Medicare Red Tape Relief Project

Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date: August 25, 2017
Name of Submitting Organization: Electronic Health Record Association (EHRA)
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Statutory___   Regulatory X

Please describe the submitting organization's interaction with the Medicare program:
Established in 2004, the Electronic Health Record (EHR) Association is comprised of 30 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. For more information, please visit www.ehra.org.

Please use the below template as an example of a submission regarding statutory or regulatory concerns, and submit any further concerns past those listed below in a separate Microsoft Word document in the same format. Submissions must be in the requested format or they will not be considered.

In the case of listed Appendices, please attach as PDF files at the end of the submission, clearly marked as "Appendix [insert label]"

In the case of a multitude of submissions, it is recommended that they be submitted in order of priority for the submitting organization or individual.

Short Description:
The Association believes strongly that the ONC Health IT Certification Program: Enhanced Oversight and Accountability rule is a prime example of an unnecessary regulation as currently constituted.

Summary:
ONC's notable expansion of its own authority to conduct direct review of certified health IT is counter to what we understand to be Congressional intent in the HITECH Act.
Of particular concern, the rule extends ONC certification authority to non-certified EHR capabilities for which there are no specific measurement criteria for conformance, outlining ONC's far-ranging and intrusive plan for implementing considerably expanded government oversight of certified health IT products from the private sector via direct review.

We believe that the final rule inappropriately expands ONC's EHR certification role far beyond the scope authorized in the HITECH Act of 2009, and introduces a number of due process flaws that must be reconsidered.

Related Statute/Regulation:
ONC Health IT Certification Program: Enhanced Oversight and Accountability, Department of Health and Human Services, Office of the National Coordinator for Health IT

Proposed Solution:
The EHR Association believes the rule is untenable and that the direct review portion of the rule should not be enforced until these concerns are extensively reviewed and addressed through a new rulemaking process. Indeed, we suggest that further review may very well lead to a decision to simply withdraw this burdensome regulation for which no substantive or pressing rationale has been established.

Short Description:
The EHRA recommends the following actions in advance of implementation of several provisions of the 21st Century Cures Act:

- HHS Office of Inspector General (OIG) delay enforcement of the information blocking provisions of the 21st Century Cures Act until six months after final rules.
- ONC provide clarity and interpretation to vendors regarding the changes required as part of certification.

Summary:
The 21st Century Cures Act requires the Secretary of Health and Human Services to define through regulations "reasonable and necessary" activities or business practices that do not constitute information blocking. The legislation did not specify a due date for this regulation, but we ask that this process be expedited to enable federal actions associated with information blocking to operate with a functionally complete definition. The EHR Association is concerned that enforcement actions undertaken prior to rulemaking to develop the clear definition of "reasonable and necessary" activities could result in unnecessary and inappropriate penalties.

Additionally, 21st Century Cures modified the requirements for certification to include the following conditions:

- Assurance that no information blocking or other actions that inhibit access, exchange, and use of electronic health information is taking place;
- Does not prohibit or restrict communication of usability, interoperability, security, user experience, business practices, and the manner in which a user of the health information technology has used such technology;
- Has published application programming interfaces (APIs) that enable access to all data elements of a patient's electronic health record;
- Has performed real-world testing of interoperability; and
- Attests to the conduct described above and submits appropriate reporting.

Related Statute/Regulation:
The 21st Century Cures Act of 2016

Proposed Solution:
The EHR Association has urged HHS Secretary Tom Price to delay enforcement by the OIG of the 21st Century Cures Act information blocking provisions until six months after final rules on both "reasonable and necessary" as well as the required final rule (within one year of enactment) covering integration of the information blocking issue into the ONC health IT certification program.

The intervening period after final rules are published will enable providers, networks, exchanges, and health IT developers the essential time necessary to make any needed changes to comply with final rules. We also requested that this deferral be made public to ensure that providers, developers, and others do not embark on wasteful and costly compliance efforts that could delay innovation and investment in meeting patient and provider needs.

The EHR Association has offered to provide technical assistance to HHS in the work to define "reasonable and necessary;" to implement the required changes in the certification process; and to define, from an implementation perspective, other terms used in the interoperability and information blocking provisions of 21st Century Cures.

Regarding the modifications required to achieve certification from ONC, the EHR Association recommends HHS provide clarity to these definitions so that these terms and concepts can be effectively operationalized. Specifically, the EHR Association requests the API criterion should only apply to CEHRT or CHIT that has been certified to the modular API criteria. We suggest that the requirement to have published APIs is well-addressed by those who certify to those capabilities and that meeting and continuing to comply with such certification, which includes making API documentation available, should meet this requirement.

With regard to real-world testing for interoperability, the EHR Association suggests ONC provide a clear definition of real-world test scenarios and clarity on how pass or fail would be defined as a measure.

Short Description:
Timelines for Medicare and Medicaid EHR Incentive Programs

Summary:
Providers have expressed concerns about the timeframe needed to implement 2015 edition CEHRT; and, therefore, we encourage CMS to finalize any decisions around adjusting the timeframe sooner rather than later to avoid last minute confusion and complications.

Another area where alignment and clarity is strongly needed is in the logic for the Meaningful Use (MU) and MIPS ACI measures. For example, for MU measures, the measure specification states that the numerator is not constrained to the reporting period when the reporting period is less than a year (i.e., 90 days). For ACI measures, the specification states that the numerator is not constrained to the EHR reporting period unless stated in the numerator statement. Additionally, there are several measures that are calculated differently between Modified Stage 2 and Stage 3 as well as differently between MU and ACI. For example, for the Patient Access Measure, the specification states that for Modified Stage 2 and Stage 3 the patient may view, download, and transmit their information during the calendar year for MU; but for ACI, this action must occur during the performance period.

Related Statute/Regulation:
2018 Quality Payment Program (QPP) Proposed Rule

Proposed Solution:

We urge CMS to be as clear as possible regarding the required edition of CEHRT across regulatory programs and alternative payment models (APM), and to harmonize the calendar year 2018 requirement across the various QPP-relevant payment models. Many alternative payment models, for example, point to the definition of CEHRT as outlined in the MU or the Quality Payment Programs. Not only do we urge CMS to create consistency across these two programs via rulemaking, we suggest it publish guidance to clarify which APMs align with the finalized QPP definition of CEHRT and use of CEHRT for specific activities, or whether they have their own, such as what appears to be the case for the Comprehensive Primary Care Plus (CPC+) program.

Short Description:
Improvements to Reduce Regulatory Burden and Eliminate Inefficiencies in Measurement and Reporting

Summary:
Overemphasizing the percentage of attainment on measures across regulatory programs, and on the certified software that supports those measures, inadvertently places the focus on measurement rather than on clinical goals and outcomes. Notable examples include:

- Secure messaging
- Patient education
- View, download, and transmit

This focus on measurement creates usability and workflow challenges and contributes to, in our view, much of the reported provider unhappiness with their EHRs.

Related Statute/Regulation:
2018 Quality Payment Program (QPP) Proposed Rule

Proposed Solution:
Fundamentally, quality program measures should prioritize improving health outcomes by providing better care and lowering costs versus reporting for the sake of reporting.

Furthermore, duplicative and sometimes conflicting reporting requirements across regulatory programs cause undue burden on providers and hospitals. For example, the electronic clinical quality measures (eCQMs) required for the CPC+ program are a subset of those required for the MIPS quality category, so providers should be able to submit quality measures one time to satisfy both CPC+ and MIPS if they do not qualify for QP status in CPC+, similar to what they are able to do when submitting quality measures via the web interface for the Shared Savings Program, which determines their score for MIPS quality.

We encourage CMS to continue its efforts to streamline reporting requirements across programs. Additionally, while we are supportive of efforts to reduce provider burden with respect to reporting requirements, the EHR Association believes CMS must find the appropriate balance between rewarding providers who have successfully transitioned toward delivering value-based care models and allowing flexibility for smaller providers and those in unique practice settings.

Short Description:
Complexity of Medicare Requirements

We urge CMS to be clear in specifying documentation expected of providers, while refraining from getting too granular with requirements.

Summary:
In some instances, Medicare requirements around provider documentation have been overly complex, such as the supporting documentation needed for CPT codes, including evaluation and management codes. In other cases, however, requirements have lacked specificity, such as the level of documentation or "proof" needed to demonstrate the successful completion of improvement activities for the MIPS program.

In addition, EHR Association members and their customers have concerns with the role of audits, the need to provide protected health information (PHI) to auditors, and the burdens imposed by auditors. This adds considerable complexity and uncertainty for providers, counter to overall program goals.

Related Statute/Regulation:
2018 Quality Payment Program Proposed Rule, 2018 Medicare Physician Fee Schedule Proposed Rule

Proposed Solution:
The EHR Association urges that CMS put some restrictions or limitations on what can be requested in provider audits and, at minimum, provide additional guidance on what is recommended to be on file and its format (e.g., the data that must be included on reports that will be submitted with audits or that need not be included).

It is challenging to support a customer who is getting audited for 2013 when each audit can ask for different data in different formats, especially when one considers state-level variation. Meaningful use objectives have changed up to four times since 2013, making it difficult to track which requirements were in place during a historical time period.

Short Description:
Setting Attainable Timeframes

Adequate time is needed to assess whether standards can support new requirements, update standards as necessary, update systems to support the new/updated standards, test access/exchange, and roll out updated software to relevant stakeholders.

Each of these steps takes time and effort so sufficient timeframes are essential.

Summary:
The electronic access to and exchange of data continues to play a significant role in moving toward value-based care. Because such access and exchange of data relies on standards, whether provided by standards development organizations (SDOs) or CMS itself, it is critical the data requirements are identified and communicated as early in the process as possible.

Unfortunately, we often experience late updates to requirements that create significant challenges from a timing perspective. Two current examples include the uncertainty around appropriate use criteria (AUC) for advanced imaging services, and the inclusion of patient relationship modifiers on claims; the specific data requirements are not yet known. Standards may not be able to support these requirements, thus providers and their health IT/EHR systems may not be able to implement the necessary updates, leaving providers not fully ready to provide the data on the target date.

Related Statute/Regulation
2018 Quality Payment Program Proposed Rule, 2018 Medicare Physician Fee Schedule Proposed Rule, 2018 Hospital Outpatient Prospective Payment System Proposed Rule

Proposed Solution:
In general, we urge CMS to set realistic expectations when setting effective dates.

We suggest an 18- to 24-month time period between final rules, including all associated guidance, and when providers are expected to be using new functionality, so that all necessary steps from standards development and updates, to testing, training, implementation, and other roll-out activities may be addressed in order to avoid unreasonable scrambling, increased risk of failure, churn, and wasted efforts.

Lack of sufficient time causes major problems for both providers and developers, with the stresses on developers often causing indirect problems for providers.