



December 14, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 through 2017 [CMS-3310-FC and CMS-3311-FC]

Dear Acting Administrator Slavitt:

On behalf of the American College of Physicians (ACP), I am writing to share our comments on the Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule. The College is the largest medical specialty society and the second-largest physician membership organization in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the final rule. The following outlines ACP's assessment of the current state of Meaningful Use (MU) as well as provides specific suggestions for the future of the program. We ask that you please consider this letter as it reflects our members' concerns relevant to their practice experience and their ability to provide excellent care for their patients.

ACP's assessment of the current situation with MU:

- 1) MU has resulted in more than just mass adoption of electronic health records (EHRs). It has, at least for many clinicians, led to positive changes to workflow and patient engagement.

- 2) However, these positive changes have now given way to an expanding majority of physicians being dissatisfied with the program, and by extension, with EHRs and health information technology (health IT) in general. This anger and disengagement could be framed as, “[t]he very same digital infrastructure that was supposed to make healthcare operations more efficient not only doesn’t facilitate work – it has added burden.”
- 3) This is particularly problematic, as the implementation of the Merit-Based Incentive Payment System (MIPS) nears, physicians and other clinicians are nowhere near the point they need to be to successfully leverage advanced clinical capabilities of health IT to support value. And they are not likely to get to where they need to be when starting from a position of anger and disengagement.
- 4) A “game-changer” would be the ideal solution to health IT’s troubled recent past. Several prominent thought leaders have advanced this idea by suggesting that the MU program simply end with the introduction of MIPS in 2017; and that further health IT maturation and use be guided by what clinicians want and need to satisfy specific quality and value targets – rather than by regulations. Because the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) legislation specifically includes MU as a component of MIPS – that is not possible. Further, the ACP believes that it is not wise to end MU at this point; as there is still a continuing benefit that MU can bring to the process of health IT-enabled care improvement that would not come simply from the market demands of clinicians attempting to satisfy quality and cost metrics. However, we believe the only way to bring any positive value from an MU component within MIPS is to re-cast MU from a program that was reliant on achieving thresholds on EHR-functional-use measures – to one that is focused on quality and safety, and supporting ongoing learning.
- 5) The transition to MIPS in 2017 provides the opportunity to transform what is now Stage 3 of MU into the quality- and value-focused program described above. Instead of continuing down the same path with a stand-alone MU program through 2018, causing further disengagement among physicians, Stage 2 should continue until a more relevant MU program is developed and integrated into MIPS.

ACP’s assessment of the actual cause of most dissatisfaction with EHRs and other health IT – it is not MU per se, just some components of it:

- 1) At the outset, MU could not be judged on outcomes, as there were no validated eMeasures to measure outcomes, and most physicians and other clinicians were not

ready for new workflows enabled and required by newly emerging health IT in order to consistently achieve better outcomes. Hence the construct of a dual measurement system—pay-for-reporting of quality measures and pay-for-performance of EHR-use or functional measures—was developed.

- a) Whereas quality measures (QMs) by their nature differ widely from each other, and typically apply to physicians based on specialty and scope of practice; EHR-functional-use measures were developed predicated on the belief that the benefit of introducing health IT into any setting of care arose from using EHRs the same way – regardless of specialty and/or setting of care.
 - b) This then led naturally to uniform process measure development; something very different from QM development. QMs are developed by organizations with specific competencies, and are supported by evidence. They are expected to evolve over time, or even disappear, depending on evolving science. EHR-functional-use measures were developed via a political process, and largely supported by belief and/or self-referential logic. Thus, if the Health IT Policy Committee (HITPC) believes something is important and appropriate across all specialties, CMS proposes and then finalizes a rule. Performance against that measure is used as validation that the measure was appropriate. And most importantly, unlike clinical QMs, which will be withdrawn if the clinical practices they support are no longer valid (or even harmful), CMS will only remove a health IT process measure if it is “topped out, redundant, or duplicative.”
- 2) With the ascendancy of EHR-functional-use measures came the need for highly defined, and in our belief, highly prescriptive processes – as to make performance assessment and thus incentive payment “fair;” given what was required had to be measured in the same fashion across all settings of care.
 - 3) This then led to re-engineering of even high-performing EHRs such that the specific way they enabled defined processes could be accurately counted as per process measure definitions.
 - 4) For purposes of program integrity, thresholds had to be applied to these process measures, such that CMS had some objective approach to apply defined incentives.

Given the assessments outlined above, these are the principles that should guide development of a more meaningful MU program:

- 1) First, while MACRA mandates an MU component within MIPS, it does not specify what that component should look like. We believe that CMS has a golden opportunity then for an MU “do-over” – and a do-over that in our view should not be focused on incremental changes from the prior program. Rather, without the need for EHR-functional-use measurement – we believe the relevant question for CMS is, “what would otherwise be missing from technology or workflow, if EHR technology and use were only incented by quality and resource-use measures (as per the current Physician Quality Reporting System (PQRS) and Value-Based Payment Modifier (VBM) programs), as well as by clinical practice improvement activities?” This is where a new, more relevant MU program should be focused.
- 2) MU should then aim to fill in key gaps, and/or strive to incent optimization of value from health IT (based on specialty and setting of care). MU must permit and even encourage flexibility and innovation.
- 3) MU function measures should not be burdensome, and should be built into existing or emerging workflows, such that as care is provided, process or activity measurements can be auto-generated. Processes and/or activities would then be determined by specialty-specific best practices or even self-determined as quality improvement or value improvement projects are.
 - a. A broad range of measures and activities should be available for selection that meet the requirements of the broad variety of specialties and their specific information needs.
- 4) MU would then evolve from a top-down, one-size-fits-all mandate to a program where “meaningfulness” is determined by the clinician and/or specialty or professional society. While clinicians within MIPS need to satisfy the quality, resource-use, and clinical practice improvement categories, as well as MU, their MU activities should be in support of and **NOT** an additional set of unrelated requirements. For example, requiring clinicians to report on a separate set of clinical QMs for MU is duplicative and burdensome as they are already required to report on the same clinical QMs to fulfill the other components of MIPS. If this tailored approach is taken, then clinicians will want to participate in MU and the program then becomes truly meaningful as it

reinforces and helps to achieve the other components of MIPS and prepares clinicians for the future of healthcare delivery.

- 5) In defining new, more appropriate MU-function measures and activities, CMS and the Office of the National Coordinator for Health Information Technology (ONC) should start by collaborating with physicians and other clinicians to determine the key tasks that physicians and other clinicians and staff will need to perform better to improve care. This further flips the existing paradigm from health IT as an end point to health IT as enabling infrastructure – a means to an end. While some tasks could be performed more efficiently with better technology and standards, physicians should have opportunities to work on these tasks now, with sub-optimal technology approaches. There should not be requirements for mature standards and certification criteria before practices can begin work on activities such as smoothing out the wrinkles in care coordination and chronic care management. MU measures should not be defined only where standards and certification criteria exist. Measures and activities should challenge practices to work on solutions in advance of standards and certification criteria so that the learnings from the activities can better inform future standards and certification criteria.

ACP's Proposals for Stage 3 – MU inside of MIPS

1) Eliminate all EHR-functional-use measure thresholds

ACP Recommendation: We call for the elimination of thresholds on MU process measures.

We believe there is no place for the continuation of EHR-functional-use measure thresholds in this last stage of MU for these reasons:

- 1) There is no EHR-functional-use process that is or should be the same for all specialties and settings of care.
- 2) Where functional-use measure workflows are more consistent with what physicians naturally do, they are more likely to be successfully implemented as part of normal workflows. However, where such natural workflows do not exist, these physicians see them as annoying distractions and develop workarounds and/or gimmicks simply to try to achieve those thresholds.

- 3) For all physicians, their focus has shifted from using health IT intuitively to improve care, to achieving thresholds rather than improving care – and this has turned out to be a growing source of distraction and dissatisfaction.

On the other hand, EHR-functional-use data are most useful when they reflect actual workflow and not what is contrived to achieve a threshold of performance. Furthermore, learning is enhanced when data include naturally occurring variance, and is not restricted to the prescriptive definition of threshold achievement that CMS is currently using. Due to the threshold requirements, CMS only gets data from the relatively few successful attestors. We learn absolutely nothing from those who failed to attest. If thresholds were not required, we would have data from far more practices. These data could tell us volumes about what works, what does not work well, and the possible causes of variation. With health IT, as with clinical medicine, we will learn a great deal from the near misses.

2) Judiciously continue EHR-functional-use measurement reporting (without thresholds) to develop new learnings on health IT-enabled care

ACP Recommendation: We urge that EHR-functional-use measures be re-designed based upon available clinical evidence and evidence of value to the practice. EHR-functional-use measures should be judiciously developed, reviewed regularly, and revised while needed – similar to the processes used for QM maintenance.

Where key questions as to health IT processes persist, data collection and analysis should continue, as this may lead to a better understanding of what works well and under what circumstances. And further, this approach to EHR-functional-use measurement must avoid the prior pitfall of narrow and/or overly prescriptive definition – as that has been the cause of compliance-driven and/or duplicative clinical workflows, poor EHR usability, and distraction from the development of more usable and useful software.

Freeing up EHR developer time and focus should allow them to be both innovative and responsive to their customers (physicians), as well as permitting physicians to be innovative and more responsive to patients. It additionally permits physicians to use the next several years to develop and test “advanced clinical processes” such that they are better prepared for clinical practice and practice improvement – under either MIPS or an Alternative Payment Model (APM).

We believe this approach is responsive to the Health Information Technology for Economic and Clinical Health (HITECH) Act and MACRA (which requires an MU component within MIPS). Workflow processes that CMS and ONC feel are theoretically useful in improving care can be

engineered into EHRs and auto-reported. CMS and ONC could then collaborate on using these process data to **learn** – rather than to **grade**. With quality and resource utilization measurement already part of MIPS, CMS and ONC are now enabled to reverse their original paradigms of “pay-for-reporting” of quality and “pay-for-performance” of EHR functional use. The correct approach should be “pay-for-reporting” of EHR functional use and “pay-for-performance” of quality. This paradigm reversal would then provide trusted and useful data and eliminate what is now rampant—the use of workarounds and gimmicks to achieve EHR-functional-use thresholds. At this point in MU, the value of counting is not in measuring compliance to an EHR-functional-use threshold, but in supplying information to the Learning Health System (LHS) that the MU program should be supporting. In that fashion, MU can leave a legacy of embedded and continuous learning, rather than an inflexible and overly prescriptive set of process measures. We will later discuss how this new approach will still allow for allocating points that will count toward the MIPS composite score.

3) Demonstrate continuing education within the domains of health IT

ACP Recommendation: We propose that CMS/ONC work with the medical and other clinical professional societies to develop and carry out a broad-based health IT education program as a component of MU.

While it is now common for health systems to contain physicians and other clinicians in leadership positions who have advanced training in clinical informatics (Chief Medical Information Officers and Chief Nursing Information Officers), medical and graduate medical education does not yet consistently impart basic and specialty-specific education on health IT, such that patients can rest assured that their physicians have sufficient knowledge to use health IT wisely. More than anything else, physicians now need guidance, best practices, implementation strategies, and new ideas. One new activity should involve continuing medical education (CME) on health IT and data management topics.

To that end, we propose that CMS and ONC work with the physician professional and specialty societies to create or endorse relevant CME, and to jointly determine the amount and frequency of such health IT-related education. We suggest the following as examples of relevant modules for continuing education:

- a) Health IT to improve quality of care for patients, and where appropriate, to improve quality for select populations;
- b) Safe use of health IT – where the focus is on reducing errors of both omission and commission;

- c) Health IT to improve value; and
- d) Health IT to engage patients and families

4) Advance practical interoperability

ACP Recommendation: EHR-functional-use measurement of data exchange should not specify the data to be exchanged.

Interoperability cannot be defined as the movement of structured sets of non-contextual data from place to place without a defined purpose. Each instance of interoperability is performed for a specific purpose and in a specific clinical context. Government regulators should not believe that it is appropriate for them to define sets of data that must be exchanged regardless of the specific context. MU has been built on the assumption that more data are always better for healthcare.

Physicians and other clinicians understand that caring for the health of humans is never cut and dried. Patients are like snowflakes – each is different from every other in ways that are often relevant to care decisions. Clinical observation data are not the clear, crisp facts that CMS and other regulators assume in their program designs. Observation data are fuzzy, context sensitive, and inaccurate. The job of physicians and other clinicians is to interpret messy and incomplete data, and to apply where possible precision judgment to the patient at hand.

The content of every data exchange should always be determined by the participants in the transaction. There is no benefit to the system in requiring the exchange of unwanted data. As long as the recipient in an exchange is able to request specific additional data, there is no need to specify required elements beyond showing that it can be done. Any measure that sets data requirements for a data exchange is imposing unjustifiable burden and waste on the participants in the exchange. Data exchange measures in MU are relevant to test and demonstrate exchange capabilities. They should not be applied to actual transactions involving the care of real patients. CMS should be willing to accept eligible professional (EP) and patient decisions regarding data to be exchanged. They should not impose friction on clinical processes for any purpose.

5) Support bi-directional and less burdensome reporting to public health

ACP Recommendation: All reporting measures should include a bi-directional component that is useful and timely. Reporting entities should be required to work towards accepting the export of a Summary of Care Document (SoCD) and minimize or eliminate any requirements

for duplicative documentation into a separate electronic form. Variation in rules and content definitions among organizations accepting reports should be eliminated.

We are most concerned with three aspects of public health reporting requirements. First, with the exception of immunizations, they are all one-way. EPs and eligible hospitals (EHs) must collect and supply data to target agencies, and there is no requirement for these agencies to report back to the EPs and EHs. Without the requirement for bi-directional data flow, these reporting requirements are framed as clerical and reporting burden, rather than providing mutual benefit. Patients and their doctors will benefit greatly from requirements that public health agencies report back in a timely manner and with meaningful data, such as intelligence about what is happening in the community.

Secondly, we are concerned that there is an expectation that public health reporting will require duplicative documentation into an electronic form, rather than the reporting system accepting the export of a SoCD. As long as the requirements for public health reporting remain solely on EPs and EHs, public health authorities will have no reason to work to coordinate and simplify reporting requirements.

And finally, we are concerned with the requirement that EPs and EHs implement a separate interface to each reporting entity. The ACP believes that significant costs and effort could be saved by requiring that reporting entities work together to simplify reporting burden. We believe this could be accomplished with the development of a standard Application Programming Interface (API) for all public health, quality, and registry reporting.

6) Develop and use flexible measures of patient engagement that respect patient and family needs and preferences

ACP Recommendation: We recommend that measures of patient engagement shift from the existing one-size-fits-all prescriptive process measures, to attestations of patient engagement activities that reflect the setting of care, context, and patient needs and preferences. EPs should have the option to develop a case report describing a patient engagement problem and the actions the practice took, including use of health IT, to resolve the problem.

By being written as generic “one-size-fits-all” patient engagement process measures, clinicians have had to focus on the performance of specific tasks, without regard to the setting of care or patient needs and/or preferences.

7) Encourage clinician engagement and innovation by allowing for new types of activities to replace existing measures

ACP Recommendation: We support the MACRA requirement that there be a variable score for MU activities. With the move from an all-or-nothing, pass-fail scoring system to a flexible system where EPs can select appropriate activities to accumulate points, we have the opportunity to abandon the one-size fits-all approach that has been used thus far. Rather than presenting a short list of options with few that truly apply to any practice situation, we can now provide EPs with a long list of activities from which to choose those that truly fit. While MACRA includes practice improvement as a component of MIPS, we feel that health IT-related projects should count as meaningful use of health IT.

It is critical that MU shift away from requiring EPs to demonstrate abilities to perform activities using EHRs whether appropriate or not. MU should consist of a broad collection of measures and activities that will help practices work on what they consider their key problems and needs. EPs should be able to select broadly defined activity areas in which they plan, implement, study and report specific interventions that they feel will help them move ahead.

The following are several examples offered in order to start a discussion on what might prove more valuable and meaningful, and to whom:

a) Precision Medicine - Participate in an LHS or other observational study effort

We agree with the emphasis that the administration has placed on precision medicine. In order for the initiative to live up to its promise, it cannot be limited to academic medical centers. No matter what their specialty, EPs may find value in getting involved with an observational study or any other activity that might be considered as evidence-generating medicine. They could run phenotyping algorithms on their data and contribute the results. They could use existing data collections such as the Observational Health Data Sciences and Informatics program (OSHDI) or a Precision Medicine Initiative (PMI) grantee, to identify appropriate treatment patterns for specific patients based upon social determinants they have collected. This alone could be considered sufficient to demonstrate MU. The organization with which they work could document the participation of EPs. This is the future of the meaningful use of health IT. ONC needs to identify and fill the gaps in standards that currently prevent full participation in precision medicine by practices that are not directly connected to academic medical centers.

b) Participation in Practice-Based Research

Participation could range from contributing de-identified data to patient education and/or recruitment for clinical trials, and for others, taking an active role as a co-investigator. Participation in practice-based research might be considered to fall into the category of practice improvement activities. However, practices have found that using the EHR and other health IT for practice-based research projects has been a very successful way to engage physicians in both the provision of care and in gaining understanding of the value of health IT in improving practice.

c) Health IT Iterative Improvement

When the dynamic of health IT design and use shifts from top-down to bottom-up, clinicians and other healthcare providers and staff have the opportunity to contribute to and even “co-own” the software personalization that helps them to consistently deliver better care. One approach that has worked well in other fields is the use of a context-aware “Feedback” button. Certified EHR systems should have a “Feedback” mechanism available such that EHR users quickly and easily collect context sensitive thoughts on the spur of the moment for submission to a vendor-managed improvement list or user-group, or for later consideration and elaboration.

d) Health IT Innovation

CMS should create a measure for reporting on an innovation involving health IT that EPs could report each year using a specified format. A simple example might be a data quality improvement project aimed at fixing variation in how a particular data element is collected at the point of care. Another example might be using health IT to identify patients that have not had preventive services and what processes have been put into place to notify them. Also, a practice could decide to work with heavily used referral partners to improve coordination and ensure better patient involvement.

e) Patient Safety and Near Miss Reporting

EPs should have the ability to easily report patient safety, adverse events, and near miss reports directly from the EHR system. While the point value would be expected to be low for a single completed report, the value to healthcare is sufficient to make this an MU activity. Safety reporting levels are unacceptably low, and MU can help to resolve this problem.

f) Development of Quality eMeasures

Our current system for developing QMs is not working well enough. (Please see our letter that was submitted to CMS on the Request for Information related to MACRA for a full discussion of our measurement concerns:

https://www.acponline.org/acp_policy/letters/acp_comment_letter_macra_rfi_2015.pdf.) We do not have a broad enough set of QMs, and many existing measures are of

such poor quality that they should not be used. Further, attempts to create eMeasures have resulted in an entirely new set of data quality problems. EPs should get credit for proposing measures that conform to the constraints of a defined template and that use existing EHR data. These eMeasures should measure implementation of evidence-based care. Registry technologies, such as Qualified Clinical Data Registries (QCDRs), offer a way for clinicians and practices to collect encounter data and analyze them for opportunities to measure and improve quality. Such a platform will provide the opportunity to focus on what truly matters at the individual- and practice-level.

We thank you for seeking our input on these important issues, and hope that you will find value in our response. Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at tkuhn@acponline.org.

Sincerely,

A handwritten signature in black ink, appearing to read "P Basch", with a long horizontal flourish extending to the right.

Peter Basch, MD, MACP
Chair, Medical Informatics Committee
American College of Physicians