March 28, 2016

311 Arsenal Street
Watertown, MA 02472

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5061-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: CMS-5061-P, Medicare Program: Expanding Uses of Medicare Data by Qualified Entities Proposed Rule

Submitted electronically through www.regulations.gov

Dear Administrator Slavitt,

athenahealth, Inc. appreciates the opportunity to provide comments on the proposal to implement expanded uses of Medicare data by Qualified Entities under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

We provide electronic health record (EHR), practice management, care coordination, patient communication, data analytics, and related services to physician practices and hospitals, working with a network of over 75,000 healthcare professionals in all 50 states. All of our providers access our services—and over 38 million active patient records—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 data and health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs.

Medicare paid claims data are the key to unlocking much needed price transparency and innovation in the health care industry, and CMS has made significant strides in the past few years toward making this data more readily available to researchers. Much more needs to be done, however, to truly realize the potential of this vast trove of data to improve care and reduce costs. As the Proposed Rule recognizes, Medicare data needs to be available for more than research purposes if its true value is going to be harnessed to drive improvement in healthcare. The real value of Medicare data will be realized through the innovation that it catalyzes.

Physicians are increasingly held accountable for the cost and quality of care through programs such as Medicare Shared Savings and the soon-to-be-implemented Merit-Based Incentive Payment System. As a result, they are increasingly turning to their technology partners to provide care coordination and analytic tools to help them and their patients make well-informed decisions. Technology developer access to claims data through the Qualified Entity ("QE") program will trigger a proliferation of such tools that, already common in nearly every other sector of our data-driven economy, are desperately needed in health care.

athenahealth's vision, shared by entrepreneurs across healthcare, is a system where claims data is used to drive efficiencies, improve quality, and reduce costs. Providers should not need to rely for crucial care decisions solely on patients' always-imperfect recollection of their medical history when that information exists in much more reliable form within claims data. A patient's entire care team can be proactively identified to facilitate seamless care coordination. Claims data can be analyzed to enable providers to understand the cost and quality implications of referral decisions. And, most importantly, claims data can empower providers and patients with the information needed to shop for healthcare.

The proposed expanded uses of Medicare claims data by QEs will go a long way to turning this vision into reality, but not if unnecessary restrictions on access and use are allowed to carry over from previous regulation. We urge CMS to consider a few revisions to the Proposed Rule that, based on our experience, will make the QE program more accessible to and useful for technology companies and entrepreneurs. This will ultimately benefit healthcare providers, who will receive more effective assistance with participating in quality improvement and assessment activities and new models of care.

1. **The Qualified Entity application should be streamlined for entities that have already demonstrated compliance with its requirements through other certification/audit programs.**

We are concerned that the application for QE status is unnecessarily burdensome for the entities likely to apply under the new provisions of the Proposed Rule. Certainly, CMS has a significant responsibility in ensuring that QEs are able to comply with the requirements of the program and protect the privacy and security of beneficiary information. However, the new provisions of the Proposed Rule are likely to encourage participation by provider groups and their service providers that are considered Covered Entities or Business Associates under the Health Insurance Portability and Accountability Act ("HIPAA"). These applicants will have greater experience and expertise in protecting patient information than the QEs approved to date. The application process should be streamlined and expedited for applicants that have already pursued certifications or accreditations that demonstrate a high level of information security and compliance with applicable law.

For example, applicants that are HITRUST certified should be able to provide proof of that certification in lieu of completing the application elements regarding data security and privacy. The HITRUST certification framework harmonizes the requirements of existing standards and regulations, including HIPAA, Payment Card Industry (PCI), Control Objectives for Information and Related Technology (COBIT), National Institute of Standards and Technology (NIST), and the Federal Trade Commission (FTC). It is more than sufficient to provide CMS the necessary reassurance of an applicant's ability to safeguard data.

Therefore, we urge CMS to allow comprehensive audits, assessments and certifications, such as HITRUST, to be used in lieu of the current evidentiary requirements in the data security and privacy section of the QE application.

2. **CMS should provide flexibility in the types of agreements that Qualified Entities and Authorized Users utilize to comply with the requirements for legally binding agreements.**

While we support the proposed required terms that must be included in a QE Data Use Agreement ("QE DUA"), we stress that CMS should not implement this provision in a way that requires QEs to have a separate agreement called a QE DUA in place with authorized users.

MACRA requires that there be some agreement in place prescribing data security and privacy requirements, but it does not explicitly require a QE DUA or preclude CMS from allowing QEs to rely on existing agreements, such as Business Associate Agreements ("BAA"), with authorized users who are Covered Entities.

If the QE DUA-required provisions already exist in another contract between the QE and the authorized user, then CMS should not require QEs to repaper those same terms. For QEs that are already Business Associates of authorized users, the imposition of a QE DUA requirement is redundant and presents an unnecessary burden and barrier to the use of claims data to improve patient care.

Therefore, we propose that CMS clarify that an existing agreement between a QE and an authorized user that includes QE DUA-required provisions is sufficient and that a separate agreement called a QE DUA is not needed. For QEs and authorized users that are not covered by HIPAA and/or do not have a pre-existing BAA in place, we believe that the use of a QE DUA is a reasonable requirement.

3. **CMS must address potential conflicts between its Data Use Agreement terms and HIPAA requirements.**

Under the Proposed Rule, a QE must comply with the data requirements in its DUA with CMS ("CMS DUA"). However, there are provisions included in the CMS DUA that conflict with mandatory HIPAA requirements. For example, the CMS DUA requires that the User agrees to destroy data after a set retention period identified in the agreement. However, under HIPAA, there is no such parallel retention/destruction period. Indeed, requiring a User to destroy data in compliance with the CMS DUA could effectively require that User to violate HIPAA. Further, and even worse, this requirement would literally obligate the User to, at a specified point, remove data from patient files. The patient safety implications of such a requirement are obvious and unacceptable.

CMS recognized in the Proposed Rule that HIPAA has established reasonable and appropriate privacy and security requirements for the healthcare industry. We agree, and for that reason support CMS' proposals that make use of HIPAA standards, such as the proposal to use HIPAA de-identification standards for non-public analyses that are not shared with the patient's provider.

As HIPAA is the standard for patients nationally, it is not appropriate for CMS to impose a higher standard for its beneficiaries. Therefore, we urge that CMS refrain from imposing requirements, such as the data destruction requirement, that are inconsistent with other HHS requirements.

4. **The confidential opportunity to review, appeal, and correct analyses should not be the same for public and non-public analyses.**

We do not support the obligation that non-public analyses can only individually identify providers or suppliers if they have been given the opportunity to review the analysis and request error corrections. The reputational risk here is not the same as with public reporting and therefore the same rigorous review process is not warranted and could be extraordinarily disruptive to care providers. While we understand that authorized users can include medical societies and state agencies with wider audiences, given the limited permitted purposes for non-public analyses, the reputational risk is still very low. We disagree with CMS's contention that the existing process finds the right balance between allowing providers and suppliers the opportunity to review analyses while also ensuring that information is disseminated in a timely manner. CMS acknowledges that they have had limited public reporting thus far to confirm that belief, and the agency should instead rely on the expertise of organizations like athenahealth that have extensive experience with data analysis and reporting and understand the undue delay that would be caused by this prospective review process.

As we move toward more frequent claims data releases with the goal of continual, real-time updates, analyses will be provided rapidly and iteratively. For example, HIT platforms could automatically update downstream cost/utilization estimates for specialists daily, making a 60-day review period completely unrealistic. Moreover, even under CMS's policy of providing quarterly data updates, a 60-day review period on top of that 90-day lag would mean that by the time a provider or supplier receives analyses relevant to his or her patients, the data will be over 5 months old and unlikely to be useful in providing actionable insights to improve patient outcomes.

Instead, we propose that providers or suppliers be notified electronically by a QE when they have been identified in analyses and have an ongoing right to review such analyses, not a prospective "right of first refusal." Given that these are non-public analyses, we believe that an ongoing right to review that does not hold up the dissemination of non-public analyses strikes a more appropriate balance between protecting the interests of providers and suppliers while promoting better clinical outcomes.

5. **Permitted uses of CMS claims data by Qualified Entities and Authorized Users should include "treatment" as defined by HIPAA to maximize the potential usefulness of the data in improving patient care.**

We support that authorized users who are subject to a QE DUA also be permitted to use data and non-public analyses for "treatment" as defined by HIPAA and not just certain aspects of "health care operations" as currently proposed. The Proposed Rule limits the use of combined data and/or Medicare claims data and/or non-public analyses that contain patient identifiable data to the activities that fall under the definition of "health care operations" in the first and second paragraph of 45 CFR 164.501, as well as fraud and abuse detection or compliance activities. The definition of "health care operations" in 45 CFR 164.501 largely focuses on quality improvement activities, including care coordination activities and activities to track and manage medical costs, and population-based activities such as those aimed at improving patient safety, quality of care and developing new models of care.

We believe that it would be highly beneficial to add "treatment" as defined by HIPAA as a permitted use of data or non-public analyses for authorized users that are subject to a QE DUA. Under HIPAA, "treatment" generally means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another. For example, if "treatment" is added as a permitted use, a primary care provider who learns through claims data that their patient has seen another provider for a cardiology consult can use that information to consult with the cardiologist and tailor and coordinate ongoing treatment accordingly. The intent of MACRA in further expanding the QE program is to provide data and analyses to providers and other authorized users to support care improvement and adding for purposes of "treatment" would help complement other permitted uses.

We also urge CMS to modify the definition of "patient" under the Proposed Rule regarding how often an individual must have contact with a provider to maintain a "patient" relationship. We believe it should be changed from at least once in the past 12 months to at least once in the past 24 months. Extending the time period to 24 months is a more reasonable expectation and will capture the individuals who can benefit the most from the claims data. Often, it is impractical for a patient to maintain a yearly or more frequent relationship with her provider. Factors such as how often insurance covers certain visits may also come into play. Moreover, patients who reside in underserved areas or face ability to pay issues may not visit their providers every year. These are the patients who would benefit most from the types of analysis enabled with the claims data. Additionally, patients with chronic care conditions who are non-compliant with recommended follow-up care would not be captured in the past 12 months definition and would not stand to benefit from the care coordination that claims data enables. Modifying the definition to at least once in the past 24 months time frame will still enable a provider to receive analyses with beneficiary identifiable information that will be useful in quality and patient care improvement efforts.

athenahealth appreciates the opportunity to share our thoughts and looks forward to continuing to work with your agency to streamline the process to become a QE and use the data to realize its full potential to improve quality and reduce costs in Medicare, as well as the larger health care system.

Sincerely,

Stephanie Zaremba
Director, Government & Regulatory Affairs
athenahealth, Inc.