requiring CEHRT to have this capability and for providers to have this capability enabled during the reporting period. However, we do not support requiring patient adoption and use of this capability at the suggested 15% rate. The clearest immediate use case is to support submission of home health devices used for chronic conditions such as glucose monitors, blood pressure monitors, etc. We can certainly imagine the longer term future including fitness trackers such as FitBit. But as a primary goal of this rule is to drive use and support for evidence-based protocols, there has not yet been conclusive evidence showing that incorporation of information from fitness monitors would further this goal. We would recommend limiting the types of patient-generated health info to help concentrate on the "high priority health conditions" and not fitness.

We would support automated inclusion of the data into the patient's chart and keeping it clearly labeled as to the source of that information. We would not support allowing patient data to amend practice data without human reconciliation.

Objective 7: Health Information Exchange

Measure 1—For more than 50 percent of transitions of care and referrals, the EP, eligible hospital 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.

With respect to CMS's request for comment on health information exchange governance mechanisms, we recommend that nationwide health information network ("NwHIN") governance mechanisms, such as Direct, should continue to be an acceptable baseline standard for information exchange. While governance mechanisms must remain flexible to allow for the development of future standards, backsliding away from the Direct standard and allowing measure 1 to be accomplished through any electronic means would increase the need for investment in point-to-point integration without any clear functional benefit.

Measure 2— For more than 40 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 incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

We do not believe that CMS should set a performance requirement that forces providers to incorporate queried information into their records for new or transitioning patients. CMS is

correct to focus on the ability of providers to receive usable information for patients transitioned or referred into their care, but the requirement to incorporate such information into a patient's EHR seems to be an imposition on clinical judgment that could have unintended consequences on medical liability.

The denominator for this measure will be very difficult to measure accurately, particularly in situations where queried information was available but deemed inaccurate by the provider. A demonstration of bi-directional test queries across CEHRT would sufficiently demonstrate that providers are able to perform the actions required in this measure without imposing on their clinical judgment.

With respect to transport requirements for this measure, we do not believe that CMS should require use of a specific standard for retrieval of patient information. Compliance with the Direct standard should be sufficient.

CMS also requested comment on whether "utilization alerts" that alert EPs when a patient is admitted, seen in the emergency room, or discharged from the hospital should be included in this measure or created as a separate measure. If included as a separate measure, it should only apply to eligible hospitals. The control point for the "push" of utilization alerts lies within the CEHRT of eligible hospitals (such as an outbound ADT feed to an EP), so EPs could not be measured against a requirement for the transmission of utilization alerts.

- 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, eligible hospital, or CAH performs clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets: Medication; Medication allergy; and Current Problem list.

We do not agree with the proposal to require reconciliation on all three information sets. For the purposes of demonstrating meaningful use of CEHRT, the requirement that providers pick two of the three to perform reconciliation will be sufficient. Furthermore, we believe that reconciliation that is automated through rules set by a provider should satisfy this measure. Finally, CMS should not provide direction on providers' workflow for review of reconciled data, as this is not relevant to the meaningful use of CEHRT.

Objective 8: Public Health and Clinical Data Registry Reporting

athenahealth supports the streamlining of Public Health and Clinical Data Registry Reporting measure. We're also encouraged by the replacement of the "ongoing submission" requirement to "active engagement". It has been our experience that public health agencies often have limited resources and are not always available to work with our providers within the required timeline. This updated language more accurately addresses that scenario and its impact on a provider's Meaningful Use attestation.

CMS also welcomed comments on the creation of a centralized repository of national, state, and local PHA and CDR readiness. athenahealth applauds the proposed creation of a such a registry and would emphatically request that the repository be ready by the start of CY 2017 as indicated in the proposed rule. We would encourage that the repository clearly capture each registry's readiness to receive data from both EP and EHs. It has been our experience that registry readiness offer differs for EPs and EHs, and even for certain specialties of EPs. This should be clearly captured in the repository. We would also request that the repository include definitive labeling of each registry's type. We expect that the new definition of public health and clinical data registries will cause confusion. The repository would be an opportunity to eliminate or mitigate this confusion by clearly defining the type of each registry.

athenahealth supports the requirement of bi-directional exchange for Measure 1, Immunization Registry Reporting. We have been successful in establishing bidirectional exchange with a number of immunization registries to date and agree that this functionality is important for patient safety and improved care.

athenahealth asks for additional clarity on the proposed Measure 3, Case Reporting. Is the goal of case reporting not similar to that of syndromic surveillance reporting? We also urge CMS to consider the applicability of case reporting for the broader EP population before including case reporting certification criterion in the 2015 Edition proposed rule. Including the functionality to both send and receive requests for case reporting information could require a significant investment without a clear benefit for our provider population, as we suspect that most would be excluded for case reporting public health option.

Quality reporting

We agree that CEHRT should include more than the minimum number of required CQMs to enable provider choice, but we encourage CMS not to require all CQMs as this causes a substantial vendor investment and a devotion of significant resources for minimal benefit to providers. We recommend that in these cases CMS weigh the potential benefit to patient care against the expected burden, which draws vendors' attention away from other initiatives that will have greater impact on practices' ability to deliver quality care.

State Flexibility for Stage 3 of Meaningful Use

We applaud CMS' revision of State flexibility under the Medicaid EHR program to limit flexibility to the public health agency measures which are the only measures which may actually require variation at the state level given local public health and clinical data registry agencies. We do not agree with the ambiguity of the statement that states can "otherwise change the public health agency reporting objective as long as it does not require functionality…". Based on our provider's experiences in Stage 1 and Stage 2 in working with public health and clinical data registry agencies, functionality is one component, but unnecessary administrative burden, complicated processes, etc. are another concern, e.g. requiring a provider to log into a separate portal to submit test messages.

Audit requirements

While not specifically mentioned in the final rule, we implore that if CMS plans to continue to audit data submitted by providers for the Meaningful Use program that the recommended audit documentation be published sooner and ideally included in the measure specification and if not there then is published prior to the start of the reporting period. In Stage 1 and Stage 2 recommended audit documentation, new requirements for vendors, such as having a vendor logo or version number present on the patient list was published well after the fact, holding providers to a higher standard than was outlined in the final rule, measure specification or FAQs.

Conclusion

We appreciate CMS's engagement of the public to inform the Meaningful Use Stage 3 rule. athenahealth is encouraged by the direction of this proposed rule and continues to welcome the opportunity to provide feedback and participate in the transformation of health care.

Sincerely,

Dan Haley
Vice President
Government and Regulatory Affairs