AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

January 10, 2013

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW.
Washington, DC 20201

Re: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records

Dear Dr. Mostashari:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 105,900 family physicians and medical students nationwide, I write in response to the request for comments regarding the stage 3 definition of meaningful use of electronic health records (EHRs) as published in the November 26, 2012 *Federal Register*.

The AAFP has a longstanding interest in and commitment to serving the needs of our members to improve the health of patients, families, and communities. As such, we are most interested in the development of the meaningful use program and use of EHRs. In general, we appreciate efforts by the Department of Health and Human Services (HHS) to drive interoperability, health information exchange, patient engagement, clinical decision support, and quality improvement.

However since stage 2 was delayed until 2014, the AAFP calls on HHS to delay stage 3 requirements until at least 2017. Furthermore, the penalty provisions should be delayed or eliminated. Rather than prematurely impose stage 3 requirements, HHS should first focus on improving the ability for physicians to achieve meaningful use stage 1 and 2 requirements. We call for this delay since we remain concerned that HHS is attempting to raise the bar for what constitutes meaningful use before the majority of physicians and hospitals are able to achieve the meaningful use stage 1 or 2 objectives. The AAFP also calls on HHS to use this time to evaluate the extent of intended and unintended outcomes of existing meaningful use requirements, using these lessons to then appropriately shape stage 3 requirements.

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As a strong supporter of health information technology (HIT) to improve quality, safety, and efficiency in health care delivery, the AAFP offers these critical recommendations in order to help ensure realization of these desired outcomes. As HHS contemplates further developments of the meaningful use program, the AAFP urges HHS to:

- Focus on the hard problems that require coordination. Fundamental needs of an HIT enabled, high-performance health care system include identity, authorization, and consent management systems; privacy and security processes and policies; computable data models that retain clinically relevant semantics; data validation and data quality metrics; educational and outreach efforts that establish appropriate expectations for clinicians and patients; mechanisms to assess impact on patient safety (risk), care quality (health outcomes), and process efficiency (usability). We need not focus on criteria like computerized provider order entry (CPOE) systems, counting and verifying electronic prescriptions (eRx), demographics, problems list, and lab results, but rather we should emphasize the foundational elements that must be in place to improve and advance the health care infrastructure. We recommend more focus for meaningful use stage 3 on impacting one or more of these hard problems rather than creating a longer, disconnected list of criteria.
- Promote simplicity, not complexity. A more complex process does not guarantee a more desirable outcome. HHS's Blue Button approach is an excellent example of this (http://www.healthit.gov/bluebutton). The AAFP urges HHS to start simple and allow rapid iteration (based on actual usage and outcomes) to avoid unnecessary complexity. The health information technology industry has a proven propensity to over-design and under-deliver. The AAFP believes that for physicians to optimize value for their patients, vendors must first optimize value for their users. We recommend that HHS promote limited and focused solutions that impact the hard problems mentioned above.
- Allow all (including computers) to function at the top of their license. High performing and well-designed EHR systems can automatically log user actions and system states without additional effort by the user. Thus, HHS should certify EHR technologies not merely to contain a specified functionality but also to monitor that eligible professionals are taking appropriate advantage of it. This should be an automated audit of the implementation and use of specified functionality, without unneeded burden on users to record/monitor their utilization. The AAFP recommends that all meaningful use stage 3 measures be reportable by certified EHR technology and not require manual record-keeping and tracking by eligible professionals.
- Remember that if something is worth doing, then it is worth doing most of the time. If HHS is to require family physicians to invest in and implement a significant process change, it should be relevant for the majority of times they perform a clinical task. Any measure that cannot be implemented with (and kept at) a performance threshold of 50% should not be considered mature enough for meaningful use. We recommend implementing measures that have broad, clinically proven impact, leaving experimentation to other programs.
- Consider that when all you have is a hammer, everything looks like a nail. Though ongoing quality improvement efforts may be served best by measures which hybridize structure, process, and outcome, a focus on clinical outcomes rather than settling for adherence to highly prescribed processes is essential for advancing the

current quality reporting environment. Quality measurement, improvement, and reporting mechanisms (of which PQRS and meaningful use are prototypes) should be encouraged and allowed to develop out of best evidence and clinical value. Clinical guidelines, clinical quality measures, and clinical decision support methods are inextricably linked and depend on research and best practice. Implementation and adaptation of these components must be rigorously evaluated and rapidly applied based on clinical environment rather than one-size-fits-all mandates. Though a shared framework for this quality improvement axis is necessary and within the scope of HHS's mandate, highly prescribed requirements and broadly applied penalties will not foster sustainable growth of quality improvement practices by clinicians. We recommend development of a foundational clinical guideline, clinical quality improvement, clinical decision support framework and its implementation through value-based incentives, not meaningful use.

- Believe, but verify. The vast majority of EHR users will do the right thing when it is the easy thing; thus, HHS should reevaluate the perceived need to create and enforce a complex set of rules to manage behavior. Meaningful use started with the laudable premise that HIT could improve safety, promote quality, and ensure efficiency in healthcare delivery, and that the government could accelerate that process by helping providers over the cost barrier to HIT adoption and utilization. Though the financial incentives are now available, clinicians are acutely aware that with each stage of meaningful use, safety, quality, and efficiency do not appear to be any closer and, for many practices, the true cost of EHR technology is far greater than the incentives available. Though the mental model of meaningful use presumes safety, quality, and efficiency improvements with implementation of its measures, the true impact of the program will not be appreciated fully for some time, and only if methods are in place to measure actual outcomes of meaningful use and clearly define the interventions and interactions that created them.

In addition to these general comments, the AAFP also offers the following specific reactions per identification numbers provided by HHS in the request for comments:

SGRP 101

CPOE for all orders is a necessary component of comprehensive clinical decision support (CDS) and an aggressive path should be laid out. Foundational to this objective, however, are controlled concept references (akin to RxNorm + NDF-RT) that apply to the entire spectrum of potential orders. "TBD" is not an acronym that should appear anywhere in stage 3 recommendations. If it is not clear to the experts on the HIT policy committee which standards or value set would be most appropriate, such a recommendation is not based on mature standards, structures, or processes. Which potential drug combinations are or are not "never" is a clinical decision and beyond the scope of HIT policy committees and HHS.

SGRP 103

Any formulary-checking element of this measure rests squarely in the realm of CDS. The AAFP recommends a focus on support of general CDS systems rather than overemphasizing the low hanging fruit of eRx without broader applicability. Unfortunately, existing implementations of drug formularies have been technologically suboptimal and a significant burden on our members in smaller practices.

SGRP 104

Many AAFP members have been concerned with the burden of collecting demographic data of questionable clinical utility. The AAFP is aware of several special interest projects whose goals have been to get their highly specific "data elements" included in meaningful use requirements. The AAFP supports collection of discrete and codified data elements where this facilitates clear clinical benefit. We would prefer to see HHS utilize interoperability of "summary care records," generalizable CDS, and clinical quality measures (CQMs) to encourage such data collection and management, rather than specifying data fields in an EHR to place demographic elements. The AAFP recommends that ONC determine how the required demographic elements used so far have shown improvement in outcomes for providers and patients. If there is no clear and implementable plan to utilize the data to improve care or cost, the data should not be required by meaningful use stage 3.

SGRP 105

The AAFP is concerned this objective is significantly off track. CDS should be considered and treated as such. CDS will have an impact on a large number of meaningful use objectives and the AAFP believes that a better focus on CDS will allow retirement of a number of meaningful use measures. The AAFP advocates that this objective is an ideal place to link isolated, billable diagnoses together into episodes of care. Patient modification of a problem list should not occur without open discussion with a clinician. The AAFP fully supports patient access to their problem list and, indeed, their medical record in its entirety. We feel strongly that the penalty phase of meaningful use is not the appropriate venue for pilot testing.

SGRP 107

The AAFP calls on HHS to establish a controlled concept reference around allergies before the industry moves forward with functionality in this area.

SGRP 108

The AAFP is in complete agreement that CQMs (plus CDS and interoperability) are the driving forces at the disposal of HHS to successfully promote HIT industry and care delivery improvement. Our comments on SGRP 104 are relevant to this objective also.

SGRP 112

Every patient should be offered the opportunity to establish and maintain an advance directive. The advance directive itself, not knowledge of the existence of an advance directive, should be immediately available to authorized individuals at the point of care. The AAFP is concerned at the implication in this item that HHS is authorized to establish a standard for advance directive status within the Clinical Document Architecture (CDA) by some target date.

SGRP 113

Expanding the use of effective CDS at the point of care is essential to achieving the triple aim. More CDS, however, does not mean better use of CDS as a single, effective CDS intervention could have more clinical impact than 100 ineffective CDS interventions. Instead, the AAFP urges HHS to focus on broader clinical goals, and allow users to implement however many CDS interventions are necessary to help them

and their patients achieve those goals. CDS interventions are not independent of evidence-based, EHR-enabled CQMs. The AAFP urges HHS not to require CDS simply due to ongoing difficulties with CQMs.

Drug-drug and drug-allergy interaction checking is arguably the most developed example of CDS available to primary care physicians. Even so, most implementations create more barriers to care than avoidance of adverse events. The AAFP recommends that certified EHR technology users be responsible for evaluating and reporting adverse events through their systems rather than just claim to be using interaction checking.

SGRP 114

The AAFP agrees that discretely maintained lab test result values can be leveraged to promote care quality, safety, and efficiency. However, realization of this goal depends on a relationship and interface between two parties. Eligible professionals (EPs) represent only one side of this relationship. CMS should use their significant purchasing power to require labs to provide affordable interfaces to EPs such that they can comply with this proposed stage 3 criterion. Where there is a lack of interfaces to hospital and regional labs, an exemption should be made available. This becomes critically important as the threshold for this measure is further increased.

SGRP 115

Interestingly, dependence on the terms "near real-time" and "dashboards" is both overly prescriptive and under-specific. "Actionable lists" are, indeed, the goal but are really nothing more than another CDS intervention. A more comprehensive approach to the clinical guideline/CQM/CDS axis should be targeted, rather than a hodgepodge list of vague feature aspirations. However, we recognize that true registry functionality is an imperative for the patient centered medical home (PCMH).

SGRP 116

Follow-up and prevention reminders per patient preference are another essential element of the PCMH and are useful to every patient in a practice. This does, however, require significant time and investment despite an inability to receive remuneration in the current payment system. Meaningful use still operates in a face-to-face, fee-for-service environment and the AAFP believes this measure is not a sustainable element of such an environment.

SGRP 118

Use of the term "image" in this measure extends significantly beyond the traditional concept of radiology and is complicated by an increasing use of images to represent traditionally numerical or time-dependent data. A requirement for EHR-integrated devices across the entire clinic, even extending to the integration of home-based monitoring devices, would push this measure well beyond a mature scope. Restricting the scope to traditional radiology images may be challenging enough with a parallel to all of the complications and pitfalls noted in relation to laboratory test result values and interfaces.

SGRP 119
The AAFP agrees that family history is an important consideration in health risk assessment and disease treatment and management. However, "high priority family history data" needs to be fully defined and clinically relevant for implementation of this measure. We do not wish to see this measure devolve into a clinically irrelevant data collection mandate.

SGRP 120
The AAFP recommends that caution and restraint should be used in any requirements for electronic note documentation. It is the requirement for documentation that has driven the current development of EHRs and why meaningful use is required to drive functionalities that focus on care delivery and improvement. The AAFP recommends no requirements about the content or structure of electronic notes in stage 3.

SGRP 121
Though not an eligible professional measure, with increasing dependence of EPs on their community or employing hospital/system, support for bidirectional interfaces for all CPOE related items (labs, radiology, etc.), encompassing orders and results, is essential.

SGRP 122
Though the AAFP is in complete agreement that "tickler file" functionality should be expected in all certified electronic health record technology (CEHRT), the time limit on this measure is inappropriate. The proposed measure assumes that once a test is ordered it should be conducted while, in practice, there are ample clinical/process reasons why a test would be ordered many days (or even weeks) before it should be performed.

Additionally, a "clinically relevant" abnormal result value may be very different from an "out of normal range" result value, and providers will require mature CDS systems to help them navigate the increasing volume and complexity of test results.

SGRP 125
We do not support future stages of meaningful use. After stage 3, sustainable payment models should be used by HHS to drive care delivery reform, not prolongation of the artificial models of meaningful use.

SGRP 130
CPOE is about accurate execution of clinical intent and the capture of data and context to drive CDS at the point of care. If this measure is not primarily intended to enable clinically proven CDS at the point of care, it should not be further considered. Tracking of Transitions of Care (ToC) is already required through other components of meaningful use.

SGRP 204A
We encourage HHS to consider how "Automated Transmit" may unintentionally disengage patients from their care. Certainly, a mechanism for patient consent

management is vital and must encompass both single event and ongoing data sharing scenarios. Please refer to additional comments in SGRP 207.

SGRP 204B

Please consider how our broader comments to SGRP 204D apply in this measure. The requirement to apply this to a small fraction (10%) of one's patient population attests to the measure's immaturity. The AAFP urges HHS to consider other and more mature measures that rely on the capture and analysis of "patient-generated health information" into which the intended certification criteria could be adopted.

SGRP 204D

With an increasing emphasis on team care, an individual's electronic health record is unlikely to sustain its perceived role as a single, authoritative perspective but will, instead, represent the ongoing opinions and actions of patients, providers, care-givers, and others. The current reality of an electronic version of the paper-based record must transform to meet the emerging needs of a constantly updated and intermittently interpreted health story. The patient voice must be present in that story as an active contributor, not merely as an editor of the official tale.

SGRP 205

This objective depends on the concepts of "episodes of care" and "care plans." Much more work must be done to operationalize these concepts as clinical tools in patient care. Many AAFP members note that they are unable to modify their EHRs' visit summaries as hard-coded by their EHR vendors.

SGRP 206

Overcoming communication barriers in the clinical setting requires a complex set of processes and procedures, many of which can be very expensive and time consuming. Patient education materials in a given language do not guarantee improved communication. There are many examples of patient education materials written in English that are essentially incomprehensible to English speakers or readers. Mechanisms to enhance patient-physician communication are essential whether the barrier is language, literacy, time, or place. These barriers must be addressed comprehensively rather than narrowly focusing on language alone.

SGRP 207

Although, the AAFP is very supportive of patients' use of secure messaging with their physicians, we do not support criteria or measures that require action by individuals outside the employ/control of the EP. Providing value to practices and patients is the path toward secure messaging in healthcare, not penalizing physicians who have already invested in the technology. Measures which depend on shared interactions must leverage influence on both sides of those relationships.

SGRP 209

The AAFP believes that, in the near term, this functionality would provide benefit to an extreme minority of patients at significant cost to all providers. Linkage to external disease registries may be a more efficient approach to this goal, placing it out of the scope of meaningful use stage 3 for EPs.

SGRP 302
Independent reconciliation events are a byproduct of disconnected, encounter-based records rather than the emerging interconnected, ongoing care plan model. Reconciliation is a time-limited information management concept that HHS must look beyond, rather than trying to add more fields to it. Focus on delivering a unified health story rather than extending the use of short-term patches to inefficient processes.

SGRP 303
Rather than viewing "transitions", "referrals", and "consultations" as disconnected events shifting the patient from one care setting or provider to another, we must envision the patient as the consistent element of the healthcare relationship and the expansion and contraction of the patients care team as the variable that requires ongoing management. In this new model, patients are not admitted to hospitals, hospitals (and their staffs) are added to (and removed from) patients' care teams. We must re-envision the medical record as more than something that accompanies a patient bouncing from one care provider to another.

SGRP 305
By providing a shared source of information for a patient's entire care team, information travels by way of (and strengthens) connections to the patient, rather than by way of potentially tenuous connections between independent care providers. Enable patient-physician relationships and the cohesiveness of the entire care team improves. Rather than trying to close the loop, avoid the creation of disconnected loops in the first place. The AAFP recommends advancement of patient controlled health records, collaborative care plans, and lower secure-communications barriers to empower patient-physician relationships in the patient centered medical home and across the medical neighborhood.

SGRP 308
Please refer to relevant comments under SGRP 305. Bombarding physicians with key clinical information from multiple channels does not enable clinical coordination. Consider the role of a single channel for clinical information and action and the implications for a care coordination module.

SGRP 401A
The proposed measure represents a reversal of the current measure from a submission-only to receipt-only perspective. Specifically using the phrase "documentation of timely and successful electronic receipt" does not imply a measure of use, but rather one of documentation. The AAFP does not believe that meaningful use measures should primarily require documentation. This should be a yes/no measure that an EP can receive immunization data, at best.

SGRP 401B
This is very clearly immunization-related CDS. The AAFP suggests that such objectives should not be separated from a comprehensive clinical guideline, CQM, CDS strategy (please refer to comments for SGRP 113). State or other immunization registries will

need to use the same transport standards as required by eligible professionals or eligible hospitals.

SGRP 403
The AAFP finds it interesting that new requirements are being added elsewhere without advancing this specific measure. We already know how hard this objective is and how slowly we are making progress in this area. The very barriers that complicate this objective persist across all of the other reporting or registry dependent objectives. The AAFP urges HHS to avoid creating nuanced versions of this objective as they will not remove or reduce the existing barriers.

SGRP 404
The AAFP believes that semantic portability of health information, an essential and pressing outcome for meaningful use, will enable broad and appropriate reuse of health information without the need for manually constructing one-off reports promulgated by paper-based processes. HHS should not back into interoperability; they should deal directly with this issue. As noted in SGRP 401B, entities will need to use the same transport standards as required by EPs.

SGRP 405
Please refer to comments in SGRP 404. Adding reports one-by-one to eligible professional requirements will not result in the broad semantic portability of health information required by a learning health care system, thus the AAFP urges HHS to not require documentation of this functionality.

IEWG 101
Infrastructure for these types of outside queries is severely lacking. A majority of AAFP members do not practice in the coverage area of a fully functional health information exchanges (HIE) which could provide this type of functionality. HHS efforts must enable ubiquitous access to and use of fundamental health information exchange prior to requiring these types of advanced queries.

IEWG 102
Currently, only closed provider directories are available, each with its own application programming interface (API), with no mechanism or set of standards to support broader access. A common approach to identity management is essential. The AAFP opposes any potential future situation in which physicians are required to endure multiple identity proofing processes for each type of directory, information exchange, credentialing, etc.

Regarding the maturity of standards - if DICOM, SNOMED, LOINC, and NCPDP are not mature enough to support meaningful use criteria (which for many implementations they appear lacking), then the quest for mature standards will be an exasperating one. The AAFP recommends the implementation of standards that have proven value in practice and the ongoing evaluation of that value.

IEWG 103
The ASTM Continuity of Care Record standard contains a consensus-driven, core, clinical data set, all of which would be needed to facilitate migration from one EHR

system to another. In addition, a standard approach to document migration is required. AIIM has a standard best practice for using the Portable Document Format (PDF) in health care. PDF is supported widely in the health care and wider computer industries.

MU01
Meaningful use must be able to learn and adapt from its own outcomes. Providing eligible professionals with partial payment for meeting a self-determined subset of objectives allows users to vote on what aspects are important and usable and, thus, significantly increases participation and learning opportunities. However since stage 2 was delayed until 2014, the AAFP recommends that HHS delay stage 3 requirements until at least 2017 and delay or eliminate the penalty provisions.

MU02
It is challenging to balance between ease of clinical documentation and ease of practice management efficiency. The AAFP continues to assert that clinical documentation should be a by-product of clinical practice. The AAFP continues to work with vendors to make systems more user-friendly.

MU03
Though a framework for HIT safety risk assessment is emerging as a definite need, we must also enable and promote reporting of HIT safety events and near-events.

MU04
A distinct need exists for a robust mechanism of patient consent with some level of adjustable granularity through metadata or similar structures. This will likely require use of role-based certificates for encryption/decryption of data at rest.

MU05
An EHR is a tool used to collect, organize and evaluate a patient's health information. The underlying concept is the entirety of a patient's longitudinal health story. Many tools should be available to collect, organize, and evaluate this data for the benefit of the individual to which it belongs. Persistence of the narrative component of the Clinical Document Architecture (CDA) as the normative component will continue to be a barrier to semantic portability of health information.

MU06
Auditing mechanisms can be applied to the availability and activity of specific functionality within EHR systems. Expand these audit logs to automate monitoring, with clinician consent, and enable tools to evaluate these logs by users.

PSTT01
A digital identity (at the appropriate technical security level) similar to the National Provider Identifier or state medical license would be preferred. The ability to associate this credential with another in order to represent roles in health care delivery would also be of benefit to individual providers and the organizations in which they work.

PSTT04
If Health Insurance Portability and Accountability Act (HIPAA) compliance is a problem, then obviously HIPAA is not having the intended impact. Use HIPAA, not meaningful use, to improve privacy and security education, policy, and process.

PSTT06
Creation and accessibility of access logs are fine for audit compliance but do not serve the purpose of improving security, preventing breaches, and identifying security deficiencies and repairing them to avoid recurrent issues. Tools to evaluate the logs must also be broadly available as a functional element of HIT implementation.

As strong supporters of HIT, we thank HHS for the opportunity to offer these critical recommendations and detailed reactions. A delay in stage 3 requirements should allow more physicians and hospitals ample time and opportunity to achieve the meaningful use stage 1 and 2 requirements. 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 Jason Mitchell, MD, the AAFP's Director of the Center for Health IT, at 913-906-6000 ext. 4102 or jmitchell@aafp.org.

Sincerely,

Glen Stream, MD, MBI, FAAFP
Board Chair