ACP
American College of Physicians
Internal Medicine | Doctors for Adults®

May 7, 2012

Centers for Medicare & Medicare Services
Department of Health and Human Services
Via http://www.regulations.gov
Re: Document ID CMS-0044-P

To Whom It May Concern:

Thank you for the opportunity to comment on the Notice of Proposed Rule-Making (NPRM) that would specify the Stage 2 criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and/or Medicaid electronic health record (EHR) incentive payments.

The American College of Physicians, representing 132,000 internal medicine physicians and medical student members, believes that the focus on meaningful use is the right way to promote and assess adoption of EHRs. We offer the following comments and recommendations in the interest of improving the implementation of the 2009 HITECH legislation and ensuring that the goals set forth by the legislation are attained expediently without creating unintended consequences.

In this document, there are four components and a concluding statement:

1. General Comments;
2. Responses to specific Meaningful Use functional measures, including for each element:
    a. Elements in the NPRM that we support;
    b. Answers to specific questions raised in the NPRM;
    c. Comments on elements in the NPRM that require clarification or modification.
3. Responses to other components of the NPRM;
4. Attached is a January 12, 2012 letter to the Office of The National Coordinator, portions of which we reference in our comments.

1. General Comments

The ACP supports the goals of the Meaningful Use program, and we support the objectives upon which each of the functional measures is based. However, we believe that the measures themselves too often do not align well with the laudable objectives. We are also concerned that the volume of work required of EPs to comply with Meaningful Use documentation requirements will overwhelm the limited time available to provide patient care. Finally, some of the proposed measures call for technologies and processes which do not yet exist in usable form. Even where they exist, the cost of implementing them (e.g., patient web portals for secure messaging and access to results) far exceeds any expected incentive payment that would accrue and creates the expectation for additional care (e-visits) that is not reimbursed by most payers. Below are general comments that we will refer to repeatedly in this document. We place the fuller explanation of our concerns here in order to reduce the amount of repetition in our specific comments. Other general concerns are contained in our January 12, 2012 letter to the ONC, which is attached to these comments.

Staging of requirements – The approach throughout Meaningful Use to-date has been for CMS to call for EPs to perform new functions at the same time as ONC is requiring EHR system vendors to add the new functionality to their systems. This commonly results in unanticipated negative consequences where the functionality is incompletely or poorly implemented, with usability challenges that make it difficult for EPs to incorporate the new functionality into existing workflows, or that forces modification of existing workflows to ones that are less efficient. As a general rule, we recommend that EPs should not be expected to demonstrate use of new functions until those functions have been implemented in systems and successfully tested in real-world settings. The current method of concurrent certification and implementation is like writing new software to control an airplane and communicate vital information about its status securely with air traffic control towers, using new standards that are not already broadly in use in the industry but "should be" by 2014, and then setting a deadline for use by hundreds of software vendors and hundreds of thousands of pilots flying a variety of planes with precious cargo on board without first proving the technology and workflows are feasible, broadly implementable and will work for virtually everyone who has reasonable competence and motivation to maintain and fly their aircraft. We do not believe this is reasonable or realistic; such expectations can be expected to result in stakeholder disengagement (lack of willingness to continue to engage in the Meaningful Use program), or inability to succeed even with their best efforts due to factors outside their control. Further, by adopting the current model of use before adequate testing, just like in the airplane analogy, we are concerned about inadvertently causing harm to patients. We believe a much more sensible approach would be for ONC-Authorized Certification Bodies (ONC-ACBs) to certify functions as in place and usable for each certified EHR technology at least 2 years ahead of CMS incorporating them into "core" measures for Meaningful Use. Meaningful Use measures should never be based upon "should" statements regarding what will be available at a future date but is not broadly available today. It is difficult enough to adopt established, proven technologies and functions that are already in place, let alone tools and technologies that are not yet established or deployed but that "should" be by 2014.

Another problem caused by the current staging process is that vendors are placed in a position of having to implement functions in advance of fully balloted and tested standards. Just as demonstration of Meaningful Use must wait for mature functionality, mature functionality requires the availability of tested standards. We understand the good intention of the proposed rule to move health IT utilization as far and fast as possible to improve health care. However, pushing so hard as to require changes in practice and adoption of new EHR functions before standards are in place, before vendors have a chance to test new functionality in practice, and without understanding the significant implications for practice workflow is dangerous, lacks credibility, and could undermine the goals of the program.

Care summaries - Each time a care summary is specified in this rule, it appears to be described slightly differently. These differences in requirements will cause unnecessary confusion and disruption throughout the care delivery process as well as risking unintentional failure to meet the "letter of the law" with regard to meeting the Meaningful Use measure. Also, none of the configurations mentioned precisely matches any existing balloted standard or implementation guide. CMS should not call for actions that are not based on approved standards/implementation guides. Doing so will cause document processing to be unnecessarily difficult. In cases where information above and beyond a care summary is required, such as for a discharge summary, a separate document should contain the situation-specific content and an attached standard care summary should be referenced. While it would seem reasonable for problems, medications, and allergies/intolerances to be required in all cases, all other sections of clinical documents

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should be specified as optional and dependent on the clinical judgment of the sending clinician. We agree, however, that all specified sections should be required for certification. It is too early to mandate a single structure for a care plan that fits all patient conditions and circumstances. This is an area that needs to evolve slowly over time. Patient decision aids are also not defined adequately. Examples of qualified aids should be included.

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2. Responses to specific Meaningful Use functional measures

CMS Stage 2 MU Proposed Objectives and Measures for EPs			
Objective	**Measure**	**Notes and Queries**	**COMMENTS**
CORE SET (EP must meet all 17 Core Set objectives)			
1. Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local, and professional guidelines to create the first record of the order.	More than 60 percent of medication, laboratory, and radiology orders created by the EP during the EHR reporting period are recorded using CPOE.	CMS invites comment on whether CPOE order entry could be expanded to include non-licensed professionals, such as scribes. CMS encourages comments on whether a different denominator could be used – the HIT Policy Committee recommended a denominator of "patients with at least one type of order." We welcome comment on whether	**Support:** We support continuation of the measure as it relates to medication orders. With regard to who can "enter" orders, we advocate for expansion to include entry not only by other licensed healthcare professionals but also to non-licensed healthcare professionals (e.g., medical assistants) entering orders under protocol. CPOE performed by other healthcare professionals, including medical assistants and healthcare assistants operating under clinical or CDS protocols, should be included in the denominator, whereas entries by clerical staff (including scribes), should not. Medical Assistant/Health Care Assistant (MA/HCA) staff are trained healthcare professionals (who may or may not be licensed depending on State regulations, but are frequently certified graduates of a program) who undergo formal healthcare training supplemented by additional practice-based training to perform various direct patient care tasks under supervision (including vitals, immunizations, specimen collection, injections, medication renewals under protocol, etc.). They also frequently review services due for patients (e.g., chronic disease management registry review and outreach on tests and treatments due) and complete them under protocol. On the other hand, professional scribes are clerical staff (secretarial, nonmedical) who are trained in documenting care in real-time in the presence of a provider, with minimal if any actual medical science training, and not specifically trained in the activities listed above for MA/HCA staff. Neither are they permitted by the commercial scribe companies who hire and train them to touch patients, handle medications, make medical decisions or enter orders. In other words, as a healthcare professional, a MA or HCA operating at the top of his/her competencies and authority can complete many care delivery tasks that a nurse could do, but only under strict protocols. On the other hand, a scribe would never be allowed to deliver any care even under protocol; they would only be authorized to transcribe what the provider actually said for them to do in the real-time setting in which it is happening.

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		laboratory and radiology orders are sufficiently different in the use of CPOE that they would require a different threshold and whether such a threshold should be a lower percentage or a yes/no attestation.	MAs and HCAs contribute directly to Meaningful Use in many practices but as the percent of orders that must be entered by a licensed healthcare professional is increased, those practices that rely on MA or HCA staff to support them will be less able to use (and employ) them to assist in delivering high quality care unless this is modified; without them EPs would likely have higher measure percentages for CPOE but fewer services due would be completed. We urge CMS to make a clear statement that entry by EPs is not, in-fact, required. We are concerned that without such a statement, institution administrators will set internal policy to require exclusion of MA and HCA staff from such data entry creating an unnecessary burden on EPs and disrupting current workflows that support efficient, safe and effective care. If MAs are not allowed to enter medication, vaccination, and test orders under protocol (e.g., medication renewals, imaging or laboratory test services due related to Clinical Quality Measures), fewer patients will get the care they need in a timely manner and MA staff will be at increased risk of job loss due to inability to complete needed tasks on behalf of the EP and still have them count for MU. We believe the key issue is not who enters the order but rather who evaluates and approves any clinical decision support prompts that require medical judgment (e.g., addressing an alert of moderate or high significance or risk). Our experience is that MA staff can be trusted, expected and required to do within the measure what most already do today, namely to treat alerts and other CDS prompts requiring a medical judgment as a "hard stop" and route to the EP or another licensed healthcare professional to review and respond to the CDS prompt or alert. We believe the measure should enable MA staff to enter orders as long as any alert or CDS prompt associated with the order must be evaluated and approved and signed by a licensed healthcare professional. **Questions:** The measure should not include laboratory and radiology orders unless certified systems and the service providers that will fulfill the order requests are capable of successfully processing the order requests and delivering the results electronically using a standard that enables simple, inexpensive interfaces that can be broadly applied to all users of the same CEHRT, rather than having to pay for "one off" interfaces for sending orders and receiving results. Also, we are

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			concerned that there is not yet sufficient evidence of benefit of the order entry (as opposed to the result) to support a CPOE requirement for Stage 2. While CPOE can facilitate an important step in addressing services that are due, it is the result of the order rather than the order itself that fulfills the relevant quality measure rather than the order itself. While we resonate with the possibility that CPOE for laboratory tests and imaging studies allows for clinical decision support (CDS) prompts that can help decrease overuse and misuse of tests, this could be incorporated into the CDS measure rather than the CPOE measure. **Concerns:** How can an EHR system count orders not entered through the system? We are concerned that the denominator cannot be accurately determined without laborious and error-prone manual record keeping of what is for most practices that have adopted EHR systems the rare event of a paper order that is not also recorded in the EHR. The definition of CPOE needs to be clearer. For example, some practices enter orders in the computer but do not explicitly use an "orders module" that creates structured data for each order and tracks all orders or transmits them electronically to labs. Practices may use web-based portals to enter in the ordering information, which resides outside of the EHR system. These types of situations are common for smaller practices, which do not generate a volume of referrals/orders sufficient to justify the cost of building and maintaining an interface. In some cases smaller practices cannot get the receiving parties (laboratory or radiology companies) to provide interfaces even if the practices are willing to cover the cost of building the interface. Would these practices be penalized for using technology that resides outside of the ONC-ATB certified EHR? If the order must be entered with in the EHR system, the practice may also be forced into a double entry workflow process to meet Meaningful Use requirements but that does not improve care.
2. Generate and transmit permissible	More than 65 percent of all permissible	CMS invites	**Support:** We support the basic measure for cases where all of the needed components are available. We

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prescriptions electronically (eRx).	prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using CEHRT.	comment on whether new eRx-technology would warrant the inclusion of controlled substances or an additional measure that would include controlled substances. We do not believe that OTC medicines will be routinely electronically prescribed and propose to continue to exclude them from the definition of a prescription. However, we encourage public comment on this assumption. CMS indicates	support the ability to specify that no formulary is available. **Questions:** While we support and encourage the inclusion of controlled substances once there is a mechanism in each state to support e-prescribing controlled substances from CEHRT without legal risk or expensive and burdensome dual authentication strategies, current procedures are too burdensome and poorly supported by technology. In addition, State Boards of Pharmacy have not yet operationalized the regulations with a clear path to e-prescribing controlled substances in individual States. The requirement should not extend to controlled substances until there is evidence that practices find the process feasible and reasonable. There is no reason to believe that EPs will hesitate once this is the case, as e-prescribing has been broadly adopted by a wide range of practices once it has been made feasible, usable within the CEHRT and broadly available. Providers should be able to include OTCs of their choosing because in some safety net settings the patients cannot get OTC meds as cheaply if they are not prescribed, and because providers may want to record the fact they have asked the patient to take them. (There is a provision in the e-prescribing to enter a drug for record keeping purposes only- not for dispensing. It also does not count for MU) We support the certification of non-EHR e-prescribing systems, such as those used in nursing homes, but we do not support inclusion in Meaningful Use requirements. **Concerns:** We feel that the exclusion for no accessible supporting pharmacy is too restrictive. While a supporting pharmacy may be available within 25 miles, this does not allow patients to choose their own pharmacy, consistent with patient-centered care. The cost and inconvenience to patients for expecting them to travel up to 25 miles from the practice location to pick up an e-prescribed medication is excessive. There may be several non-supporting pharmacies within a few blocks, while the nearest supporting pharmacy may be several miles away. This exclusion

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		that the drug formulary need not be relevant for each patient – the comparison could return a result of "formulary unavailable for patient and medication combination" and still allow the EP to meet the measure. CMS invites comment on whether an additional exclusion is needed to account for instances where EPs prescribe medications in a facility (e.g., a nursing home) where they are compelled to use	as written is particularly burdensome on the elderly, disabled, poor, and those without adequate transportation options. This measure does not respect the realities of patient preferences. We remained concerned with the negative effects of current e-prescribing requirements. We need the ability to electronically communicate to pharmacies that a medication has been discontinued. This will prevent pharmacies from the potentially dangerous practice of refilling a medication that has been discontinued. We need the ability to e-prescribe new medications and renewals at the time of a visit that will not be executed/dispensed until a later date (renew and hold in system until patient contacts the pharmacy to dispense). Our members report that some mail-order pharmacies are still not compliant with e-prescribing requirements. (Grossman JM, Cross, DA, Boukus, ER, Cohen, JR, Transmitting and processing electronic prescriptions: experiences of physician practices and pharmacies. J Am Med Inform Assoc 2012;19:353-359 Published Online First: 18 November 2011 doi:10.1136/amiajnl-2011-000515.) Formulary checking can be expensive depending on the system design. In most cases before the formulary can be checked the eligibility of the patient is automatically run. In some systems the eligibility check is done on a per use basis and ranges from $0.25 to $0.45 per check. Others charge a monthly or yearly fee. In prices obtained by 4 EHR vendors the prices range from $500 to $1200 per provider per year.

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		an ordering system that may not be CEHRT.	
3. Record all of the following demographics: (A) Preferred language; (B) Gender; (C) Race; (D) Ethnicity; (E) Date of Birth.	More than 80 percent of all unique patients seen by the EP during the EHR reporting period have demographics recorded as structured data.	CMS invites comment on whether disability status and/or gender identity and/or sexual orientation should also be recorded.	**Support:** We support the measure as written. **Questions:** We would not support inclusion of disability status. There is no consensus on a classification scheme – with each medical specialty using a different value set. There is no agreement on definitions. Some patients also object to being labeled as "disabled". We would not support collection of sexual orientation data, both because of lack of consensus on a classification set, but, more importantly, because of the sensitive nature of such a question. Asking for this information for the purposes of documenting in the EHR to satisfy MU objectives could harm the patient's relationship with care providers and increase their concerns about the privacy, confidentiality and security of their PHI, especially with the requirement to exchange data with other organizations. **Concerns:** We have serious concerns with the value sets chosen for race and ethnicity. The current selection is insufficient to meet the purpose and goals of the data collection exercise. More options are needed for "other," "multiple," "undetermined," multiple classes of Hispanics, Middle Eastern/Arab, etc. CMS and ONC must improve the transparency and clarity of the objectives and measures by specifying what is required in the final rule rather than requiring users to find other federal documents and FAQs that were difficult to find and to understand in the Stage 1 Final Rule. At a minimum, an electronic version of the Final Rule with up-to-date hyperlinks to all outside

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			documents that must be referenced to fully understand the rule is needed. Linking to a long document is also undesirable; any hyperlinks should take the reader directly to a bookmarked section of the document that pertains. See discussions of **Data requirements** in attached letter.
4. Record and chart changes in the following vital signs: (A) Height/Length; (B) Weight; (C) Blood pressure (ages 3 and over); (D) Calculate and display body mass index (BMI); (E) Plot and display growth charts for patients 0-20 years, including BMI.	More than 80 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients 3 and over only) and height/length and weight (for all ages) recorded as structured data.	[We] propose to remove the height/length and weight age limits and raise the blood pressure limit to 3 years of age and older, but we encourage public comment on the age limitations of vital signs. We believe there are situations where height/length and weight may be relevant, but blood pressure is not. We are less certain that there would be cases where blood	**Support:** We support the proposed increase from 50% to 80% for stage 2 but request specification of a timeframe for any vital sign listed that is likely to change (e.g., only BP and weight for an adult during the measurement period; only height and weight for a child). Growth charts would not be used or required in most internal medicine, or geriatrics practices, or most obstetrical practices. Some means should be provided to align the requirements with the practice needs. This could easily be accomplished by setting the age cut for requiring growth charts at age 16 or 18 rather than age 20, except in pediatric and family practice settings.

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		pressure is relevant, but height/length and weight are not. We propose for Stage 2 to split the exclusion so that an EP can choose to record height/length and weight only and exclude blood pressure or record blood pressure only and exclude height/length and weight. We encourage comments on this split and whether it should or should not go both ways.	
5. Record smoking status for patients 13 years old and older.	More than 80 percent of all unique patients 13 years old or older	We continue to believe that there are insufficient electronic	**Support:** We support this measure as written. **Question:** We would not support collection of information regarding second-hand smoke due to lack of an agreed-upon classification, lack of evidence as to its value, and lack of industry

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	seen by the EP during the EHR reporting period have smoking status recorded as structured data.	standards for collecting information on other types of tobacco use and that situations where a patient might use multiple types of tobacco would damage the standardized collection of smoking data, but we request comment on whether this is the case. We encourage commenters to submit information to us that demonstrates consensus and/or standards around the collection of second hand smoking data that would provide the	experience with such data. **Concerns:** We would give consideration to a proposal to change the subject from "smoking status" to "tobacco use." Our concerns would include lack of an agreed-upon classification, lack of evidence as to its value, and lack of industry experience with such data. CMS and ONC must improve the transparency and clarity of their specifications by designating value sets directly in the rules and not requiring users to examine other federal documents and FAQs in search of required and allowable values. We also found it burdensome to have to change smoking status values from clinician-friendly and informative values (e.g., quit <6 months), to less informative equivalents (former smoker), which added to the burden of qualifying for meaningful use but did not improve patient care. See discussions of **Meaningful measures** in attached letter.

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		basis on which to create an additional tobacco-related measure that is applicable to all EPs and hospitals	
6. Use clinical decision support to improve performance on high priority health conditions.	(1) Implement five clinical decision support interventions related to five or more clinical quality measures, if applicable, at a relevant point in patient care for the entire EHR reporting period; and (2) The EP has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.		**Support:** We support an increase in the use of decision support over the Stage 1 requirement. **Questions:** **Concerns:** Most practices have little experience managing decision support rules. This is a case where smaller institutions are at a great disadvantage. Until there is significant evidence of the efficacy and implementability of complex decision support rules in small practices, the measure requirements should be minimal. The requirement that the CDS rules apply to the selected quality measures is unnecessarily restrictive. We urge that practices be given more latitude in how they choose to implement CDS. We are also concerned that not every specialty/subspecialty will be able to find 5 CDS areas tied to 5 of the 12 CQMs they will be required to report on that are relevant to their scope of practice. Rather than having CDS they will not act on based on CQMs not relevant to their scope of practice, we would recommend they be allowed to create other CDS rules if fewer than 5 apply to their scope of practice. The mechanism by which a CDS alert is presented to the EP should be left to the discretion of the practice.

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			While it may be helpful to have metadata regarding provenance available, we are concerned that it may not always be available in commonly used tools, and we are concerned that its presentation to the EP might become intrusive. There is more than sufficient evidence that current implementations of drug-drug and drug-allergy checking are problematic. Further, the evidence supporting their efficacy is scant. For example, Bates and his group have found that the presentation of alerts at any level lower than severe can result in even severe alerts being ignored. Further, there is no consensus regarding the definition of severity among drug databases. Doctors have found current rule bases to be filled with errors and improper advice. Use of drug-drug and drug-allergy alerts should not be required until evidence of rule quality and system efficacy improves significantly. This measure must allow physician judgment regarding the setting of thresholds for severity, frequency and degree to which the interaction is established. See general comment on staging of requirements.
7. Incorporate clinical lab-test results into CEHRT as structured data.	More than 55 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either a positive/negative or numerical format are incorporated in CEHRT as structured data.	Is the move from Menu to Core, and the increase in reporting level from 40 to 55 percent, achievable and advisable? Lab tests would be counted individually, not as panels or groups – CMS solicits comment	**Support:** We support the proposal that systems be capable of importing lab results into the clinical record as discrete data. **Questions:** We object to the move to core and the increase in reporting level. The reporting level should account for the incremental cost to the practice of adding an interface from each laboratory service provider to its system. The proposed counting of individual labs presents unnecessary complexity to EHR system design and to reporting. **Concerns:**

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		on whether such individual accounting is practical. While we are not proposing to move beyond numeric and yes/no tests, we request comments on whether standards and other capabilities would allow us to expand the measure to all quantitative results (all results that can be compared on as a ratio or on a difference scale).	This measure presents an unfair burden to smaller practices. Reports from members suggest that small practices receive reports from in excess of 20 different laboratories. It can cost in excess of $10,000 to connect one lab to a practice. Even if this cost were reduced by an order of magnitude, the cost of achieving this single measure could easily exceed any incentive payment or eventual penalty. Unless service providers are required to transmit in a standard, specific format that can be digested by all EHRs, EPs should not be burdened with the work of adding structure to results received as unstructured data. Hospitals are required by regulation to store and send lab results as structured data for public reporting purposes. Hospitals should also be required to send laboratory results as structured data to EPs. While it can be argued that a practice would not have to receive structured data from all corresponding labs in order to complete this measure, this situation is unacceptable from a clinical and patient safety perspective. If the EP is to rely on his or her EHR system to provide proper alerts, then all required data must be available in structured form. It should not be up to the EP to pay out thousands of dollars to connect to each possible lab, and it should be unacceptable for any lab to refuse to provide all results in structured format. Further, it is an unrealistic expectation that EPs would dedicate personnel time to manually enter unstructured laboratory data into structured fields within their EHR. This is costly and also introduces the potential for significant human error. What is meant by tests with yes/no answers? We presume that you really mean those that have two answers such as present/absent, detected/not detected, reactive/non-reactive, positive/negative and so on. It will be important to provide examples of what is meant by yes/no. What you appear to be trying to characterize are ordinal tests (also describes numerically valued tests that can be divided into ratio and difference scales). (Stevens SS. Measurement, Statistics, and the Schemapiric View. Science. 30 Aug 1968;161(3844):849-56.) You might better describe what is wanted as ordinal test.

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			See general comment on staging of requirements. See discussions of **Data requirements, Administrative burdens, Meaningful measures, and Hold all participants accountable** in attached letter.
8. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.	Generate at least one report listing patients of the EP with a specific condition.	CMS requests comment on whether to increase this number beyond one.	**Support:** We support this proposed measure as written.
9. Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.	More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference.		**Support:** We support this proposed measure as long as appointment reminders count in the numerator. Remembering to show up for an appointment may be the most important "next step" in ensuring that the patient receives preventive and follow-up care. **Concerns:** We request clarification of the operative definition of "reminder." Remembering to keep the appointment is an important first step to follow-up and preventive care and therefore should be counted. The burden and cost to capture and conform to each patient's preferred communication method is a concern.

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Objective	**Measure**	**Notes and Queries**	**COMMENTS**
10. 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.	(1) More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient within 4 business days after the information is available to the EP) online access to their information subject to the EP's discretion to withhold certain information; and (2) More than 10 percent of all unique patients (or their authorized representatives) seen by the EP during the EHR reporting period view, download or transmit to a third		**Support:** We fully support the right of all patients to have electronic access to their health information if desired. We also support the option clinicians have to withhold certain reports or documents when appropriate or required. **Questions:** This should not be a core measure because of the ongoing cost and technical challenges to widespread adoption and use of this technology. Are there usage data to suggest that a sufficient proportion of patients are likely to register for such a portal and then be able to successfully access, view, download and transmit their data without technical assistance? Is it incumbent on practices to provide such technical assistance? It seems unlikely that we'd be expected to help them if they had trouble calling us because their cell phone was too complicated for them to use yet it seems like we now have to be prepared to become an IT support service for patients. It is too early to mandate a structure for a care plan. This is an area that needs to evolve slowly over time. **Concerns:** This proposed measure generated the most concerns among our members. It is unreasonable to place the ability of EPs to achieve Meaningful Use in their ability to convince their patient to perform activities that patients may not wish to perform. Unless CMS has evidence that this is easy to achieve across a variety of settings and patient populations meaningful use payments should not hinge on the belief that 10% of patients will be willing and able to do so across all EP practices. If it adds value for patients, we won't have to convince

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CMS Stage 2 MU Proposed Objectives and Measures for EPs			
Objective	**Measure**	**Notes and Queries**	**COMMENTS**
	party their health information.		them to use it or count the number of patients who do so. Consider the challenge of convincing the patient to go online to see what was just talked about and provided to them a printed clinical visit summary. Why would they also bother to go online to view it? If the argument is that labs will be available in the future, many labs already send results via standard mail as a service to patients. Do we want EPs of such patients to ask labs to stop mailing results so that patients are more motivated to go online to view them as their only option for seeing their results? This is an area where one size clearly does not fit all. Some patient populations want such capabilities and will use them effectively. Other patient populations either have no interest or insufficient resources to be able to access their health information, or are even actively hostile to the technologies. Small practices with higher proportions of patients with lower socio-economic and education status could easily be prevented from achieving Meaningful Use because of this specific measure despite a significantly greater proportional investment. Our members report that the practices have plateaued at about 30% of patients signing up for patient portal use. Unless CMS has significant and reliable evidence that 50% of patients in small and rural practices register and use patient portals when available in the practice, this proposed threshold is unsupportable based on the current evidence. This measure is also not patient-friendly in that facilitating Meaningful Use for EPs the patient sees could require patients who receive care in multiple practices to have to log into multiple systems with multiple logins and passwords to view or download multiple subsets of their health information. If the patient has a PCP with a robust portal that includes information also present in the portals of specialists in other practices with separate portals, patients are not likely to visit the other portals, which puts those specialists at risk of failing to achieve Meaningful Use. In practices that have adopted best practices for patient-provider-computer interaction in the exam room, patients routinely view their health information on the computer with the EP who can help them interpret the data, view CDS, review problems, reconcile medications, update allergies, make care, decisions, view/print clinical visit summaries, etc. If the goal of

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			ONC/CMS is for patients to interact with their records in the office, we would prefer to find a way to support this approach rather that the workflow interrupting and potentially computer security compromising approach of expecting them to log into the portal in the office or the exam room. Portal access is designed to provide useful information between visits, not during visits. Interacting with caregivers who are using their actual EHR chart to review information and deliver care is the better approach for in-office information access. Additional points: • Patients actively refusing to accept the invitation to go online should be deducted from the denominator. • Efficacy and broad feasibility has not been demonstrated. • Studies show low patient participation rates. • Concerns about quality of patient portal software available to small practices. • This will be a significant, non-reimbursable cost to the practice and an administrative burden for practice staff. • How will a system document that information was "viewed" by a patient? Would landing on a page that contains any patient health information count? The fact that some feel that a mandate is required to force this patient engagement activity is evidence that the market is not ready to accept this. When only 10%-30% of patients given the information needed to register for the portal subsequently do so, it is clear that the demand is not yet as high as may be reflected in surveys in which 80%-90% of patients would like to ***be able*** to communicate with their EP online. When the technology availability, usability and perceived value improve, the market (EPs and patients) will accept it with enthusiasm. The delivery of clinical results to the patient, which in general we support, could add a new demand on the physicians' time if patients routinely ask providers to explain test abnormalities. With 20 tests in a panel, on average, one will be abnormal in most patients even if the patient has no health problems and the finding is not significant (e.g., slightly elevated BUN or $C0_2$ due to fasting). We recommend that portal technology vendors be required as part of CEHRT to

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			incorporate consumer-friendly information links (perhaps to a free resource like the NLM's MedlinePlus) to answer most of the patient's questions about the information they view on the portal. Further, if the deliver-to-the-third-party capability would be used to deliver reports to any physicians, it raises the question of legal responsibility for such data. Ideally the 3rd party provider would not have to accept data from a patient who was not under active care and would be absolved from legal responsibilities until he/she had a face-to-face or could refuse unsolicited clinical data. The exemption relying on access to high speed internet as determined by the FCC is going to be difficult and confusing for providers to implement. For instance, what happens if part of their patient population falls with in this area and another does not? How will a practice be easily able to identify whether the patients reside in one of these areas? Perhaps the EP should be able to document that a patient does not have web access. See general comment regarding care summaries. See general comment on staging of requirements. See discussions of **Protect the encounter, Administrative burdens, and Patient engagement** in attached letter.
11. Provide clinical summaries for patients for each office visit.	Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.	We encourage EPs to develop the most robust care plan that is warranted by the situation. We also welcome comments on both	**Support:** We support the provision of visit summaries to patients. This has proven to be popular with a significant proportion of patients. **Questions:** Patient decision aids are not defined.

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		our description of a care plan and whether a description is necessary for purpose of meaningful use.	**Concerns:** The reduced time limit is unworkable in many typical clinical scenarios. We recommend a time limit of five business days. Some patients do not want clinical summaries, particularly if they are long and complex. We recommend changing the measure to "provide on request" as this will reduce wasted effort and paper. An unrecognized concern is the poor "signal-to-noise" involved in requiring that the care summary include many categories of specific content that are either unrelated to the current encounter or unchanged from previous encounters. EPs must be given the opportunity to exercise clinical judgment in all situations involving the content to be communicated. Clinical summaries should not fail to count in the numerator if they do not include information that the EP feels is not relevant to that patient at that time. Providing excessive information is a patient safety risk. See general comment regarding care summaries. See discussions of **Meaningful measures** and **Patient engagement** in attached letter.
12. Use CEHRT to identify patient-specific education resources and provide those resources to the patient.	Patient-specific education resources identified by CEHRT are provided to patients for more than 10 percent of all office visits by the EP.	CMS invites comment on whether patient-specific education resources at appropriate literacy levels and with appropriate cultural competencies	**Support:** We support this proposed objective. **Concerns:** We are concerned with the lack of specificity in the measure. The measure itself must define precisely what "identified by Certified EHR Technology" means. Current vendor implementations are counter-intuitive, do not fit with preferred workflows, and often require purchase of expensive additional products.

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		could be successfully identified at this time through the use of CEHRT.	See general comment on staging of requirements.
13. Use secure electronic messaging to communicate with patients on relevant health information.	A secure message was sent using the electronic messaging function of CEHRT by more than 10 percent of unique patients seen during the EHR reporting period.		**Support:** We support the objective to use secure electronic messaging between EPs and patients. **Questions:** The threshold is too high if the measure is based upon patient actions. The threshold could work if EP behavior is measured instead of patient behavior. **Concerns:** We are concerned that inexpensive, easy to use encryption functionality may not yet be generally available to small practices. This is another measure where the relative burden is significantly higher for small practices. In the absence of compensation, this measure requires EPs to provide uncompensated care delivery. Some EPs express concerns about the patient safety risks involved in providing medical advice via email, which patients will sometimes send to us via standard email even though a portal is in place because they now recognize our willingness to communicate electronically and find their own personal email more convenient than logging into a separate portal. This measure should focus on EP behavior rather than patient behavior. For example, there could be a threshold number of percentage of patient messages that are responded to within a

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			set period of time. Some patients are willing to exchange messages via standard email do not agree with the importance of secure messaging and are not willing to take the extra steps in using secure systems and encrypted messages. See general comment on staging of requirements. See discussions of **Patient engagement** and **A bridge too far** in attached letter.
14. The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The EP performs medication reconciliation for more than 65 percent of all transitions of care in which the patient is transitioned into the care of the EP.		**Support:** We support the performance of medication reconciliation in all appropriate circumstances. **Concerns:** See general comment on staging of requirements. Technology and standards needed to properly support and document medication reconciliation is not yet widely deployed. The objective and measure must allow for clinical judgment regarding the relevance of the action at each opportunity. This measure should only apply when it is important and relevant to the specialty, scope of practice, and task to be completed. The requirement for "dosage, frequency, and route" should not be required when it is not part of the expected scope/expertise of the EP or relevant to the care the patient is getting at that time. Requiring specialists to manage the details of medications that are not prescribed in their normal scope of practice represents a patient safety risk. Removing a medication that a patient says he/she is not taking may not only be inaccurate but also ill-advised, with the appropriate action not being to remove the medication from the list but rather to note that the patient is not taking the medication and to communicate this

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			information to the prescribing physician so appropriate action can be taken. Our members report important errors affecting patient safety resulting from the assumption that the list must exactly match what the patient reports he/she is taking or has on what is often an outdated or incomplete list on a discharge summary, clinical visit summary from a different office or a piece of paper the patient keeps in his/her wallet or purse. We are concerned that the definition of the active medication list as "a list of medications that a given patient is currently taking" will have the unintended consequences mentioned above. The objective includes the term "or believes an encounter is relevant" but the measure does not. Many of our members believe that medication reconciliation is relevant for every visit and that it is actually more work to accurately assess and then document to the CEHRT whether the visit meets the definition of a transition in, so we encourage retaining the term "or believes an encounter is relevant" in the measure as well. See discussions of **Meaningful measures** in attached letter.
15. The EP who transitions a patient to another setting of care or provider of care or refers the patient to another provider of care should provide summary care record for each transition of care or referral.	(1) The EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals (2) The EP that transitions or refers their patient	CMS solicits comments on whether the problem list should be extended to include "when applicable, functional and cognitive limitations" or whether a separate list should be included for such	**Support:** We support the provision of a summary care record for each transition of care or referral. We support the measure requiring the provision of a summary in 65% of transitions and referrals. **Questions:** We recommend against any specification of content regarding functional and cognitive limitations. There is not sufficient consensus around appropriate classification of these functions. The summary of care document for hospitals adds "Diagnostic test results available at time of discharge" to the base summary record. We presume this would mean x-ray reports, cardiac echoes, pathology reports, etc. Giving some examples of the kind of test results would help

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	to another setting of care or provider of care electronically transmits using CEHRT to a recipient with no organizational affiliation and using a different CEHRT vendor than the sender a summary of care record for more than 10 percent of transitions of care and referrals.	limitations.	implementers. We assume that you mean the most recent result for of each type of test, but some explicit statement about what is intended would be helpful. **Concerns:** See general comment regarding care summaries. See general comment on staging of requirements. This is another measure where the relative burden is significantly higher for small practices. It seems unlikely that practices (especially small practices) will be capable of electronic exchange with other small practices by 2014, let alone those with a different CEHRT vendor. EPs envision having to create and manage separate accounts and communications channels with every other corresponding practice – leading to a combinatorial nightmare and significant uncompensated expense. The requirements regarding sending outside of one's system and EHR brand are clearly not in widespread existence or use today and it is not clear that they will be by 2014. As such this requirement, while laudable in intent is unworkable and over-reaching. An unrecognized concern is the poor "signal-to-noise" involved in requiring that the care summary include specific content that could be unrelated to the current information exchange that is needed. EPs must be given the opportunity to exercise clinical judgment in all situations involving the content to be communicated. Clinical summaries should not fail to count in the numerator if they do not include information that the EP feels is not relevant for that patient at that time. Providing excessive information is a patient safety risk. PCPs already bemoan the lengthy consultant notes that have become bloated in the era of EHR "documentation for billing" and have pleaded for a more condensed version of their impressions and recommendations. Indeed, the recent interest and evolution from SOAP notes to APSO notes reflect the problem with bloated notes needed for billing vs. the more condensed notes for quality of care or communication to others. Please do not require clinical summaries to contain

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			everything that "might be important" and instead allow us to include what we feel to be important for a particular patient, including requiring as part of certification the ability to select items to include and default to things that have changed (added, removed, modified). Throughout this NPRM it is not always clear that the problem list may also include symptoms that have not yet been linked to a specific diagnosis. (We understand that, for purposes of meaningful use, the definition of problem list excludes issues, such as lack of home care, that do not refer to patient medical conditions.) Please be explicit about what can and can not be included in a problem list and provide detailed examples. It would be helpful if the same definitions could be used throughout. We are also concerned that the definition of an up-to-date problem list as "a list populated with the most recent diagnoses known by the EP or hospital" as risking the removal of problems that are current and important but do not meet an EP's intuitive definition of "most recent known by the EP" such that a 20-year history of diabetes is removed because it is not recent enough and a diagnosis of asthma is removed because the EP caring for them today doesn't see any evidence of it.
16. Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic immunization data from CEHRT to an immunization registry or immunization information system for the entire EHR reporting period.		**Support:** We support the submission of data to immunizations registries only if such capabilities are generally available, use a widely available standard for data transmission and can be implemented at low cost. **Concerns:** All measures requiring exchange with registries must require fully bi-directional exchanges. In all cases, the EP must be informed by the registry about what is already known about the patient who is being reported upon. See general comment on staging of requirements. See discussions of **Hold all participants accountable** in attached letter.

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17. Protect electronic health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.		**Support:** We support the implementation of appropriate security capabilities only if such capabilities are generally available and low cost. **Concerns:** We are concerned with the lack of detail provided regarding what it means for data to be at rest. If this includes data being processed in a client-server environment, then the requirement will result is excessive cost increases and performance reductions. If the rule is meant to apply to data stored on a local workstation, then the rule should state this explicitly. See general comment on staging of requirements. See discussions of **Provide useful guidance and assistance** in attached letter.
MENU SET (EP must meet 3 of 5 Menu Set objectives)			
1. Imaging results	More than 40	CMS solicits	**Support:**

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and information are accessible through CEHRT.	percent of all scans and tests whose result is an image ordered by the EP are accessible through CEHRT.	comment on a potential second measure, a threshold of 10 percent of all scans and tests whose result is one or more images ordered by the EP be exchanged with another provider of care.	We support satisfaction of the requirement by the availability of either the official reading of the image or a link to the image itself, but not both. **Questions:** We do not support a requirement for EPs to exchange images. **Concerns:** This is another measure where the relative burden is significantly higher for small practices. This is not a one-size-fits-all situation. Our members have informed us that their need to view an image may depend upon a combination of factors including previous experiences with the type of image, the imaging facility, and the reading clinician.
2. Record patient family health history as structured data.	More than 20 percent of all unique patients seen by the EP have a structured data entry for one or more first-degree relatives.		**Questions:** The NPRM does not make clear how often this action must be taken. Requiring that an update be performed during the reporting period would be excessive and not supported by evidence. **Concerns:** The requirement that the measure apply only to "first-degree" relatives actually makes calculation much more difficult. CEHRTs would have a difficult challenge in sorting first-degree relatives from others in a typical family history. We are unaware of any justification for updating the family history on a yearly basis even if it requires the recording of just one family member's history as one proposed measure seems to require. Family histories often don't change that fast. A careful and very large study in 2011 suggested updating the family history on a 5-to-10 year interval, not a yearly basis. (Ziogas A, Horick NK, Kinney AY, et al. Clinically relevant changes in family history of cancer over time.

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			JAMA. 2011;306(2):172-178.) See general comment on staging of requirements.
3. Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period.	CMS invites comment on its proposal to leave syndromic surveillance in the Menu set for EPs while requiring it in the Core set for hospitals.	**Support:** We support the submission of syndromic surveillance data to public health agencies only if such capabilities are generally available and low cost. We agree that this measure should not be moved to core. **Concerns:** Almost all current public health reporting properly comes from laboratories, not from EPs. We are concerned that EP reporting may be duplicative and cause confusion and error. We are also concerned that EP reporting may result in increased unnecessary follow-up requests from public health agencies. See general comment on staging of requirements. We do not believe that capabilities will be available at reasonable cost by 2014.
4. Capability to identify and report cancer case information from CEHRT to a cancer registry, except where prohibited, and in	Successful ongoing submission of cancer case information from CEHRT to a cancer registry for the entire EHR		**Support:** We support the submission of case data to cancer registries only if such capabilities are generally available and low cost. **Concerns:** See general comment on staging of requirements.

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accordance with applicable law and practice.	reporting period.		We do not believe that capabilities will be available at reasonable cost by 2014.
5. Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of specific case information from CEHRT to a specialized registry for the entire EHR reporting period.		**Support:** We support the submission of case data to cancer registries only if such capabilities are generally available and low cost. **Concerns:** See general comment on staging of requirements. We do not believe that capabilities will be available and at reasonable cost by 2014.

3. Responses to other components of the NPRM

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Page and Topic	Request for comment	Comment
241-242 Group Reporting	When commenting on the group reporting option we are providing the following list of suggested topics, but this list is by no means exhaustive: What should the definition of a group be for the exercise of group reporting? For example, under the PQRS Group Reporting Option, a group is defined as a physician group practice, as defined by a single Tax Payer Identification Number, with 25 or more individual eligible professionals who have reassigned their billing rights to the TIN.	How would multiple locations be dealt with in Group reporting? It seems that this could be a larger issue for groups with hourly doctors?
245	The certification rules at 45 CFR part 170 differentiate between ambulatory and inpatient EHRs, and it is unclear whether the EPs in this case would have inpatient or ambulatory technology. We request comments on this issue.	There are also cases where doctors billing enough outpatient care are actually using the inpatient systems to document their notes. This is especially common with surgeons. Do providers have to be using an ambulatory system in an ambulatory encounter or can either system be used?
254 Payment Adjustment	We believe that these proposed EHR reporting periods provide adequate time both for the systems changes that will be required for us to apply any applicable payment adjustments in CY 2015 and subsequent years, and for EPs to be informed in advance of the payment year whether any adjustment(s) will apply. They also provide appropriate flexibility by allowing more recent adopters of EHR technology a reasonable opportunity to establish their meaningful use of the technology and to avoid	This proposal does not give doctors enough time to prepare, given the well-documented market delays in installing systems. Depending on the product this delay can be as long as 18 months according to vendors participating in the AmericanEHR Partners (AEP) program. Wait times are longer for smaller practices, as vendors triage clients. Small practices may be disproportionally penalized through no fault of their own. There are also concerns with the timing of stage 2 updates and whether vendors will be capable of meeting them. Should doctors really penalized for this failure by the vendors? Some accommodation must be made for EPs who are unable to meet Stage 2 MU due to lack of availability of certified software. Perhaps there should be a 90-day reporting period for the first year each time an EP moves to a new stage of MU.

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	application of the payment adjustments.	
271	They also provide appropriate flexibility by allowing more recent adopters of EHR technology a reasonable opportunity to establish their meaningful use of the technology and to avoid application of the payment adjustments. We welcome comments on this proposal.	The MU rules should always allow stage 1 criteria as the starting point. Even as the products improve and the market advances we have to be cognizant that the practices starting adoption will need time to accommodate to the absolute basics of working with a new system.
275	We welcome comment concerning the appropriateness of adapting these rules to the exception under the EHR program, and about whether modifications or other revisions to these rules would be appropriate in the EHR context.	We urge CMS to follow the model used in the e-prescribing program. There should be one set of criteria for practices wanting to qualify for the bonus payment and a different, lower bar for those practices attempting to avoid the penalty. How much can a practice be held responsible for the activity of their providers outside the activity they provide as part of their relationship with the practice? It seems like the rule creates a system of double jeopardy for practices, if not EP's. Some type of exemption should exist for these situations. Also given that the payment is based on activities prior to the year that they occur, what happens if an EP moves to a different practice? Does their activity follow to the new practice? If so doesn't this mean that practices will be penalized for hiring a doctor that has not achieved meaningful use in the prior year? This could create a substantial disincentive for practices/hospitals using an EHR to hire doctors that have been working in paper-based systems. There needs to be clarification of how doctors just coming out of residency are handled. Will there be a grace period for the physicians or will practices automatically be penalized for the first year until this new doctors have been using the certified EHR for a year?
381	We invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the EPs and eligible hospitals affected by the proposed rule.	Data are presented to estimate the costs to developers but nothing to asses cost to the clinician base. Small practice expenses to run a more and more sophisticated system are going up a lot faster than any perceived gain to the bottom line. The assumption at the end of the document that the positives will be more than the negatives financially in the long run is not supported. We expect a significant proportion of EPs, especially the ones in smaller groups, to opt out. They do not see any midterm or long term benefits to their lives financially.

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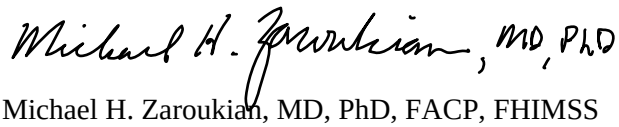
Conclusion

Despite the concerns identified in this document, ACP wishes to reaffirm its strong support of CMS and the Office of the National Coordinator for Health IT in the effort to transition the healthcare delivery system from paper to connected, robust, health information technology. We believe that well designed health IT is critically important to improving the quality of healthcare and will likely contribute to reducing the cost of evidence-based care.

However, in general, we feel that the NPRM core and menu measures underestimate the challenges to EPs, EHs and CAHs of such a transition, even for those doing well with Stage 1. We believe that substantive changes will be needed in the Final Rule to keep EPs and EHs engaged and willing to continue striving to achieve and advance Meaningful Use of CEHRT in Stage 2.

CMS needs to be aware that the Proposed Rule in its current form includes core measures that even our most experienced and advanced EHR users are not confident they will be able to meet. We look forward to a Final Rule that is significantly responsive to these concerns and inspires greater confidence among our members that the measures are reasonable, feasible, and achievable by all those willing to strive to achieve them.

Sincerely yours,



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ACP
American College of Physicians
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January 12, 2012

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Mostashari:

On behalf of the American College of Physicians, I am writing to share our views on Stage 2 of Meaningful Use. ACP is the largest physician specialty society and second-largest physician membership organization in the United States. ACP represents 132,000 internal medicine physicians and medical student members. Internists specialize in primary and comprehensive care of adolescents and adults.

ACP applauds the HIT Policy Committee and its Meaningful Use Work Group for their diligence and hard work in developing recommendations for Stage 2 of Meaningful Use. As you work to transform HIT Policy Committee recommendations into ambitious yet broadly achievable measures, we urge you to keep in mind the guiding principles and general concerns we provide below. While we support the goals represented in the Meaningful Use (MU) objectives, we are concerned about the appropriateness and feasibility of some of the chosen measures.

Totality of measures – While we view many of the individual measures as appropriate, our members tell us that their ability and even willingness to strive to achieve Meaningful Use is severely strained by factors such as the sheer number of measures to be met, the lack of a clear and understandable "single source of truth" regarding what is required to meet them, the need to work with vendors to achieve and report them accurately, and the perceived legal, financial and reputational risk to EPs if vendor-designed reports are not accurate. These challenges, which we feel contribute to the relatively low number of EPs that will have successfully attested for Meaningful Use in 2011, reflect the reality that meeting the functional (core and menu) measures of Meaningful Use Stage I is proving to be much more difficult than some predicted. The College believes that its members are already experiencing "change fatigue" as they strive to meet the timelines required for Stage 1 Meaningful Use, 5010/D.0, ICD-10, and the ARRA Privacy and Security regulations. We believe that asking them to take on yet another set of ambitious and strenuous changes without first proving through experience and data that the great majority of motivated EPs has been able to successfully demonstrate achievement of Stage I Meaningful Use and is ready to take on the additional challenges of Stage 2 is a potential failure path that will interfere with the program's intended desire to improve quality and bend the cost curve.

Protect the encounter - We urge you to be especially diligent in protecting the precious time available for face-to-face encounters between patients and clinicians. It would be better to minimize measures that can only be satisfied through direct physician EHR documentation (without allowing for delegated documentation assistance by staff) because such requirements will take away from the time that physicians have to engage patients in discussions about their health problems, concerns, treatment

decisions and preventive care needs. The incremental value of requiring that physicians spend time educating and counseling patients about access to portals, new technologies and services, complex privacy options, and how to manage online personal information must be weighed against the potential that these activities will detract from actual provision of personalized health care during visits or other encounters. Doctors and other health care professionals should not be held accountable for educating and advising their patients about Meaningful Use measures that do not directly impact care delivery.

Data requirements - Data to support EHR-based quality measurement and reporting should rely upon information routinely collected during the course of providing clinical care, including relevant data supplied by patients. EHR-based quality measurement should include the goal of facilitating the real-time collection of data that support the effective use of point-of-care clinical decision support algorithms.

Administrative burdens - EHR-based quality measurement and reporting must not increase administrative work and/or impose uncompensated financial costs upon physicians and other health care providers, health care organizations, or patients.

Consistent, high-quality Clinical Quality Measures - The rules for attributing a patient to an EP (For example, number of patient visits with an EP required to hold that provider accountable for a CQM) should be consistently defined across all measures. It is hard enough to attribute patients to care providers with any reasonable accuracy without also having to change the calculation on a measure-by-measure basis due to unnecessary variation between measures.

The Meaningful Use CQM metrics must not become another stand-alone set of measures that add to the complexity of quality improvement and potentially impede the delivery of healthcare they are intended to improve. Not everything that can be counted actually counts, and not everything that counts can be easily measured. Be parsimonious in selecting only high-quality measures ("SMART" Specific, Measurable, Attainable, Realistic, Timely) that are meaningful to the specialty of the providers who will be held accountable for them. Also be mindful that the definition of a meaningful action when a care deficiency is identified depends on the specialty and scope of practice of the individual EP, so sometimes the most meaningful measure of quality would be to note that an issue has been discussed with a patient who has been advised and assisted as necessary in getting follow-up care with an EP in another specialty.

Do not recommend metrics for which there is no current technical standard, value set, and accepted definition. Engage measure developers when a desired measure does not exist so that the appropriate e-measure can be developed, tested, and then recommended for adoption.

We believe that the Department of Health and Human Services needs to better coordinate measurement and data collection across programs. The latest CMS proposal that EHR technology certified for use in the EHR Incentive Program may not meet the requirements of PQRS is simply unacceptable.

Patient engagement – All patients deserve to have their preferences honored whenever possible. We urge you not to propose rules that remove choice from a patient's control, such as requiring a particular communication method. Some of the proposed measures that are intended to be patient-centered actually limit patient choice and reduce patient options. As the recent Google Health failure demonstrates, it is far too early for the federal government to pick winners when it comes to patient-facing technologies. We remain concerned about the requirement that EPs demonstrate that a set percentage of their patients

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access a personal health record (PHR). If a PHR is designed appropriately and creates value a requirement for access is not necessary – use will grow based on the desire of all parties to exchange information. On the other hand, there are unknowns regarding how best to provide such information and realistic concerns about potential harm to patients from misinterpreting clinical information (i.e., “melanocytes” being interpreted as “melanoma”). It is equally inappropriate to require that patients view their records in the portals of every different practice or setting they visit. The challenge for patients of having to manage multiple login IDs, passwords, and different user interfaces are likely to hamper uptake and result in failure of some physicians to achieve Meaningful Use.

Further, holding physicians accountable for patient utilization of PHRs is like holding pharmacists accountable for patients’ compliance with medication usage – or using a non-medical example, holding a mechanic responsible for drivers complying with car maintenance schedules. Therefore, the most responsible approach is to articulate the requirement that certified EHRs include this functionality and that practices provide timely electronic access – but also stipulate in the narrative that this recommendation is being made with the understanding that there needs to be explicit guidance, based on evidence and research, about how best to present such information in a way that minimizes the potential for harm to patients and families. These stipulations also apply to the metric for providing clinical summaries for each encounter and electronic access to the clinical record.

Meaningful measures – Keep in mind that what might seem like a good idea in the abstract can become irrelevant and even silly when fully implemented in a rule. It is also important not to become overly prescriptive in a measure such that a value that has meaning clinically (e.g., smoking status: quit < 6 mo) becomes one that must be changed to be compliant while having less meaning (former smoker), or one that is used by few if any practicing physicians (current some day smoker). Having to stop to change the smoking status from “never” to “never smoker” on hundreds of patients just to be in compliance with a meaningful use measure for a 90-day reporting period is a real story from one of our members that is pure waste and risks losing physician engagement and buy-in.

Focus on Clinical Quality Measures (CQMs) - If CQMs are designed and picked appropriately, it is possible that some of the functional measures could be relaxed or dropped, because reporting a CQM could be dependent on the fundamental elements being captured in some other manner. CQMs should be what ultimately counts most. Stage 2/3 of MU should not automatically assume that all Stage 1 functional measures should stay, or that those that worked necessarily need to have their thresholds increased. While not every measure of MU is related to a CQM, we believe this approach (focusing on measuring what counts and can be counted) is the appropriate direction for Stages 2 and 3. The other point to consider is that appropriately designed CQMs can help measure the "between the ears" thinking of clinicians; what do clinicians do in certain clinical situations? Do they escalate therapy for hypertensive patients not under control? Do EPs react and respond to CDSS alerts? These could be aligned with Maintenance of Certification/Maintenance of Licensure (MOC/MOL) activities and create more value for physicians in particular. If a CQM is clearly defined (attribution, denominator, numerator, exclusions), accurately coded, relevant to one's scope of practice, and validated as correct - it could be exceedingly powerful. Couple that with aligned incentives and you have an unstoppable force that is also aligned with what clinicians believe to be good care. However, the beneficial change expected to result from using health IT is less likely to occur if 1) the CQM is not clearly defined; 2) the attribution model is not fair,

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understandable and consistent; 3) the implementation of the rule into the EMR is done wrong; or 4) if the CQM validation is not done or believable to EPs.

A bridge too far – While we applaud your intention to use stretch goals to move U.S. healthcare forward, we are concerned with proposals to enact measures for which there are insufficient mature technologies, standards, products, or evidence of efficacy. While the HIT Policy Committee has shown reluctance to consider "immature" data standards, this reluctance does not appear to extend to ideas for new care delivery activities, such as shared care plans or longitudinal records, which do not exist outside of small demonstrations. Further, the implementation of Meaningful Use at the level of clinical care is inextricably – and perhaps inappropriately - tied to the same timeline as the development, testing and certification of new functionality in certified EHR systems. This linkage should be re-examined and potentially uncoupled to allow rapid progress in EHR system development, measurement testing and verification in controlled settings *followed* by use in practice. Continuing to push technology vendors and clinical practices at the same pace could lead to unintended and serious consequences with regard to patient safety.

Provide useful guidance and assistance - Evidence exists that the specific methods by which the activities are implemented make all the difference between whether they are useful or wasteful. Small practices do not have the necessary expertise and experience to implement many of the current and proposed measures appropriately. The existing support programs, such as the Regional Extension Centers, cannot provide the help that practices need to all of the practices that need the help, particularly outside the primary care domain. For every measure specified, clear and comprehensive implementation guidance is needed. Also, early experience has clearly demonstrated that some certified vendor implementations of more complex functions are extremely difficult to use. Future certification requirements must take into account the usability of the functions.

Hold all participants accountable – Meaningful Use holds only those who actually deliver patient care responsible for all of the outcomes being measured. Providers must exchange information with other entities, yet the non-EP entities with whom they must communicate may have no obligations under Meaningful Use. For any measure that involves communicating outside the practice, the exchange partners (labs, pharmacies, payers, and public and private reporting entities) must be held equally accountable for the success of the exchange.

The Medical Informatics Committee of the American College of Physicians respectfully submits this letter hoping that it will assist ONC in the important work of improving healthcare in the United States through the appropriate use of health information technologies.

Sincerely yours,

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