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

March 10, 2010

Centers for Medicare & Medicare Services
Department of Health and Human Services
Via http://www.regulations.gov

Re: Document ID CMS-2009-0117-0002

To Whom It May Concern:

Thank you for the opportunity to comment on the Notice of Proposed Rule-Making (NPRM) that would implement provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5) that provide incentive payments to eligible professionals and hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology.

The American College of Physicians, representing 129,000 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 ARRA 2009 and ensuring that the goals set forth by the legislation are attained expediently without creating unintended consequences.
In this document, there are six sections and a concluding statement:

1. General Comments;
2. Responses to NPRM specific questions;
3. Comments on Table 2 of the NPRM (Stage 1 Criteria);
4. Comments on Table 4, Core Measures;
5. Comments on Table 10, Measure Group for Primary Care;
6. Comments on Health IT Policy Committee recommendations of February 2010

1. General Comments

ACP believes that the most important goal for 2011 meaningful use criteria should be to move eligible providers and hospitals towards the routine capture of relevant clinical data in structured formats at the point of care. The best way to measure this activity is to ask all EPs to generate the Quality Data Set (QDS) which is applicable to all providers of care. The QDS provides a common technological framework defining the clinical data necessary to measure performance. All other higher level functions for the use of health IT depend on this foundational aspect of data collection. While we understand and support the desire to rapidly implement health information exchange, quality reporting, and the use of clinical decision support systems, the

reality is that many of these functions and the measures of their use will not ready for 2011. Premature adoption may result in adverse effects. Most EHR vendors will not be able to ensure by 2011 that systems, processes, and measures have been adequately tested in practice. Further, eligible providers/hospitals, in the interest of meeting proposed meaningful use criteria, may focus on reporting before they have made the necessary culture and data-collection changes to support a robust, long-term strategy of quality improvement.

In addition to this overriding issue, we have the following general concerns:

- **Too Many Measures:** There are simply too many general measures required. The amount of effort required to report so many measures is enormous. The NPRM vastly underestimates the amount of work necessary to prepare for reporting. For 2011, meaningful use can be demonstrated adequately with far fewer measures – and measures that demonstrate that data are being captured in structured format., ACP believes that this should be the primary goal for 2011. Once health care organizations have the initial experience of collecting and reporting quality measures, the number of measures can be increased with increasing rapidity.

- **Pass-Fail:** Demonstrating meaningful use, as described, is essentially one, large, composite, pass-fail measure. It seems highly unlikely that any physician or other healthcare provider would be capable of reporting successfully on every metric. Experience with the PQRI program has demonstrated the difficulty of successfully reporting on just three clinical measures. Physicians and other healthcare providers should be able to receive credit for achieving meaningful use for building the foundation for higher levels of meaningful use even if, for 2011, they cannot demonstrate compliance with all measures. Further, the NPRM should recognize that a growing number of practices across the U.S. are undergoing transformation to the patient-centered medical home model of care. CMS should consider granting meaningful use "equivalence" to those practices that have achieved recognition under programs such as the National Committee for Quality Assurance (NCQA) Physician Practice Connections – Patient-Centered Medical Home process.

Eliminate Denominators: A number of the measures require the manual counting of activities to establish a denominator since they would not be captured electronically. Examples include the number of orders issued without CPOE, the number of prescriptions issued without e-prescribing, lab results not received electronically, and paper care summaries provided to patients. This counting would require additional uncompensated labor that will detract from care delivery activities and become a new expense to the practice. ACP believes that all measures that require manual counting of activities should be removed or modified to eliminate this need. Percentages should not be required. If a practice is capturing data in structured format, then reporting raw counts of the performance of measure should be an adequate demonstration of meaningful use in 2011. Denominators should not be required unless the certification process includes a requirement that certified EHR technology captures the information as a matter of routine clinical care.

- **Define All Terms:** Operational definitions are required for all of the terms used in the measures. Without clear and unambiguous definitions for concepts like "order," "test," and

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"result," for example, it will be impossible for practices to report accurately and consistently. With respect to lab tests, does the requirement refer to individual components of a profile ordered or each profile (i.e., basic metabolic profile versus sodium, potassium, BUN, creatinine, etc.)?

- **Timing of Measures**: The specified timing of reporting does not always correspond to the timing of appropriate clinical care. CMS is attempting to arbitrarily shift all timing of clinical activities and even thinking about when it is appropriate for activities to take place to the artificial "measurement year." Everything in healthcare will have to move to this cycle in order to achieve measurement objectives.

- **Relevance of Measures**: Many of the measures (such as recording height/weight and reminders for preventive care) are not applicable to all EPs.

- **Attribution:** The NPRM does not address the issue of attribution. How should the responsibility for specific care activities be attributed among the various physician and other healthcare professionals caring for individual patients? Must every care provider provide all meaningful use services to all patients seen no matter how many other providers may have performed the same activities? Without clear and specific attribution rules, this incentive program will generate an enormous number of unnecessary care activities and an enormous waste.

- **Untested Data Collection and Reporting Requirements:** CMS is proposing measures that require the collection of specific structured data elements that no existing EHR system currently collects. While it is true that EHR system developers will add these capabilities, actual collection of accurate data by physicians and other healthcare professionals has never been done. CMS should allow at least two years to transpire between specifying collection of data elements and reporting requirements that rely on the accurate collection of those data elements. During that period, CMS should perform field evaluations of the accuracy of collection.

- **Inappropriate Changes in How Healthcare is Delivered:** Some proposed measures require that specific individuals perform certain activities involving ordering and data collection. These requirements are inappropriate and contrary to the way many practices operate. CMS should not direct practices to change the way they manage workflow and the assignment of responsibilities among their staff. For example, it is common for EP's to partially enter orders that are then queued for a staff member to complete and execute. Also, it is common for the tasks described in the proposed measures to be performed by staff other than EPs. Some of the proposed measures will discourage the concept of team-based care delivery by imposing specific responsibilities on physicians and other EPs.

- **Unrelated to Meaningful Use:** Many of the clinical measures do not require the use of an EHR system or any other health IT. In some cases (i.e., insurance verification), a practice management system is the key technology needed to satisfy meaningful use – not certified EHR technology. The meaningful use criterion should be justified for each measure.

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- **Unacceptable Burdens Especially for Small Practices:** Small practices, which deliver the bulk of medical care and for whom electronic health records are being encouraged, will be unfairly burdened and be subject to unreimbursed additional costs as a consequence of the proposed rule. Unless revised, the NPRM will result in the need for additional personnel and the associated costs – over and above the software and hardware costs of purchasing certified EHR technology. This will be perceived as an unfunded mandate by physicians and may slow or halt significant development of computerization and conversion to electronic health records.

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2. Responses to NPRM specific questions

NPRM ("We welcome, invite, request")	ACP Comments
NPRM Statement (page numbers refer to PDF of NPRM)	
P27 However, in subsequent years we do not see that flexibility still being required. Therefore, for purposes of the incentive payments under sections 1848(o), 1853(l)(3),1886(n), 1853(m)(3), 1814(l), and 1903(t) of the Act, we propose that the length of the EHR reporting period be different for the first payment year than from all other payment years. We invite interested parties to comment on this proposal if they believe that the EHR reporting period should vary from payment year to payment year	ACP agrees with the concept of a different reporting period for the first payment year.
P29 We invite comments on the appropriate length for the EHR reporting period. We urge those commenting to either endorse our proposed initial 90-day period followed by full year EHR reporting periods or to recommend a specific alternative	ACP agrees with a reporting period of 90-days for the initial payment year.

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NPRM ("We welcome, invite, request")	ACP Comments
P47 While we welcome comments on all aspects of the Stage 1 criteria of meaningful use, we specifically encourage comments on the following considerations. While we believe that requiring satisfaction of all objectives is appropriate for the majority of providers, we are concerned that certain providers may have difficulty meeting one or more of the proposed objectives. We solicit comments on whether this may be the case, and invite commenters to identify the objectives and associated measures that may prove out of reach for certain provider types or specialties, and to suggest specific objective criteria we could use to determine whether an objective and associated measure is appropriate for different provider types or specialists	ACP is concerned that the Stage 1 criteria are designed as one, large, composite, pass/fail measure. It seems highly unlikely that any physician or other healthcare provider would be capable of reporting successfully on every metric. Experience with the PQRI program has demonstrated the difficulty of successfully reporting on just three clinical measures. Physicians and other healthcare providers should be able to achieve meaningful use even if a portion of the measures are not successfully reported. ACP believes that the key goal for 2011 is to capture relevant clinical data in structured formats at the point of care. The best way to measure this activity is to ask all EPs to generate the Quality Data Set (QDS) which is applicable to all providers of care. Our comments below identify concerns regarding specific measures and our support for others.
P54 We welcome comment on whether use of CPOE varies between hospitals and EPs in ways that should be addressed. ● Implement drug-drug, drug-allergy, drug-formulary checks. ● Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®	These checks and the maintenance of the problem list based on a standard vocabulary are important in both venues of care. Order entry is essentially the same process in both venues.

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NPRM ("We welcome, invite, request")	ACP Comments
P59 Electronic access may be provided by a number of secure electronic methods (for example, PHR, patient portal, CD, USB drive). Timely is defined as within 96 hours of the information being available to the EP either through the receipt of final lab results or a patient interaction that updates the EP's knowledge of the patient's health. We judge 96 hours to be a reasonable amount of time to ensure that certified EHR technology is up to date. We welcome comment on if a shorter or longer time is advantageous	ACP is concerned with this requirement for the following reasons: 1. The period of time should be referred to as work-days as opposed to hours (4 work days) 2. This measure would require the calculation of a denominator which will be difficult without introducing manual processes. ACP recommends that practices be asked to report simply the number of lab reports that are provided within 4 work day of receipt of such information. Simple secure e-messaging is a cost-effective approach to this need and should be included with the other exemplars.

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NPRM ("We welcome, invite, request")	ACP Comments
P68 We are proposing that to be a meaningful EHR user an EP must have 50 percent or more of their patient encounters during the EHR reporting period at a practice/location or practices/locations equipped with certified EHR technology. An EP for who does not conduct 50 percent of their patient encounters in any one practice/location would have to meet the 50 percent threshold through a combination of practices/locations. While control is less assured in this situation, CMS still needs to advance the health care priorities of the definition of meaningful use and provide some level of equity. We invite comments as to whether this denominator is feasible to obtain for EPs, whether this exclusion (the denominator for patients seen when certified EHR technology is not available) is appropriate, whether a minimum threshold is necessary and whether 50 percent is an appropriate threshold. We note that in evaluating the 50 percent threshold, our proposal is to review all locations/organizations at which an EP practices. So, for example, if the EP practices at both an FQHC and within his or her individual practice, we would include in our review both of these locations	ACP supports the 50% threshold.

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NPRM ("We welcome, invite, request")	ACP Comments
P109 We specifically intend to build up the following health IT functionality measures for Stage 2 meaningful use criteria: • "CPOE use" will include not only the percentage of orders entered directly by providers through CPOEs but also the electronic transmission of those orders, • "Incorporate clinical lab-test results into EHR as structured data" will be expanded to include the full array of diagnostic test data used for the treatment and diagnosis of disease, where feasible, including blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, and pulmonary function tests • Measures that currently allow the provision and exchange of unstructured data (for example, the provision of clinical care summaries on paper) will require the provision and exchange of electronic and structured data, where feasible • Measures that currently require the performance of a capability test (for example, capability to provide electronic syndromic surveillance data to public health agencies) will be revised to require the actual submission of that data. We invite comment on our intent to propose the above measure for Stage 2 in future rulemaking and also invite comment on any other health IT functionality measures not included in this list	ACP believes that the proposed Stage 2 criteria should be postponed until there is evidence that all needed capabilities are likely to be in place and available at reasonable cost to EPs. Standards, technologies, infrastructure, partner capacity, and measures required to implement these proposed Stage 2 criteria are too immature to be ready for mainstream use in 2013. Optimally safe and effective care processes often include entry of orders by protocol (e.g., a peak and trough levels are ordered automatically—if they have not been ordered by a physician or pharmacist--when an aminoglycoside is ordered). The criterion should be that orders are entered electronically by an authorizing provider or according to an explicit organizational protocol.

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NPRM ("We welcome, invite, request")	ACP Comments
P118 We are targeting finalization and publication of the detailed specifications documents for all 2011 payment year Medicare EHR incentive program clinical quality measures for eligible hospitals on the CMS website on or before April 1, 2010. We intend that a detailed specifications document for all 2012 payment year Medicare EHR incentive program clinical quality measures for EPs be posted on the our web site on or before April 1, 2011. This would provide final specifications documents at least 9 months in advance of the start of the applicable payment year for clinical quality measure EHR reporting period. We invite comments on our proposed timelines to post specification documents for these clinical quality measures to the CMS website	ACP does not believe that the proposed timelines are workable. The expectations do not allow sufficient time for functionality to be implemented in EHR systems (with typical development cycles running 18 months) and for EPs to become sufficiently competent in their proper use. Potential adverse effects include inadequate integrated testing of EHR modules, and endangering patient care and safety.
P121 We welcome comments on the inclusion or exclusion of any given clinical quality measure or measures proposed herein in the EHR incentive programs clinical quality measure set for EPs or eligible hospitals for the 2011 and 2012 payment years, and to our approach in selecting clinical quality measures	See below and comments on Table 10 (Section 5).

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NPRM ("We welcome, invite, request")	ACP Comments
P139 We welcome comment on not only the clinical utility of the measures we have proposed, but also their state of readiness for use in the EHR incentive programs. For those measures where electronic specifications do not currently exist, we solicit comment on how quickly electronic specifications can be developed and the period of time that might be required for effective implementation from the time the electronic specifications of final measures are posted and made available to vendors. We intend to publish electronic specifications for the proposed clinical quality measures on the CMS website as soon as they become available from the measure developer(s). Electronic specifications may be developed concurrently with the development of measures themselves and potentially with the NQF endorsement processes	ACP is concerned regarding the measures proposed because, to date, none have been converted into electronic format, implemented in any clinical system, used by any provider, or reported upon as is being required by the NPRM. While ACP strongly supports the ultimate goal of EHR-based quality measurement and reporting, the NPRM bases meaningful use on standards and technologies that are not only unproven, but are not even complete. Premature implementation of untested measures could endanger patient care and safety.
P141 In summary, we believe that this initial set of clinical quality measures is broad enough to allow for reporting for EPs and addresses high priority conditions. We recognize the importance of integrating the measures into certified EHR products for calculation of measures results, and that not all measures may be feasible for 2011 and 2012. We invite comment on the advisability of including the measures proposed for payment years 2011 and 2012. Although we recognize many other important clinical quality measures of health care provided by EPs, we anticipate expanding the set of clinical quality measures in future years and list a number of clinical quality measures for future consideration in section II.A.3.g of this preamble, on which we also invite comment. We invite comments on our proposed clinical quality	See Sections 4 and 5 (comments on Table 4 and Table 10 from NPRM).

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NPRM ("We welcome, invite, request")	ACP Comments
measures for EP.	
P143 We propose to require for 2011 and 2012 that EP's will select a specialty measures group, on which to report on all applicable cases for each of the measures in the specialty group. The same specialty measures group selected for the first payment year would be required for reporting for the second payment year. We invite comment on whether there are EPs who believe no specialty group will be applicable to them. In accordance with public comments, we will specify in the final rule which EP specialties will be exempt from selecting and reporting on a specialty measures group. EPs that are so-designated will be required to attest, to CMS or the State, to the inapplicability of any of the specialty groups and will not be required to report information on clinical quality measures from a specialty group for 2011 or 2012, though the EP will still be required to report information on all of the clinical quality measures listed in the core measure set in, Table 4, as applicable for their patients	See Sections 4 and 5 (comments on Table 4 and Table 10 from NPRM). It is important to narrow the number of measures and provide choice within specialty groups. The primary care measurement group is considerably longer than other specialty groups. The measurement requirements should be equitable across all specialties with respect to the number of measures, the clinical complexity assessed, and the logistical requirements to collect and report data.
P169 We invite comments on our three proposed clinical quality measures data submission methodologies as they pertain to CMS for Medicare and to States for Medicaid. We propose that Medicare EPs and eligible hospitals would be required to report the required clinical quality measures information electronically using certified EHR technology via one of three methods. The primary method would require the EP or eligible hospital to log into a CMS-designated portal. Once the EP or eligible hospital has logged into the portal, they would be required to submit, through an upload process, data payload based on specified structures, such as Clinical Data Architecture (CDA), and accompanying templates produced as output from their	ACP is concerned regarding the measures proposed because, to date, none have been converted into electronic format, implemented in any clinical system, used by any provider, or reported upon as is being required by the NPRM. While ACP strongly supports the ultimate goal of EHR-based quality measurement and reporting, the NPRM bases meaningful use on standards and technologies that are not only unproven, but are not even complete. Further, many physicians experienced considerable frustration with data submission for PQRI and the process through which they accessed the reporting website. The idea of requiring busy physicians to log into a website and

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NPRM ("We welcome, invite, request")	ACP Comments
certified EHR technology. As an alternative to this data submission method, we propose to permit Medicare EPs and eligible hospitals to submit the required clinical quality measures data using certified EHR technology through Health Information Exchange (HIE)/Health Information Organization (HIO). This alternative data submission method would be dependent on the Secretary's ability to collect data through a HIE/HIO network and would require the EP or eligible hospital who chooses to submit data via an HIE/HIO network to be a participating member of the HIE/HIO network. Medicare EPs and eligible hospitals would be required to submit their data payload based on specified structures or profiles, such as Clinical Data Architecture (CDA), and accompanying templates. The EP's or eligible hospital's data payload should be an output from their respective certified EHR products, in the form and manner specified from their HIE/HIO adopted architecture into the CMS HIE/HIO adopted architecture. As another potential alternative, we propose to accept submission through registries dependent upon the development of the necessary capacity and infrastructure to do so using certified EHRs. We intend to post the technical requirements for portal submission and the alternative HIE/HIO submission, the HIE/HIO participating member definition, and other specifications for submission on our web site for Medicare EPs on or before July 1, 2011 and for Medicare eligible hospitals on or before April 1, 2011 for EHR adoption and incorporation and to accommodate EHR vendors	type data into web applications will not be received well by physicians. Should such a portal be constructed, it must not require anything but the most minimal manual data entry (for identification purposes), permit office staff to do the upload, and be automated, easy, and quick. The other alternatives recommended (i.e., through an HIE/HIO network) will only be available to EPs who have access to an HIE/HIO. We have significant concerns about whether HIE/HIO networks will have sufficient time to incorporate the technical requirements for portal submission, test their implementation, provide access to the multiple EHR systems (both complete EHRs and aggregated EHR modules), and to accommodate the needs/questions from those EPs who elect to use the exchanges.
P349 However, there are still some Meaningful Use objectives and associated measures (Set B) where reporting may require EPs to manually gather the information necessary to report numerators and denominators or to take any other additional steps before attesting that the objective has been met, we have estimated that it would	ACP has significant concerns about the time estimates used in the NPRM. We believe that the time required to report is at least ten times more than what is suggested, error-prone, and untenable to audit. If an EHR cannot perform a needed count (see comments earlier under Section 1 regarding denominators), then only numerators should be

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NPRM ("We welcome, invite, request")	ACP Comments
take 1 hour for the EP to gather that information and report the result. For example, the measure "At least 80 percent of all patients who request an electronic copy of their health information are provided it within 48 hours" requires EPs to not only provide that information (a third party disclosure) but also attest to the provision of that information for 80 percent of all patients who request that information. Another example is the CPOE measure. The numerator for the CPOE measure could be generated by the certified EHR technology adopted by the EP, as all orders entered through CPOE could be tracked. However, the denominator for this measure could require EPs to manually track the number of orders entered through paper-based processes. Alternatively, EPs may choose to purchase EHRs equipped with additional functionality to enable the tracking of all orders, whether entered using CPOE or otherwise, in which case reporting burden may be less than an hour but the capital costs will be higher. We invite comments on what the incremental costs of such additional functionality may be and what the reporting burden using EHRs equipped with this functionality might be. Table 33 below lists those objectives and associated measures which we estimate will require 0.5 hours to fulfill ("Set A") and those objectives and associated measures which we estimate will take 1 hour each ("Set B"). We welcome comments on our burden estimates for each particular measure, as well as what the incremental capital costs attributable to each measure might be. Estimates of total capital costs at the bottom of Table 33 are derived from the estimates used in the "Industry Costs" section in Section V.G.4	required. It is unreasonable and inconsistent with the move towards meaningful use for CMS to require doctors and other healthcare professionals to perform manual operations in order to calculate percentages for meaningful use.

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3. Comments on Table 4, Core Measures

TABLE 2: Stage 1 Criteria for Meaningful Use

Stage 1 Objectives		Stage 1 Measures	ACP Comments
Eligible Professionals	**Hospitals**		
Use CPOE	Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)	For EPs, CPOE is used for at least 80% of all orders For eligible hospitals, CPOE is used for 10% of all orders	This measure will be difficult due to the denominator issue. How will practices be able to determine how many orders were written versus entered via CPOE? 2. The standard for hospitals should be 80% also. At 10%, electronic orders would be so infrequent that they might introduce care-process compromise. This presumes that there is the ability for hospital labs, radiology centers, commercial labs, etc to receive such orders. Direct order by EP is not always desirable or appropriate. Denominator should not be required.[*] Since there is a separate measure for e-prescribing, how are prescriptions to be counted in this measure?

[*] "Denominators should not be required" as used in this grid should be interpreted to mean unless the certification process includes a requirement that certified EHR technology captures the information as a matter of routine clinical care.

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
			Are all imaging studies, diagnostic studies, referrals, DMEs included? What are EPs to do if they order through a hospital that requires faxing? In many cases the order interfaces provided by the receiving entities are extremely poor and difficult to use. Specialist EPs may draw their patients from a far wider geographic area than primary care EPs. For these EPs interfacing with every relevant order-receiving entity will be even less feasible than for generalist EPs.
Implement drug-drug, drug-allergy, drug-formulary checks	Implement drug-drug, drug-allergy, drug-formulary checks	The EP/eligible hospital has enabled this functionality	This should specify that it drug-formulary checks are applicable only when a formulary is available.
Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT ®	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT ®	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data	ACP supports the objective. Denominator should not be required. What is the definition of "problem?" EPs should only have to attest to maintaining an up-to-date problem list.
Generate and transmit permissible		At least 75% of all permissible prescriptions written by the EP are	ACP supports the objective. This measure will be difficult to determine because of the

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
prescriptions electronically (eRx)		transmitted electronically using certified EHR technology	denominator issue - how will EPs know how many permissible prescriptions were *not* transmitted electronically? Denominators should not be required. We recommend the elimination of the threshold of 75%. EPs should attest to the use of e-prescribing at least 25 times during the reporting period. Define "transmitted electronically" - could this be by fax? This also is presumes the ability of pharmacies throughout the country to receive e-prescriptions. Electronic transmission from hospitals of prescriptions for post-discharge medications should not be required until pharmacies are able to receive prescription cancellations in the same electronic system in which they receive prescriptions.
Maintain active medication list	Maintain active medication list	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data	ACP supports the objective. Denominator should not be required. EPs should attest to maintaining an up-to-date medication list.
Maintain active medication allergy list	Maintain active medication allergy list	At least 80% of all unique patients seen, by the EP or admitted to the eligible hospital have at least one entry or (an indication of	ACP supports the objective. The word "none" is not the typical language used: "No known drug allergies" is the acceptable phrase.

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
		"none" if the patient has no medication allergies) recorded as structured data	Consider adding a requirement for non-drug allergies (i.e., food, environmental) and reactions Denominator should not be required. EPs should attest to maintaining an up-to-date allergy list.
Record demographics o preferred language o insurance type o gender o race o ethnicity o date of birth	Record demographics o preferred language o insurance type o gender o race o ethnicity o date of birth o date and cause of death in the event of mortality	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data	ACP supports the objective. Clarification: Does this mean that 80% have entries for ALL of these elements or that 80% of entries for at least 1 of these elements? Even this numerator would be hard for most organizations to measure electronically. Consider adding presence/absence of advance directives. Denominator should not be required. EPs should attest to recording these elements in the record.
Record and chart changes in vital signs: o height o weight o blood pressure o Calculate and display: BMI o Plot and display growth charts for	Record and chart changes in vital signs: o height o weight o blood pressure o Calculate and display: BMI o Plot and display growth charts for children 2-20 years,	For at least 80% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2-20	ACP supports the objective. Adult providers do not typically record growth charts for patients 18+. Recommend altering the age range from 2-18. Denominator should not be required.

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
children 2-20 years, including BMI.	including BMI.		
Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	At least 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital have "smoking status" recorded	ACP supports the objective. Consider lowering the age at which smoking is asked. Also, consider recording exposure to second-hand smoke for children/adolescents. Denominator should not be required. How often must this be determined? Once a year? Every visit?
Incorporate clinical lab-test results into EHR as structured data	Incorporate clinical lab-test results into EHR as structured data	At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data	This measure also has a denominator issue. How will practices determine how many tests are ordered? Is this by panel? Individual specific test? Denominator should not be required. Specialist EPs may draw their patients from a far wider geographic area than primary care EPs. Are these EPs expected to pay to interface with every lab that their patients in rural areas or even in other states may choose to use? Data from the NY State EHR Project indicate that only 32% of practices are able to get even one lab's results electronically.

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
			EPs should attest to the use of structured laboratory/test data.
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate at least one report listing patients of the EP or eligible hospital with a specific condition.	Is the intent of this objective to generate a list for all of these needs or one list for one of them? If the latter, then change the word "and" or "or." Should this be tied to one of the clinical measures that need to be reported (specialty group)?
Report ambulatory quality measures to CMS or the States	Report hospital quality measures to CMS or the States	For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of this proposed rule For 2012, electronically submit the measures as discussed in section II(A)(3) of this proposed rule	See specific measures
Send reminders to patients per patient preference for preventive/ follow up care		Reminder sent to at least 50% of all unique patients seen by the EP that are age 50 or over	ACP supports the objective. This needs to take into account patient preferences which may include not receiving reminders. What about pediatric patients who also need reminders for vaccines, well-child checks? What about adults under 50? Reminders for what? *All* preventive services? Routine follow-up care? Chronic conditions? This needs to be

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
			defined. What is the expected frequency of reminders? Too often will be inappropriate clinically, and cause confusion and concern for all patients. Denominator should not be required.
Implement 5 clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement 5 clinical decision support rules relevant to the clinical quality metrics the EP/Eligible Hospital is responsible for as described further in section II(A)(3).	This objective presumes the availability of clinical decision support systems and rules for five measures in each specialty and the capability of certified EHR technology to track compliance with these guidelines. Both presumptions are incorrect. What defines, "compliance" in the context of care? Patient compliance? EP compliance? What action does an EP need to take/not to take to be "compliant" with a CDS rule? While ACP understands the reason for including such an objective, we do not believe that this is appropriate for Stage 1.
Check insurance eligibility electronically from public and private payers	Check insurance eligibility electronically from public and private payers	Insurance eligibility checked electronically for at least 80% of all unique patients seen by the EP or admitted to the eligible hospital	This is not a typical meaningful use measure of health IT but a practice management system function. EHR systems typically do not provide this function. CMS should not require that EHR systems perform administrative activities that are better handled by other systems. Denominator should not be required.

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
Submit claims electronically to public and private payers.	Submit claims electronically to public and private payers.	At least 80% of all claims filed electronically by the EP or the eligible hospital	This is not a typical meaningful use measure of health IT but a practice management system function. EHR systems typically do not provide this function. CMS should not require that EHR systems perform administrative activities that are better handled by other systems. Denominator should not be required.
Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request	At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours	How will the practice record who has requested versus who has received the appropriate electronic copy and whether the records have been sent within 48 hours? The time period should be expressed on work days - not hours. Denominator should not be required. Note: We are aware that it took Geisinger several hundred person hours to create an electronic report that could be produced for patients. Very few health care organizations and even fewer independent practices will be able to complete this requirement unless it is a very specific requirements for certification of EHR technology.
	Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon	At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and	Denominator should not be required.

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
	request	procedures are provided it	
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP		At least 10% of all unique patients seen by the EP are provided timely electronic access to their health information	There should be some exception for sensitive reports and the ability for health care professionals to exert professional judgment. EPs may want to discuss results with patients before making them available. Is the expectation that all information available is reported? A standardized report? Does a patient portal/connected personal health record satisfy this objective? Time period should be expressed in workdays not hours (i.e., 4 work days). Denominator should not be required. Many practices will be reluctant to open a patient portal early in their EHR implementation as this will create considerable change for their office workflow. Paper reports should be acceptable.
Provide clinical summaries for patients for each office visit		Clinical summaries are provided for at least 80% of all office visits	See above. Same concerns.

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
Capability to exchange key clinical information (for example, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information	Such a one-time action is not meaningful use. Interoperability typically requires functionality and customization for which vendors often impose extra charges. Are EPs expected to pay additional costs for features which must only be used once to qualify?
Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation for at least 80% of relevant encounters and transitions of care	This metric has a denominator problem. How do clinicians monitor and count "relevant encounters" for the purposes of this measure? What is a “relevant encounter”? All routine outpatient follow-up visits? We suggest replacing “relevant encounters and each transition of care” with “physician visits and hospital admissions /discharges”. For outpatient providers’ patients, medication reconciliation should be done multiple times a year but not necessarily at every visit (e.g., a quick wound check; blood pressure check after recent change in medication; laboratory test discussion). Define medication reconciliation as confirming with the patient what drugs they are taking and documenting the fact (ideally with a button in the EHR).

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
			Denominators should not be required unless the certification process includes a requirement that certified EHR technology captures the information as a matter of routine clinical care. EPs should be able to attest to meeting this requirement.
Provide summary care record for each transition of care and referral	Provide summary care record for each transition of care and referral	Provide summary of care record for at least 80% of transitions of care and referrals	This seems to require a time frame, e.g. Provide summary of care record for at least X% of transitions of care and referral within 2-3 days of the transition or referral. Define transitions of care as hospital discharge or admissions and referrals as between primary care and subspecialty care in the ambulatory space.ACP supports the idea of a high threshold at the time of discharge, but that's been hard for even large health systems to achieve this threshold. What must a summary of care contain? Is it to be the same for all patients in all situations? Denominator should not be required. Provide an after-visit summary for 80% of physician visits and a discharge summary for 80% of hospital discharges.
Capability to submit electronic data to immunization registries and actual submission where required and accepted	Capability to submit electronic data to immunization registries and actual submission where required and accepted	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries	Can this be a simulated test? Capability to submit electronic data to standards-based immunization registries that do not require interfacing to proprietary software systems and actual submission where required and accepted. This measure should specific what data elements are required (e.g., immunizations, lot number, expiration date, date administered). Interoperability typically requires functionality and

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
			customization for which vendors often impose extra charges.
	Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received	Performed at least one test of the EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically)	Can this be a simulated test? As above regarding standards and interfaces. The Feds should create one data set that includes all required submissions and could be sent to one Federal agency, who would then provide access to authorized agents (governmental or non-governmental). Interoperability typically requires functionality and customization for which vendors often impose extra charges. Are EPs expected to pay additional costs for features which must only be used once to qualify?
Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically)	Can this be a simulated test? As above. Interoperability typically requires functionality and customization for which vendors often impose extra charges. Are EPs expected to pay additional costs for features which must only be used once to qualify?

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Stage 1 Objectives		Stage 1 Measures	ACP Comments
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary	What does this entail? This activity seems to be unrelated to the meaningful use of EHR technology. It should be eliminated.

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4. Comments on Core Measures (Table 4)

TABLE 4: Measure Group: Core for All EPs, Medicare or Medicaid		
Measure Number	**Clinical Quality Measure Title**	**ACP Comments**
PQRI 114 NQF 0028	**Title:** Preventive Care and Screening: Inquiry Regarding Tobacco Use	ACP supports screening for tobacco use.
NQF 0013	**Title:** Blood pressure measurement	ACP supports blood pressure screening.
NQF 0022	**Title:** Drugs to be avoided in the elderly: a. Patients who receive at least one drug to be avoided. b. Patients who receive at least two different drugs to be avoided	There is no agreement on what drugs should be avoided. This measure is inappropriate and should be removed. There needs to be a standard, widely circulated list of drugs along with a standard set of exclusions for the patient continuing on the drug (e.g., "Patient insists after careful education."; "Benefits outweigh risks."). If this activity moves forward, CMS and ONC must assure that the list is evidence-based and maintained as such over time. Finally, this is not appropriate for all EPs. Remove or clarify.

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5. Comments on Table 10, Measure Group for Primary Care

ACP is concerned about the number of measures in this measurement group. The final rule should be very explicit about how many measures are required and be equitable across all specialties with respect to the number of clinical measures and the complexity of care associated with the conditions/situations being measured. Since the majority of these measures are in current use through the Physician Quality Reporting Initiative (PQRI), analyses from the PQRI program should be used to help identify those measures for which primary care physicians are most able to report electronically (i.e., not through claims-based reports). Simply duplicating the PQRI program through certified EHR technology and relying on claims-based reporting is not a test of meaningful use. A group of measures currently capable of being reported electronically, as identified in the 2010 EHR Measure Specifications document (http://www.cms.hhs.gov/PQRI/Downloads/2010_EHR_Measure_Specifications_121809_FINAL.pdf) should be the list from which physicians can choose 3-5 measures for reporting through certified EHR technology. Very clear, acceptable exclusions need to be identified for each of these measures and incorporated into the methodology by which the information is captured within the certified EHR technology.

TABLE 10: Measure Group: Primary Care		
Measure Number	**Clinical Quality Measure Title & Description**	**ACP Comments**
PQRI 114 NQF 0028	**Title**: Preventive Care and Screening: Inquiry Regarding Tobacco Use	If retained as a core measure, then this need not be part of the primary care group.
PQRI 115 NQF 0027	**Title**: Preventive Care and Screening: Advising Smokers to Quit	
PQRI 202 NQF 0075	**Title**: Ischemic Vascular Disease (IVD): Complete Lipid Profile	
PQRI 203 NQF 0075	**Title:** Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL– C) Control	
PQRI 204 NQF 0068	**Title:** Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic	
NQF 0038	**Title**: Childhood Immunization Status	
PQRI 112 NQF 0031	**Title**: Preventive Care and Screening: Screening Mammography	This measure is challenging and requires more validation given the controversy about the appropriate age groups and frequency of mammography.

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TABLE 10: Measure Group: Primary Care		
Measure Number	**Clinical Quality Measure Title & Description**	**ACP Comments**
PQRI 113 NQF 0034	**Title**: Preventive Care and Screening: Colorectal Cancer Screening	
PQRI 1 NQF 0059	**Title:** Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus	
NQF 0052	**Title**: Low back pain: use of imaging studies	
NQF 0018	**Title**: Controlling High Blood Pressure	
PQRI 128 NQF 0421	**Title**: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up	
PQRI 65 NQF 0069	**Title:** Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use	
PQRI 66 NQF 0002	**Title:** Appropriate Testing for Children with Pharyngitis	
PQRI 110 NQF 0041	**Title:** Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old	
PQRI 197 NQF 0074	**Title**: Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol	
NQF 0001	**Title:** Asthma Assessment	
NQF 0004	**Title:** Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement	Primary care typically screens for alcohol and drug dependence and then refers for treatment – especially for drug dependence. Therefore, the application of this measure is not appropriate for many practices.
NQF 0024	**Title:** Body Mass Index (BMI) 2 through 18 years of age	Why is the age cutoff for this measure 18 years old?
NQF 0032	**Title**: Cervical Cancer Screening	
NQF 0036	**Title:** Use of appropriate medications for people with asthma	
NQF 0060	**Title:** Hemoglobin A1c test for pediatric patients	

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TABLE 10: Measure Group: Primary Care		
Measure Number	**Clinical Quality Measure Title & Description**	**ACP Comments**
NQF 0105	**Title:** New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management (b) Effective Acute Phase Treatment (c)Effective Continuation Phase Treatment	These data are difficult to capture and the treatment for depression often involves health professionals outside of a primary care practice.
NQF 0106	**Title:** Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents	
NQF 0107	**Title:** Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents	
NQF 0108	**Title:** ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication.	
NQF 0110	**Title:** Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use	Primary care typically screens for mental health conditions and then refers for treatment – bipolar disorder. Therefore, the application of this measure is not appropriate for many practices.
Not applicable	**Title**: Comprehensive Diabetes Care: HbA1c Control (<8.0 percent)	
Not applicable	**Title:** Appropriate antibiotic use for ear infections	

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6. Comments on Health IT Policy Committee Recommendations, February 2010

The Health IT Policy Committee submitted a set of recommendations to ONC on February 17, 2010 regarding this NPRM. We urge CMS to reject the following recommendations of the Committee for the reasons stated elsewhere in this document. While characterized as adding flexibility to the NPRM and meaningful use, in general, the recommendations would add additional, burdensome requirements that are duplicative, difficult to implement, require unreasonable denominator counting, and will negatively affect delivery workflows.

These are the Recommendations that ACP does not support:

Recommendation 3.0: Providers should produce quality reports stratified by race, ethnicity, gender, primary language, and insurance type.

Recommendation 4.0: EPs and hospitals should report the percentage of patients with up-to-date problem lists, medication lists, and medication allergy lists

Recommendation 6.1: EPs and hospitals should report on the percentage of patients for whom they use the EHR to suggest patient-specific education resources.

Recommendation 7.0: All EPs should report to CMS the percentage of all medication, entered into the EHR as a generic formulation, when generic options exist in the relevant drug class.

Recommendation 7.1: CMS should explicitly require that at least one of the five clinical decision support rules address efficient diagnostic test ordering.

Recommendation 9.0: The numerator for the CPOE measure should define a qualifying CPOE order as one that is directly entered by the authorizing provider for the order

Recommendation 10.0: Change the measure to read, "For a chosen preventive health service or follow up (the EP chooses a relevant preventive or follow up service for their specialty), report on the percent of patients who were eligible for that service who were reminded.

Recommendation 12.0: Eligible professionals and hospitals should be given the flexibility to defer up to 6 meaningful-use criteria as described in the table below, but must meet all mandatory objectives.

ACP supports Recommendation 1.0 noted below, as long as it preserves the option to use transcription, voice recognition software, direct entry by an EP (or any combination of these modes of documentation) and does not introduce a requirement to use structured templates.

> ***Recommendation 1.0: Include "Document a progress note for each encounter" for Stage 1 EP MU definition.***

Conclusion

Despite the criticisms and concerns identified in this document, ACP strongly supports 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

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well designed health IT is critical to improving the quality of healthcare and will likely contribute to reducing the cost of evidence-based care. However, in general, the NPRM underestimates the challenges of such a transition. As stated in the opening section, ACP believes that the most important goal for 2011 meaningful use criteria should be to move eligible providers and hospitals towards the routine capture of relevant clinical data in structured formats at the point of care. Simple measures demonstrating the appropriate collection of these data (raw numbers, not percentages) and attestation that the practice is using the capabilities inherent to existing certified EHR technology in 2011 will be a significant achievement. Motivating eligible providers to adopt, implement and use certified EHR technology to this level in 2011 would help ensure that the proper foundation has been built upon which the higher level functions described throughout the NPRM can be achieved in future years.

Sincerely,

James M. Walker, MD, FACP
Chair, Medical Informatics Subcommittee
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