33 W. Monroe, Suite 1700
Chicago, IL 60603
swillis@himss.org
Phone: 312-915-9518
Twitter: @EHRAssociation

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
P.O. Box 8016
Baltimore, MD 21244-8016

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Washington, DC 20201

On behalf of the Electronic Health Record Association (EHRA), we submit the following comments on the Centers for Medicare and Medicaid Services (CMS) Notice of Proposed Rulemaking (NPRM) on the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program. These comments are based on the collective perspectives and experiences of more than 30 EHRA member companies who serve the majority of hospitals and ambulatory care providers using EHRs across the United States. Our comments focus on the proposed changes to the EHR incentive program.

Overall Comments on Program Alignment and Mid-course Program Changes

We appreciate the opportunity to comment on this proposed rule as well as CMS' stated intention to reduce administrative burden and enable eligible hospitals (EHs) and critical access hospitals (CAHs) to focus more on patient care. As CMS looks for methods to simplify the program, particular attention must be given to alignment across Medicare and Medicaid requirements. Disparate requirements will increase complexity and is counter to CMS's goal.

The EHRA strongly recommends that CMS align the reporting requirements between the Medicare and Medicaid EHR Incentive Programs. CMS's attestation data shows that in the past 95% of EH and CAH participants have both Medicare and Medicaid participation. Separate requirements for Medicare and Medicaid will therefore have a widespread adverse impact on hospital participants and their health IT developers.

Furthermore, we advocate to align CMS requirements for the Medicare and Medicaid EHR incentive programs with the Merit-Based Incentive Payment System (MIPS) with the goal that only one set of metrics is used across MIPs, meaningful use (MU) for Medicare, and MU for Medicaid. Subtle variances in metrics across programs should be avoided, where alignment and reuse of existing metrics should be the priority. This will also facilitate efficiency for CMS and ONC if they reuse the same specifications, sub-regulatory guidance (such as FAQs), and certification criteria applied to all programs uniformly.

To provide an example of our concerns, it would be problematic if CMS adopted different policies across these programs with regard to the timing of reporting periods and actions. If one program limits reporting to actions within a reporting period, all of these programs should do so. Similarly, if one program permits actions outside of a reporting period, then all of the programs should do so. Variation of that type would introduce unnecessary report complexity without commensurate clinical value.

More generally, we believe that changes to the EHR incentive program at this late date relative to the current or next reporting period will be costly in both real and opportunity costs and will have a negative impact on the program, wasting provider and vendor time and resources that would be better deployed elsewhere to add value. We, therefore, strongly recommend that CMS make every effort to incorporate the comments received up to and including this comment cycle, across the range of pending proposed regulations affecting the EHR incentive program and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)/MIPS/Advanced Payment Models (APMs), in order to set appropriate and achievable requirements and deadlines so that mid-year revisions are no longer necessary.

In addition to concerns with the creation of dual Medicare and Medicaid criteria, we highlight the proposed changes to the "Definition of 'EHR Reporting Period' and 'EHR Reporting Period for a Payment Adjustment Year.'" We certainly recognize that many providers have been calling for a change to 90-day reporting for 2016 and understand the benefits that this change will offer. Nonetheless, providers will not be notified of final changes that require a shorter reporting period until mid-way through the last possible reporting period of the year. Unfortunately, the lateness of this and other rules tends to create disincentives for engaging early in this and similar incentive programs, and even penalizes those who pursued a full year in good faith. We have seen similar impacts during the ICD-10 transition and prior late-breaking MU changes where delays in implementation deadlines led some providers to expect further delays or reduced scale, and those providers were unprepared as a result.

We also comment on a third example of mid-course adjustments that will create costs, including opportunity costs: the proposal, which we understand to take effect in 2017, for "Modifications to Measure Calculations to Actions Outside of the EHR Reporting Period." The EHRA previously estimated development time for making changes to measurement logic involving actions taken before, during, or after the measurement period. The average among our member companies is 155 hours per product, which totals 44,000 hours across the industry when all certified products are taken into account. This means that even what seems like a minor reporting change can be a significant investment for the entire industry, notwithstanding that most of our certified products are available and in use for the 2017 reporting year already and would require updates as a result of this proposed modification.

Given the industry-wide cost of such changes, we propose that they only be incorporated with Stage 3 reports for MU, when developers are already making changes, and not be required for continued participation in Stage 2.

In addition, we seek clarification on the proposed modifications to measure calculations related to actions outside of the EHR reporting period. Our understanding of this policy change is that only Objective 5, Health Information Exchange, would be affected, but we ask for confirmation or clarification in the Final Rule. CMS would be well served by listing the timing expectations for each objective explicitly. We also strongly recommend that CMS explicitly state in the Final Rule that these timing changes take effect only with the start of Stage 3.

Finally, CMS requested comments on whether these proposed changes should also apply for EHs and CAHs attesting under a state's Medicaid EHR incentive program. Consistent with our earlier statement on program alignment, the EHRA strongly recommends that every program be harmonized so that only one report is required per EHR product. One of our member companies conducted a survey of a representative set of hospitals that use their product, and found that greater than half of these hospitals indicate the importance of both the Medicare and Medicaid EHR incentive programs to them. The burden of participating in two separate programs with two sets of requirements (i.e., requiring two new reports) would be substantial to an estimated >50% of all EHs.

Changes to Medicare Meaningful Use Criteria

The Association is generally in support of the specific proposed changes that harmonize the existing EHR incentive program with MIPS. One benefit of the MIPS base and performance structure is that it relieves providers of the burden of meeting a variety of high measure thresholds that may not add value to their practices or patients. Eliminating measures and adjusting thresholds is a good, albeit incomplete, start toward what we believe should be much more complete convergence between the hospital EHR incentive program and the quality and Advancing Care Information (ACI) components of MIPS. That said, we defer our comments on most individual measure threshold changes to provider groups.

With regards to the Patient Access Measure, we appreciate the recognition of the complexity of application programming interface (API) and corresponding application roll-out. We note that both the MU Final Rule and this NPRM are very ambiguous regarding CMS's intent and definition of the API and of the application consuming the API that is actually accessible to the patient. The text in the MU Final Rule, which is not further clarified in this NPRM but built on, can be interpreted that providers are required to provide:

- The API;
- At least one application that consumes it; and
- A means to onboard patient-desired applications.

However, we have input from a CMS representative that only the API is required. We specifically ask that CMS provide clarity in the Final Rule and associated guidance emphasizing that the providers' obligation is only to make the **API available** (including documentation on how to connect to such API), and not the application(s) that could use the API. APIs may or may not (and traditionally do not) have user interfaces that make them directly accessible to patients; usually an application is required to provide patients access to their data.

At this late date, clarity on this requirement must be achieved quickly considering that 50% for both view/download/transmit (VDT) and API access is a high burden relative to the MIPS "one patient" plus performance approach. We request that CMS remove the ambiguity in this Final Rule.
We make ourselves available for a discussion on this topic.

We request clarification that measurement and documentation of API access not require the kind of detailed measurement that is often used for VDT access, focusing on providers' obligation to provide a process and material that shows that they are making the CEHRT API available for integration with application developers – analogous to the "active engagement" threshold for public health interfaces, which are also not in the complete control of providers and their CEHRT. We believe that this interpretation is correct based on our review of the current proposed and prior Final Rules and e-mail correspondence with CMS staff, but believe that very explicit CMS guidance on this issue would be helpful to providers.

The discussion of the Patient-Specific Education Measure in the proposed rule highlights a primary issue with this measure in its current or proposed specification – that patients may not desire or be able to access electronic education materials. Reducing the measure threshold does not address the fact that the mode of education delivery should be based on patient needs instead of requiring electronic delivery as the "Stage 3" specification does. Given that performance on this measure ranks alongside high performing, topped-out measures, we believe the industry is consistently providing education according to the needs of individual patients.

More generally, we caution CMS about updating measure thresholds each year, within stages of the EHR incentive program. Especially now that Stage 3 is intended to be the final stage, any updates to the measures and thresholds in future years are likely to cause substantial confusion for the provider community. To illustrate the changes made so far with regards to the ambulatory Medicare EHR incentive program, please see Appendix A below. Note that every measure change must be absorbed by the EHRs and providers, requiring updates to education, provider behavior, and product functionality.

Finally, CMS requested comments on how measures can be made more stringent in future years, consistent with the requirements of section 1886(n)(3)(A) of the Act. Overall, "stringency" does not necessarily need to translate into making every measure more stringent. Changes to the program should meet the goals of the Act, including improving patient care and effectively managing costs. Initiating a feasible program by setting realistic standards, maintaining stability by not introducing last-minute changes to programs, and tying the program to improved health outcomes will not only align the EHR incentive program with the MIPS, but will also create a more useful program overall. To quote the relevant part of the Act, "The Secretary shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph." "Stringent" is defined as "(of regulations, requirements, or conditions) strict, precise, and exacting." If the goal is to improve use of EHRs and health care quality, then the measures can be made more precise by becoming more focused on that goal. If performance on such measures improves, similar to the MIPS model of performance scoring in the ACI category, then the bar for achievement continues to rise and stringency is effectively in place.

In summary, we believe that changes to the EHR incentive program at this late date will have a very costly and negative impact on the program. We strongly recommend that CMS make every effort to incorporate these and earlier comments across the range of pending proposed regulations affecting the EHR incentive program and MACRA/MIPS/APMs in order to set appropriate and achievable requirements and deadlines so that mid-year revisions are no longer necessary.
Sincerely,

Sasha TerMaat
Chair, EHR Association
Epic

Richard Loomis, MD
Vice Chair, EHR Association
Practice Fusion

HIMSS EHR Association Executive Committee

Hans J. Buitendijk
Cerner Corporation

Leigh Burchell
Allscripts

Pamela Chapman
e-MDs

Sarah Corley, MD
NextGen Healthcare

Rick Reeves, RPh
Evident

About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of 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.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

Appendix A
Medicare EHR Incentive Program Changes

Medicare EHR Incentive Program Changes	Stage 1			
Measure/Objective	**2011**	**2012**	**2013**	**2014**
CPOE for Medication Orders	Core 1; 30%		Alternate measure	
Drug interaction checks	Core 2; Enabled			
Problem List	Core 3; 80%			
eRx	Core 4; 40%			
Medication List	Core 5; 80%			
Allergy List	Core 6; 80%			
Demographics	Core 7; 50%			
Vital Signs	Core 8; 50%		New age limitations	
Smoking Status	Core 9; 50%			
Report CQMs	Core 10; action completed			Removed
CDS rule	Core 11; 1 rule enabled			Core 10
Electronic health info to patients	Core 12; 50%			Removed
Clinical Summaries	Core 13; 50%			Core 12
Electronic exchange clinical info	Core 14; action completed		Removed	
Security Audit	Core 15; action completed		Core 14	Core 13
Drug formulary	Menu 1; enabled			
Lab results	Menu 2; 40%			
Patient List	Menu 3; action completed			
Patient Reminders	Menu 4; 20%			
Timely access patient records	Menu 5; 10%			Removed
Patient Education	Menu 6; 10%			Menu 5
Medication Reconciliation	Menu 7; 50%			Menu 6
Summary of care patient transitions	Menu 8; 50%			Menu 7
Immunization Registry Reporting	Menu 9; action completed			Menu 8
Syndromic Surveillance Reporting	Menu 10; action completed			Menu 9

Patient electronic access				Core 11; 50%
View Download Transmit				
CPOE Lab Orders				
CPOE Radiology Orders				
Secure Electronic Messaging				
Electronic Notes				
Imaging Results				
Family Health History				
Transition of Care Electronic				
Electronic Exchange Summary of Care				
Report Cancer Cases				
Report Specific Cases				
Specialized Registry Reporting				

Medicare EHR Incentive Program Changes	**Stage 2**			
Measure/Objective	**2014**	**2015**	**2016**	**2017**
CPOE for Medication Orders	0.6	Obj 3		
Drug interaction checks	Core 6	Obj 2		
Problem List	Removed			
eRx	Core 2; 50%	Obj 4		
Medication List	Removed			
Allergy List	Removed			
Demographics	Core 3; 80%	Removed		
Vital Signs	Core 4; 80%	Removed		
Smoking Status	Core 5; 80%	Removed		
Report CQMs				
CDS rule	Core 6; 5 rules enabled	Obj 2		
Electronic health info to patients				
Clinical Summaries	Core 8	Removed		
Electronic exchange clinical info				

Security Audit	Core 9	Obj 1		
Drug formulary	Core 2	Obj 4		
Lab results	Core 10; 55%	Removed		
Patient List	Core 11	Removed		
Patient Reminders	Core 12; 10%	Removed		
Timely access patient records				
Patient Education	Core 13	Obj 6		
Medication Reconciliation	Core 14	Obj 7		
Summary of care patient transitions	Core 15	Removed		
Immunization Registry Reporting	Core 16	Obj 10		
Syndromic Surveillance Reporting	Menu 1	Obj 10		
Patient electronic access	Core 7	Obj 8 Measure 1		
View Download Transmit	Core 7B; 5%	Obj 8 Measure 2; at least 1 patient		5%
CPOE Lab Orders	Core 1B; 30%	Obj 3		
CPOE Radiology Orders	Core 1C; 30%	Obj 3		
Secure Electronic Messaging	Core 17; 5%	Obj 9; Enabled	At least 1 patient	5%
Electronic Notes	Menu 2; 30%	Removed		
Imaging Results	Menu 3; 10%	Removed		
Family Health History	Menu 4; 20%	Removed		
Transition of Care Electronic	Core 15B; 10%	Obj 5; Summary of Care Record	Health Information Exchange	
Electronic Exchange Summary of Care	Core 15C; action completed	Removed		
Report Cancer Cases	Menu 5; action completed	Removed		
Report Specific Cases	Menu 6; action completed	Removed		
Specialized Registry Reporting		Obj 10; action completed		