



May 28, 2015

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

**Re: 80 FR 16731; Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3; Proposed Rule [RIN 0938-AS26]**

**Dear Administrator Slavitt:**

On behalf of the American College of Physicians (ACP) I am writing to share our views on the Electronic Health Record Incentive Program-Stage 3 proposed rule. ACP is the largest physician medical specialty society, and the second largest physician membership organization in the United States. ACP members include 141,000 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 this proposed rule.

The ACP applauds the CMS staff for their diligence and hard work in developing this proposal for Stage 3 of the Electronic Health Record Incentive Program. We ask that you please consider this letter and the attached comment table, containing comments from ACP's Medical Informatics Committee, as they reflect concerns of our members relevant to their practice experience and their ability to provide excellent care for our patients. Some of the key themes and recommendations from the comment table are summarized below.

Most importantly, at the time CMS and ONC posted the Meaningful Use (MU) Stage 3 and 2015 Certification proposed rules (March 20, 2015), and even the Stage 2 Modification proposed rule (April 10), no one could have known that Congress would pass the MACRA on April 14. The MACRA is now law, and it requires modifications to the EHR Incentive Program as well as the PQRS and VBM programs. At a

minimum, MU must be modified to deal with group reporting, virtual groups, risk adjustment, and the fact that the program will no longer apply to many, perhaps most, EPs who will be participating in Alternative Payment Models (APMs). CMS has an opportunity to reexamine all of these programs in light of their new role in moving the country to a new, value-based payment and healthcare delivery system. We see this opportunity as a chance to rethink everything that we do regarding quality and value, and develop a comprehensive new approach that meets the needs of our members and their patients.

**We urge CMS and ONC to make the most of the opportunity presented by MACRA by postponing the start of Stage 3, reconsidering and reworking MU along with the other components of MIPS, and by extending the proposed Stage 2 modifications, as revised, until the new comprehensive program is ready to be implemented.**

We appreciate CMS's efforts to create a glide path to a single stage of Meaningful Use (MU) with a single set of rules or measures as we believe this will ease the transition into the MIPS program. However, we do not believe the proposed set of measures and rules are correct. CMS has opted for easily quantified process measures, as opposed to outcomes based measures that result in improvement of care delivery through the use of health IT.

The proposed prescriptive process measures do not sufficiently encourage marketplace innovation, and will soon be outdated. If the proposal is finalized, the vendor software design and build decisions will conform to CMS's prescriptive definitions, which will constrain usability. The rule should accommodate specialty and scope of practice specific outcome measures, creating a process that allows for revision as these outcome measures are developed and improved.

CMS should not further decrease variation in reporting requirements between specialties and provider settings, in an effort to streamline the process. A one size fits all approach generates criticism of clinical inappropriateness, and is not reflective of the optimization of health IT across the spectrum.

Public health and clinical data registries should support the bidirectional exchange of health information with providers that is mutually beneficial for both parties involved. As proposed, Eligible Professionals (EPs) and Eligible Hospitals (EHs) must collect and supply data to target agencies without receiving information in return, which amounts to clerical data entry rather than truly meaningful use. Patients and providers would benefit greatly from the availability of timely public health data.

CMS should address the lack of registry readiness, in certain areas, to accept data. Information about public health and clinical data registries should be made available on CMS's website, and measure exclusions should be provided when relevant.

CMS should ensure that public health reporting will not require duplicative documentation into an electronic form. All public health authorities must be compelled to coordinate and simplify reporting requirements, such as accepting the export of a Summary of Care Document.

Thinking about the final stage of MU proactively, there are other things that should be considered, and could take the place of prescriptive process measures. These relate to general competencies of EHR use that pertain to safety, quality, value, and patient engagement. Rather than being prescriptive, they could be developed in conjunction with the appropriate specialty and professional societies. These could include:

- Annual program / CME re competency in EHR safety. ONC could author course and regular updates, in partnership with relevant specialty and professional societies.
- Annual program / CME re competency of EHR to improve quality and/or population health. ONC could author course and regular updates, in partnership with relevant specialty and professional societies.
- Annual program / CME re competency of EHR to improve value. ONC could author course and regular updates, in partnership with relevant specialty and professional societies.
- Annual program / CME re EHR use and patient engagement. ONC could author course and regular updates, in partnership with relevant specialty and professional societies.

We hope that these comments will aid in developing a more appropriate MIPS-related stage of the MU program. In addition, we hope that there will be regular opportunities for us to be involved in future updates to the MU program. Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at [tkuhn@acponline.org](mailto:tkuhn@acponline.org).



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American College of Physicians

Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**COMMENTS DUE:** May 29, 2015

Excerpts from the MU Stage 3 Proposed Rule	Medical Informatics Committee Comments
<p><b>Purpose of Regulatory Action</b></p> <p>In this proposed rule, we specify the policies that would be applicable for Stage 3 of the Medicare and Medicaid EHR Incentive Programs. Under Stage 3, we are proposing a set of requirements that EPs, eligible hospitals, and CAHs must achieve in order to meet meaningful use, qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs, and avoid downward payment adjustments under Medicare.</p> <p>Stage 3 of meaningful use is expected to be the final Stage and would incorporate portions of the prior Stages into its requirements. In addition, following a proposed optional year in 2017, beginning in 2018 all providers would report on the same definition of meaningful use at the Stage 3 level regardless of their prior participation, moving all participants in the EHR Incentive Programs to a single Stage of meaningful use in 2018.</p>	<p>As the process stands now, Stage 3 of MU will not exist as a stand-alone program at all. By 2017, MU will be a component of MIPS, with a far different set of goals and objectives. We urge CMS and ONC to make the most of the opportunity presented by MACRA by postponing the start of Stage 3, reconsidering and reworking MU along with the other components of MIPS, and by extending the proposed Stage 2 modifications, as revised, until that new comprehensive program is ready to be implemented. It would be better for all if CMS simply extended its modified plan for 2015-2017 to cover 2018. This will save everyone from the heavy lift of a new program for 2018 and the expected heavy lift for a new program that will begin in 2019 to meet the requirements of the MIPS program.</p> <p>We are concerned that, as proposed, Stage 3 of MU will not encourage innovation and will be out of date as early as 2018. The continuation of process measures with thresholds means that prescriptive definitions (including the difficulty in understanding exactly what they mean in practice), will control EHR software design and vendor build decisions, testing, certification, and will continue the problems with usability made worse by regulatory process. The final and open-</p>

ended stage of meaningful use will become a fundamental part of the post-SGR Medicare world for the foreseeable future. This proposal should be based on outcome measures (as they are developed and improved) that are specialty and scope of practice specific so that they are actually meaningful to physicians, which the current process measures are not.

If the focus of MU continues to be on process measures, then physicians will need to continue to develop workflows to report on those measures to meet regulatory requirements – these workflows are not aligned with providing patient care in a proactive, high value way that also includes managing the health of a practice's patient population.

It would be a disaster for physician engagement (including physicians desiring to stay within the Medicare program) if a system exists in perpetuity where our best performers could be ultimately judged and financially penalized by MU remnants resulting in "gotchas."

We do appreciate the effort to have a glide path to a single Stage of meaningful use, which includes one set of rules or measures, as this will ease the transition to MIPS. We do not believe that the measures and rules proposed here are the right sets. CMS has chosen measures that can be counted easily rather than measures that would demonstrate the results of improvements in care through the use of health IT.

Additionally, we are concerned about the ability of EPs who have been left behind to catch up. The cost burdens of all of the

	<p>additional technology required to meet inappropriate thresholds plus the costs involved in managing the processes and dealing with a poorly designed and poorly executed audit process have proven too much for many small and medium practices to bear.</p> <p>Please note that in the financial projections, CMS has projected that the nearly 51% of physicians who have already either failed or didn't care to attest for Meaningful Use in 2013 and 2014, will become reengaged; as CMS apparently anticipates something closer to a 5% failure rate for 2018, the first year of Stage 3. We do not see how such a low failure rate projection can be justified, given current data.</p>
<p><b>Meaningful Use in 2017 and Subsequent</b></p> <p>All providers, other than Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time, would be required to attest based on a full year of data for a single set of meaningful use objectives and measures to demonstrate Stage 3 of meaningful use, which is proposed as optional for an EHR reporting period in 2017 and mandatory for an EHR reporting period in 2018, and subsequent years for all providers participating in the Medicare and Medicaid EHR Incentive Programs.</p>	<p>Experience has shown that new physicians and physicians switching EHRs have more difficulty attesting to a full calendar year. Every practice needs to set aside months of time to convert systems, transfer data, retrain staff, and start from the beginning to re-analyze and rework the roles and workflows to accommodate the requirements of the new system. The rationale for eliminating 90-day attestation periods is not clear to us, except that it makes program management easier.</p>
<p><b>Calendar Year Reporting</b></p> <p>We are proposing to change the definitions of "EHR reporting period" and "EHR reporting period for a payment adjustment year" under § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would be one full calendar year, with a limited exception under the Medicaid EHR Incentive Program for providers</p>	<p>Experience has shown that new physicians and physicians switching EHRs have more difficulty attesting to a full calendar year. The rationale for eliminating 90-day attestation periods is not clear to us, except that it makes program management easier.</p>

<p>demonstrating meaningful use for the first time as discussed later in this section and in section II.A.2.b. of this proposed rule.</p>	
<p><b>Eliminate 90 day EHR reporting period</b></p> <p>We are further proposing to eliminate the 90-day EHR reporting period for new meaningful EHR users beginning in 2017, with a limited exception for Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time.</p>	<p>Experience has shown that new physicians and physicians switching EHRs have more difficulty attesting to a full calendar year. The rationale for eliminating 90-day attestation periods is not clear to us, except that it makes program management easier.</p> <p>Full-year reporting requires folks who are trying to catch up to collect data for a year, only to find they fall short and then have to wait another year to try again. Every practice needs to set aside months of time to retrain staff, and start from the beginning to re-analyze and rework the roles and workflows to accommodate the requirements of the measures that gave them difficulty. A 3-month reporting period allows EPs to find shortcomings, implement corrective actions, and catch up.</p>
<p><b>Criteria for MU Stage 3</b></p> <p>Many of the recommendations CMS/ONC received included allowing a provider to fail any two objectives (in effect making all objectives "menu" objectives) and still meet meaningful use, or to allow providers to receive an incentive payment or avoid a downward payment adjustment based on varied percentages of performance, and removing all measure thresholds.</p> <p>...For these reasons, we intend to continue to require providers to meet the objectives and measures of meaningful use as required for the program, rather than allowing providers to fail any two objectives of their choice or making all objectives menu objectives.</p> <p>Therefore, our proposals for Stage 3 would continue the precedent of focusing on the advanced use of certified</p>	<p>CMS has made a mistake by choosing to respond to criticism of a one-size-fits-all definition of meaningful use by further removing the differences between EPs and eligible hospitals. The approach may seem to simplify criteria, but it actually precludes what should be seen as enabling infrastructure able to support many different specialties and many environments. As long as the same set of rules applies for all doctors in all specialties and scopes of practice, there will always be legitimate criticism that what is required is clinically inappropriate, and not reflecting optimization of health IT for that field of practice.</p>

<p>EHR technology. They would reduce the reporting burden; eliminate measures that are now redundant, duplicative, and "topped out"; create a single set of objectives for all providers with limited variation between EPs, eligible hospitals, and CAHs as necessary; and provide flexibility within the objectives to allow providers to focus on implementations that support their practice.</p> <p>We welcome public comments on our proposed approach for topped out objectives and measures.</p>	<p>While the selection of measures may fit a primary care workflow, the way that care coordination and patient engagement are defined will fit poorly in the workflows of other specialties. A single set of objectives with limited variation between EPs will result in clinically irrelevant burdens for most.</p> <p>We have no objection to CMS using any criteria they would like to remove processes and workflows from process measurement. That said, the conclusion that a measure is "topped out" might only be reflecting an approach to compliance, rather than certainty that a particular process has been so thoroughly mastered. To be fair, CMS does point out that their determination of something being "topped out" does not mean that the process is not deserving of further consideration. We think it's important to call this out, as in fact the study of patient safety and near misses is based on looking closely at the exceptions to 100%.</p> <p>While examination of attestation percentages of successful EPs might suggest capabilities of those EPs, this does not allow CMS and ONC to say anything about the capabilities of the far larger group of unsuccessful EPs. Our examination of a small sample of REC data shows many clear reasons why EPs were unsuccessful. Rather than base MU requirements on the perceived capabilities of successful attestors, CMS and ONC must address the causes for failure of the majority of EPs.</p>
<p><b>Electronic Versus paper-based Objectives and Measures</b></p> <p>In Stages 1 and 2, we require or allow providers the option to include paper-based formats for certain</p>	<p>This is reasonably expressed, and consistent with the focus on electronic communications. However, it is important</p>

<p>objectives and measures. For these objectives and measures, providers would print, fax, mail, or otherwise produce a paper document and manually count these actions to include in the measure calculation.</p> <p>This does not imply that we do not support the continued use of paper-based materials in a practice setting. Some patients may prefer to receive a paper version of their clinical summary or may want to receive education items or reminders on paper or some other method that is not electronic. We strongly recommend that providers continue to provide patients with visit summaries, patient health information, and preventative care recommendations in the format that is most relevant for each individual patient and easiest for that patient to access. In some cases, this may include the continued use of non-IT-based resources. We are simply proposing that paper-based formats would not be required or allowed for the purposes of the objectives and measures for Stage 3 of meaningful use. We welcome public comments on this proposal.</p>	<p>to note that physicians must then reframe how they request patient preferences to address the patient's preferred communication style, noting that they will largely communicate electronically, but also on paper if desired.</p>
<p><b>Objectives and Measures for Meaningful Use in 2017 and Subsequent Years</b></p> <p><b>Protect Patient Health Information:</b> Foundational to Meaningful Use and Certified EHR Technology; Recommended by HIT Policy Committee</p> <p><b>Electronic Prescribing (eRx):</b> Foundational to Meaningful Use; National Quality Strategy Alignment</p> <p><b>Clinical Decision Support (CDS):</b> Foundational to Certified EHR Technology; Recommended by HIT Policy Committee; National Quality Strategy Alignment</p> <p><b>Computerized Provider Order Entry (CPOE):</b> Foundational to Certified EHR Technology National; Quality Strategy Alignment</p> <p><b>Patient Electronic Access to Health Information:</b> Recommended by HIT Policy Committee National; Quality Strategy Alignment</p>	<p>The College is concerned that CMS and ONC's monitoring and review process only focuses on EPs and whether or not they are able to meet these objectives. We strongly recommend that the agencies implement other approaches, involving additional critical stakeholders such as payers and PBMs, given that there are many elements of these measures that are not within the control of the EP.</p> <p>For example, one of the rationales for continuing to have a process measure for ePrescribing, is that more work remains to be done. We are certain that in any given year, this conclusion will be the same. The current ePrescribing system does not provide prescribers and their patients with accurate and complete information on drug availability and pricing, as well as patient</p>

<p><b>Coordination of Care through Patient Engagement:</b> Recommended by HIT Policy Committee; National Quality Strategy Alignment</p> <p><b>Health Information Exchange (HIE):</b> Foundational to Meaningful Use and Certified EHR Technology; Recommended by HIT Policy Committee; National Quality Strategy Alignment</p> <p><b>Public Health and Clinical Data Registry Reporting:</b> Recommended by HIT Policy; Committee National Quality Strategy Alignment</p> <p>CMS and ONC will continue to monitor and review performance on the objectives and measures finalized for Stage 3 to continue to evaluate them for rigor and efficacy and, if necessary, propose changes in future this is rulemaking.</p>	<p>benefit eligibility. While efforts are underway to enhance the technical standards in use, no efforts are being expended by anyone in CMS or ONC to compel improvements to the data supplied by the payers and PBMs. We need assurance that CMS and ONC are willing to use other tools at their disposal, which include removing a measure or imposing requirements on other participants.</p> <p>For a thorough discussion of our ePrescribing concerns, see below where the ePrescribing objective is discussed.</p>
<p><b>Flexibility within Meaningful Use Objectives and Measures</b></p> <p>We are proposing to incorporate flexibility within certain objectives proposed for Stage 3 for providers to choose the measures most relevant to their unique practice setting. This means that as part of successfully demonstrating meaningful use, providers would be required to attest to the results for the numerators and denominators of all measures associated with an objective; however, a provider would only need to meet the thresholds for two of the three associated measures.</p> <p>We propose that if a provider meets the exclusion criteria for a particular measure within an objective which allows providers to meet the thresholds for two of three measures (namely, the Coordination of Care through Patient Engagement objective and the Health Information Exchange objective), the provider may exclude the measure and must meet the thresholds of the remaining two measures to meet the objective. If a provider meets</p>	<p>The approach to exclusions is reasonable; however, true flexibility would allow for providers in all specialties and scopes of practice to satisfy a measure using workflows appropriate to their specialties.</p>

<p>the exclusion criteria for two measures for such an objective, the provider may exclude those measures and must meet the threshold of the remaining measure to meet the objective. If a provider meets the exclusion criteria for all three measures for such an objective, the provider may exclude those measures and would be considered to have met the objective.</p>	
<p><b>Denominators</b></p> <p>We propose to maintain the policy that EPs who practice at multiple locations or switch CEHRT during the EHR reporting period may determine for themselves the method for counting unique patients in the denominators to count unique patient across all locations equipped with different CEHRT, or to count at each location equipped with CEHRT. In cases where a provider switches CEHRT products at a single location during the EHR reporting period, they also have the flexibility to count a patient as unique on each side of the switch and not across it. EPs in these scenarios must choose one of these methods for counting unique patients and apply it consistently throughout the entire EHR reporting period.</p> <p>A patient is seen by the EP when the EP has a real time physical encounter with the patient in which they render any service to the patient. We also consider a patient seen through telehealth as a patient "seen by the EP" (telehealth may include the commonly known telemedicine as well as telepsychiatry, telenursing, and other diverse forms of technology-assisted health care).</p>	<p>This proposed flexibility in denominator definition is encouraging and appreciated.</p> <p>A nephrologist seeing patients and documenting in the DaVita dialysis system and on a different system in their office (and perhaps a third system at their hospital, not to mention multiple hospitals) is not going to be able to achieve this. The rule must account for the fact that many subspecialists must deal with the fact that much of their data are collected and maintained in non-certified specialty systems that do not interoperate with certified EHR systems.</p> <p>More clarity is needed in the definition of "telehealth." We are concerned that this paragraph goes on to describe a "virtual visit" as a non-telehealth visit. This does not accommodate chronic care management (CPT 99490), which does not have a face-to-face encounter, is not a true telehealth benefit under the Medicare program, and is supposedly applicable to 2/3 of Medicare beneficiaries.</p>
<p>However, in cases where the EP and the patient do not have a real time physical or telehealth encounter, but the EP renders a consultative service for the patient, such as reading an EKG, virtual visits, or asynchronous telehealth, the EP may choose whether to include the patient in the denominator as "seen by the EP." This is necessary so that these providers can avoid reporting a zero in the denominator and be able to satisfy meaningful use.</p>	<p>As above, this does not accommodate chronic care management (CPT 99490).</p>

However, we stress that once providers choose, they must maintain that denominator choice for the entire EHR reporting period and for all relevant meaningful use measures.

- Office visits. The denominators of the measures that reference "office visits" may be limited to only those patients whose records are maintained using CEHRT. An office visit is defined as any billable visit that includes the following:

- ++ Concurrent care or transfer of care visits,

- ++ Consultant visits, or

- ++ Prolonged physician service without direct, face-to-face patient contact (for example, telehealth).

- All medication, laboratory, and diagnostic imaging orders created during the reporting period

- Transitions of care and referrals including at least--

- ++ When the EP is the recipient of the transition or referral, the first encounter with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving EP; and

- ++ When the EP is the initiator of the transition or referral, transitions and referrals ordered by the EP.

Transitions of care are the movement of a patient from one setting of care to another. Referrals are cases where one provider refers a patient to another, but the referring provider maintains their care of the patient as well. For the purposes of distinguishing settings of care in determining the movement of a patient, we propose that a transition or referral may take place when a patient is transitioned or referred between providers with different billing identities, such as a different National Provider Identifier (NPI) or hospital CMS Certification Number (CCN). We also propose that in the cases where a provider

As above, this does not accommodate chronic care management (CPT 99490).

We find the definition of transition of care and referrals confusing and potentially problematic. A transition occurs when the EP is the recipient of the transition or referral. After four years of trying to use the definition of a transition to establish a denominator for medication reconciliation, we believe this is problematic. For example, EPs often ask patients if they have been to another physician, emergency room, or been hospitalized since their last visit. Often they do not exactly recall, so time is spent trying to establish a timeline. And even when they can answer, they may have been to another physician within the health system. So really the transition has already been managed. It is too complicated to ask, "Have you been to another physician, or had an ED visit or hospitalization outside

<p>has a patient who seeks out and receives care from another provider without a prior referral, the first provider may include that transition as a referral if the patient subsequently identifies the other provider of care.</p> <p>For further explanation of the terms "unique patient," "seen by the EP," "office visit," "transitions of care," and "referrals," we refer readers to the discussion at 77 FR 53982 through 53983.</p>	<p>of XYZ Health System, and if so, am I the first physician in XYZ Health System that you have seen since that last visit/ED visit/hospitalization?" Answering that question may take up the entire 15 minute office visit. On the other hand, there are many circumstances where a "transition" as defined has not taken place, but the EP determines that a measureable action, such as medication reconciliation is indicated. Arriving at the denominator may be the most complicated part of measures involving transfers. A better approach for CMS is to accept clinician judgment as to the definition, and to accept the resulting data as helpful in better understanding the true nature of transitions in the future.</p>
<p><b>Patient-Authorized Representatives</b></p> <p>In the Stage 3 Coordination of Care through Patient Engagement objective and the Patient Electronic Access objective outlined in section II.A.1.c.(2).(i). of this proposed rule, we propose the inclusion of patient-authorized representatives in the numerators as equivalent to the inclusion of the patient. We recognize that patients often consult with and rely on trusted family members and other caregivers to help coordinate care, understand health information, and make health care decisions. Accordingly, as part of these objectives, we encourage providers to provide access to health information to patient-authorized representatives in accordance with all applicable laws. We expect that patient-authorized representatives accessing such information under these objectives could include a wide variety of sources, including caregivers and various family members.</p>	<p>We support this proposal. Physicians and staff often misunderstand HIPAA and subsequently refuse to appropriately disclose information to a patient authorized representative.</p>
<p><b>Objective 1: Protect Patient Health Information</b></p> <p><b>Proposed Objective:</b> Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of</p>	<p>We agree with the intent of proposed measure #1; however, small or even medium size practices will not have the expertise to do this, nor be able to afford to</p>

<p>appropriate technical, administrative, and physical safeguards.</p> <p><b>Proposed Measure (objective 1):</b> Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.</p> <p>We propose that the timing or review of the security risk analysis to satisfy this proposed measure must be as follows:</p> <ul style="list-style-type: none"> <li>• EPs, eligible hospitals, and CAHs must conduct the security risk analysis upon installation of CEHRT or upon upgrade to a new Edition of certified EHR Technology.</li> </ul> <p>The initial security risk analysis and testing may occur prior to the beginning of the first EHR reporting period using that certified EHR technology.</p> <ul style="list-style-type: none"> <li>• In subsequent years, a provider must review the security risk analysis of the CEHRT and the administrative, physical, and technical safeguards implemented, and make updates to its analysis as necessary, but at least once per EHR reporting period.</li> </ul>	<p>do it. Further, we are concerned about consulting firms attempting to sell small practices more than is necessary to achieve the desired result. Therefore, ONC would be doing a public service by including a free toolkit for this, periodic surveys for cost and burden of accomplishing this, and periodic surveys to see if existing approaches are actually effective.</p>
<p><b>Objective 2: Electronic Prescribing</b></p> <p><b>Proposed Objective:</b> EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).</p> <p>We propose to continue to define "prescription" as the authorization by a provider to dispense a drug that would not be dispensed without such authorization.</p> <p>This includes authorization for refills of previously authorized drugs. We propose to continue to generally</p>	<p>We support the approach CMS and ONC are taking to electronic prescription of controlled substances.</p>

define a "permissible prescription" as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II-V (DEA website at <http://www.deadiversion.usdoj.gov/schedules/index.html> (77 FR 53989) with a slight modification to allow for inclusion of scheduled drugs where such drugs are permissible to be electronically prescribed.

Therefore, we are proposing that providers who practice in a state where controlled substances may be electronically prescribed who wish to include these prescriptions in the numerator and denominator may do so under the definition of "permissible prescriptions" for their practice. If a provider chooses to include such prescriptions, they must do so uniformly across all patients and across all allowable schedules for the duration of the EHR reporting period.

**Proposed EP Measure (objective 2):** More than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

We believe that with continued experience with this objective and the continued expansion of the pharmacy market acceptance of electronic prescriptions, providers can meet an even higher threshold and should be encouraged to do so in line with the statutory directive to seek to improve the use of EHRs and health care quality over time by requiring more stringent measures of meaningful use (see section 1848(o)(2)(A)(iii) of the Act). Therefore, we are proposing a threshold of 80 percent for this measure for Stage 3.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period or Number of prescriptions written for drugs requiring a prescription in order to be dispensed during the EHR reporting period.

This metric should not be continued in Stage 3. While ePrescribing is specifically called out in the HITECH Act, we request independent verification that there is a legislative requirement for continuance of this process measure. EPrescribing more than meets the definition of a "topped out" measure, as CMS claims that the mean rate of ePrescribing by those who have attested to meaningful use is greater than 90%. CMS justifies continuing this as a process measure, as "providers can meet an even higher threshold and should be encouraged to do so, in line with the statutory directive." The statutory directive does not say that all prescription should be sent electronically. If CMS would like to see a threshold closer to 100%, it should mandate ePrescribing as a condition of Part D. It should not push physicians to the point of unreasonableness, where patients are free to decline.

Further, while CMS is correct that there are many aspects of ePrescribing that should

<p><u>Numerator:</u> The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.</p> <p><u>Threshold:</u> The resulting percentage must be more than 80 percent in order for an EP to meet this measure.</p> <p><u>Exclusions:</u> Any EP who: (1) writes fewer than 100 permissible prescriptions during the EHR reporting period; or (2) does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period.</p>	<p>and could be improved, we do not agree that increasing the threshold for mandatory ePrescribing either improves what needs to be improved, or creates market conditions for improvement. For many doctors (perhaps most), ePrescribing is a monopoly, and physicians have no market leverage over the application, or its network.</p> <p>Additionally while CMS feels comfortable assuming that their data confirm that ePrescribing has a solid and growing presence, it is ignoring the fact (and this is true for other process measures) that EPs who have trouble meeting this measure, are sometimes coercing patients, sending e-prescriptions and printing prescriptions - where the patient has requested printed prescriptions, or sometimes sending the same prescription multiple times.</p> <p>Patients should prefer ePrescribing because it saves them time at the pharmacy, or time mailing written prescriptions to mail order pharmacies. Known reasons for not using ePrescribing include:</p> <ul style="list-style-type: none"> <li>• Patient has not identified a preferred pharmacy – and either doesn't want to choose one when asked, or is not sure of its description (store number or exact street address).</li> <li>• Description of pharmacies in ePrescribing list are often not how patients would describe them (e.g., XYZ drug store at the Corner of 1st and Main; or in the ABC Shopping Center)</li> <li>• Providers want to send all prescriptions due or near due during an office visit – as this reduces phone calls, inbound ePrescribing requests between visits. Patients may not – as there is no standard message yet for “do not fill until requested” – and many patients express the concern that they cannot</li> </ul>
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	<p>afford all their medications at the same time.</p> <ul style="list-style-type: none"><li>• There is no way at present to create an ePrescription to permit comparison shopping at different drug stores.</li></ul> <p>There is still work to do to make ePrescribing better and less error-prone, including: 1) enabling Rx cancel; 2) having a structured message with an e-prescription, which advises the pharmacist when to fill the prescription; 3) modifying the existing PBM practice of providing pharmacy coverage cards with a fax number, and not including information as to the relevant PBM location that accepts e-prescriptions; 4) requiring other systems, such as Kaiser and the VA, to accept e-prescriptions from physicians outside their organizations.</p> <p>For all of its imperfections, ePrescribing is now the norm. There is no reason for the expense of creating a permanent threshold measure requirement to be built inside of EHRs. The activity of building in defined process measures with automated counters is error-prone and expensive, and in fact may be a barrier to further work on ePrescribing and electronic medication management.</p> <ul style="list-style-type: none"><li>• ePrescribing as a vehicle for medication safety was based on reducing errors translation due to illegibility. And while legibility as a cause of incorrect medications has all but disappeared, legibility was never a common source of medication errors, and other sources of medication errors (wrong choice of medication, wrong dose, wrong instructions, errors in dispensing and labeling, patient confusion due to</li></ul>
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	<p>frequent generic substitution drug name / shape / color, etc.) continue.</p> <ul style="list-style-type: none"> <li>• ePrescribing has resulted in new errors due to drop-down lists with incorrect choices (choice of medication, instructions)</li> <li>• ePrescribing has resulted in a reduction in appropriate review by those who would review and correct (when necessary) medication orders <ul style="list-style-type: none"> <li>o Clinical pharmacists – during the dispense process</li> <li>o Nursing – during the administration process</li> </ul> </li> <li>• ePrescribing has also not led to the processes that CMS/ONC describe above as furthering work on improving ePrescribing; where topics could include: choice of medication; cost of medication; understanding of medication instructions; medication adherence strategies; accuracy of eFormularies; furtherance of accurate communication between prescriber and pharmacist re reasons for overriding drug-drug / drug-allergy interactions, drug dosing overrides, etc.</li> </ul> <p>The prior history of ePrescribing incentives and mandates – starting with the Medicare ePrescribing incentive program and progressing thru the first two stages of MU has not resulted in any work being done on any of the issues listed above. Rather, it has only led to a market pressure on pharmacies to update equipment to accept ePrescribing, and on doctors to change their old habits of handwriting, printing, or faxing prescriptions. And while SureScripts, the primary network for sending ePrescriptions in the US has annual “Safer Prescribing” award designations for states – these awards are determined by the</p>
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	<p>number/percent of prescriptions sent electronically – and not on any actual measures of medication safety.</p> <p>One of the rationales for continuing to have a process measure for ePrescribing, is that more work remains to be done. We are certain that in any given year, this conclusion will be the same. The current ePrescribing system does not provide prescribers and their patients with accurate and complete information on drug availability and pricing, as well as patient benefit eligibility. While efforts are underway to enhance the technical standards in use, no efforts are being expended by anyone in CMS or ONC to compel improvements to the data supplied by the payers and PBMs. We need assurance that CMS and ONC are willing to use other tools at their disposal, which include removing a measure or imposing requirements on other participants.</p> <p>Bottom line, there is no reason (unless legislative) to continue a process measure for ePrescribing – except to collect data and to permit input by providers, patients, and pharmacist such that ePrescribing gets better over time. In that case, a threshold is unnecessary.</p>
<p><b>Objective 3: Clinical Decision Support</b></p> <p><b>Proposed Objective:</b> Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.</p> <p>First, we offer further explanation of the concept of the relevant point of care and note that providers should implement the CDS intervention at a relevant point in clinical workflows when the intervention can influence clinical decision making before diagnostic or treatment</p>	<p>This is a good example of why inserting unnecessary complexity into the definition does nothing but confuse the audience. With payment policy beginning to shift from pay for volume to pay for value, it is in the best interest of EPs to utilize whatever tools are available, to improve care and value, specific to the physician specialty and/or scope of practice. If one's specialty is one that routinely deals with what are</p>

action is taken in response to the intervention. Second, many providers may associate CDS with pop-up alerts; however, these alerts are not the only method of providing CDS. CDS should not be viewed as simply an interruptive alert, notification, or explicit care suggestion. Well-designed CDS encompasses a variety of workflow-optimized information tools, which can be presented to providers, clinical and support staff, patients, and other caregivers at various points in time.

We encourage innovative efforts to use CDS to improve care quality, efficiency, and outcomes. HIT functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care. CDS is not intended to replace clinician judgment, but rather, is a tool to assist care team members in making timely, informed, and higher quality decisions.

We propose to retain both measures of the Stage 2 objective for Stage 3 and we are proposing that these additional options mentioned previously on the actions, functions, and interventions may constitute CDS for purposes of meaningful use would meet the measure requirements outlined in the proposed measures.

defined as "high-priority health conditions," then having CDS interventions focused on improving performance on high-priority health conditions is clearly aligned with one scope of practice. But that is not the case for all EPs. In these other instances, we are sending physicians confusing messages - that they need to focus on quality and cost for what is within their scope of practice, but to meet the regulatory requirements of meaningful use they must also have available CDS interventions for high-priority health conditions that may or may not have anything to do with their scope of practice. As there is no requirement to use these CDS interventions, we are giving physicians exactly the wrong message - pay close attention to those you need to pay close attention to, but others are there just for consistency, and you can ignore them. We cannot imagine how we can teach this to a new generation of physicians.

We commend CMS for the definition of CDS interventions, as they now state explicitly, what they implied in the Stage 2 final rule. We urge CMS to provide additional options in its current and proposed requirement that CDS interventions align with a current CQM, enabling providers the flexibility to choose CDS interventions that align with their own clinical priorities. We believe that this change to the proposed rule will improve patient safety and clinical quality by allow providers to focus their efforts on more targeted CDS interventions.

Unfortunately, as CDS moves away from alerts to better approaches, measurement becomes more difficult. As

<p><b>Proposed Measures (objective 3):</b> EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:</p> <p><b>Measure 1:</b> Implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period.</p> <p>Absent four CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.</p> <p><b>Measure 2:</b> The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.</p> <p><u>Exclusion:</u> For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.</p> <p>In alignment with the HHS National Quality Strategy goals, providers are encouraged to implement CDS related to quality measurement and improvement goals on the following areas:</p> <ul style="list-style-type: none"> <li>• Preventive care.</li> <li>• Chronic condition management.</li> <li>• Heart disease and hypertension.</li> </ul>	<p>implementations no longer appear as alerts, but instead are simply integrated into standard workflows, we will need explicit guidance on how these interventions are identified, documented, and counted.</p> <p>Measure 1: We object to the number of interventions required. For certain specialties, such as internal medicine, it will be easy to not only reach five but to exceed five. However for other specialties, where there are not four relevant clinical quality measures, EPs are mandated to implement clinical decision support interventions related to high priority health conditions, which may have no relevance to their practice. As stated above, this would be a mistake, as it creates powerful tools in the electronic record, which the physician then learns to ignore.</p> <p>Measure 2: We have no objection, but we see no reason why there is a meaningful use measure for this, as physicians are already obligated to perform appropriate and drug-allergy interaction checking prior to prescribing medication, and can be sued for an adverse event related to unsafe prescribing.</p> <p>Furthermore, according to David Bates, the leading national expert on health IT and medication safety, drug-drug and drug-allergy interaction checking are the major source of alert fatigue and a small source (~3-5%) of alerts leading to safer medication practices.</p> <p>There are many procedural specialties where CMS's assertion that every EP should</p>
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<ul style="list-style-type: none"> <li>• Appropriateness of diagnostic orders or procedures such as labs, diagnostic imaging, genetic testing, pharmacogenetic and pharmacogenomic test result support or other diagnostic testing.</li> <li>• Advanced medication-related decision support, to include pharmacogenetic and pharmacogenomic test result support.</li> </ul> <p>Given the wide range of CDS interventions currently available and the continuing development of new technologies, we do not believe that any EP, eligible hospital, or CAH would be unable to identify and implement five CDS interventions as previously described. Therefore, we do not propose any exclusion for the first measure of this objective.</p>	<p>be able to identify and implement five CDS interventions as described, is clearly wrong.</p> <p>It is not necessary for CMS to specify a number, and just assume that professionals will implement appropriate safeguards and technology to support their efficient and effective care delivery. In some instances, there may be hundreds of CDS interventions, and others; there may be less than five. Value-based care should create the appropriate market conditions for appropriate choice and use of clinical decision support interventions.</p>
<p><b>Objective 4: Computerized Provider Order Entry</b></p> <p><b>Proposed Objective:</b> Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.</p> <p>However, for Stage 3, we are proposing to expand the objective to include diagnostic imaging, which is a broader category including other imaging tests such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology. This change addresses the needs of specialists and allows for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement.</p> <p>In Stage 3, we propose to continue the policy from the Stage 2 final rule at 77 FR 53986 that orders entered by any licensed healthcare professional or credentialed medical assistant would count toward this objective. A credentialed medical assistant may enter orders if they are credentialed to perform the duties of a medical assistant by a credentialing body other than the</p>	<p>Continuation and even expansion of metrics for CPOE on its face seems to be reasonable. That said, as this is the final proposed Stage of meaningful use, there must be a higher standard of reasonableness. For example, there is some evidence showing that CPOE results in or can result in safer ordering. That said, most of that evidence is based on altering medication dosage based on dosing alerts, and not the existing alerts typically associated with CPOE, which are drug-drug and drug-allergy interactions. The evidence is not beyond question, and that there is other evidence to suggest that improving medication administration is even more important than CPOE. As previously stated in this proposed rule, in the absence of new legislation or rulemaking, the Sec. of HHS only has discretion to increase the threshold of this measure, and not modify it based on new evidence. And that means that when new studies are released which show that the incidence of medication harm events and near-misses are continuing to increase, in spite of the fact</p>

<p>employer. If a staff member of the eligible provider is appropriately credentialed and performs assistive services similar to a medical assistant, but carries a more specific title due to either specialization of their duties or to the specialty of the medical professional they assist, orders entered by that staff member would be included in this objective. We further note that medical staff whose organizational or job title, or the title of their credential, is other than medical assistant may enter orders if these staff are credentialed to perform the equivalent duties of a credentialed medical assistant by a credentialing body other than their employer and perform such duties as part of their organizational or job title. We defer to the provider's discretion to determine the appropriateness of the credentialing of staff to ensure that any staff entering orders have the clinical training and knowledge required to enter orders for CPOE. This determination must be made by the EP or representative of the eligible hospital or CAH based on—</p> <ul style="list-style-type: none"> <li>• Organizational workflows;</li> <li>• Appropriate credentialing of the staff member by an organization other than the employing organization;</li> <li>• Analysis of duties performed by the staff member in question; and</li> <li>• Compliance with all applicable federal, state, and local laws and professional guidelines.</li> </ul>	<p>that CPOE may have nothing to do with these events and near misses, the Secretary may be obligated to increase the threshold for CPOE. By forcing further workflow change, this may paradoxically lead to a further increase in unsafe medication practices.</p> <p>Furthermore, while we appreciate that this proposal allows for the entry of orders by almost any licensed or credentialed healthcare professional, we are concerned that this accommodation may actually defeat the purpose of the measure. For example, a certified medical assistant can be a high school graduate who went through a medical assistant program and passed a certification exam. In this rule CMS appears to suggest that such individual has a similar enough level of education and experience to that of a physician - and thus could make the kind of judgments that physicians could or should make when evaluating alerts triggered by orders. CMS deals with this issue in its payment rules by not having specified role criteria for order entry; rather, it relies on physician or provider signature of the note, which includes explicit responsibility for all orders.</p>
<p>However, as stated in the Stage 2 final rule at 77 FR 53986, it is apparent that the prevalent time when CDS interventions are presented is when the order is entered into CEHRT, and that not all EHRs also present CDS when the order is authorized (assuming such a multiple step ordering process is in place). This means that the person entering the order would be required to enter the order correctly, evaluate a CDS intervention either using their own judgment or through accurate relay of the information to the ordering provider, and then either make a change to the order based on the information</p>	<p>Unless the person creating the order interacts with the EHR system, there is no opportunity for an order to be changed / modified – based on alerts. It is important to also mention that one of the biggest problems now with electronic systems is not that the right person does not have access to alerts – but rather that the right person is so over-alerted that there is question as to how to reduce alerting such that the viewer does not suffer alert fatigue</p>

provided by the CDS intervention or bypass the intervention. The execution of this role represents a significant impact on patient safety; therefore, we continue to maintain for Stage 3 that a layperson is not qualified to perform these tasks. We believe that the order must be entered by a qualified individual. We further propose that if the individual entering the orders is not the licensed healthcare professional, the order must be entered with the direct supervision or active engagement of a licensed healthcare professional.

We propose to maintain for Stage 3 our existing policy for Stages 1 and 2 that the CPOE function should be used the first time the order becomes part of the patient's medical record and before any action can be taken on the order. The numerator of this objective also includes orders entered using CPOE initially when the patient record became part of the certified EHR. This does not include paper orders entered initially into the patient record and then transferred to CEHRT by other individuals at a later time, nor does it include orders entered into technology not compliant with the CEHRT definition and transferred into the CEHRT at a later time. In addition, based on the discussion in the Stage 2 final rule (77 FR 53986), we propose to maintain for Stage 3 that "protocol" or "standing" orders may be excluded from this objective. The defining characteristic of these orders is that they are not created due to a specific clinical determination by the ordering provider for a given patient, but rather are predetermined for patients with a given set of characteristics (for example, administer medication X and order lab Y for all patients undergoing a certain specific procedure or refills for given medication). We agree that this category of orders warrant different considerations than orders that are due to a specific clinical determination by the ordering provider for a specific patient. Therefore, we allow providers to exclude orders that are predetermined for a given set of patient characteristics or for a given procedure from the calculation of CPOE numerators and denominators. However, the exclusion of this type of order may not be a blanket policy for patients presenting with a specific

and thus miss key alerts.

Furthermore, the typical ordering workflows in outpatient settings are different, whereas verbal orders are uncommon, many medication orders are for renewals of previously ordered medications, where the renewal request comes in via telephone, secure messaging, or inbound ePrescribing – and except for inbound ePrescribing (which is auto-queued), the queuing is most often done by support staff, either a medical assistant or clerical staff. The queued renewal orders are then presented to the provider for signature, or the queued orders in some instances may be approved as part of practice policy (e.g., chronic meds may be renewed if patient has had a visit within x months, a return visit scheduled within y months, and particular labs done – either any, or within a certain range – within z months).

In an effort to respond to this safely and widely used workflow, some commenters suggested redefining CPOE as either 'computerized provider order entry' or 'computerized provider order evaluation'; where evaluation occurred prior to an order being acted upon, and also required the provider to view all actionable alerts. Rather, the definition of provider was extended to any licensed or certified healthcare professional, which includes almost anyone in a provider's office who might be entering orders (with the exception of non-clinical staff). While this was appreciated in the Stage 2 Final Rule as a reasonable accommodation – as CPOE is also a "topped-out" measure per CMS, and whatever evidence exists for the benefit of

<p>diagnosis or symptom which requires the evaluation and determination of the provider for the order.</p>	<p>CPOE does not include CPOE done by medical assistants, it begs the question as to why CPOE needs to continue as a threshold measure.</p> <p>CMS's attempt to make this measure sound reasonable may actually defeat its purpose. There are not sufficient data to support that CPOE, as defined under meaningful use, results in safer and/or more appropriate ordering. Perhaps the best way to approach this issue, if anything is required, would be to collect data, and not require a threshold. That data collection could help to inform attributes of safer ordering— such as looking at CPOE by role, as well as the value of more targeted alerting vs. bulk dismissal of alerts – such that CPOE becomes more consistently effective and not just assume that what is suggested is necessarily appropriate. Simply increasing the threshold does not result in safer ordering. And modifying the definition of licensed healthcare professional does not either.</p> <p>Another concern with continuing a prescriptive approach to process measurement of CPOE is inadvertently stifling innovation. For example, if an EHR counts a patient request for a medication renewal, where that request comes in either through a portal or via some other representation of the patient's medication list, as the first entry into the order system, then to be compliant with this metric, a system would have to require a duplicative entry or checkbox by the physician rather than just allowing what makes most sense - which would be physician review, and approval upon signature.</p>
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<p><b>Proposed Measures (objective 4):</b> An EP, eligible hospital or CAH must meet all three measures.</p> <p><b>Proposed Measure 1:</b> More than 80 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;</p> <p><b>Proposed Measure 2:</b> More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and</p> <p><b>Proposed Measure 3:</b> More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.</p> <p>We propose to continue a separate percentage threshold for all three types of orders: medication, laboratory, and diagnostic imaging. We continue to believe that an aggregate denominator cannot best capture differentiated performance on the individual order types within the objective, and therefore maintain a separate denominator for each order type.</p> <p>Based on our review of attestation data from Stages 1 and 2 demonstrating provider performance on the CPOE measures, we propose to increase the threshold for medication orders to 80 percent and to increase the threshold for diagnostic imaging orders and laboratory orders to 60 percent. Median performance for Stage 1 on medication orders is 95 percent for EPs and 93 percent for eligible hospitals and CAHs. Stage 2 median performance on laboratory and radiology orders is 80 percent and 83 percent for eligible hospitals and CAHs and 100 percent for EPs for both measures.</p>	<p>See comments above.</p> <p>We strongly recommend that this measure not be continued in Stage 3. We ask that CMS clarify their reasoning in terms of continuing to propose a separate percentage threshold for all three types of orders.</p> <p>This is another example, similar to that of ePrescribing, where CMS's review of</p>
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<p>We believe it is reasonable to expect the actual use of CPOE for medication orders to increase from 60 percent in Stage 2 to 80 percent in Stage 3 and the actual use of CPOE for diagnostic imaging and laboratory orders to increase from 30 percent in Stage 2 to 60 percent in Stage 3. We note that despite the expansion of the category for radiology orders to diagnostic imaging orders, we do not anticipate a negative impact on the ability of providers to meet the higher threshold as the adoption of the expanded functionality does not require additional workflow implementation and allows for inclusion of a wider range of orders already being captured by many providers. Therefore, for medication orders we propose the threshold at 80 percent and for diagnostic imaging and laboratory orders we propose the threshold at 60 percent for Stage 3.</p>	<p>attestation data from Stage 1 showed the median performance for medication orders was 95% for EPs and 93% for hospitals. If that is true, it meets CMS's internally derived guidance for considering this a "topped out" measure. Similarly, their review of attestation data shows a median performance on lab and radiology orders 80% and 83% for hospitals, and 100% for EPs. Again suggesting that this measure has "topped out" and can be retired.</p>
<p><b>Objective 5: Patient Electronic Access to Health Information</b></p> <p>In this Stage 3 Patient Electronic Access Objective, we are proposing to incorporate certain measures and objectives from Stage 2 into a single objective focused on providing patients with timely access to information related to their care. This proposed objective is a consolidation of the first measure of the Stage 2 Core Objective for EPs of "Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP" and the Stage 2 Core Objective for EPs to "Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient."</p> <p>In Stage 2, there are objectives that allow providers to communicate and provide information to patients through paper-based means, such as clinical summaries of office visits and patient-specific education resources. Although these methods of communication and information exchange are embraced by many providers and patients and we continue to support their use, we will no longer require or allow providers to capture and</p>	<p>While we appreciate CMS's intent in no longer allowing EPs to capture and calculate the provision of clinical summaries and patient specific educational resources on paper, this intent does not fit with other goals and objectives - such as patient centeredness and capturing and responding to patient preference, including a patient preference to affirmatively not create a clinical summary in electronic</p>

<p>calculate these actions or attest to these measures for meaningful use Stage 3. While we believe that providing patients access to health information in many formats is beneficial to patient-centered communication, care delivery, and quality improvement, meaningful use Stage 3 focuses exclusively on electronic, certified EHR technology supported communication.</p>	<p>format. If a patient has indicated a preference, it should always be the driver of action – not the measure specification.</p>
<p>We are also proposing to expand the options through which providers may engage with patients under the EHR Incentive Programs. Specifically, we are proposing an additional functionality, known as application-program interfaces (APIs), which would allow providers to enable new functionalities to support data access and patient exchange. An API is a set of programming protocols established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current "patient portals." From the provider perspective, using this option would mean the provider would not be required to separately purchase or implement a "patient portal," nor would they need to implement or purchase a separate mechanism to provide the secure download and transmit functions for their patients because the API would provide the patient the ability to download or transmit their health information to a third party. If the provider elects to implement an API, the provider would only need to fully enable the API functionality, provide patients with detailed instructions on how to authenticate, and provide supplemental information on available applications which leverage the API.</p> <p>Therefore, we are proposing for the Patient Electronic Access objective to allow providers to enable API functionality in accordance with the proposed ONC requirements in the 2015 Edition proposed rule published elsewhere in this issue of the Federal Register.</p> <p>We seek comment on what additional requirements might be needed to ensure that if the eligible hospital,</p>	<p>We appreciate the flexibility and thinking behind explicitly recommending an API. We note that CMS discusses this as presumably a less costly and cumbersome approach to the existing technology of a patient portal. We also appreciate that this API approach may resolve what is increasingly heard from patients - their disinterest in needing to use a different portal for each physician. That said, prior to codifying this into a forever rule, the full costs of implementing and using these APIs must be calculated and considered prior to rule-making. EPs have been burdened with a long list of communication requirements that have cost far more than anyone considered acceptable. Additionally, by specifying portal or API, CMS will likely hinder innovation surrounding whatever connectivity process may lie around the next corner.</p> <p>Without defining standards for APIs, it is likely that each vendor will implement an API differently. This will result in little if any gain over requiring patients to enroll in different portals for different EPs.</p> <p>Evidence thus far from the Meaningful Use program – because of how it defines “access” is only helpful for determining a lowered barrier to patient engagement, but not an affirmation of patient engagement. Access is defined as a patient being offered</p>

<p>CAH or EP selects the API option-- (1) the functionality supports a patient's right to have his or her protected health information sent directly to a third party designated by the patient; and (2) patients have at least the same access to and use of their health information that they have under the view, download, and transmit option.</p>	<p>access, declining access, or having signed up at least once for an electronic system of access. Companion data on how frequently patients make use of such access to electronic information shows that actual access is far less. This alone suggests a change in label of the objective to "availability" rather than "access". Further, as the definition of "access" is structured (offered, using, or declined) such that it could and/or should be a consistent practice operation, in much the same way that name, date of birth, and insurance information is expected 100% of the time. We could see this being incorporated into a future "notice of privacy rights, electronic information security practices, and electronic access to PHI" – which is then an annual YES/NO attestation.</p> <p>We have serious concerns as to protection of PHI where an API is chosen as the vehicle to provide patients with their data. Are API developers and operators subject to HIPAA business associate requirements? This must be clarified before we open this door. We are also concerned that patients will be at the mercy of whatever bad actions any third-party vendor using the API supposedly acting for the patient, does with the data extracted.</p>
<p><b>Proposed Objective (5):</b> The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.</p> <p>We note that for this objective, the provider is only required to provide access to the information through these means; the patient is not required to take action in order for the provider to meet this objective. In the</p>	<p>"Health information" is not sufficiently defined within this objective. Does "health information" here refer only to a C-CDA or to new results; or does this also include office visit notes, and if so, will this be requiring that office visit notes be completed within 24 hours of a visit?</p> <p>Prior rules have acknowledged that some physicians prefer to review results and</p>

<p>Patient Electronic Access to Health Information objective, we note that "provides access" means that the patient has all the tools they need to gain access to their health information including any necessary instructions, user identification information, or the steps required to access their information if they have previously elected to "opt-out" of electronic access. If this information is provided to the patient in a clear and actionable manner, the provider may count the patient for this objective. Additionally, this objective should not require the provider to make extraordinary efforts to assist patients in use or access of the information, but the provider must inform patients of these options, and provide sufficient guidance so that all patients could leverage this access.</p>	<p>comment upon them, prior to release to patients, and thus prior rules have referred to business days rather than a time requirement that would require review during nights and weekends. Proposing a 24-hour threshold is problematic in that CMS is requiring only one approach to data release to patients no matter what the availability of the physician may reasonably be.</p>
<p><b>Proposed Measures:</b> EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:</p> <p><b>Proposed Measure 1:</b> For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):</p> <p>(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or</p> <p>(2) The patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.</p> <p><b>Proposed Measure 2:</b> The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR</p>	<p>It is unclear that moving from a 50%+ to 80%+ threshold will actually further patient engagement. The same question exists for timeliness of information. While it is entirely understandable that patient health information should be available in a timely manner, as well as at a reasonable cost – it is not clear that the shortening of the time threshold (from 3 days to within 24 hours) necessarily serves the needs of most patients, nor does it necessarily lead to more engaged patients.</p> <p>When this measure (measure 2) was made a core measure in Stage 2, we objected to the denominator being all patients seen, rather than some other denominator, such as all patients with the new medication, all patients with a new diagnosis, all patients who are unable to meet a clinical goal, etc. What that Stage 2 measure then required was a substitution of thoughtfulness with boilerplate logic, as that would be the only way to guarantee compliance with the threshold. That reasoning and objection are strengthened in Stage 3, where the threshold increases from 10% to 35%. We</p>

<p>reporting period.</p>	<p>can be certain that the approach that vendors and physicians will take will be one that offers links to educational material based on what is in the problem list, medication list, or where there is nothing, based on the patient's age and sex. A thoughtful strategy to only give patients what they truly need will not result in enough patients receiving material to achieve a threshold. This is another issue that should not be “set in stone” as a forever measure - but rather one that gathers more information to help us to better determine what patients actually need. The comment that a 35% threshold ensures that the threshold is not infringing on the physician's freedom to choose educational resources and to which patients these resources will be provided is unsupportable. Reliably achieving above a 35% threshold requires algorithms - likely determined by the vendor, and not reliant on individual physician actions - thus defeating the rationale for this measure.</p>
<p>We propose that for measure 1, the patient must be able to access this information on demand, such as through a patient portal, personal health record (PHR), or API and have everything necessary to access the information even if they opt out. All three functionalities (view, download, and transmit) or an API must be present and accessible to meet the measure. The functionality must support a patient's right to have his or her protected health information sent directly to a third party designated by the patient consistent with the provision of access requirements at 45 CFR 164.524(c) of the HIPAA Privacy Rule.</p> <p>However, if the provider can demonstrate that at least one application that leverages the API is available (preferably at no cost to the patient) and that more than 80 percent of all unique patients have been provided</p>	<p>We request CMS review of prior attestations regarding these measures, to see if the median physician score for access to information in the provision of patient specific educational resources also has already met their criteria for a "topped out" measure.</p> <p>There are several related concerns with this set of measures:</p> <ul style="list-style-type: none"> <li>• It appears that CMS expects an office note to be completed now within 24 hours of an office visit. CMS also comments that automation makes it possible to reduce “processing time” to return</li> </ul>

instructions on how to access the information; the provider need not create, purchase, or implement redundant software to enable view, download, and transmit capability independently of the API.

We propose to increase the threshold for measure 1 from the Stage 1 and Stage 2 threshold of 50 percent to a threshold of 80 percent for Stage 3. We believe that all patients should be provided access to their electronic health record; however, we are setting the threshold at 80 percent based on the highest threshold defined for measures based on unique patients seen by the provider during the EHR reporting period in the Stage 2 final rule (for example see 77 FR 53993). Based on the continued progress toward automation and standardization of data capture supported by CEHRT which facilitates a faster response time, we further propose to decrease patient wait time for the availability of information to within 24 hours of the office visit or of the information becoming available to the provider for potential inclusion in the case of lab or other test results which require sufficient time for processing and returning results.

For measure 2, we propose to increase the threshold that was finalized in Stage 2 from 10 percent to 35 percent. We believe that the 35 percent threshold both ensures that providers are using CEHRT to identify patient-specific education resources and is low enough to not infringe on the provider's freedom to choose education resources and to which patients these resources will be provided.

We continue to propose that both measures for this objective must be met using CEHRT. For the purposes of meeting this objective, this would mean the capabilities provided by a patient portal, PHR, or any other means of online access that would permit a patient or authorized representatives to view, download, and transmit their personal health information and/or any API enabled, must be certified in accordance with the certification requirements adopted by ONC.

results to patients within 24 hours.

As mentioned above, this is only the case if CMS is considering eliminating physician review as at least one pathway to returning results to patients (with annotation), unless they are assuming also that physician review and annotation of results is also on a 24/7 cycle.

- As providers cannot and should not be expected to have 24/7 availability for interpretation and communication of all results, this proposed rule finds no merit in the remaining controversy over lab result delivery by making it mandatory for results to concurrently flow to a portal or API. This untested and new reality of immediate resulting to patients may lead to an unintended consequences, similar to the well-known and unsafe practice of only communicating abnormal results to patients (AKA – “no news = good news”).
- A remaining controversy in the ready release of electronic results to patients is the understanding the value as well as the workflow in release of raw data vs. data plus an interpretation from the ordering provider. PCPs would say that it is only in rare cases that an isolated result, without broad and historical context, provides any value. Physicians routinely compare the most recent result with prior results, and further with the med list, the allergy list, and the most

	<p>recent care plan; and thus release the information with guidance as what it means, as well as next steps (such as increasing a medication, changing a medication, following the current path of diet, exercise, and weight loss, etc.). Not only is there controversy in the provider community as to what the best approach is; but it may also be that for many patients, the availability of information without interpretation is not all that helpful or wanted.</p>
<p><b>Proposed Measure 1:</b> To calculate the percentage, CMS and ONC have worked together to define the following for this measure:</p> <p><u>Denominator:</u> The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p> <p><u>Numerator:</u> The number of patients in the denominator who are provided access to information within 24 hours of its availability to the EP or eligible hospital/CAH. Threshold: The resulting percentage must be more than 80 percent in order for a provider to meet this measure.</p> <p><u>Exclusions:</u> An EP may exclude from the measure if they have no office visits during the EHR reporting period.</p> <p><b>Proposed Measure 2:</b> To calculate the percentage, CMS and ONC have worked together to define the following for this measure:</p> <p><u>Denominator:</u> The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p>	<p>We seek further clarification as to exactly how the numerator should be calculated for Measure 1. For example, does a unique patient count as "one" in the numerator if the patient is provided access; or does a patient count as "one" in the numerator if the patient is provided access and also every instance of health information that could be provided to the patient is also made available within 24 hours? Thus, the patient has access and one lab result out of 10 fails to be made accessible within a portal or via the API within the 24-hour threshold, does that result in that patient not being counted in the numerator?</p> <p>The second measure of this objective is that 35%+ of all patients seen have access to patient-specific electronic information. There are several problems with this as a process measure, with an automated and a threshold. (In order to calculate measures automatically, EHR systems must implement counters in their software that can track the number of times an event happens. The logic of these counters can get quite complex, and changes in</p>

Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT.

Threshold: The resulting percentage must be more than 35 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

measures require reprogramming counters.) As mentioned previously, as the delivery approach for electronic patient-specific education is proposed as either via a portal or an ONC-approved API, and further, there is no requirement for patients to download, read, or message back the provider that they have read and/or understood that information, it is actually unclear that without an exceedingly cumbersome or complicated approach, it may not be possible to accurately count these events. Further, as with many process measures, how the definition is ultimately written in the final rule, and how it is implemented by each vendor is almost certain to be prescriptive, and thus other and even more useful methods (such as queuing up specific information pre-visit, or while in the waiting room, or even in the exam room, may not necessarily count.

Depending on specialty or scope of practice, the provision of educational material may not be warranted (such as a practice seeing mostly patients for follow-up of chronic conditions, where those conditions are stable, and there are no new diagnoses or medications prescribed.

Further, the denominator is based on all patients seen, and not just on patients with new diagnoses, or on new medications, or who have unmet care opportunities or goals (people who might actually need information). This measure is written such that people must be offered information, whether they need it or not – which means that the approach is likely to be even broader, such that what is provided is so generic as to be not useful. This is very

	<p>similar to what patients get from many emergency rooms today – many pages of generic information that is not particularly useful. A better approach would be similar to availability of PHI, which is an attestation of electronic availability, and perhaps methods built into EHRs and other health IT to allow for continuing study as to what methods are perceived as valuable to patients, and what methods are associated with better outcomes.</p>
<p><b>Alternate Proposals:</b></p> <p>We note that for measure one we are seeking comment on the following set of alternate proposals for providers to meet the measure using the functions of CEHRT outlined previously in this section. These alternate proposals involve the requirements to use a view, download, and transmit function or an API to provide patients access to their health information. We believe the current view, download, and transmit functions are widely in use and represent the current standard for patient access to their health record. However, we believe that the use of APIs could potentially replace this function and move toward a more accessible means for patients to access their information. Therefore, we are seeking comment on alternatives which would present a different mix of CEHRT functionality for providers to use for patients seeking to access their records. The proposed first measure discussed previously would allow providers the option either to give patients access to the view, download, and transmit functionality, or to give patients access to an API. Specifically, we are seeking comment on whether the API option should be required rather than optional for providers, and if so, should providers also be required to offer the view, download, and transmit function.</p>	<p>We are not in favor of any of the alternate proposals, unless there was certainty as to the cost of utilizing an ONC specified API.</p> <p>Without defining standards for APIs, it is likely that each vendor will implement an API differently. This will result in little if any gain over requiring patients to enroll in different portals for different EPs. If Stage 3 is to support an API, it must define that API to some extent. Version 1 should be fairly simple – focusing on the key data elements of interest – problems, medications, allergies, lab results and the narrative assessments and plans.</p>
<p><b>Proposed Objective (6):</b> Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.</p>	<p>The implication of this approach is that providers will have to incorporate schemes to automate electronic access and</p>

<p><b>Proposed Measures:</b> We are proposing that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Coordination of Care through Patient Engagement Objective. These three measures support the communication continuum between providers, patients, and the patient's authorized representatives through the use of view, download, and transmit functionality. They also support using API functionality through patient engagement with their health data, but also potentially through secure messaging functions and standards, and the capture and inclusion of data collected from non-clinical settings, including patient-generated health data.</p>	<p>communications broadly, even where patients are not interested, and to be prepared to provide the equivalent of a paper copy should patients want it. The same concept would apply to provider-to-provider communication – but with two key provisos, which are to require that electronic provider-to-provider communications also: 1) include the patient; and 2) must allow the patient to be a part of the conversation. It should be noted that this technology is not widely available; nor are the clinical workflows that would accompany such technology. For example, if a specialist is messaging the other care team providers as to new findings and recommended changes to a medication, and including the patient in that conversation, to whom does a patient reply go to, and who would be responsible for answering the patient? Without such clarity – this well-meaning suggestion is likely to result in multiple providers answering somewhat differently, with confusion resulting.</p>
<p><b>Proposed Measure 1:</b> During the EHR reporting period, more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP, eligible hospital or CAH may meet the measure by either:</p> <p>(1) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; or</p> <p>(2) More than 25 percent of all unique patients (or</p>	<p>This is not only a step too far but it is completely unreasonable. This is the clearest example of why a proposed threshold may seem manageable for some EPs, and impossible for others. As ONC and CMS know, engaging with one's personal clinical information is dependent upon many factors, including the patient, and what information is available to be engaged with. There is no denominator exclusion for EPs who do not provide testing and who do not have electronic patient information available other than demographics, and perhaps the patient's problem list, medication list, and/or allergy list.</p>

patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

For measure 1, we are proposing to increase the threshold for the measure from 5 percent to 25 percent based on provider performance on the related Stage 2 measure requiring more than 5 percent of patients to view, download, or transmit to a third party the health information made available to them by the provider.

Stage 2 median performance for an EP on this measure is 32 percent and 11 percent for eligible hospitals.

Therefore, we are proposing more than 25 percent of all unique patients (or the patient's authorized representatives) seen by the EP, eligible hospital or CAH during the EHR reporting period must view, download, or transmit to a third party their health information or access their health information through the use of an ONC-certified API that can be used by third-party applications or devices. For the API option, we propose that providers must attest that they have enabled an API and that at least one application which leverages the API is available to patients (or the patient-authorized representatives) to retrieve health information from the provider's certified EHR.

CMS recognizes that there may be inherent challenges in measuring patient access to CEHRT through third-party applications that utilize an ONC-certified API, and we solicit comment on the nature of those challenges and what solutions can be put in place to overcome them. For example, are there specific requirements around the use of APIs or are there specific certification requirements for APIs that could make the measurement of this objective easier. We also solicit comment on suggested alternate proposals for measuring patient access to CEHRT through third-party applications that utilize an API, including the pros and cons of measuring a minimum number of patients (one or more) who must access their health

This level cannot happen for most patients and most EPs. The best performance we have heard is 30-40% of Kaiser patients, in some of the Kaiser areas, using the Epic portal. We already know that physicians and health systems have had to resort to gimmicks and in some cases even bribery (such as gift cards) to get patients to click on a feature of a patient portal. And even then, many physicians are unable to reach the existing threshold of 5%. While this may not be an issue for most internists, it certainly will be for others. CMS is basing this 25% figure on Stage 2 median performance. Note that many more hospitals have attested for Stage 2, and thus the 11% figure is a more accurate median performance for EHs. EHs can do this because they can invest in a person with a tablet, which can see every about-to-be discharged patient and say, "Here, let me show you how to do this..." This measure is not achievable by practices. Only a small percentage of EPs have attested for Stage 2 thus far, and thus the 32% median performance cannot be generalized across all EPs.

Is also unclear as to how EPs can or should monitor what patients do with their data, once the data are provided with an API. We are in the "Wild West" phase of health app development. Patients will be at the mercy of all sorts of inappropriate behaviors by the apps they use. Physicians have a legal responsibility to protect the patient's data no matter how the data leave the practice.

The creation of a new approach, an ONC

<p>information through the use of an API in order to meet the measure of this objective.</p>	<p>approved API is certainly appropriate, as the patient experience with portals to date has been far less appealing than expected. That said, this measure remains problematic:</p> <ul style="list-style-type: none"> <li>• Specifying technologies is by definition not supportive of innovation, either in technology or workflow.</li> <li>• Specifying technologies also means that automated counters need to be built into EHRs, and this includes a technology that is not yet mature (the API alternative).</li> <li>• Prescribed processes tend to lead to poor usability / clunky workflows.</li> </ul> <p>For all of these reasons, VDT should be continued in much the same way as proposed for 2015-2017, and not require an automated counter built into EHR technology, and not require a threshold measure.</p>
<p><b>Proposed Measure 2:</b> For more than 35 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient's authorized representatives), or in response to a secure message sent by the patient (or the patient's authorized representative).</p> <p>For measure 2, the EP, eligible hospital, CAH, or the provider's authorized "Communicate" means when a provider sends a message to a patient (or the patient's authorized representatives) or when a patient (or the patient's authorized representatives) sends a message to the provider. In patient-to-provider communication, the provider must respond to the patient (or the patient's authorized representatives) for purposes of this measure.</p>	<p>This measure was clearly designed to incent secure messaging or use of an API. CMS tried to make this measure numerator more reasonable by including a second definition - physician to patient communications. Certainly all physicians could do this, but the question is why. Communications to patients, similar to reminders, can be seen as more closely tied to market forces, and thus directly amenable to incentivizing by the market. Sending blast or automated messages out is a useless measure. Most such messages do not generate a response</p> <p>We are troubled that CMS is proposing to change the definition of "communicate" for patient to physician communications to</p>

We propose to increase the threshold for this measure over the threshold for the Stage 2 measure because for Stage 3 provider initiated messages would count toward the measure numerator.

For measure 2, we propose to include in the measure numerator situations where providers communicate with other care team members using the secure messaging function of certified EHR technology, and the patient is engaged in the message and has the ability to be an active participant in the conversation between care providers.

However, we seek comment on how this action could be counted in the numerator, and the extent to which that interaction could or should be counted for eligible providers engaged in the communication. For example, should only the initiating provider be allowed to include the communication as an action in the numerator? Or, should any provider who contributes to such a message during the EHR reporting period be allowed to count the communication? In addition, we seek comment on what should be considered a contribution to the patient-centered communication; for example, a contribution must be active participation or response, a contribution may be viewing the communication, or a contribution may be simple inclusion in the communication.

We specify that the secure messages sent should contain relevant health information specific to the patient in order to meet the measure of this objective. We believe the provider is the best judge of what health information should be considered relevant in this context. For the purposes of this measure, we are proposing that secure messaging content may include, but is not limited to, questions about test results, problems, and medications; suggestions for follow-up care or preventative screenings; confirmations of diagnosis and care plan goals; and information regarding patient progress. However, we note that messages with content exclusively relating to billing questions, appointment scheduling, or other administrative subjects should not be included in the numerator. For care team secure messaging with the

include “the provider must respond,” as this appears to be an attempt to regulate good behavior and proper manners. This is a misuse of CMS's regulatory authority. Patients have market influence over physicians who are poor communicators, and that is by switching physicians. Patients do this all the time.

We are troubled with CMS newly defining communication between care team members using the secure messaging function of CEHRT, by stating that the patient must be “engaged in the message and has the ability to be an active participant in the conversation between care providers.” This may appear to be a good idea, but it is not something done today, with or without electronic communications. We are not aware of readily available technology that supports this concept of multi-party communication. We are troubled by the use of “engaged” without further definition – which implies more than “copied on.”

The proposed definition is additionally troubling; as it seeks to define communications between care team members (or between physicians only, it is not clear) as being about test results, problems, medications, follow-up care or preventive screenings, etc. We would have thought this proposal by CMS was actually looking at copying patients on communications only between physicians, and in particular, only when there was a need to reconcile a difference of opinion on diagnosis or medication. Otherwise, this seems to be already handled, by patients having ready access to results and their own health information within 24 hours.

<p>patient included in the conversation, we also believe the provider may exercise discretion if further communications resulting from the initial action should be excluded from patient disclosure to prevent harm. We note that if such a message is excluded, all subsequent actions related to that message would not count toward the numerator.</p>	<p>The insertion of this requirement hinders something that has not yet developed, which is the regular use of secure messaging between physicians to coordinate patient care. Further, as in the measure above, one could envision a clear rationale based on specialty or scope of practice, and the need again for a gimmick for others. Thus, primary care providers could send a generic message about flu shots every fall to all patients – and those specialties not dealing with preventive or chronic care will just have to come up with something. Having a prescriptive process measure where it is unclear if novel approaches or new technology will be counted creates a chilling effect – such that gimmicks will be favored over innovation.</p> <p>Further, this measure requires the EHR to know the content of the message, such that it does not count messaging about reminders for existing appointments or messaging about billing. Building an automated counter for this requirement seems especially challenging,</p> <p>This is a new idea and deserves testing and study, but not to be codified in a permanent process measure.</p>
<p><b>Proposed Measure 3:</b> Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p> <p>For measure 3, EPs, eligible hospitals, and CAHs (or their authorized representatives) must incorporate health data obtained from a non-clinical setting in a patient's electronic health record for more than 15 percent of</p>	<p>Incorporation of patient generated health data is clearly important to provider efficiency, and when this technology becomes more readily available, one would think that it would be readily stimulated by a physician's desire to be efficient. Less than 15% of a typical EP's patients receive any among these services. It would not be possible to meet the measure, even with 100% efficiency. There is no need to have this be a permanent process measure, that</p>

<p>unique patients seen during the EHR reporting period. We note that the use of the term "clinical" means different things in relation to place of service for billing for Medicare and Medicaid services.</p> <p>However, for purposes of this measure only, we are proposing that a non-clinical setting shall be defined as a setting with any provider who is not an EP, eligible hospital or CAH as defined for the Medicare and Medicaid EHR Incentive Programs. Therefore, for this measure, a non-clinical setting is any provider or setting of care which is not an EP, eligible hospital, or CAH in either the Medicare or Medicaid EHR Incentive Programs and where the care provider does not have shared access to the EP, eligible hospital, or CAHs certified EHR. This may include, but is not limited to, health and care-related data from care providers such as nutritionists, physical therapists, occupational therapists, psychologists, and home health care providers as well as data obtained from patients themselves. We specifically mention this last item and refer to this sub-category as patient-generated health data, which may result from patient self-monitoring of their health (such as recording vital signs, activity and exercise, medication intake, and nutrition), either on their own, or at the direction of a member of the care team. We are proposing this measure in response to requests from providers to support the capture and incorporation of patient-generated health data, and the capture and incorporation of data from a non-clinical setting into an EHR. Providers have expressed a desire to have this information captured in a useful and structured way and made available in the EHR. The capture and incorporation of this information is an integral part of ensuring that providers and patients have adequate information to partner in making clinical care decisions, especially for patients with chronic disease and complex health conditions for whom self-monitoring is an important part of an ongoing care plan.</p>	<p>builds into EHRs the cost and likely inflexibility of automated counting functionality.</p> <p>Further, CMS is being disingenuous by asserting they are responding to providers' wishes to have such technology, by including it as a process measure in meaningful use. A physician wishing to have technology available is very different than a physician wishing to be measured for its use. Further, CMS appears to be excluding the use of patient generated health data that most providers would find most helpful, as they appear to be excluding patient generated health data that is generated inside the provider's office. For example, providers often have questionnaires available to patients, and patients can complete these either at home, or within the providers' office, sometimes using a kiosk, or mobile device.</p>
<p>We are seeking comment on how the information for measure 3 could be captured, standardized, and incorporated into an EHR. For the purposes of this</p>	<p>This is another example of CMS creating a process measure as opposed to just allowing reasonableness to occur in the</p>

measure, the types of data that would satisfy the measure is broad. It may include, but is not limited to social service data, data generated by a patient or a patient's authorized representatives, advance directives, medical device data, home health monitoring data, and fitness monitor data. In addition, the sources of data vary and may include mobile applications for tracking health and nutrition, home health devices with tracking capabilities such as scales and blood pressure monitors, wearable devices such as activity trackers or heart monitors, patient reported outcome data, and other methods of input for patient and non-clinical setting generated health data. We emphasize that these represent several examples of the data types that could be covered under this measure. We also note that while the scope of data covered by this measure is broad, it may not include data related to billing, payment, or other insurance information. As part of determining the proper scope of this measure, we are seeking comment on the following questions:

- Should the data require verification by an authorized provider?
- Should the incorporation of the data be automated?
- Should there be structured data elements available for this data as fields in an EHR?
- Should the data be incorporated in the CEHRT with or without provider verification?
- Should the provenance of the data be recorded in all cases and for all types of data?

We also seek comment on whether this proposed measure should have a denominator limited to patients with whom the provider has multiple encounters, such as unique patients seen by the provider two or more times during the EHR reporting period.

We also seek comment on whether this measure should be divided into two distinct measures. The first measure would include only the specific sub-category of patient-generated health data, or data generated predominantly through patient self-monitoring rather than by a provider.

setting of newly available technology. A process measure is not needed here. It will just add to cost and poor usability of EHRs.

These questions are reasonable questions, but they reflect the fact that this is not appropriate for a process measure. Rather, this is something that should be studied, as the technology becomes more available. A physician would want to verify any information being placed in the EHR, as physicians currently have a duty to respond to clinical information from or about a patient. We do not believe the incorporation of the data should be automated. Not all data coming in should be captured as structured data elements. While this might be appealing to those interested in secondary use of the data, we know from other areas that such requirements often cause more documentation burden and can result in a stilted narrative. Lastly, the provenance of the data should be recorded for all cases.

This entire requirement could be simplified if CMS just limited the measure to services that are being billed to the Medicare program (i.e. OT, PT, clinical psychology)

<p>The second measure would include all other data from a non-clinical setting. This would result in the objective including four measures with providers having an option of which two measures to focus on for the EHR reporting period.</p> <p>We also seek comment on whether the third measure should be proposed for eligible hospitals and CAHs, or remain an option only for eligible professionals. For those commenters who believe it should not be applicable for eligible hospitals and CAHs, we seek further comment on whether eligible hospitals and CAHs should then choose one of the remaining two measures or be required to attest to both.</p>	<p>since CMS/ONC/OIG can use the claims data to validate.</p>
<p>Providers must attest to the numerator and denominator for all three measures, and must meet the threshold for two of the three measures to meet the objective for Stage 3 of meaningful use:</p> <p><b>Proposed Measure 1:</b> We have identified the following for measure 1 of this objective:</p> <p><b>Option 1:</b> View, Download, or Transmit to a Third Party</p> <p><u>Denominator:</u> Number of unique patients seen by the EP, or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p> <p><u>Numerator:</u> The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information.</p> <p><u>Threshold:</u> The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.</p> <p><b>Option 2:</b> API</p> <p><u>Denominator:</u> The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency</p>	<p>CMS is basing this increased threshold on their assessment of prior attestations. There is reason to doubt their interpretation. We know that many physicians and hospitals are using prizes (or the potential to win a prize) to obtain patient usage of the data, and that the one-time activity that CMS is measuring does not likely reflect patient engagement. In such an environment, increasing the threshold only guarantees that more prizes and similar artificial approaches will be needed. The argument against this measure during the Stage 2 NPRM process still holds. There are some specialties or scopes of practice in which patient engagement with their own data is expected; and other specialties where there is no compelling data for patients to engage with, and thus engagement is not expected. This measure should be dropped.</p>

<p>department (POS 21 or 23) during the EHR reporting period.</p> <p><b>Numerator:</b> The number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an ONC-certified API.</p> <p><b>Threshold:</b> The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.</p> <p><b>Exclusions:</b> Applicable for either option discussed previously, the following providers may exclude from the measure:</p>	
<p><b>Measure 2:</b></p> <p><b>Denominator:</b> Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p> <p><b>Numerator:</b> The number of patients in the denominator for whom a secure electronic message is sent to the patient, the patient's authorized representatives, or in response to a secure message sent by the patient.</p> <p><b>Threshold:</b> The resulting percentage must be more than 35 percent in order for an EP, eligible hospital, or CAH to meet this measure.</p> <p><b>Exclusion:</b> Any EP who has no office visits during the EHR reporting period may exclude from the measure.</p> <p><b>Measure 3:</b></p> <p><b>Denominator:</b> Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p> <p><b>Numerator:</b> The number of patients in the denominator</p>	<p>As stated before, measure 2 is not necessary, as the market is sufficient to create a physician need to message patients, and to respond to patients.</p> <p>Also as stated above, measure 3 is not needed, as once CEHRT has the ability to process and include patient generated health data, most physicians would find this capability adds to their efficiency. Creating this as a process measure is likely only to add unnecessary cost and complexity.</p> <p>Bottom line, this measure is also problematic, as it:</p> <ul style="list-style-type: none"> <li>• Requires an automated counter, with all of the cost and usability issues as detailed above</li> <li>• Is unclear in definition as to what could be counted, and it may exclude the most logical use – such as a patient survey or questionnaire taken within a provider office</li> </ul> <p>The technology and use cases are still immature, and a threshold measure would not necessarily stimulate the market, nor result in information gathering, other than</p>

<p>for whom data from non-clinical settings, which may include patient-generated health data, is captured through the certified EHR technology into the patient record.</p> <p><u>Threshold:</u> The resulting percentage must be more than 15 percent in order for an EP, eligible hospital, or CAH to meet this measure.</p> <p><u>Exclusion:</u> Any EP who has no office visits during the EHR reporting period may exclude from the measure.</p>	<p>that when pressed, providers will come up with gimmicks to satisfy process measure thresholds. We recommend elimination of thresholds. CMS can then use the data collected, both from those who might have met the threshold, but more importantly, from those would did not, to gain a better understanding of when there is real value in performing these activities.</p>
<p><b>Objective 7: Health Information Exchange</b></p> <p><b>Proposed Objective:</b> The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.</p> <p>Referrals are cases where one provider refers a patient to another provider, but the referring provider also continues to provide care to the patient. In this rule, we also recognize there may be circumstances when a patient refers himself or herself to a setting of care without a provider's prior knowledge or intervention. These referrals may be included as a subset of the existing referral framework and they are an important part of the care coordination loop for which summary of care record exchange is integral. Therefore, a provider should include these instances in their denominator for the measures if the patient subsequently identifies the provider from whom they received care. In addition, the provider may count such a referral in the numerator for each measure if they undertake the action required to meet the measure upon disclosure and identification of the provider from whom the patient received care.</p> <p>In the Stage 2 final rule, we indicated that a transition or referral within a single setting of care does not qualify as</p>	<p>While we appreciate the need to share information with those caring for the same patient, our concern is not with the numerator, but with the denominator. How will physicians identify when the patient is in the denominator, and how often must that occur? The prior measure of medication reconciliation at transitions of care provides us with a clear history of the difficulty of manual denominator creation.</p> <p>With more and more providers falling off the Meaningful Use progression, getting such information will become increasingly difficult. Again, if there is a clinical imperative, there is no need for a permanent measure. Physicians learn to stop referring to those who are poor communicators.</p>

<p>a transition of care (77 FR 53983). We received public comments and questions requesting clearer characterization of when a setting of care can be considered distinct from another setting of care. For example, questions arose whether EPs who work within the same provider practice are considered the same or two distinct settings of care. Similarly, questions arose whether an EP who practices in an outpatient setting that is affiliated with an inpatient facility is considered a separate entity.</p> <p>Therefore, for the purposes of distinguishing settings of care in determining the movement of a patient, we explain that for a transition or referral, it must take place between providers which have, at the minimum, different billing identities within the EHR Incentive Programs, such as a different National Provider Identifiers (NPI) or hospital CMS Certification Numbers (CCN) to count toward this objective.</p>	
<p>We stated in the Stage 2 proposed rule at 77 FR 13723 that if the receiving provider has access to the medical record maintained by the provider initiating the transition or referral, then the summary of care record would not need to be provided and that patient may be excluded from the denominators of the measures for the objective.</p> <p>We further note that this access may vary from read-only access of a specific record, to full access with authoring capabilities, depending on provider agreements and system implementation among practice settings. In many cases, a clinical care summary for transfers within organizations sharing access to an EHR may not be necessary, such as a hospital sharing their CEHRT with affiliated providers in ambulatory settings who have full access to the patient information. However, public comments received and questions submitted by the public on the Stage 2 Summary of Care Objective reveal that there may be benefits to the provision of a summary of care document following a transition or referral of a patient, even when access to medical records is already available. For example, a summary of care document</p>	<p>We understand CMS's intent to distinguish by billing identity within the EHR program, however, physicians would not know the billing identities within the EHR incentive program, of colleagues to whom they refer or provide concurrent care for the same patients. This clarification is not helpful. We suggest that CMS choose an alternative method of discrimination such as postal address or main phone number.</p>

<p>would notify the receiving provider of relevant information about the latest patient encounter as well as highlight the most up-to-date information. In addition, the "push" of a summary of care document may function as an alert to the recipient provider of the transition that a patient has received care elsewhere and would encourage the provider to review a patient's medical record for follow-up care or reconciliation of clinical information.</p> <p>Therefore, we are revising this objective for Stage 3 to allow the inclusion of transitions of care and referrals in which the recipient provider may already have access to the medical record maintained in the referring provider's CEHRT, as long as the providers have different billing identities within the EHR Incentive Program. We note that for a transition or referral to be included in the numerator, if the receiving provider already has access to the CEHRT of the initiating provider of the transition or referral, simply accessing the patient's health information does not count toward meeting this objective. However, if the initiating provider also sends a summary of care document, this transition can be included in the denominator and the numerator, as long as this transition is counted consistently across the organization.</p>	<p>CMS is attempting to resolve the issue of whether a SoCD needs to be sent where the other physician has full or limited access to the same EHR, by suggesting that in all cases the answer is YES – as the SoCD may serve an important notification function. This clarification is also not helpful. While that may be true, sending “notifications” where that notification additionally contains a full SoCD is a lot of unnecessary traffic and creates completely unnecessary downstream reconciliation work. A notification contains the elements needed to notify. A SoCD contains a significant portion of a patient’s record. Neither should be used when the other better meets the purpose. This is another example of why adding a prescriptive process measure adds enormous complexity.</p> <p>CMS is stating that the most appropriate and efficient action of review does not count towards the measure (reviewing the record and note.) It can only count as a numerator even if the SoCD is sent and reviewed, “as long as this transition is counted consistently across the organization.” As stated above, this is unnecessarily complicated and cumbersome. The ability to count these actions in a consistent way across an organization will be difficult, if not impossible.</p>
<p><b>Proposed Measures:</b> We are proposing that providers</p>	<p>We support this sort of flexibility for all MU</p>

<p>must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Health Information Exchange Objective.</p>	<p>measures.</p>
<p><b>Proposed Measure 1:</b> 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.</p> <p>For the first measure, we are maintaining the requirements established in the Stage 2 final rule to capture structured data within the certified EHR and to generate a summary of care document using CEHRT for purposes of this measure (77 FR 54014). For purposes of this measure, we are requiring that the summary of care document created by CEHRT be sent electronically to the receiving provider.</p> <p>In the Stage 2 final rule at 77 FR 54016, we specified all summary of care documents must include the following information in order to meet the objective, if the provider knows it:</p> <ul style="list-style-type: none"> <li>● Patient name.</li> <li>● Referring or transitioning provider's name and office contact information (EP only).</li> <li>● Procedures.</li> <li>● Encounter diagnosis.</li> <li>● Immunizations.</li> <li>● Laboratory test results.</li> <li>● Vital signs (height, weight, blood pressure, BMI).</li> <li>● Smoking status.</li> <li>● Functional status, including activities of daily living, cognitive and disability status.</li> <li>● Demographic information (preferred language, sex, race, ethnicity, date of birth).</li> <li>● Care plan field, including goals and instructions.</li> <li>● Care team including the primary care provider of record and any additional known care team members beyond the referring or transitioning provider and the receiving provider.</li> </ul>	<p>This threshold will put pressure on EPs to routinely create and send SoCDs regardless of whether the receiving physician has the same billing identity. This will lead to an enormous increase in electronic traffic and storage, as well as adding to the unnecessary but required work of clinical reconciliation.</p> <p>The requirements for functional status, care plans, and care team members is structured such that if any data exists in those fields, they must be sent whether they are up to date or not. These are fields that do not necessarily remain accurate over time, and are not routinely updated at every encounter. This requirement then mandates the universal send of potentially unreliable or misleading information. Given that effort is required on the part of the EP to block the sending of data in the SoCD, The default in most systems is to send everything) the fact that an EP has chosen to do so, should be enough evidence to indicate appropriate use of clinical judgment in withholding information.</p>

<ul style="list-style-type: none"> <li>• Discharge instructions (Hospital Only).</li> <li>• Reason for referral (EP only).</li> </ul>	
<p>In circumstances where there is no information available to populate one or more of the fields included in the CCDS, either because the EP, eligible hospital, or CAH can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the EP, eligible hospital, or CAH may leave the field blank and still meet the requirements for the measure.</p> <p>However, all summary of care documents used to meet this objective must be populated with the following information using the CCDS certification standards for those fields:</p> <ul style="list-style-type: none"> <li>• Current problem list (Providers may also include historical problems at their discretion).</li> <li>• A current medication list.</li> <li>• A current medication allergy list.</li> </ul> <p>We propose to maintain that all summary of care documents contain the most recent and up-to-date information on all elements. In the event that there are no current diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies; the EP, eligible hospital, or CAH must record or document within the required fields that there are no problems, no medications, or no medication allergies recorded for the patient to satisfy the measure of this objective. The EP or hospital must verify that the fields for problem list, medication list, and medication allergy list are not blank and include the most recent information known by the EP or hospital as of the time of generating the summary of care document.</p>	<p>It appears that CMS and ONC have removed (or at least are suggesting that it could be removed) one of the barriers to exchange – the mandate that every Summary of Care contain all known information in all fields. Except where providers have taken it upon themselves to narrow down what is communicated, these documents have been excessively long, and often “bury headlines” – and thus “say a lot but communicate nothing.” If this is part of the final rule – CMS will have taken a big step forwards. However, problems remain again not with the intent or function, but rather with operationalizing the definitions.</p> <p>CMS appears to be stating a duty to review and reconcile all fields in the SoCD at every occurrence of publication and send – not just an obligation concerning the problem, medication, and allergy lists. This is inappropriate.</p>
<p>For summary of care documents at transitions of care, we encourage providers to send a list of items that he or she believes to be pertinent and relevant to the patient's care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. While a current problem list must always be included, the</p>	<p>We need clarity on this statement. Is CMS saying that EPs can use judgment in what is included in the SoCD, or only use judgment when it comes to the problem list?</p>

<p>provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.</p> <p>Similarly, for Stage 3 we have received comments from stakeholders and through public forums and correspondence on the potential of allowing only clinically relevant laboratory test results and clinical notes (rather than all laboratory tests results and clinical notes) in the summary of care document for purposes of meeting the objective.</p> <p>We believe that while there may be a benefit and efficiency to be gained in the potential to limit laboratory test results or clinical notes to those most relevant for a patient's care; a single definition of clinical relevance may not be appropriate for all providers, all settings, or all individual patient diagnosis. Furthermore, we note that should a reasonable limitation around a concept of "clinical relevance" be added; a provider must still have the CEHRT functionality to include and send all labs or clinical notes.</p> <p>Therefore, we defer to provider discretion on the circumstances and cases wherein a limitation around clinical relevance may be beneficial and note that such a limitation would be incumbent on the provider to define and develop in partnership with their health IT developer as best fits their organizational needs and patient population. We specify that while the provider has the discretion to define the relevant clinical notes or relevant laboratory results to send as part of the summary of care record, providers must be able to provide all clinical notes or laboratory results through an electronic transmission of a summary of care document if that level of detail is subsequently requested by a provider receiving a transition of care or referral or the patient is transitioning to another setting of care. We note that this proposal would apply for lab results, clinical notes, problem lists, and the care plan within the summary of care document.</p>	<p>Again to clarify, CMS is suggesting that providers are allowed to determine what is reasonable to include in labs and testing information. If that survives into the FR, how will CMS instruct auditors to look for reasonableness, and will that determination be so difficult to demonstrate that providers will ignore the potential and just do what is easiest, which is to send everything?</p> <p>The SoCD has been redefined by this rule to include clinical notes without discussion, evidence, or request for input. This topic requires thorough discussion before inclusion.</p>
<p><b>Proposed Measure 2:</b> For more than 40 percent of</p>	<p>It appears that EPs must demonstrate</p>

<p>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.</p> <p>For the second measure, we are proposing to address the other end of the transition of care continuum. In the Stage 2 rule, we limited the action required by providers to sending an electronic transmission of a summary of care document. We did not have a related requirement for the recipient of that transmission. We did not adopt a certification requirement for the receiving end of a transition or referral or for the measure related to sending the summary, as that is a factor outside the sending provider's immediate control. However, in Stage 3 of meaningful use, we are proposing a measure for the provider as the recipient of a transition or referral requiring them to actively seek to incorporate an electronic summary of care document into the patient record when a patient is referred to them or otherwise transferred into their care. This proposal is designed to complete the electronic transmission loop and support providers in using CEHRT to support the multiple roles a provider plays in meaningful health information exchange.</p> <p>For the purposes of defining the cases in the denominator, we are proposing that what constitutes "unavailable" and therefore, may be excluded from the denominator, will be that a provider—</p> <ul style="list-style-type: none"> <li>• Requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and</li> <li>• Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or the provider does not have access to HIE functionality to support such a query.</li> </ul>	<p>incorporation of a SoCD 40%+ of times where there is a transition or referral AND the EP has never encountered the patient before. What is the definition of “never?” Is it tied to CMS billing definitions for a new patient – someone never seen before or not seen within 3 years? Also, as many young adult patients do not see their doctor except episodically, will this requirement over-specify the need to consider someone as “new”, when in fact this patient is a healthy young adult who is appropriately seeing a provider every several years.</p> <p>It will be difficult to track and measure whether a summary was requested and whether a summary was received in direct reply to that specific request.</p> <p>This will also be difficult to track and measure whether a valid query was sent and whether data specific to the query was or was not returned.</p>
<p>We seek comment on whether electronic alerts received</p>	<p>These alerts are often captured anyway, as</p>

by EPs from hospitals when a patient is admitted, seen in the emergency room or discharged from the hospital-- so called "utilization alerts"--should be included in measure two, or as a separate measure. Use of this form of health information exchange is increasingly rapidly, driven by hospital and EP efforts to improve care transitions and reduce readmissions. We also seek comment on which information from a utilization alert would typically be incorporated into a patient's record and how this is done today.

For both the first and second measures, we are proposing that a provider may use a wide range of health IT system for health information exchange to receive or send an electronic summary of care document, but must use their certified EHR technology to create the summary of care document sent or to incorporate the summary of care document received into the patient record. We are also proposing that the receipt of the summary of care document (CCDA) may be passive (provider is sent the CCDA and incorporates it) or active (provider requests a direct transfer of the CCDA or provider queries an HIE for the CCDA).

Specifically we seek comment on whether providers who create a summary of care record using CEHRT for purposes of Measure 1 should be permitted to send the created summary of care record either-- (1) through any electronic means; or (2) in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network.

We additionally seek comment on whether providers who are receiving a summary of care record using CEHRT for the purposes of Measure 2 should have a similar requirement for the transport of summary of care documents requested from a transitioning provider.

Finally, we seek comment on how a governance mechanism established by ONC at a later date could be incorporated into the EHR Incentive Programs for purposes of encouraging interoperable exchange that benefits patients and providers, including how the

they are typically considered part of a clinical record. However, capturing in a way such that they count as a denominator will add cost and complexity to EHR build and certification. Further, as hospital capture of PCP is notoriously unreliable, we are concerned that, if captured as a denominator, and the information is not correct, the EHR will now look for a numerator event for something that will never happen (i.e., a transition visit to the misidentified PCP).

We strongly believe that this proposed measure should be eliminated. If it remains, only permitting it to occur via the ONC sanctioned governance model is codifying anticompetitive and anti-innovative requirements. We are too early in the process of developing reliable exchange to understand the ramifications of a fixed governance model. This comment applies to the first and second question.

A governance model for what is permitted and trusted to be secure is important, but once it is tied to capture of numerator and denominator capture and thresholds, it is in a position of monopolistic control over physicians. It is not necessarily engineered to be up-to-date or effective, just self-

<p>governance mechanism should be captured in the numerator, denominator, and thresholds for both the first (send) and second (receive) measures of this Health Information exchange objective.</p>	<p>referential and self-sustaining. We would never set such conditions for mail, packages, email, etc.</p>
<p><b>Proposed Measure 3:</b> 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 a clinical information reconciliation.</p> <p>The provider must implement clinical information reconciliation for the following three clinical information sets:</p> <ul style="list-style-type: none"> <li>• Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication.</li> <li>• Medication allergy. Review of the patient's known allergic medications.</li> <li>• Current Problem list. Review of the patient's current and active diagnoses.</li> </ul> <p>For the third measure, we are proposing a measure of clinical information reconciliation which incorporates the Stage 2 objective for medication reconciliation and expands the options to allow for the reconciliation of other clinical information such as medication allergies, and problems which will allow providers additional flexibility in meeting the measure in a way that is relevant to their scope of practice. In the Stage 2 final rule, we outlined the benefits of medication reconciliation, which enables providers to validate that the patient's list of active medications is accurate (77 FR 54011 through 54012). This activity improves patient safety, improves care quality, and improves the validity of information that the provider shares with others through health information exchange. We believe that reconciliation of medication allergies and problems affords similar benefits.</p>	<p>This appears to be an instance where CMS is granting flexibility that is significant. That said, it is not necessary to have such a measure, as there is already a Joint Commission standard for medication review and reconciliation.</p> <p>Having technology available that makes clinical reconciliation possible will make the work of those who do it easier. It should not be mandated for everyone. Building this in as a permanent process measure adds unnecessary cost and complexity.</p> <p>This measure is described as requiring two contradictory actions. In one instance, it states that providers will perform a clinical reconciliation on all 3 specified lists – problem list, medication list, and medication allergy list. In another instance, it is stated that providers will have a choice of reconciling one of the three, and in another place possibly two of three, thus permitting flexibility based on specialty and scope of practice. The College strongly recommends that the requirement be for one of the three, as that will make the measure more palatable and more responsive to the varying needs of different specialties.</p>
<p>We recognize that workflows to reconcile clinical information vary widely across providers and settings of</p>	

care, and we request comment on the challenges that this objective might present for providers, and how such challenges might be mitigated, while preserving the policy intent of the measure. In particular, we solicit comment on the following:

- Automation and Manual Reconciliation. The Stage 2 measure does not specify whether reconciliation must be automated or manual. Some providers have expressed concern over the automatic inclusion of data in the patient record from referring providers, while others have indicated that requiring manual reconciliation imposes significant workflow burden. We also seek comment on whether the use and display of meta-tagged data could address concerns related to the origin of data and thereby permit more automated reconciliation of these data elements.
- Review of Reconciled Information. Depending on clinical setting, this measure could be accomplished through manual reconciliation or through automated functionality. In either scenario, should the reconciliation or review of automated functionality be performed only by the same staff allowed under the Stage 3 requirements for the Computerized Provider Order Entry objective?
- What impact would the requirement of clinical information reconciliation have on workflow for specialists? Are there particular specialties where this measure would be difficult to meet?
- What additional exclusions, if any, should be considered for this measure?

We also encourage comment on the proposal to require reconciliation of all three clinical information reconciliation data sets, or if we should potentially require providers to choose 2 of 3 information reconciliation data sets relevant to their specialty or patient population. We expect that most providers would find that conducting clinical information reconciliation for medications, medication allergies, and problem lists is relevant for every patient encountered. We solicit

CMS should not enter into this debate. Whether a provider chooses to accept everything by default or review everything is an individual choice, and as technology and clinical list provenance improve, what seems like a question today may be much clearer tomorrow.

We are concerned about the possibility of negative unintended consequences when there is a requirement for specialists to perform reconciliation without a great deal of specific guidance. We see this leading to clinical mayhem and causing patient safety risks. A dermatologist may have a very specific name for a diagnosis that the PCP may simply call psoriasis. Patients come to an Internist labeled simply as having COPD by a specialist, but may have more specifically emphysema and/or chronic bronchitis; or labeled as COPD, with no obstructive lung disease and their shortness of breath is from obesity, deconditioning, heart failure, or any combination thereof. Without national consensus on how to

examples describing challenges and burdens that providers who deliver specialist care or employ unique clinical workflow practices may experience in completing clinical information reconciliation for all three data sets and whether an exclusion should be considered for providers for whom such reconciliation may not be relevant to their scope of practice or patient population.

Additionally, we solicit comments around the necessity to conduct different types of clinical information reconciliation of data for each individual patient. For example, it is possible that the data for certain patients should always be reviewed for medication allergy reconciliation, when it may not be as relevant to other patient populations.

We propose that to meet this objective, a provider must attest to the numerator and denominator for all three measures but would only be required to successfully meet the threshold for two of the three proposed measures. We invite public comment on this proposal.

manage diagnosis lists (on medical history or problem lists), we do not see how this becomes a useful measure.

Manual reconciliation does impose a significant burden, but this burden is important for some providers and should be recognized in the payment model as legitimate work.

Comparison and reconciliation of lists may be important to reconcile two or more physicians' views of a med list. What this rule ignores is what many physicians choose to do when we have doubts as to what a patient is actually taking—we have them bring in their actual medication bottles, as sometimes both lists are wrong.

We are glad CMS is also raising the question of who should do this review. Should it be the same staff allowed to enter orders? To be consistent, the answer should be YES, but similar to the concern raised with CPOE – allowing such staff to perform clinical reconciliation will likely result in reconciled lists that are less accurate than if physicians performed or attested to the reconciliation.

CMS needs to study the difficulties of problem list reconciliation that exist today. In most instances, problem list reconciliation is a primary care or principal provider duty, and not one that is delegated to others.

We urge caution in requiring medication reconciliation from specialists without a clearer understanding of active medication list etiquette. There have been many instances of specialists' staff removing chronic medications from a medication list

	<p>– as the patient didn't take them that day, or ran out – rather than noting, "not currently taking." Many health systems have implemented rules about who can remove chronic medications from the medication list.</p> <p>More work needs to occur on clinical reconciliation, including where and when it adds clarity and safety, and where it is just forcing check-box checking. And with confusion as to denominator counts, having this as a process measure with a threshold will remain problematic. Note that the measure for medication reconciliation was most problematic not because of what it asked for, but because creating the denominator was a manual process, and it was often not done. Additionally, CMS would not accept a figure that suggested it was done more than 100% of the time, which was the typical aftermath of performing an activity that was part of normal workflow, and forgetting to manually indicate that a denominator should be present.</p>
<p>Measure 1: To calculate the percentage of the first measure, CMS and ONC have worked together to define the following for this measure:</p> <p><u>Denominator:</u> Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.</p> <p><u>Numerator:</u> The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.</p> <p><u>Threshold:</u> The percentage must be more than 50</p>	<p>Clarification is needed as to how this denominator will be calculated. We have seen it connected to referrals, but how it will work for transitions or self-referrals is not clear.</p>

<p>percent in order for an EP, eligible hospital, or CAH to meet this measure.</p> <p><u>Exclusion:</u> An EP neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.</p> <p>Measure 2: To calculate the percentage of the second measure, CMS and ONC have worked together to define the following for this measure:</p> <p><u>Denominator:</u> Number of patient encounters during the EHR reporting period for which an EP, eligible hospital, or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.</p> <p><u>Numerator:</u> Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.</p> <p><u>Threshold:</u> The percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.</p> <p><u>Exclusion:</u> Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.</p>	<p>Again, this denominator will not be able to be accurately calculated – as receive = received or queried and then received + HIE lookup. A failure to receive a response or lack of a SoCD in the HIE = “unavailable.”</p> <p>Clarity is also needed as to how the numerators will be associated with the denominators.</p>
<p><b>Measure 3:</b> To calculate the percentage, CMS and ONC have worked together to define the following for this measure:</p> <p><u>Denominator:</u> Number of transitions of care or referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.</p> <p><u>Numerator:</u> The number of transitions of care or referrals in the denominator where the following three clinical</p>	<p>It is not clear if this is the same denominator as for measure #1, which excludes patients for whom the SoCD is not available. ACP recommends that it should be the same denominator as #1. Otherwise, the right activity by the provider may still result in a failure to be successful with this measure.</p>

<p>information reconciliations were performed: medication list, medication allergy list, and current problem list.</p> <p><b>Threshold:</b> The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.</p> <p><b>Exclusion:</b> Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.</p>	<p>The description here is for all three components of clinical reconciliation, whereas the description above calls for only meeting one threshold. This should be clarified.</p>
<p><b>Objective 8: Public Health and Clinical Data Registry Reporting</b></p> <p><b>Proposed Objective:</b> The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.</p> <p>For purposes of meeting this new objective, EPs, eligible hospitals and CAHs would be required to demonstrate that "active engagement" with a PHA or CDR has occurred. Active engagement means that the provider is in the process of moving towards sending "production data" to a PHA or CDR, or— is sending production data to a PHA or CDR. We note that the term "production data" refers to data generated through clinical processes involving patient care, and it is here used to distinguish between this data and "test data" which may be submitted for the purposes of enrolling in and testing electronic data transfers. We propose that "active engagement" may be demonstrated by any of the following options:</p> <p><b>Active Engagement Option 1 – Completed Registration to Submit Data:</b> The EP, eligible hospital, or CAH registered to submit data with the PHA or, where applicable, the CDR to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP,</p>	<p>A major concern with these reporting requirements is that they are all one-way. EPs and EHs must collect and supply data to target agencies, but there is no requirement at all for these agencies to report back to the providers. The definition of "active engagement" must be expanded to require that all health data exchanges be bidirectional. Otherwise, these reporting measures demonstrate clerical data entry rather than meaningful use. 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.</p> <p>EPs and hospitals are required to engage with all of the PHAs and CDRs in their service area, which often includes several states and other jurisdictions. Unless public authorities are compelled to coordinate and simplify requirements, providers are guaranteed undue complexity and expense. As is already known from prior stages of MU, having a requirement that providers connect to disparate registries has not created a market force for registries to accept the output from EHRs. The proposed immunization reporting measure</p>

<p>eligible hospital, or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation. This option allows providers to meet the measure when the PHA or the CDR has limited resources to initiate the testing and validation process. Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.</p> <p><b>Active Engagement Option 2 - Testing and Validation:</b> The EP, eligible hospital, or CAH is in the process of testing and validation of the electronic submission of data. Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.</p> <p><b>Active Engagement Option 3 – Production:</b> The EP, eligible hospital, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.</p> <p>We also propose to provide support to providers seeking to meet the requirements of this objective by creating a centralized repository of national, state, and local PHA and CDR readiness.</p> <p>We expect that the centralized repository will include readiness updates for PHAs and CDRs at the state, local, and national level. We welcome your comments on the use and structure of the centralized repository.</p>	<p>requires bidirectional exchange. All reporting measures should require the same.</p> <p>How does this requirement deal with the lack of registry readiness in certain areas to accept data? Again, the onus is on EPs to connect, or regularly check the central repository, rather than additionally creating a utility to which providers can send production data, and it is the local registries concern to connect to that hub.</p>
<p><b>Proposed Measures (objective 8):</b> We are proposing a total of six possible measures for this objective. EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of three measures.</p> <p>MEASURES FOR OBJECTIVE 8: PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE</p> <p>Measure 1 – Immunization Registry Reporting</p>	

<ul style="list-style-type: none"> <li>• Maximum times measures can count towards objective for EP: 1</li> <li>• Maximum times measure can count towards objective for eligible hospitals or CAH: 1</li> </ul> <p>Measure 2 – Syndromic Surveillance Reporting</p> <ul style="list-style-type: none"> <li>• Maximum times measures can count towards objective for EP: 1</li> <li>• Maximum times measure can count towards objective for eligible hospitals or CAH: 1</li> </ul>	<p>Immunization registries still have unique and nonstandard requirements. EHRs must not be required to accommodate all of them. There is a responsibility on IIS' to update their systems to a single standard.</p> <p>We are not aware of registries being ready to accept syndromic surveillance reporting from EPs. This is not really an option and should be excluded.</p>
<p>Measure 3 – Case Reporting</p> <ul style="list-style-type: none"> <li>• Maximum times measures can count towards objective for EP: 1</li> <li>• Maximum times measure can count towards objective for eligible hospitals or CAH: 1</li> </ul> <p>Measure 4 – Public Health Registry Reporting</p> <ul style="list-style-type: none"> <li>• Maximum times measures can count towards objective for EP: 3</li> <li>• Maximum times measure can count towards objective for eligible hospitals or CAH: 4</li> </ul> <p>Measure 5 – Clinical Data Registry Reporting</p> <ul style="list-style-type: none"> <li>• Maximum times measures can count towards objective for EP: 3</li> <li>• Maximum times measure can count towards</li> </ul>	<p>We are not aware of an available standard for Case reporting.</p> <p>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 an SoCD? All public health authorities must be compelled to coordinate and simplify reporting requirements or burden will not be decreased.</p> <p>We need examples of public health registries. Will reporting require duplicative documentation into an electronic form, rather than the reporting system accepting the export of an SoCD? Authorities must be compelled to coordinate and simplify reporting requirements.</p> <p>Same questions for Clinical data registry reporting.</p> <p>All public health registries must be brought into full compatibility by 2018. It is</p>

<p>objective for eligible hospitals or CAH: 4</p> <p>Measure 6 – Electronic Reportable Laboratory Results</p> <ul style="list-style-type: none"> <li>• Maximum times measures can count towards objective for EP: N/A</li> <li>• Maximum times measure can count towards objective for eligible hospitals or CAH: 1</li> </ul>	<p>unacceptable for physicians to have to pay vendors to support all of the registries for all of the states. It will be far less expensive to the health care system for all public registries to achieve full compatibility in accepting reports.</p>
<p><b>Measure 1 – Immunization Registry Reporting:</b> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).</p> <p>We believe the immunization registry reporting measure remains a priority for Stage 3 because the exchange of information between certified EHR technology and immunization registries allows a provider to use the most complete immunization history available to inform decisions about the vaccines a patient may need. Public health agencies and providers also use immunization information for emergency preparedness and to estimate population immunization coverage levels of certain vaccines.</p> <p>We propose that to successfully meet the requirements of this measure, bidirectional data exchange between the provider's certified EHR technology and the immunization registry/IIS is required. We understand that many states and local public health jurisdictions are exchanging immunization data bidirectionally with providers, and that the number of states and localities able to support bidirectional exchange continues to increase.</p> <p>We believe that patients, providers, and the public health community would benefit from technology that can accommodate bidirectional immunization data exchange. We welcome comment on this proposal.</p> <p><u>Exclusion for Measure 1:</u> Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting</p>	<p>We fully support bidirectional exchange of immunization data. CMS should require that all health data exchanges and reporting measures be bidirectional. Otherwise, these reporting measures demonstrate clerical data entry rather than meaningful use. Patients and their doctors</p>

<p>measure if the EP, eligible hospital, or CAH: (1) does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period; (2) operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.</p>	<p>will benefit greatly from requirements that public health agencies report back in a timely manner and with meaningful data.</p> <p>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 an SoCD? All public health authorities must be compelled to coordinate and simplify reporting requirements or burden will not be decreased.</p>
<p><b>Measure 2 – Syndromic Surveillance Reporting:</b> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23). This measure remains a policy priority for Stage 3 because electronic syndromic surveillance is valuable for early detection of outbreaks, as well as monitoring disease and condition trends.</p> <p>Because eligible hospitals and CAHs send syndromic surveillance data using different methods as compared to EPs, we are defining slightly different exclusions for each setting as described later in this section.</p> <p><u>Exclusion for EPs for Measure 2:</u> Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP:</p> <p>(1) does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in their jurisdiction; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs</p>	<p>EPs and EHs must collect and supply data to target agencies, but there is no requirement at all for these agencies to report back to the providers. The definition of “active engagement” must be expanded to require that all health data exchanges be bidirectional. Otherwise, these reporting measures demonstrate clerical data entry rather than meaningful use. Patients and their doctors will benefit greatly from requirements that public health agencies report back in a timely manner and with meaningful data. The proposed immunization reporting measure requires bidirectional exchange. All reporting measures should require the same.</p> <p>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 an SoCD. All public health authorities must be compelled to coordinate and simplify reporting requirements or burden will not be decreased.</p>

<p>at the start of the EHR reporting period.</p>	
<p><b>Measure 3 - Case Reporting:</b> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</p> <p>This is a new reporting option that was not part of Stage 2. The collection of electronic case reporting data greatly improves reporting efficiencies between providers and the PHA. Public health agencies collect "reportable conditions", as defined by the state, territorial, and local PHAs to monitor disease trends and support the management of outbreaks. In many circumstances, there has been low reporting compliance because providers do not know when, where, or how to report. In some cases, the time burden to report can also contribute to low reporting compliance. However, electronic case reporting presents a core benefit to public health improvement and a variety of stakeholders have identified electronic case reporting as a high value element of patient and continuity of care. Further, we believe that electronic case reporting reduces burdensome paper-based and labor-intensive case reporting. Electronic reporting will support more rapid exchange of case reporting information between PHAs and providers and can include structured questions or data fields to prompt the provider to supply additional required or care-relevant information.</p> <p><u>Exclusion for Measure 3:</u> Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the EP, eligible hospital, or CAH: (1) does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.</p>	<p>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 an SoCD. All public health authorities must be compelled to coordinate and simplify reporting requirements or burden will not be decreased. Development by PHAs of such additional queries should be based on use of structured data that already exists, and not requiring duplicative documentation or documentation irrelevant for patient care.</p> <p>Note that functionality to support additional queries does not yet exist, so it may not really be an option for 2017. Since the proposed standard is still a long way from actual publication, we must assume that it will not be ready for vendor implementation in time for certification. Unlike some standards, a great deal of new functionality must be developed by the vendors to support this sort of query.</p>

**Measure 4 - Public Health Registry Reporting:** The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.

...propose to split public health registry reporting from clinical data registry reporting into two separate measures which better define the potential types of registries available for reporting. We propose to define a "public health registry" as a registry that is administered by, or on behalf of, a local, state, territorial, or national PHA and which collects data for public health purposes. While immunization registries are a type of public health registry, we propose to keep immunization registry reporting separate from the public health registry reporting measure to retain continuity from Stage 1 and 2 policy in which immunization registry reporting was a distinct and separate objective (77 FR 54023). We believe it is important to retain the public health registry reporting option for Stage 3 because these registries allow the public health community to monitor health and disease trends, and inform the development of programs and policy for population and community health improvement.

For the Stage 3 public health registry reporting measure, given the desire to provide more flexible options for providers to report to the registries most applicable for their scope of practice, we propose that EPs would have the option of counting cancer case reporting under the public health registry reporting measure. We note that cancer case reporting is not an option for eligible hospitals and CAHs under this measure because hospitals have traditionally diagnosed or treated cancers and have the infrastructure needed to report cancer cases.

Exclusions for Measure 4: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH: (1) does not diagnose or directly treat any disease or condition associated with a public health registry in their

Public Health registries (excluding immunization registries) may not exist at present, so this may not actually be an option. We would like to know which states have compatible PH registries in addition to immunization registries. In a recent public forum, CMS suggested that EPs will be obligated to perform some level of research to determine if there is a locally available registry. This is an unnecessary burden. CMS should provide an up to date list of available registries in a convenient online location.

EPs and EHs must collect and supply data to target agencies, but there is no requirement at all for these agencies to report back to the providers. The definition of "active engagement" must be expanded to require that all health data exchanges be bidirectional. Otherwise, these reporting measures demonstrate clerical data entry rather than meaningful use. Patients and their doctors will benefit greatly from requirements that public health agencies report back in a timely manner and with meaningful data. The proposed immunization reporting measure requires bidirectional exchange. All reporting measures should require the same.

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. All public health authorities must be compelled to coordinate and simplify reporting requirements or burden will not be decreased.

<p>jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.</p>	
<p><b>Measure 5 – Clinical Data Registry Reporting:</b> The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.</p> <p>For Stage 3, we propose to include clinical data registry reporting as an independent measure. The National Quality Registry Network defines clinical data registries as those that record information about the health status of patients and the health care they receive over varying periods of time.<sup>12</sup> We propose to further differentiate between clinical data registries and public health registries as follows: for the purposes of meaningful use, "public health registries" are those administered by, or on behalf of, a local, state, territorial, or national public health agencies; and "clinical data registries" are administered by, or on behalf of, other non-public health agency entities.</p> <p><u>Exclusions for Measure 5:</u> Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH: (1) does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the</p>	<p>Clinical data registries do exist, and all come with an additional cost to providers. Are clinical data registries required to accept the output of a CEHRT? If that is not the case, this requirement may be forcing a behavior upon which providers have no leverage in terms of cost.</p>

EHR reporting period.	
<p><b>The use of CEHRT for the Public Health and Clinical Data Registry Reporting Objective (8)</b></p> <p>To meet all of the measures within this public health objective EPs, eligible hospitals, and CAHs must use CEHRT as we propose to define it under § 495.4 in this proposed rule and use the standards included in the 2015 Edition proposed rule. We anticipate that as new public health registries and clinical data registries are created, ONC and CMS will work with the public health community and clinical specialty societies to develop ONC-certified electronic reporting standards for those registries so that providers have the option to count participation in those registries under the measures of this objective. ONC will look to adopt such standards, as appropriate, in future rules published by ONC.</p>	<p>It is time for CMS to re-think its focus on the EHR. It is clear that the industry is moving away from a system or an application to a collection of loosely connected data sets and services. The notion of “CEHRT” has been removed from the ONC rule, except for the need to address the requirements of this rule. Where and how services are performed and whether data are exchanged or simply queried should be of no concern to the EHR Incentive Program.</p>
<p><b>Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2017 and Subsequent Years</b></p> <p><u>Clinical Quality Measure Reporting Requirements for EPs</u></p> <p>To further our goals of alignment and avoiding redundant or duplicative reporting across the various CMS quality reporting programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for EPs for 2017 and subsequent years in the Medicare Physician Fee Schedule (PFS) rulemaking, which also establishes the requirements for PQRS and other quality programs affecting EPs.</p> <p>We note that the form and manner of reporting of CQMs for Medicare EPs would also be included in the PFS, while for Medicaid we would continue to allow the states to determine form and method requirements subject to CMS approval.</p>	<p>We are concerned that decoupling quality reporting functionality from the rest of the program requirements will only increase the difficulties that all parties have had in meeting the reporting requirements. There is tremendous confusion among system developers, measure developers, and EPs over which version of which eCQM should be used when. The current annual process actually includes many variations from the plan and fails to accommodate standards and measures changes in an orderly fashion.</p>
<p><b>EHR Technology Certification Requirements for Reporting of CQMs</b></p> <p>We realize that requiring EHRs to be certified to more than the minimum number of CQMs required by the</p>	<p>This is a reasonable proposal only if all EP measures have been reviewed for appropriateness, as some measures include hospital activity and thus imply knowledge of activities that the EP EHR may have no</p>

<p>Medicare and Medicaid EHR Incentive Programs may increase the burden on EHR vendors. However, in the interest of EPs, eligible hospitals, and CAHs being able to choose to report eQMs that represent their patient populations, we would like to see EP vendors certify to all eQMs that are in the EP selection list, or eligible hospital/CAH vendors certify to all eQMs in the selection list for those stakeholders.</p>	<p>knowledge.</p>
<p>We note that all providers would be required to fully upgrade to EHR technology certified to the 2015 Edition for the EHR reporting period in 2018. We also reiterate that providers may elect to attest to Stage 3 of the program using EHR technology certified to the 2015 Edition beginning in 2017.</p> <p>As part of this proposal, we would like to seek comment on alternate flexibility options. Specifically, we are seeking comment on whether the flexible option to attest to Stages 1 or 2 should be limited to only those providers who could not fully implement EHR technology certified to the 2015 Edition in 2017. We are also seeking comment on whether those providers with fully implemented EHR technology certified to the 2015 Edition in 2017 should be required to attest to Stage 3 only in 2017. Finally, we seek comment on whether providers should not have the option to attest to Stage 3 in 2017 regardless of an upgrade to EHR technology certified to the 2015 Edition in 2017, and should instead be required to wait to demonstrate Stage 3 until 2018 using EHR technology certified to the 2015 Edition.</p>	<p>Given our recent history, where CMS needed to perform an emergency revision to the 2014 reporting period due to its failure to acknowledge that the implementation timetable was impossible to achieve, it should be obvious to all that no EP will have fully implemented a system capable of Stage 3 reporting by 1/1/2017. Further, even if a vendor is capable of delivering a certified system to a practice in 2017, the practice will be unable to attest in 2017 due to the downtime required to implement the new system and all of the new measures.</p> <p>Realistically, 2017 will be a continuation of Stage 2. Additionally, 2018 should be a 90-day reporting year to allow practices the opportunity to upgrade, implement, and report successfully.</p>
<p><b>EHR Reporting Period for Determining whether an EP is Subject to the Payment Adjustment for CY 2018 and Subsequent Calendar Years</b></p> <p>In this Stage 3 proposed rule, we propose to eliminate the exception discussed previously for a 90-day EHR reporting period for new meaningful EHR users beginning with the EHR reporting period in 2017, with a limited exception for Medicaid EPs demonstrating meaningful use for the first time. We propose that for EPs who have successfully demonstrated meaningful use in a prior year as well as</p>	<p>Not allowing less than full calendar year reporting periods makes it impossible for those switching EHRs to successfully attest. In addition to shouldering the costs of a new system and conversion from the old system, all practices will be faced with the Medicare penalty two years later.</p>

those who have not, the EHR reporting period for a payment adjustment year would be the full calendar year that is 2 years before the payment adjustment year.	
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