February 26, 2010

Ms. Charlene M. Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Attn. CMS-0033-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Ms. Frizzera,

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents more than 94,700 physicians and medical students nationwide. It is the only medical society devoted solely to primary care. Nearly one in four of all office visits are made to family physicians. This is 215 million office visits each year – nearly 48 million more than the next medical specialty. Today, family physicians provide the majority of care for America's underserved and rural populations.

I am writing to offer comments on the regulations defining Meaningful Use (CMS-0033-P). The AAFP applauds the Centers for Medicare and Medicaid Services and the Office of the National Coordinator for Health Information Technology for the extraordinary amount of thought and work that went into crafting these regulations.

The AAFP has been advocating for the adoption of health information technology for the last decade. We have also been working to transform family medicine practices and the health care system for nearly 20 years. AAFP physician informaticists have led the movement toward EHR interoperability through the development and industry-wide deployment of the Continuity of Care Record (CCR) standard. This new set of "Meaningful Use" regulations shares a similar vision and objectives with AAFP policy, and we are excited about the potential health IT progress made possible with these regulations.

We are especially encouraged by the focus on care coordination, quality, and patient-centeredness. It is our hope that we can move the health care system rapidly toward more patient-centered, coordinated, and reliably high quality care. However, we believe that certain aspects in the details of these regulations are unworkable, excessive, or redundant, and will actually impede the very goals of the legislation. Listed below are our recommendations for modification to strengthen and improve the Meaningful Use regulations.

Increase Participation Through Partial Incentives

We are greatly concerned about the capacity for many eligible providers, especially those in small and medium practices, to achieve all of the required criteria by 2011 and 2012. We believe that a huge opportunity may be missed, if an "all or nothing" approach is used for achieving Meaningful Use based on these proposed criteria. The AAFP does not want to discourage practices who cannot achieve 100% of the requirements from using, improving or implementing EHR's simply because they will receive no incentive for anything less. We strongly believe that offering a partial incentive for partial Meaningful Use will vastly increase the number eligible providers who will make the attempt to become meaningful users.

Consider Parity Between Medicare FFS and Medicaid Program's First Year Requirements

Currently the rule permits incentive payments be made in the first year for acquisition of certified EHR technology to physicians who meet the Medicaid eligibility requirements. A heavier burden of meaningful use attestation is imposed on physicians who meet the Medicare FFS program's requirements. We believe that consideration should be given to create parity for the first year between the two programs, allowing physicians in small and medium sized medical practices to receive incentive payment according to the Medicaid requirements for EITHER program, with attestation of meaningful use a requirement for payment in the second year.

Increase Achievement of Meaningful Use through Focused Reporting

We agree that the stated goals for eligible providers are appropriate. However, we cannot say the same about the eligible provider functional and quality measures for those goals. We are very concerned about the administrative burdens that would be placed on eligible physicians to report the measures as proposed. We strongly believe that efforts and resources in the practice need to be focused on the transformation of their practice and achieving high quality care -- not on tracking denominators for process measures. We strongly recommend that those Meaningful Use measures be changed from a percentage to recording of absolute counts.

Allow Eligible Providers to Devote Resources to Outcomes Reporting and Actual Meaningful Use

Throughout the NPRM (CMS-0033-P), there is acknowledgement that once an eligible provider has the IT capability and utilizes it, they are highly likely to continue utilizing the functionality. We agree with this statement and it is the reason why absolute counts are sufficient for IT functionality measures. If it is absolutely necessary (and we believe it is not) to report numerators and denominators for these measures, we recommend that shorter reporting periods (i.e., 30 days) be used.

We also are concerned about the high thresholds that are required for these IT functionality measures, which does not take into account the diversity of the current health information technology utilization. If CMS believes it is absolutely necessary to report numerators and denominators for these measures, we strongly recommend that there should be two thresholds: one threshold that is absolute, and one based on a percentage of increased utilization.

Let us give an example:

> Let us posit that for IT Measure #1 the absolute threshold is 80%. If a practice reaches the 80% then they pass the measure. If a practice does not meet that threshold, they would have to demonstrate improvement. The second threshold could be, if adoption is less than 50%, the eligible provider would have to demonstrate a 25% improvement; if adoption is greater or equal to 50% they have to demonstrate a 10% improvement. For the first threshold there would be a requirement for a 30-day reporting period, and for the second threshold there would be a requirement for two 30-day reporting periods within the reporting year.

Ensure Incentives for Team-Based Care

On page 47, second paragraph, the proposed regulation states, "Except as otherwise indicated, each objective must be satisfied by an individual …" We strongly recommend defining "satisfied" as explicitly NOT requiring the eligible provider to actually perform the task, but rather to be responsible for ensuring its completion. This is critical to patient-centered care via a team-based approach to care, which is fundamental to helping address the issues of primary care shortages and health care costs.

Do Not Exclude Primary Care Physician in Hospital Organizations

We are concerned about the potential for family physicians, and other ambulatory based physicians, who have a practice, which is part of a larger hospital-based organization, being excluded from the definition of eligible

provider. We do not believe this is the legislative intent. Family medicine includes several residencies and practices that bill under the hospital facility type, but they are responsible for the investment in health IT. We recommend that any physician or practice that purchases a certified EHR technology be eligible for incentives under Medicare and Medicaid.

Comments on Specific Meaningful Use Goals

EHR Reporting Period

As stated numerous times in the NPRM, there is the assumption that once a meaningful user has and uses certified technology they are likely to continue. We agree with this statement based on our years of experience working with thousands of family physician adopters of EHR technology. For this reason, and the fact that we are very concerned about the administrative burden placed on providers to validate their status as meaningful users, we strongly recommend that the reporting for those focused on process, such as CPOE and e-prescribing, be changed to either absolute counts or their reporting periods be shorted to 30 days. Attestation or absolute counts could be used for the remainder of the reporting period.

Computerized Provider Order Entry (CPOE)

§495.6(d)(1)(i) Objective. Use computerized provider order entry (CPOE). (ii) Measure. CPOE is used for at least 80 percent of all orders.

Many times the definition of "all orders" for the eligible provider is suggested to be limited to medication, laboratory, and diagnostic imaging. We strongly recommend that an explicit definition of "all orders" for eligible providers be defined. We strongly recommend that the definition include only medications, immunizations, laboratory tests, diagnostic tests, and referrals to other eligible providers. In addition, there should be a clear indication that team-based achievement of CPOE is acceptable (see "Ensure Incentives for Team-Based Care" above).

We believe that the administrative burden to report on the CPOE measure is excessive to the point of being unachievable for most eligible providers. Many eligible providers will have to perform double entry, as many laboratories, hospitals, and diagnostic imaging centers do not accept standard electronic orders and the practice would be required to keep a registry of all non-CPOE orders to calculate the denominator.

Based on the current state of adoption of CPOE in the ambulatory environment and the issues stated above, we recommend that the CPOE measure be removed until electronic orders are routinely transmittable.

Regarding CPOE and Stage 2, we agree that electronic transmission of orders is important for quality, safety, and efficiency. We recommend that CMS and ONC look for ways to incent or force receiving entities to accept and process orders sent via electronic standards. We also recommend that CPOE requirements for eligible providers be delayed until these orders are routinely transmittable.

E-prescribing

§495.6(d)(2)(i) Objective. Generate and transmit permissible prescriptions electronically (eRx). (ii) Measure. At least 75 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

As stated many times in the NPRM, eligible providers that have and use certified EHR technology are highly likely to continue to use it. In talking with many of the members of the American Academy of Family Physicians the reasons for not sending an electronic prescription for those physicians with e-prescribing capability are not

associated with the practice but associated with the desire of the patient or the lack of acceptance by the pharmacy. This lack of acceptance by the pharmacy appears to be a large issue for mail order pharmacies. Only approximately 16% of prescriptions are sent electronically today, which means that a threshold of 75% of prescriptions sent electronically is not achievable by the majority of eligible providers because of conditions not under their control. Therefore, we recommend that the e-prescribing measure be a reporting of an absolute count of e-prescribed medications, which is consistent with the CMS 2010 e-prescribing incentive measure.

If this measure remains as a numerator and denominator, the threshold should be reduced to a maximum of 30% and allow for incremental improvement based on the current state of adoption (see section "Allow Eligible Providers to Devote Resources to Outcomes Reporting and Actual Meaningful Use" above). In our experience, if an eligible provider has and uses e-prescribing, the reason for not sending an electronic prescription is not because of the decision of the eligible provider.

Record Demographics

§495.6(c)(5)(i) Objective. Record the following demographics (A) Preferred Language. (B) Insurance type. (C) Gender. (D) Race. (E) Ethnicity. (F) Date of birth. (ii) Measure. At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH have the demographics specified in paragraphs (c)(5)(i)(A) through (G) of this section recorded as structured data.

We believe a definition of "insurance type" in the required demographics is needed. Without a definition and controlled vocabulary, there cannot be accurate reporting on this datum across eligible providers.

While preferred language is important, we believe that this is not something widely collected routinely today and the infrastructure to report and analyze aggregate reports is lacking. For these reasons, we strongly recommend moving the requirement for recording preferred language to Stage 2 Meaningful Use.

Record Vital Signs

§495.6(c)(6)(i) Objective. (A) Record and chart changes in the following vital signs: (1) Height. (2) Weight. (3) Blood pressure. (B) Calculate and display the body mass index (BMI) for patients 2 years and older. (C) Plot and display growth charts for children 2 to 20 years including body mass index. (ii) Measure. For at least 80 percent of all unique patients age 2 years or older seen by the EP or admitted to the eligible hospital, record blood pressure and BMI and plot the growth chart for children age 2 to 20 years old.

One of the core quality measures eligible providers must report deals with the management of blood pressure, which means the requirement to record blood pressure is a duplicative measure. For this reason, we recommend the recording of blood pressure be removed as a Meaningful Use utilization measure.

It is important to record height and weight for patients under the age of 2 years. With electronic tools, one does not have to plot a height, weight, etc. to determine if the value is within a normal percentile or its trend over time. For these reasons, we recommend that recording of blood pressure be removed from this measure and that recording height and weight be extended to patients of all ages. For most adults, a measurement of height at each visit does not have clinical value; therefore, we recommend the measurement of height be at least one visit per year for patients 20 years or older.

We believe that it is important to determine and track height and weight over time and their relationship to established norms. "Plotting" of these measures is a paper-based construct, and yet what is needed is to display these values and their relationship to norms. "Plotting" on the screen in only one way this goal can be achieved. We recommend that "plotting" vitals signs be removed. We also recommend that recording BMI be removed, and instead calculation and display of BMI be included as a criteria for a certified EHR technology.

Incorporate Clinical Lab-test Results

§495.6(c)(8)(i) Objective. Incorporate clinical lab-test results into EHR as structured data. (ii) Measure. At least 50 percent of all clinical lab tests results ordered by the EP or authorized provider of the hospital during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

We agree with the goals of having lab-test results stored discretely in the EHR. Having discrete data is critical to drive quality with health IT. We are concerned about the administrative burden of entering all of the results manually for those practices that do not have access to a lab interface. There currently is no requirement for laboratories to provide EHR interfaces, which provide these discrete lab-test results. Requiring that the eligible providers purchase an EHR technology that has the ability to receive these results only works when the source of the lab results has the ability and will to send them with the same standards.

We recommend the inclusion of a hardship clause for those practices that have lab test data sources that currently cannot provide electronic interfaces that are interoperable with the certified EHR technology interfaces required for eligible providers. Manually entered data is prone to errors, so there is the potential of harm from manually entered lab test results, just as there is the risk of errors with the pharmacy hand entering a prescription. More aggressive work by ONC and the industry is needed to get laboratory data sources interoperable with small practices. Currently, those lab companies and EHR vendors that have interfaces charge practices for providing and maintaining the interfaces. These costs can be $10,000 - $20,000 per interface, which is prohibitive for many practices, especially those in small practices and those practices that must use multiple lab companies.

Regarding lab-results and Stage 2, we agree that structured laboratory data entered discretely into an EHR are important for quality, safety, and efficiency. We recommend that CMS and ONC look for ways to incent or force sending entities to send results sent via identified standards and make those interfaces available for connectivity by certified EHR technology.

Generate List of Patients by Specific Condition

§495.6(c)(9)(i) Objective. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research and outreach. (ii) Measure. Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.

The ability of an eligible professional to identify groups of patients by specified characteristics is a pre-requisite for all of the core quality measurement reporting criteria. The intent of this utilization measure is satisfied by an eligible professional's ability to submit core quality measures. We, therefore, recommend removal of this utilization measure in order to reduce unnecessary administrative burden on eligible professionals.

Implement five clinical decision support rules

§495.6(c)(10)(i) Objective. Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules. (ii) Measure. Implement five clinical decision support rules relevant to the clinical quality metrics reported under this subpart.

The definition of "Clinical Decision Support" needs to be clarified. We would recommend that the definition focus on the "leveraging of health IT systems to apply evidence-based medicine at the point of care, which could include but is not limited to: evidence-based templates; decision trees; reminders; and linked online education resources."

Provide patients with an electronic copy of their health information

§495.6(d) (5)(i) Objective. Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request. (ii) Measure. At least 80 percent of all patient requests for an electronic copy of their health information are provided within 48 hours.

The term "health information" is used throughout the NPRM. The definition of the term is alluded to but never is explicitly defined. We recommend that the definition of "health information" for the NPRM be "at a minimum what is required for the exchange of patient summary information, namely lab-test results, medications, immunizations, allergies, problems, vital signs, patient instructions, and demographic information."

Due to scheduled closures of practices, especially over weekends, it may be extremely challenging to meet the 48-hour deadline, even with the best intentions and appropriate process. We recommend a three-business day deadline to address this issue.

Provide patients with timely electronic access to their health information within 96 hours

§495.6(d) (6)(i) Objective. Provide patients with timely electronic access to their health information (including diagnostic test results, problem list, medication lists, and allergies) within 96 hours of the information being available to the EP. (ii) Measure. At least 10 percent of all unique patients seen by the EP are provided timely electronic access to their health information.

There are many challenges to achieving this measure. We would recommend that this measure be an absolute count with a goal of greater than one.

If the measure stays as a percentage, we have a concern that some eligible physicians, especially in rural areas, may not have 10% of their unique patients with the desire or technology to access their information electronically. We do not believe it is patient-centered to force this onto patients; therefore there should be an exception for those eligible physicians with less than 10% of their patients requesting such timely electronic access to their health information.

Submit Claims electronically

§495.6(c)(12)(i) Objective. Submit claims electronically to public and private payers. (ii) Measure. At least 80 percent of all claims filed electronically by the EP or the eligible hospital or CAH.

The submission of claims electronically is already a requirement under HIPAA; therefore, this measure only adds further administrative burden. We recommend that this criterion be removed from the Meaningful Use definition.

Recording of Smoking Status

§495.6(c) (7)(i) Objective. Record smoking status for patients 13 years old or older. (ii) Measure. At least 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital or CAH have "smoking status" recorded.

One of the core quality measures that are required for all eligible providers is the tracking of smoking status. Therefore, the criterion for recording the smoking status for patients over the age of 13 is redundant and only adds an administrative burden to the eligible provider to report. We recommend that this measure be removed.

Capability to exchange key clinical information among providers of care

§495.6(d) (8)(i) Objective. Capability to exchange key clinical information among providers of care and patient authorized entities electronically. (ii) Measure. Perform at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

Small practices do not have the resources for elaborate testing on information systems and electronic data interchange. We recommend that "testing" be defined and that it not be elaborate or require technical skills that small practices cannot perform. We believe there is a real risk for entities to gouge eligible providers to "assist" them with such testing.

Capability to submit electronic data to immunization registries

§495.6(c)(15)(i) Objective: Capability to submit electronic data to immunization registries and actual submission where required and accepted. (ii) Measure: Performed at least one test of certified EHR technology's capability to submit electronic data to immunization registries.

Small practices do not have the resources for elaborate testing on information systems and electronic data interchange. We recommend that "testing" be defined and that it not be elaborate or require technical skills that small practices cannot perform. We believe there is a real risk for entities to gouge eligible providers to "assist" them with such testing.

Capability to provide electronic submission of reportable lab results to public health

§495.6(c)(16)(i) Objective. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice. (ii) Measure. 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 the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically).

Small practices do not have the resources for elaborate testing on information systems and electronic data interchange. We recommend that "testing" be defined and that it not be elaborate or require technical skills that small practices cannot perform. We believe there is a real risk for entities to gouge eligible providers to "assist" them with such testing.

Protect electronic health information

§495.6(c)(17)(i) Objective. Protect electronic health information created or maintained by certified EHR technology through the implementation of appropriate technical capabilities. (ii) Measure. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary.

Protecting health information is a critical function of an ambulatory practice. HIPAA sets a standard for both privacy and security of electronic health information. We recommend that the measure for this goal be limited to complying with the HIPAA standards for privacy and security, for Stage 1.

Conclusion

In conclusion, for the reasons stated above, CMS should significantly modify the proposed rule to ensure participation by the majority of eligible physicians so that we can continue to transform our health care system rapidly toward more patient-centered, coordinated, comprehensive and reliably high quality care.

We appreciate the opportunity to provide comments to CMS on this important matter.

Sincerely,

Ted Epperly, M.D.
Board Chair