AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

May 7, 2012

The Honorable Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0044–P
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2

Dear Acting Administrator Tavenner:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 105,900 family physicians and medical students nationwide, I am writing in response to the proposed *Medicare and Medicaid Programs; Electronic Health Record Incentive Program, Stage 2* (CMS–0044–P) regulation that was published in the March 7, 2012 *Federal Register*.

We applaud the Department of Health and Human Services (HHS) through the Centers for Medicare & Medicaid (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) on your efforts to drive interoperability, health information exchange, patient engagement, and quality measurement. These are key capabilities of a health system designed to manage cost and deliver safe, high quality care. The AAFP has been driving change for over a decade to increase the adoption of health information technology to achieve these outcomes within our membership.

The AAFP appreciates the opportunity to express our key concerns with the proposed rule, specifically regarding:

- Modification of Stage 1 Rules
- Penalties associated with action (or inaction) of others outside the practice
- Lack of interoperability by partners leading to excessive complexity in compliance with several proposed criteria
- Assurance of a simple, open, and standard transport mechanism for health information exchange is very important to permit eligible providers to meet the new Meaningful Use Stage 2 objectives

To ensure continuing progress in implementation of Meaningful Use by family physicians and the achievement of desired outcomes, the AAFP provides CMS and ONC with the following comments on the proposed rule.

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Modification of Stage 1 Rules

The AAFP appreciates HHS's attempt to refine and clarify the Meaningful Use Stage 1 regulation. However, we are concerned that modifying established Stage 1 criteria will lead to significant confusion among eligible professionals as they begin their meaningful use journey. We recommend that ample restraint be exercised in making changes to established Stage 1 regulation, and that only those modifications to fix unintended barriers to Stage 1 adoption be implemented. We believe that eligible professionals (EPs) should be extended the option to follow either the original Stage 1 rules or the modified "2014 Stage 1" rules.

Throughout the proposed rule, repeated references are made about experiences with Meaningful Use Stage 1 and how they informed decisions to modify the Stage 1 rule and shape Stage 2 criteria. We encourage HHS not to ignore diffusion of technology theory, which distinguishes the characteristics and capabilities of innovators and early adopters from the larger grouping of early majority, late majority, and laggards. The existing data on Meaningful Use adoption, in our opinion, is limited to innovators and early adopters. Their ability and efficiency in use of electronic health records are not likely predictive of the ability and efficiency of EPs who have yet to embrace meaningful use. We strongly urge HHS to use caution in assuming that outstanding performance on Meaningful Use measures, so far, indicates generalized success and that the bar should be dramatically raised. Successfully onboarding later adopters is likely to require a gentler approach.

Penalties Associated with Inactivity by Others Outside of the Practice

The Electronic Health Record (EHR) Incentive Program (i.e. Meaningful Use) has both an incentive and penalty ("payment adjustment") component. If the program was based on incentives alone, more aggressive criteria could be leveraged by Medicare and tolerated by participants. Since nontrivial penalties loom for Medicare eligible professionals in 2014, we are deeply concerned with criteria that mandate action by individuals and organizations outside the control of the eligible professional.

This is seen in the criterion *"More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information."* This criterion mandates action by the patient (or their authorized representative). We cannot support this criterion in its current form and believe that CMS should remove this requirement in the final rule.

Please understand that we have no objection to requiring Meaningful Users to be proactive in encouraging and assisting their patients to "view, download, or transmit to a third party their health information." We offer an alternative approach to the way the current objective is defined whereby EPs would be required to document that they have the technology, that it provides connectivity with patients based on their ability/preferences for accessing it (secure provider website, patient health record, mobile devices, paper, etc.), have reached out to patients to encourage their use of it, and have measured the extent to which it is being used.

Lack of Interoperability by Partners Leading to Excessive Complexity in Compliance with the Proposed Criteria

This is not a new issue, as the AAFP voiced our initial concern during the rule making around Meaningful Use Stage 1 and the structured laboratory result criterion. That criterion renders an EP dependent on an external laboratory entity providing structured labs in a standard way that their certified electronic health record technology (CEHRT) can accept. If such interoperability is

available to the eligible professional, compliance with the criterion is extremely easy and leads to better outcomes. If the laboratory does not make such interoperability available, the criterion is a significant administrative burden and increases the risk of error through manual data entry. We appreciate that independent laboratory companies are outside the authority of Meaningful Use, however, we believe that eligible hospitals are not. We urge HHS to require eligible hospitals providing laboratory services to community practices to deliver results using industry standards that CEHRTs are certified to accept.

For Stage 2, it is proposed that laboratory and radiology orders be added to the computerized physician order entry (CPOE) criterion. This also inequitably burdens EPs due to the lack of acceptance of interoperability standards for electronic orders from CEHRT by external partners. This places an undue administrative burden on eligible professionals through double entry of laboratory and radiology orders to comply with this modified Stage 2 CPOE criterion. We recommend that laboratory and radiology orders not be included in the Stage 2 CPOE criterion at this time.

Assurance of a Simple, Open, Secure, and Standard Transport Mechanism for Health Information Exchange between Eligible Professionals Using Different CEHRT

We applaud the intentions of HHS in choosing the Direct Project's protocols as a single standard for interoperable data exchange between non-affiliated physicians and medical practices using different EHR products from different vendors. The set of protocols and specifications developed by the ONC, during 2010-11 under the public-private collaborative known as the Direct Project, has made it theoretically possible for every EHR technology to offer users a way to send and receive electronic information easily and securely across the boundaries of organization, business model, and EHR system/vendor, and for the purposes intended in the objectives of Transitions of Care.

The AAFP must express our concern, however, that it seems almost impossible for providers to be able to meet these new objectives for Transitions of Care without the prerequisite simplification, interoperability, and universality afforded by the Direct standard, and therefore it is imperative that CMS and ONC require that all EHRs certify as compliant with the Direct protocols and specifications as currently developed, before 2014. If CMS and ONC allow EHR vendors to "opt out" of a baseline compliance with the Direct standard, we believe the result may well be numerous stand-alone and isolated instances of "walled gardens" or "tethered Direct exchanges."

We recognize that the market for Directed exchange may well mature such that, over time, clinical partners may utilize additional protocols alongside Direct's S/MIME over SMTP to support care coordination and other Transitions of Care uses. But to start out with excessive optionality, in our opinion, would almost certainly result in a continued lack of interoperability between EHRs, and thus the inability of many physicians to meet the relevant new Stage 2 Meaningful Use objectives.

The following are specific comments regarding the details within the proposed rule:

"We propose to maintain the same core-menu structure."

The AAFP is supportive of the core-menu approach as it can give flexibility to eligible professionals as they struggle with their specific challenges to achieving Meaningful Use. However, the range of options afforded EPs in Stage 2 is much narrower than those of Stage 1. We support increasing expectations on services and performance with subsequent stages of

Meaningful Use, but would like to see more flexibility maintained in the menu options. This allows EPs to implement technologies that meet their own practice needs and interests in addition to the broader, baseline requirements of Meaningful Use.

Payment Adjustments and Exceptions

The proposed rule states, "*Medicare payment adjustments are required by statute to take effect in 2015. We propose a process by which payment adjustment would be determined by a prior reporting period. Therefore, we propose that any successful meaningful user in 2013 would avoid payment adjustment in 2015. Also, any Medicare provider that first meets meaningful use in 2014 would avoid the penalty if they are able to demonstrate meaningful use at least 3 months prior to the end of the calendar or fiscal year (respectively) and meet the registration and attestation requirement by July 1, 2014 (eligible hospitals) or October 1, 2014 (EPs).*"

Though we appreciate the advance notice of the surprisingly premature branding of EPs as noncompliant with Meaningful Use and subject to Medicare penalties, we are still extremely concerned that the CMS implementation is not the only interpretation of the language of the *American Recovery and Reinvestment Act* (ARRA) describing penalties for those eligible professionals that are not Meaningful Users in 2015. The AAFP does not believe that the ARRA describes penalties for not being a Meaningful User in 2014. If the statute states, "required to take effect in 2015," why not start the penalty 90 days (e.g. the time CMS needs to administratively determine if an eligible professional is a Meaningful User) after the start of 2015? This would give eligible professionals all of 2014 to become Meaningful Users, which would be consistent with the description of the penalties in the statute. Some family physicians still are seething from the premature application of penalties in the CMS E-Prescribing Incentive Program. As noted previously in our comments, a "gentler" approach to onboarding "late adopters" might best provide the desired outcome of the maximum number or meaningful users in the minimum amount of time. Additionally, application of the penalty for an entire year, even after an EP may have successfully attested to Meaningful Use in that year, does not promote the cooperative trust necessary to transform our disconnected health care system into a learning health care system.

"Changes to Stage 2 Criteria for Meaningful Use"

We strongly recommend that any changes to a given "stage" of meaningful use (intended to provide clarity and reduce unintended barriers) after is has been rendered in its final form be optional for EPs through all applicable program years. We are concerned that changing of the rules in the middle of the game will create unnecessary confusion in an already complex program.

"We believe that the expansion to laboratory and radiology furthers the goals of the CPOE objective, that such orders are commonly included in CPOE roll outs and that this is a logical step in the progression of meaningful use."

The AAFP agrees that including laboratory and radiology orders is a logical next step in CPOE, but we are concerned that is it not a practical next step in the ambulatory environment. Without the common ability to transmit to an entity willing to accept an electronic order and the lack of standards for such, there is an administrative burden to double enter those orders. We recommend that for eligible professionals that laboratory and radiology orders not be included in the CPOE criterion at this time.

"CPOE function be used only by licensed healthcare professionals remains necessary"
We believe it is not necessary to restrict compliance for this criterion to only licensed healthcare professionals and actually deters from team-based care and the use of evidence-based guidelines. We recommend that the criterion of CPOE not be restricted to only licensed healthcare professionals. The AAFP is unwilling to support a regulatory proposal that would inhibit the provision of patient centered medical homes to patients across the entire US.

"We believe the EHRs can calculate a denominator of all orders entered into the Certified EHR Technology, with the numerator limited to those entered into Certified EHR Technology using CPOE."
This statement can be true only if the order is entered in discrete and computable manner. We are concerned that many eligible professionals "enter" an order as part of their note. This results in unstructured data that a certified EHR technology would not be able to evaluate and count. We believe that eligible professionals will be required to hand count orders to determine this denominator, which represents an excessive administrative burden and may actually detract for the quality of patient care.

"Consolidated Objective: Implement drug-drug and drug-allergy interaction checks."
We agree with the consolidation of this measure.

"We propose to define a permissible prescription as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II – V"
We agree that controlled substances should not be considered permissible prescriptions under Meaningful Use at this time, but we look forward to the development and successful implementation of a single prescribing workflow for all medications within the broad domain of family medicine.

"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"
We agree although we are concerned about the ability of CEHRT to determine if an electronic prescription was for an OTC and was inadvertently counted in the numerator. Eligible professionals should not be penalized if their CEHRT mistakenly includes e-prescribed OTCs in the numerator.

"We propose a new exclusion for Stage 2 that would allow EPs to exclude this objective, if no pharmacies within 25 miles of an EP's practice location at the start of his/her EHR reporting period accept electronic prescriptions."
We agree with this exclusion. We would like to see similar exclusions for other criteria requiring interoperability with outside entities not covered under the Meaningful Use authority such as laboratory and radiology service providers.

"We are proposing to consolidate the objectives for maintaining an up-to-date problem list, active medication list, and active medication allergy list with the Stage 2 objective for providing a summary of care for each transition of care or referral"
We agree with this change.

"We encourage public comment on the burden and ability of including disability status for patients as part of the data collection for this objective"

The AAFP is concerned about such a burden and would strongly recommend that this not be a core criterion. We would recommend that HHS consider “functional status” as opposed to “disability status” as it has more clinical value, less legal implication, and includes all types of disability status.

"We also seek comment on whether, we should also include the recording of gender identity and/or sexual orientation."
We are supportive of the issue of gender identity and/or sexual orientation, yet we do not believe Meaningful Use is the right vehicle to address these issues. The AAFP recommends that this is not included in Meaningful Use criteria.

“Proposed Objective: Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0-20 years, including BMI.”
We recommend that "plot" be stricken from the criterion, as it is a paper based construct. Instead, the AAFP recommends a focus on the display of actual growth against normal growth.

“Proposed EP Measure: Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.”
We are concerned that 24 hours is too short a turnaround time and will result in patients receiving incomplete and potentially misleading data in their summaries. The AAFP suggests a 48-72 hour window to lessen this possibility, though we would encourage best practices to provide patients with accurate and actionable information as soon as possible in the course of their evaluation and management.

The smoking status objective
The AAFP’s experience with our national Tar Wars program continues to reinforce early intervention with children in the fifth grade (age 11). We request that CMS decrease the intervention age for patients from 13 years to 11 years. We also encourage CMS to expand beyond the narrow concept of “smoking” to the more appropriate public health scope of “tobacco use.”

“We propose to require the following information to be part of the clinical summary for Stage 2… "Current problem list and any updates to it; Current medication list and any updates to it; Current medical allergy list and any updates to it.…”
It is unclear what is required for "and any updates to it." If there are required updates, then a “list” could not be considered “current”. Providing “current” lists would seem to be sufficient for this requirement. We recommend removing "and any updates to it" from these criteria.

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you might need. Please contact Steven E. Waldren, MD, director of the Center for Health IT, at 913-906-6000x4100 or swaldren@aafp.org.

Sincerely,

Roland A. Goertz, MD, MBA, FAAFP
Board Chair