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Dear Drs. Mostashari and Tang:

On behalf of the American College of Physicians, I am writing to share our views on Stage 3 of Meaningful Use. ACP is the largest physician specialty society and second-largest physician membership organization in the United States. ACP represents 132,000 internal medicine physicians and medical student members. Internists specialize in primary and comprehensive care of adolescents and adults.

ACP applauds the HIT Policy Committee and its Meaningful Use Work Group for their diligence and hard work in developing recommendations for the Meaningful Use portion of the EHR Incentive Program. As you work to transform the Meaningful Use Workgroup recommendations for Stage 3 into ambitious yet broadly achievable measures, we urge you to keep in mind the guiding principles and general concerns we provide below. While we support the goals represented by the Meaningful Use (MU) objectives, we are concerned about the appropriateness, focus and feasibility of some of the proposed measures, as well as the potential unintended consequences of these well-intended efforts.

Totality of measures & usability – While many of the individual measures are appropriate, our members tell us that their ability and even willingness to strive to achieve Meaningful Use is severely strained by factors such as: a) the sheer number of measures to be met; b) the lack of a clear, understandable and unambiguous “single source of truth” regarding what is required to meet them; c) the expected magnitude of the work with vendors needed to achieve and report measures accurately, and d) the perceived legal, financial and reputational risk to Eligible Professionals (EPs) if vendor-designed reports are not accurate, something we have found to be the case for multiple measures and vendors in Stage 1. We believe that asking EPs to take on a too ambitious and strenuous set of changes in Stage 2 and again in Stage 3 will interfere with the program’s intended goals. We need experience and data that: a) indicate that the key features related to Meaningful Use in Certified EHR Technology are perceived by EPs to be usable in practice; b) demonstrate that the majority of motivated EPs has been able to successfully achieve Stage 1 Meaningful Use; c) predict that most are likely to similarly succeed with Stage 2; and d) show that they feel confident that they will be prepared for the additional challenges of Stage 3. Without such supporting evidence, we are concerned that the laws of physics will apply and that the mass of new requirements multiplied by the rate of acceleration

of the pace of required change constitutes an excessive force that will push EPs to frustration, disenchantment, and eventual failure to achieve the desired improvements in quality and cost.

Focus: Measure refinement vs. thresholds and expansions – We resonate with many of the concepts advanced by Dr. Lawrence Weed in his discussions of problem-oriented medical records going back as far as the late 1960s. In this view, the patient’s chart is not simply a collection of scribbled notes to partially capture events for future recall or current billing, but rather a “guidance system” and “thesis” that more closely represents a patient-centered research notebook of careful observations, results, interpretations, conclusions and reflections about future directions.

We would like to see the Meaningful Use measures focus more on encouraging physicians and other health professionals to record, review, manage, and share information that more fully supports these goals. One example would be to advance the objective of ensuring an accurate and up-to-date problem list rather than dropping the problem list as a MU measure and assuming that this issue has been addressed with the minimal requirements specified in Stage 1.

Another example would be requiring structured association of problems with medication, laboratory and imaging orders, so it is clear what tests and treatments are associated with which problem(s). Creating measures that adds structure and clinical decision support to problem assessments and plans would further encourage thoughtful documentation as well as the assemblage, review and comparison with prior assessments within efficient workflows.

Specific concerns and suggestions:

- **Refine and evolve existing measures rather than add new measures.** In other words, optimize the measures implemented in a previous stage based on data and experience to enhance their effects on quality and patient care. Do not simply modify the thresholds for successful performance. Establish clearer definitions that resonate with EPs for quality care (IOM definition of quality – patient-centered, effective, safe, timely, efficient and equitable), that can more easily integrate into workflows, engage patients, support public health goals, and be measured from EHRs without laborious processes, etc.
- **Do not introduce new functions without appropriate testing.** Measures should be thoroughly tested in a simulator environment for effectiveness, safety, usefulness, usability and user acceptance (provider and patient) for recording by – or in the presence of – the patient before they are required. Untested proposed functions may present unintended consequences, especially patient safety risks. Functions must have a history of safe and effective use in actual practice before clinicians should be required to use them to avoid penalties. The recent report by Walker et al. (Health IT Hazard Manager Beta-Test: Final Report; AHRQ Publication No. 12-0058-EF) underscores the importance of assessing health IT safety, identifying IT hazards and mitigating them.
- **Choose additional documentation requirements wisely and seek to reduce existing requirements that do not add value to the patient record.** The patient’s office visit note is becoming choked with information that is included principally to support billing requirements and documented evidence of Meaningful Use rather than a concise document reflecting only the relevant information needed to illuminate the path to problem identification, assessment, planning, effective action (quality and value) and education. The succinct one to two page office note or hospital progress note has become 7 pages of documentation for billing or Meaningful Use documentation that can too easily obscure the most clinically useful data to inform the best current and future care.

- **Require usability testing with a specific focus on reducing data collection burdens.** EHRs need to dramatically reduce the burden involved in data capture through improved usability, data capture at times outside of the care encounter (e.g., patient-entered data between visits), and capture by methods other than direct physician or staff interaction with the system.
- **Do not add functional requirements that have not been adequately defined.** There is often a difference between Meaningful Use and best use. While Meaningful Use includes important elements that facilitate the goals of the HITECH Act to capture and share data, promote improved clinical processes and enable better outcomes, continuing to add to a long list of functional requirements that have not been sufficiently defined, refined or harmonized (up-to-date problem list, medication reconciliation, summary of care record) and that utilize technologies that are nascent or not widely available risks unintended negative consequences, including unusable and possibly dangerous systems or workflows.
- **Understand the implications of intensively focusing vendors' programming capacity on Meaningful Use requirements.** The race by vendors to implement under-specified and un-tested functionality to meet deadlines for Meaningful Use certification is expensive for all stakeholders, and could introduce potential disruptions of care delivery. Vendors are prioritizing the delivering systems that conform to the letter of the requirements as they understand them without the time necessary to integrate the functionalities into desirable workflows or to test to ensure that quality, safety or usability problems are not introduced.

Consider the direct and indirect cost implications to EPs when adding new Meaningful Use requirements. Whereas the EHR incentive program was never designed to cover all of the costs of EHR purchase/implementation, the motivation to expend additional financial and personnel resources to achieve increasing requirements in Stages 2 and 3 will likely diminish as the program moves from decreasing incentives to the penalty phase. While we expect that most physicians will use EHR technology effectively in their practices, we are concerned that too many will choose to accept the penalty and accept fewer Medicare patients rather than spend resources to achieve measures that they do not perceive to add commensurate value, or simply cost more to implement than their practices can afford to spend. Stage 3 measures must be considered in this light.

In prior comments, ACP has strongly urged ONC and CMS to separate the certification of EHRs from the requirement to implement new features/functions into practice. In our comment letter for the Stage 2 NPRM, we wrote:

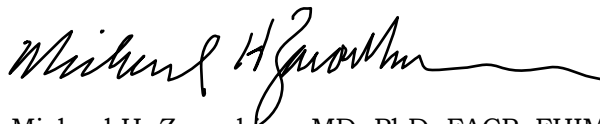
The approach throughout Meaningful Use to-date has been for CMS to call for EPs to perform new functions at the same time as ONC is requiring EHR system vendors to add the new functionality to their systems. This commonly results in unanticipated negative consequences where the functionality is incompletely or poorly implemented, with usability challenges that make it difficult for EPs to incorporate the new functionality into existing workflows, or that forces modification of existing workflows to ones that are less efficient. As a general rule, we recommend that EPs should not be expected to demonstrate use of new functions until those functions have been implemented in systems and successfully tested in real-world settings. The current method of concurrent certification and implementation is like writing new software to control an airplane and communicate vital information about its status securely with air traffic control towers, using new standards that are not already broadly in use in the industry but "should be" by 2014, and then setting a deadline for use by hundreds of software vendors and hundreds of thousands of pilots flying a variety of planes with precious cargo on board without first proving the technology and workflows are feasible, broadly implementable and will work for

virtually everyone who has reasonable competence and motivation to maintain and fly their aircraft. We do not believe this is reasonable or realistic; such expectations can be expected to result in stakeholder disengagement (lack of willingness to continue to engage in the Meaningful Use program), or inability to succeed even with their best efforts due to factors outside their control. Further, by adopting the current model of use before adequate testing, just like in the airplane analogy, we are concerned about inadvertently causing harm to patients. We believe a much more sensible approach would be for ONC-Authorized Certification Bodies (ONC-ACBs) to certify functions as in place and usable for each certified EHR technology at least 2 years ahead of CMS incorporating them into "core" measures for Meaningful Use. Meaningful Use measures should never be based upon "should" statements regarding what will be available at a future date but is not broadly available today. It is difficult enough to adopt established, proven technologies and functions that are already in place, let alone tools and technologies that are not yet established or deployed but that "should" be by 2014.

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

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Michael H. Zaroukian", with a long horizontal flourish extending to the right.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS
Chair, Medical Informatics Committee
American College of Physicians