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January 14, 2013

Farzad Mostashari, MD, ScM
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Health Information Technology; HIT Policy Committee: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records [HHS-OS-2012-0007]

Dear Dr. Mostashari:

The American College of Cardiology (ACC) is pleased to submit comments on the draft recommendations of the Health Information Technology Policy Committee (HITPC) on Stage 3 of the federal Electronic Health Record (EHR) Incentive Program. The College is a 40,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. We appreciate the opportunity to respond to the Committee's draft recommendations.

General comments

The College has long been supportive of the creation of a nationwide health information structure. Incorporating health information technology (IT) into a physician practice has been shown to improve patient safety, reduce medication errors, and allow for better coordination of care. Creating a nationwide health information infrastructure requires coordinated efforts by the government, private payers, providers and patients, and it will not happen overnight. If any of the affected groups is removed from the equation, this major transformation will not happen. As such, the College recognizes that while the implementation of EHR systems is only one step in the process of improving the quality of care received by patients in this country, it is a critical one. Quality is only one of the many areas of healthcare that will be improved by the implementation of electronic health record (EHR) solutions. It can also lead to improved practice workflows and increased efficiencies.

That said, it is critical that implementation of EHRs proceed with deliberate speed. The Committee's desire for implementation must not get ahead of the technology, the ability of vendors to develop cost-effective solutions, and the ability of physicians to purchase and implement the new solutions while maintaining high-quality patient care. Additionally, the Committee must understand that the EHR Incentive Program may not be the appropriate mechanism for accomplishing all of the HITPC's health IT policy goals. The Committee must accept the reality that that only so much pressure can be placed on physicians and hospitals to force change. Instead, in recognition of the role they play, pressure must be exerted on other actors, such as laboratories, imaging centers and EHR vendors to encourage the adoption of health IT. *Rather than requiring actions by physicians – or only requiring actions by physicians, the ACC urges HITPC recommend that CMS and ONC work with these other healthcare entities to develop a true nationwide health IT network.*

Because most, if not all, of the pressure to adopt health IT has been placed on physicians and hospitals, there are significant gaps that must be filled in before that nationwide health IT network can exist. Without those pieces, much of what the HITPC proposes seems more like science fiction than mere forward thinking. Indeed, the proposals seem ambitious and imaginative, but almost impossible to actually accomplish, especially without much in the way of underlying data, interoperability and communication standards.

While the ACC respects the desire by HITPC and the government to plan ahead and to anticipate progress made in the adoption of health IT, the College is once again concerned by the development of recommendations for future policy actions before an evaluation has been conducted of the current state, let alone the inability to predict the outcome of the Stage 2 implementation. While the College understands a crucial role for government in the effort to establish a nationwide health information structure is to use its considerable leverage to change behavior, the ACC is concerned that the sum total of the requirements contained within this proposal seek to change behavior rapidly without respect for the potential consequences. If physicians and their practice staff become too concerned with implementing an EHR on the government's timeline and in a manner that meets the government's expectations without performing the necessary groundwork, patient care may suffer, not the outcome intended by anyone, least of all those who believe that a more digital approach to healthcare will ultimately improve care. *The ACC urges HITPC to delay submitting recommendations to CMS and ONC until after Stage 2 is implemented and sufficient time passes to allow for an understanding of the effects of Stage 2 on the practice and business of medicine.* In so doing, the Committee would enable the public to provide it with feedback that represents a thorough understanding of the program's effects and how best to move forward. Ultimately, enabling the provision of the most educated feedback possible is in the best interests of the program and the public.

Not only should HITPC delay submitting these specific Stage 3 recommendations, the ACC urges HITPC to recommend that the Department of Health and Human Services (HHS) delay implementation of Stage 3. As became apparent with Stage 2, eligible professionals need sufficient time to update their systems and understand the new requirements. In order to give them the opportunity to actually meet the requirements, the requirements and the time they are given to meet them must be reasonable. Additionally, EHR vendors need time to make the necessary changes to the EHRs to meet any new certification criteria and standards requirements. Standards developers will need time to ensure their standards are ready for implementation, and certification and testing bodies will need to create and promulgate updated plans for testing and certification to reflect any changes to those elements of the EHR Incentive Program. *Because of this, the ACC strongly believes that 2016 will be too soon for the implementation of Stage 3 and prevails upon HITPC to curb its desire to push ahead with implementation of Stage 3 at the*

expense of eligible professionals who, by 2016, will not only be denied incentives for failure to participate, but will also be subject to payment adjustments should they not meet the requirements of the EHR Incentive Program.

Specific comments

Despite the College's concern about the implementation pace proposed by HITPC, the ACC does support the continued preference for determining compliance based on graduated percentiles. Requiring less compliance for newer objectives is a common sense approach towards encouraging adoption of a new adoption, while still allowing physicians room to make individual decisions and to ensure appropriate implementation.

However, the ACC is disquieted by the increasing number of objectives that require the sharing of data between EHRs and lab or radiology sources. The adoption of health IT by labs and imaging centers is beyond the control of eligible professionals. Additionally, each connection requires the development of an interface. While eligible professionals may be able to exert some pressure, labs and imaging centers will make determinations regarding the priority of developing those interfaces based on business calculations that are outside the control of those eligible professionals. *The College urges HITPC to scale back objectives that require the electronic exchange of information between eligible professionals and external entities until a more efficient mechanism for such exchange is available.*

Also disturbing are the number of objectives and measures that require the development of entirely new standards or rely on standards that still require an extensive amount of work before they can be implemented in EHRs. While implementation of Stage 3 will not begin for at least three years, EHR vendors and other relevant entities must begin work on prototypes in the coming months to ensure readiness. Assuming that this work can be accomplished in time is not wise, based on previous experience with implementation of Stage 1 and the early stages of the development of Stage 2, as well as experience with the implementation of each HIPAA standard. *The ACC urges HITPC to substantially reduce the number of objectives and measures that rely on the development of new standards or standards requiring considerable work before they are ready for implementation. Where new or developing standards are required, the College urges the government to devote the necessary resources towards ensuring completion in time for implementation.*

Additionally, as the number of requirements for successful participation in the EHR Incentive Program increases, so does the amount of information in a patient's electronic medical record. While this may be beneficial for patients with complex conditions, specialists generally do not need to access to a patient's complete record; instead, the amount of information will be overwhelming and may even obscure relevant information, rendering the adoption of health IT useless and potentially dangerous. The ACC recommends the adoption of standards that will limit the information available for initial viewing by a physician to the information needed typically by his or her specialty. Expanded views of a patient's medical record should only be available at the physician's initiation. This initial set of information should be based on a standard determined by each medical specialty. For instance, the initial information available to cardiologists should be based on the *ACC/AHA Key Data Elements and Definitions of a Base Cardiovascular Vocabulary for Electronic Health Records*¹ and developed in consultation with the College. The base set of

¹Weintraub WS, Karlsberg RP, Tchong JE, Buxton AE, Boris JR, Dove JT, Fonarow GC, Goldberg LR, Heidenreich P, Hendel RC, Jacobs AK, Lewis W, Mirro MJ, Shahian DM. ACCF/AHA 2011 key data elements and definitions of a base cardiovascular

information for other specialties should be developed similarly in consultation with the particular specialty. By limiting the amount of information available upon initial review of a patient's medical record, we ensure that physicians are not bombarded with an excessive amount of information and can provide a higher quality of care to their patients.

SGRP objectives

SGRP 101

The ACC supports the inclusion of SGRP 101 as proposed, assuming that the data from Stage 2 demonstrates that physicians have overwhelmingly been able to meet or exceed the Stage 2 requirements. In the event that this is not the case, the ACC would oppose increasing the measure threshold. The inclusion of RxNorm in the certification criteria is critical because it will help provide a standard for normalized names for clinical drugs and links those names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, paving the way for interoperability between those systems and EHRs. The ACC currently experiences difficulty obtaining data on test results and dates for the PINNACLE Registry, let alone information on who reviewed the test results and when. Requiring EHRs to be able to isolate and record this information will be critical towards improving the quality of patient care. The inclusion of RxNorm as a criterion for EHR certification will be critical towards progress in this area.

Despite ACC's support for this measure, the College continues to raise concerns about the inclusion of objectives that require computer entry without the ability to electronically transmit the information. Without that ability, the potential remains high for the requisite information to be conveyed improperly or not conveyed at all. Additionally, it requires two steps for what should be a one-step process for the practitioner. *The ACC urges HITPC to work with the relevant entities to increase the rate at which the necessary steps are being implemented to develop the necessary infrastructure for electronic transmission of protected health information.*

SGRP 130

While ACC is generally supportive of computerized provider order entry (CPOE), requiring CPOE for referrals/transition of care orders without the ability to actually electronically transmit is of concern to the College. This will require that practitioners issue referrals/transition of care orders twice: once electronically and once using current methods of transmission, which may include paper, telephone, facsimile or similar mechanism. By so doing, the HITPC proposes to increase yet again the amount of redundancy in practitioners' workflow, thereby increasing the amount of paperwork spent per patient on administrative tasks rather than patient care. *The College urges caution before implementing another such objective and measure.*

SGRP 103

The ACC continues to support requirements that all permissible prescriptions be generated and transmitted electronically. The ACC does not object to the new proposal to ensure that, before prescriptions are transmitted, they are compared to at least one drug formulary and reviewed for generic substitutions. *However, the College asks that the measure include language to ensure that professionals are not bound to accept the generic substitutions if it would be inappropriate in*

vocabulary for electronic health records: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards. J Am Coll Cardiol 2011;58:202-22.

their clinical judgment. Health IT must not be viewed as a substitute for a clinician’s education and experience. Instead, it is intended to aid clinicians in providing the highest quality of care, supplementing their knowledge and experience rather than supplanting it. Thus, language indicating recognition of this is critical.

Additionally, the ACC requests that HITPC clarify the eligible professional (EP) measure for SGRP 103. Based on its current form, it appears as though it is the drug formulary that must be transmitted electronically. The College believes that HITPC intended the measure to read “More than 50 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary (including a review for potential generic substitutions) and are transmitted electronically using Certified EHR Technology.” Alternatively, the language could be altered to read “More than 50 percent of all permissible prescriptions written by the EP, after be compared to at least one drug formulary and reviewed for potential generic substitutions, are transmitted electronically using Certified EHR Technology.”

SGRP 104

The ACC objects to the proposed retirement of the demographics objective and measure. Removing these from the list of requirements could result in a reversal of the progress that has been made in capturing this information. This information continues to be important for patient management, regardless of practitioner type or specialty. The ACC urges HITPC to reconsider its proposal to remove this objective and to leave it as is.

SGRP 105-106

The ACC supports requiring EHRs to provide functionalities to assist in meeting program requirements. That said, the College is concerned about the increased emphasis on implementation and use of clinical decision support tools for a broad array of issues. Overreliance on clinical decision support tools can decrease an EP’s ability to furnish individualized patient care. Mechanisms that increase the prevalence of “cookie cutter” medicine without sufficient supporting evidence only hinder the provision of quality patient care. Additionally, studies have already demonstrated the difficulties associated with increased use of clinical decision support tools, including “click fatigue.” Too many “pop-ups” preventing EPs from entering patient information could prevent a clinician from seeing the truly important messages that actually improve patient care and potentially prevent harm. The ACC urges caution in increasing the number of clinical decision support rules required. Instead, *the ACC recommends that key areas should be identified with input from medical specialty societies, along with relevant tools to support those specialty-specific targets.*

SGRP 107

The ACC supports the inclusion of certification criteria that aid in decreasing the burden of program requirements, such as maintaining active medication allergy lists.

SGRP 108

The ACC objects to the proposed retirement of the vital signs objective and measure. Removing these from the list of requirements could result in a reversal of the progress that has been made in capturing this information. This information continues to be important for patient management, regardless of practitioner type or specialty. In order to continue to improve patient care, vital signs must be continue to be measured, especially given the obesity epidemic in this country and

its implications for cardiovascular disease, diabetes and many other diseases/conditions. *The ACC urges HITPC to reconsider its proposal to remove this objective and to leave it as is.*

SGRP 109

The ACC objects to the proposed retirement of the smoking objective and measure. Removing these from the list of requirements could result in a reversal of the progress that has been made in capturing this information. This information continues to be important for patient management, regardless of practitioner type or specialty. In order to continue to improve patient care, smoking rates must continue to be measured, especially given the implications for cardiovascular disease, diabetes, cancer and many other diseases/conditions. The ACC urges HITPC to reconsider its proposal to remove this objective and to leave it as is.

SGRP 113

The ACC supports the standardization of the ability of EHR systems to “consume” clinical decision support rules. In fact, this is necessary to enable the objective. The concept of a central repository of relevant clinical decision support content is critical to the success of this Stage 3 objective. As discussed above, the College is concerned about the increased emphasis on implementation and use of clinical decision support tools for a broad array of issues. As discussed earlier with respect to SGRP 105-106, the College believes that an overreliance on clinical decision support tools can decrease an EP’s ability to furnish individualized patient care. The ACC urges caution in increasing the number of clinical decision support rules required. Additionally, the College urges HITPC to work with vendors of clinical decision support tools to explore methods for implementing these rules that do not lead to “click fatigue” and similar problems.

Regarding the future proposals, the ACC continues to oppose the implementation of any prior authorization programs or requirements that impede the ability of a physician to use his or her clinical judgment in making decisions regarding patient care. Given that some private payers continue to require prior authorization in certain situations, structured data fields, formats and data transmission standards will ease some of the burden and reduce some of the inefficiencies in the current processes.

SGRP 115

As a long-time proponent of performance measurement and the use of data for quality improvement, the ACC is pleased to see that HITPC recognizes the importance of being able to generate patient-oriented dashboards. In fact, one of the primary purposes for registries is to do just this. The PINNACLE Registry, the outpatient component of the National Cardiovascular Data Registry[®], focuses on gathering data from EHRs to generate information for care quality improvement and benchmarks physicians against their peers nationwide. *Rather than requiring all physicians do this through their EHR, the ACC urges HITPC to recommend that physicians who participate in clinical registries sponsored by national specialty societies that gather data for quality improvement purposes and provide participating physicians within benchmarked performance reports be considered to have met this requirement.*

SGRP 116

Given that specialists frequently provide consultations or treat patients for a limited duration, an exemption from an objective and measure of this nature would be appropriate. *In the event that*

there is no exemption for specialists, the ACC would urge this measure be re-crafted to take into account the appropriateness of reminders for patients who may not require follow up from the particular physician.

SGRP 118

Diagnostic imaging is a critical component of cardiovascular care. As such, incorporating the results of such tests and the images themselves is crucial to the diagnosis and treatment of patients with cardiovascular disease. The key barrier preventing the incorporation of images in the ambulatory setting is the limited expertise that EHR vendors have in image rendition and the development of the relevant software. Moving this objective and measure to the core set will require a commitment from ambulatory EHR system vendors and image system vendors to cooperate and make the necessary system changes. Because the efforts to bring images from the electronic imaging system into inpatient and emergency department EHRs are more mature than in the ambulatory setting, the ACC would support moving this requirement from the menu set to the core for hospitals, assuming that this is demonstrated by Stage 2 data.

One concern that continues to exist in the inpatient setting and emergency department is the lack of a standard interface for the necessary integration of the image display into the EHR system. This is emerging as a significant challenge. Although the absence of a standard may have been intended to promote innovation, it actually hinders effective implementation since each EHR system may need to design custom interfaces for each possible PACS with which it would integrate the imaging function. In fact, an EHR system vendor may implement a proprietary interface with only a single PACS vendor and not support any others, thus defeating the goal of broad interoperability between EHR and PACS. IHE is also working to address this use case through the development of the IHE Invoke Image Display implementation guide, expected to be published in Spring 2013. The ACC recommends that a standard interface be adopted for the integration of the image display into the EHR system as part of the next iteration of the EHR certification criteria and that these criteria be based on the IHE Invoke Image Display implementation guide to allow implementation and deployment of this critical functionality in the most cost-effective manner possible.

While many of these capabilities may exist in the in-patient setting and the emergency department, it is far more common in the ambulatory setting for EHRs and image systems to be entirely separate. To encourage cooperation between EHR system vendors and image system vendors, the ACC has sponsored the development of an interoperability implementation guide for this use case through the Integrating the Healthcare Enterprise (IHE) collaboration. The IHE Image-Enabled Office implementation guide defines a standards-based approach for integrating an ambulatory EHR system with an imaging suite, and like the Invoke Image Display implementation guide, uses broadly adopted web service technology.

The College urges HITPC to recommend that the ambulatory EHR certification criteria include the ability to integrate with an imaging suite and that these criteria be based on the IHE Image-Enabled Office implementation guide.

SGRP 204B-D

The ACC continues to urge that all recommendations to incorporate patient-generated information be held for future stages until the necessary infrastructure has been created for a nationwide health information system. While patient engagement in care is crucial, the primary goal of the EHR Incentive Program is to encourage EHR adoption and to facilitate the ability of physicians to access patient medical records to improve patient care. Thus, objectives and

measures that encourage the incorporation of features that assist in development of the health IT infrastructure should be prioritized over patient engagement functionalities.

From time to time, patients may discover what they believe to be an error in their medical records. Any tool developed to allow them to request an amendment to that record must make clear that while they may request amendments to their record, that request may not be granted if deemed inaccurate or inappropriate by their treating physician, as provided by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

SGRP 205

With respect to SGRP 205, HITPC asks for recommendations as to specific information to be included in a clinical summary. Unfortunately, the ACC is unable to provide such recommendations because the information that needs to be conveyed in a clinical summary varies based on patient condition. Each condition requires the provision of highly specific information to aid the patient in understanding their visit, their condition, actions they need to take regarding their condition and other related information. *The ACC suggests that HITPC not recommend that the government standardize the clinical summary.* In the event that HITPC includes such a recommendation, the College urges the Committee to work with the medical specialty societies to develop condition-specific standards.

SGRP 207

The ACC continues to raise concerns about measures that force physicians to rely on actions taken by others. Physicians should not be held hostage to a refusal of or a lack of interest by patients in communicating with their physicians via secure electronic messaging. While hospitals may be able to afford additional staff to educate reluctant patients on such options, physician practices are already facing significant financial challenges as a result of the current economic climate, declining reimbursements and increasing government requirements and simply do not have the resources for additional personnel. *The ACC urges HITPC recommend that this be a menu measure and the threshold be kept at five percent. Additionally, the ACC requests clarification around the term “patients” to ensure that the measurement is based on active patients, rather than all patients, including those who may only visit the physician for a consultation.*

SGRP 209

The College supports the inclusion of a certification criterion that would provide EHRs with the capability to query research enrollment systems to identify available clinical trials.

SGRP 302

One of the objections to the adoption of health IT has been the fear that it will prevent physicians from talking to their patients, that their heads will instead be buried in their computers rather than engaging with their patients. Proposed SGRP 302 does nothing to lessen those fears. In its attempt to automate as much as possible, HITPC overreaches by proposing that EHRs be used to reconcile not only relevant health information, such as medication allergies and the like, but also social history. Including such a requirement for the reconciliation of non-objective items, such as social history, will require the expending of large amounts of effort for little to no gain. Instead, all efforts to use EHRs to improve patient care should be limited to objective, quantifiable issues. Decisions pertaining to the relevance of subjective information should be left to the physician

based on that engagement that both parties need to ensure high quality patient care. The ACC opposes this proposed recommendation.

SGRP 304

SGRP 304 is overly ambitious and seems to be leading in the direction of creating some type of “push button” medicine. The information needed for care plans are condition and situation specific. *The ACC opposes this proposal as detracting from the physician-patient relationship and failing to recognize the need for flexibility and customization of care plans based on a patient’s individual condition and situation.*

SGRP 305

As discussed with respect to clinical decision support, requirements for numerous acknowledgments could lead to message fatigue, which defeats the intent of this objective. While larger systems may not encounter difficulties with message acknowledgements, small physician practices will be overwhelmed and could potentially be distracted from providing the highest quality patient care. *The ACC urges HITPC to use caution before making recommendations to the government that will only create more work for physician practices and only improve patient care minimally.*

SGRP 127

While creating an interdisciplinary problem list with the goal of improving care coordination is admirable, such tools have been of limited utility in healthcare environments. The fractured nature of care today limits the benefit of interdisciplinary problem lists, especially when compared to the burden imposed by the requirement. Instead, physicians will be overwhelmed by the amount of unnecessary information they receive. Thus, the ACC would oppose such a requirement.

SGRP 308

The ACC applauds the efforts of HITPC to harness the potential for EHRs to assist in care coordination and supports incorporating SGRP 308 as a potential objective for Stage 3. That said, the ACC has concerns about the mechanism to be used for identifying individuals that should be notified. Identifying the technology to do so will not be the issue; rather, the problem will be identifying the relevant individuals. The objective should reflect the need for a mechanism for determining correct individuals to whom messages should be delivered, not simply that a message can be delivered. *Before including SGRP as a requirement, the ACC recommends that HITPC work to identify methods for identifying the correct individuals for notification of significant patient events.*

SGRP 405

Registries have the potential to improve individual patient care, as well as population health, and the ACC has long been a proponent of registries for these very reasons. That said, it is important that registries be designed properly, collect relevant information and provide reports that benchmark physicians against their peers. The current definition of registry is vague and includes little information as to what is required of a registry to ensure that it adds value to the clinical evidence base. *The ACC urges HITPC to recommend to the government a more narrow definition*

that requires registries to return meaningful and useful process, performance, outcomes and quality data to participating sites based on data submitted.

Specifically, the College believes that registries must:

- *Demonstrate an adequate organizational structure that is multifunctional, unbiased, HIPAA-compliant and representative of relevant parties*
- *Employ evidence-based science with standardized data elements and definitions that are developed with input and consensus among national experts, then made publicly available and used for national benchmarking purposes*
- *Include built-in rigorous data quality procedures to ensure accuracy by providing training and education, conducting auditing, developing completeness requirements, and requiring the entry of consecutive patients*
- *Offer timely support services and training to participating sites, including best practices on incorporating data collection into their workflow*

Studies of data gathered from cardiovascular registries have been used to identify strategies for improving the quality of care for cardiovascular patients. For many years, the National Cardiovascular Data Registry[®] (NCDR[®]) has been focused on the collection of data from hospitals. Data abstractors input the information into the registry from hospital records. This requires additional time and resources on the part of participating hospitals, but they also gain the quality and benchmarking data that they would not otherwise be able to obtain.

The PINNACLE Registry[®], one of the ACC's newest registries, focuses on what has long been recognized as the missing component of the NCDR: the ambulatory setting. With data on more than 1.5 million patient encounters involving close to 500,000 patients, the PINNACLE Registry is cardiology's largest ambulatory quality improvement registry. As part of the NCDR suite of clinical registries, the PINNACLE Registry gives clinicians credible quality measurement solutions. The registry provides a centralized system for clinical practices to promote practice innovations and achieve clinical excellence. Participants receive:

- Easy-to-interpret quarterly benchmark reports that provide information on the quality of care furnished and pinpoints opportunities for improvement
- Access to relevant data focusing on coronary artery disease, hypertension, heart failure and atrial fibrillation—the four most common cardiovascular conditions
- Minimal data collection that delivers maximum clinical value
- Multiple methods of data submission that fit seamlessly into any practice's workflow

Practices participating in the PINNACLE Registry must use an EHR. Relevant information is extracted from the EHR into the registry. This information is used to generate the benchmark reports and to inform cardiologists regarding the quality of care that they provide to their patients. At its core, the PINNACLE Registry is designed to assess and improve cardiovascular care quality, processes and outcomes.

The benefits of participation in NCDR for cardiovascular specialists are many. NCDR is uniquely positioned to assist practitioners in identifying and closing gaps in quality of care, reducing wasteful and inefficient care variations and implementing effective, continuous quality improvement processes. It helps:

- Generate quality measures for third parties, including the Physician Quality Reporting System (PQRS)
- Demonstrate tangible benefits for practices

- Apply the data for other purposes, especially for Performance Improvement Continuing Medical Education programs resulting in Maintenance of Certification Part IV credit
- Provide benchmarking and comparative feedback on physician/team/hospital performance
- Monitor device safety and performance
- Track compliance with recommended care guidelines across time
- Furnish benchmarked performance reports to inform hospital/practice site and provider-specific quality improvement initiatives
- Identify existing gaps in documentation and care delivery
- Manage population health
- Create a longitudinal care record for each patient

In fact, when a panel of cardiologists was asked what was appealing about participating in the PINNACLE Registry, potential increases in reimbursement received the lowest number of responses. Instead, their ability to compare their performances against national benchmarks and improvement of the quality of patient care they furnish to their patients scored the highest.

Based on the ACC's experiences with the NCDR, the College has developed best practices for providing individual and aggregated data feedback to physicians and their teams. It is important to furnish reports regularly, as close to the end of data submission periods as possible. This feedback should include multiple levels of aggregation: practice/hospital/business unit level; site/location level; and provider level, when applicable. Additionally, it should offer both numeric and graphic representations of current performance, as well as performance over time. An executive summary report should be produced for wide distribution along with detailed reports for more targeted uses. And perhaps, as important as the reports themselves are the quality improvement toolkit offerings and ideas that should be paired with them.

The data needed for registry participation may come from a variety of sources. In the case of the PINNACLE Registry, nearly all of the data is collected directly from providers and practices themselves. Data occurs via two primary methods: direct data entry and extraction from EHRs and back end "system integration" data mapping. In the case of the hospital-based registries, data abstractors input the data directly into the registries. At present time, none of the NCDR registries are linked to health information exchanges; however, this is under consideration for the PINNACLE Registry.

The current proposal recommends the inclusion of a certification criterion for EHRs to be able to build and send standardized message report formats to an external registry. The ACC supports this recommendation. However, it is not sufficient by itself. There must be a standard to allow for electronic transmission of the report. *To this end, the ACC recommends the development of standards for data transmission that will ease the electronic submission of data to registries and the return of benchmark reports to physicians and other providers.*

Clinical data registries such as NCDR are extremely sophisticated in the types of data they collect, far more sophisticated than today's EHRs, relying on data from a variety of clinical information systems in addition to EHRs. To that end, NCDR works with various vendors to create software and interfaces that are certified by the registries to collect and validate the relevant data. *Rather than seeking to replace these processes, the ACC urges HITPC to work with the ACC and other medical specialty societies with registries to develop recommendations that will complement the work that is currently being done by these groups and to aid in efforts to automate as much of the registry data collection as possible.*

As for the measure itself, the measure should look to patient encounters rather than patients for success or failure. Calculating this measure based on patient encounters will ensure completeness of data and be more easily measured than number of patients. *The ACC would welcome the opportunity to provide additional information to HITPC on national specialty society registries, their benefits and the current difficulties that exist regarding data transmission from EHRs to registries.*

SGRP 408

The ACC supports the inclusion of requirements that EHRs be able to build and send standardized adverse event report messages to the Food and Drug Administration (FDA). This will substantially reduce the burden and increase the incentives for physicians to submit such reports to the FDA. Computer-generated adverse event reports based on information contained within the EHR increase the likelihood that the reports the FDA receives will contain the necessary information, increasing their usefulness and decreasing the burden on the FDA, as well as the burden on the physician. While a great deal of work remains to be done in this area, the ACC recommends that this proposal be moved from a future stage to Stage 3 because of its importance to the health of the American public.

Additional recommendations for objectives

While HITPC's work is certainly comprehensive, the ACC has two additional recommendations for inclusion in upcoming stages of the EHR Incentive Program: the incorporation of ECG requirements into the certification criteria and the inclusion of the unique device identifier (UDI).

Electrocardiograms (ECGs) are a ubiquitous screening and diagnostic modality fundamental to cardiovascular patient care. *Because of their importance to high quality patient care, the ACC recommends that the next stage of the EHR certification criteria require that all EHR systems provide access to ECG results and that the certification criteria be based on the IHE Retrieve ECG for Display implementation guide.*

Stage 3 should also contain provisions requiring the inclusion of fields for the unique device identifier (UDI), as well as objectives and measures that would facilitate the inclusion of the UDI in patient medical records. The inclusion of the UDI will facilitate the provision of high quality care, reporting of adverse events and surveillance of medical devices after FDA approval. *The ACC urges HITPC to require relevant certification criteria and objectives relevant to the UDI in Stage 3.*

Information exchange objectives

IEWG 101

The ACC supports efforts to create a nationwide health information network whereby information can be exchanged across EHRs, regardless of vendor. Requiring EHRs to be able to do so would be a tremendous leap forward, but the ACC does have some concerns with this requirement based on the state of EHRs today. For large physician practices and hospital systems, communication across EHRs is less a technical issue and more an issue of security and privacy. A security and privacy framework will need to be established first to assure tight controls that prevent abuse. The College notes that there is movement here already. For instance, the Care Everywhere functionality of EPIC has already morphed in areas where a majority of institutions are using EPIC. Because they are using the same EHR vendor, these systems can now share information on

patients, whereas previously, there were hurdles to get into other institutions to collect data on individual patients.

Smaller physician practices, on the other hand, will struggle to set up and maintain the connectivity. They are not using large EHR system vendors; in fact, frequently, they have implemented EHRs developed by smaller vendors that have few customers, or at least end users, as compared to the vendors of EHRs for large hospital systems. These smaller systems may not have the resources to implement these criteria in the absence of common standards or the elimination of the need for separate interfaces for each health information exchange, EHR or other entity with which they must exchange information or conduct a query. *As such, the ACC urges HITPC to withdraw this recommendation until the development of the Nationwide Health Information Network (NwHIN) Exchange is complete.*

IEWG 102

The ACC supports the need for EHRs to query external provider directories. However, before this can occur, standards must be developed. The ACC does not believe they are far enough along in development to be deployed and implemented as part of Stage 3. *Because of this, the ACC urges the HITPC to withdraw this recommendation.*

IEWG 103

The ACC believes that IEWG 103 is critical and much needed. The College supports the inclusion of this in the next iteration of EHR certification criteria.

Meaningful use objectives

The ACC strongly supports the Million Hearts initiative and its goal to prevent one million heart attacks and strokes in the next five years through improved community and clinical prevention. As a partner with the Department of Health and Human Services in this initiative, the College is collecting a number of related clinical quality measures through the PINNACLE Registry and has published a number of pieces on the results. Additionally, the ACC has worked with its state chapters to champion the Million Hearts initiative and to advocate at the state level on related issues.

The ACC is concerned that the approach HITPC proposes to take toward development of specialty-specific objectives is too narrowly targeted and risks either unfairly burdening some specialists or encouraging other physicians to practice outside their area of expertise. For example, HITPC apparently intends to include objectives and new measures specific to improving high blood pressure control and cardiovascular health. While the College supports including hypertension in a list of possible conditions on which physicians may choose to focus, a specific objective or measure pertaining to hypertension that all physicians are required to meet is inappropriate. Physicians in only a small number of specialties have the expertise to treat patients for hypertension and related concerns, so requiring that all physicians meet this objective could force some physicians to act outside their area of expertise. Alternatively, including objectives and measures related to hypertension and cardiovascular disease for those physicians in relevant specialties without also establishing specialty specific measures and objects for other areas of medicine would serve only to increase the number of objectives or measures that must be met by those in specialties with the expertise to treat these conditions. Given the extensive list of objectives that all physicians must already meet, adding specialty specific objectives and measures for some specialty areas it would be make it even more challenging for those specialists

to successfully participate in the EHR Incentive Program and could even discourage participation if the costs of each additional requirement are sufficiently high enough to offset the incentive payments or even the payment adjustment. *The College urges HITPC to reconsider its proposed path and ensure that the implementation of specialty specific objectives is accomplished in a fair and balanced manner.*

MU 03

The ACC strongly supports efforts to encourage patient and physician monitoring of hypertension. That said, NQF 0018 is overly prescriptive and does not allow for situations where all methods for controlling hypertension may have been employed to no avail. Additionally, the measure fails to allow for recognition of strides made toward controlling a patient's blood pressure even if it remains outside the window indicating control. Without such flexibility built into a measure, we run the risk of penalizing physicians for their patients' unique physiology. *Given this, the ACC continues to object to the inclusion of this measure in the EHR Incentive Program.*

MU 04

Reductions in the use of tobacco have contributed significantly to the decrease in morbidity and mortality rates from heart disease; as such, the College is strongly supportive of efforts to reduce tobacco use. That said, *the ACC is concerned by the proposed recommendation that health IT be used to generate referrals for patients who need to stop smoking or using tobacco, given the differing requirements for coverage of smoking cessation support across insurance plans and states.*

MU 05

Cardiology has long been at the forefront of health IT adoption and incorporation into clinical practice in variety of capacities, including as a mechanism for gathering data to provide evidence regarding clinical practice. Unfortunately, Stages 1 and 2 of the federal EHR Incentive Program have focused exclusively on the adoption and implementation of core EHRs, rather than recognizing the importance of a complete set of cooperating systems for effective physician workflows and for innovation in diagnosis and care. This exclusive focus has diverted capital investments and IT staff support away from departmental systems and onto core EHR technologies. Many hospital system departments, especially in specialties such as cardiology, are unable to introduce innovations to address the continuing evolution in patient care, or simply to improve efficiency in their workflows because those improvements are not part of the core EHR deployment required by the EHR Incentive Program regulations.

Cardiovascular disease is consistently at or near the top of lists of the most deadly diseases in this country. As such, innovations in diagnostics and treatment have been critically important and have garnered a great deal of attention over the last twenty years. Even before the advent of the EHR, cardiology found that innovation is best fostered in an environment that supports the development of modules focused on specific target issues and evidence. Cardiology in particular has seen translation of research into bedside practice and improved clinical outcomes through the development of innovative IT modules outside the scope of the core EHR system. For example, decreasing the amount of time between a patient's appearance in the emergency room and the patient's arrival in the cardiac catheterization laboratory has only been possible using a collection of focused information systems working in harmony to streamline workflow to and within the catheterization laboratory.

Based on the experience and evidence garnered by cardiologists, the ACC supports a modular approach to health IT. The cardiology community has found that an effective modular health IT environment must have a strong foundation in standards-based interoperability to allow those modules to connect to a stable infrastructure. The need for standards is proportional to the number of modules involved in the workflow. Implementation guides with broad domain consensus are essential, especially for the multi-system cardiology department.

To this end, the ACC has worked in concert with other professional societies to support the development of both DICOM standards for cardiology imaging and interoperability implementation guides through IHE. The IHE implementation guides profile the consistent use of Health Level 7 standards for patient demographics, orders and results; DICOM for imaging management and results; CDA for clinical care documentation; and web services for display-oriented integration. These guides have been implemented by a wide variety of vendors in commercially released products with validated interoperability. The ACC considers the IHE implementation guides to be a proven mechanism for implementation of coordinated workflow across multiple systems, including EHRs, to implement key cardiac patient care processes and recommends that HITPC include the work produced by IHE in its proposal for the next iteration of EHR certification criteria to encourage the integration of the various information systems relied upon by physicians and hospitals to provide high quality patient care. *Specifically, the College urges HITPC include the IHE Scheduled Workflow, Displayable Reports, Patient Identifier Cross Reference and Patient Demographics Query implementation guides in its proposal for the next set of EHR certification criteria.*

MU 06

Given the increasingly extensive requirements for successful participation in the federal EHR Incentive Program, the ACC supports allowing flexibility in meeting the program requirements. As the program evolves, it has become apparent that there may be different functionalities needed by different specialties or care settings. *Approaches for allowing and encouraging the development and incorporation of these different functionalities should include providing EPs with additional flexibility in methods for successfully participating in the EHR Incentive Program.*

Quality measure objectives

QMWG 01-02

HITPC must include more health professionals and representatives of health professionals in discussions. Despite the fact that this program directly affects physicians and other health professionals more than anyone else, few members of HITPC are actual practitioners or work with organizations that represent practicing physicians. Not only are physicians directly affected by the implementation of an EHR and the various requirements of the EHR Incentive Program, but they also work directly with patients and can speak to patient behavior. For instance, there have been repeated calls from patient and consumer organizations for patient portals; yet, physicians who have deployed such portals can attest to the low usage of such technologies, despite extensive and expensive education efforts.

Additionally, longer comment periods are a necessity if HITPC is to receive well-informed, thoughtful public comment. The 45-day comment period provided to respond to this draft set of recommendations is simply not sufficient, especially when holidays are accounted for. Every

organization has its own internal process for developing its policies, which include mechanisms for gathering initial feedback, drafting policies and approving them.

QMWG 05-06

The ACC believes there is value in building both point-of-care process measures and value-centered outcome measures. As such, HITPC should not focus exclusively on one type of measure over the other. Indeed, the question posed presents a false dichotomy. HITPC's suggestion that a third approach be considered promoting process-outcome measure suites where combinations of outcome measures are associated with process measures is an intriguing approach that deserves serious consideration and discussion. *The ACC urges HITPC and the government to continue these discussions with measure developers, including the medical specialty societies, to identify the best methods for developing measures and the best types of measures.*

QMWG 10-11

Clinicians are under increasing pressure to spend less and less time with each patient. Federal policies should be designed to maximize a clinician's patient time, rather than adding to the administrative burden. Ensuring the alignment of clinical quality measures with meaningful use objectives will not improve the quality of patient care. Instead, it will create more check boxes and detract from the amount of time clinicians have available to spend with patients. The ACC urges HITPC to focus on ensuring the development of a process for developing meaningful measures, rather than to give primary emphasis to the alignment of clinical quality measures and meaningful use objectives.

QMWG 12

The ACC supports the efforts made by the National Quality Forum (NQF) to identify domains for clinical quality measure development. *The work performed by NQF should be highlighted and prioritized for Stage 3.*

QMWG 14-20

As an early supporter of clinical quality measurement and a measure developer, the ACC truly understands the difficulties associated with the development of clinical quality measures. *To this end, the College supports the inclusion of a measure development innovation track for clinical quality measures.* However, the ACC urges HITPC to use caution when making recommendations regarding the details for such a track. As instructed by statute, HHS has taken some small steps towards the alignment of clinical quality measurement programs. Any innovation track for the clinical quality measure reporting requirement of the EHR Incentive Program must not detract from those efforts. Aligning clinical quality measurement programs within the federal healthcare programs benefits CMS, clinicians and patients. Thus, any innovation track should have the potential to benefit those same parties, as well.

A process will be needed to evaluate measures developed through the innovation track. Any new clinical quality measures, included those developed through this proposed track, should include proposed measure specifications, such as cohort, denominator, numerator, data, source and evidence base, to allow for evaluation of the proposal, as well as an explanation as to why a new measure is needed. In the event that it captures information similar to existing clinical quality

measures, submitters should expect to justify to HHS (or other reviewer) why the existing measure is inadequate or how the proposed measure's purpose is different.

It is important for HITPC to be aware that despite its efforts to make recommendations to automate the collection of clinical quality measure-related data, there will always be a human component to the data collection. As such, there is a limit to the number of clinical quality measures on which a healthcare professional should be expected to collect data, calculate and report to the government or other payers. Additionally, the more data collected on a wider variety of activities, the less clinicians will be able to focus on areas where improvement is truly needed. Clinical quality measures should focus on high priority areas in healthcare where there is clear evidence that taking certain actions will have a clear, demonstrable effect on patient care and/or patient health. *Rather than focusing on the appropriate number of clinical quality measures to be reported, the ACC urges HITPC to apply itself to developing recommendations that focus on high priority areas where there is clear evidence of the positive effects of the clinical quality measure interventions.*

QMWG 21-23

The College has a long history of supporting clinical quality measurement and performance improvement, through its development of guidelines and consensus documents on evidence-based practice to developing clinical quality measures to collecting clinical quality measure data and analyzing that data through NCDR. Evidence has demonstrated that improving the automation in data collection has expanded the population covered by clinical quality measurement and improved the accuracy of the data for benchmarking and advancing clinical practice. However, this type of specialty registry data collection is typically performed in a departmental information system, not in the core EHR system.

Efficient collection of quality measure data is only possible with effective multi-source interfaces and automated processes between the EHR and these separate modules. To this end, the ACC supports the inclusion of certification criteria that provide standards for interfaces for accessing typical demographic, lab, pharmacy, discharge, claims and other data needed for participation in specialty clinical registries.

Further improvements in e-clinical quality measures can come from standardization of discrete data elements collected in the clinical documentation and then translated into the submission data set without further manual manipulation. This requires an end-to-end view of the e-clinical quality measure process, including defining relevant data elements in Clinical Data Architecture (CDA) Level 3 clinical documentation and aligning them with registry data elements. For example, IHE and ACC are working together to standardize both the cardiac catheterization laboratory report's CDA content and the content required for NCDR data submission in a coordinated technical specification.

Through this experience, the ACC and IHE have learned a great deal about the creation of such specifications. The current tools for the CDA implementation guides, the open source Model Driven Health Tools, are inadequate to support the definition and clinical review of large sets of discrete data elements necessary for some quality-related purposes. For instance, an effort to translate the ACC-led consensus document on Key Data Elements for Cardiac Imaging² and its

² Hendel RC, Budoff MJ, Cardella JF, et al. ACC/AHA/ACR/ASE/ASNC/HRS/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR/SIR 2008 key data elements and definitions for cardiac imaging: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Cardiac Imaging). J Am Coll Cardiol. 2009;53:91-124.

100 discrete data elements into a CDA implementation guide was unsuccessful because of the ineffectiveness of the tools. Focused investment in tools for developing CDA-based discrete data for coordinated clinical and quality purposes would have significant returns for cardiology and the broader e-clinical quality measure development effort across all care areas. *The ACC urges that HITPC recommend increased funding for the development of tools that support the definition of discrete data sets in CDA-based clinical documentation that will be usable in the e-clinical quality measure development process.*

Privacy and security objectives

PSTT 04

The ACC recognizes the importance of ensuring that patient health information is kept protected and secure and supports efforts by the government to include relevant objectives and criteria as part of the federal EHR Incentive Program. However, the College does not believe that collecting attestations regarding the implementation of HIPAA Security Rule provisions is a worthwhile exercise. Physician practices and hospitals are already subject to the penalties of the HIPAA Security Rule, as well as the Privacy Rule. Requiring eligible professionals and hospitals to also attest to doing so is redundant and unproductive. *The ACC urges the HITPC to withdraw this proposal, while welcoming proposals that serve to protect the privacy and security of patient health information.*

PSTT 06

The College supports the creation of audit logs to ensure accounting for disclosures, surveillance for unauthorized access or disclosure and incident investigation associated with alleged unauthorized access. That said, as discussed above with respect to attesting to compliance with the HIPAA Security Rule, physician practices and hospitals are already subject to penalties if they fail to comply with this requirement. *As such, the ACC opposes the creation of a purely administrative checkbox requirement to attest to creating such logs and maintaining them for a specified period of time.* Such a requirement accomplishes little other than adding to the administrative burdens of already overwhelmed and financially constrained physician practices.

ONC questions

ONC 02

Patient matching is a critical component of true electronic health information exchange. Without an easy method for matching patient records across health settings, it will be difficult to definitively associate the correct record with the relevant patient, potentially opening EPs to HIPAA violations and creating new problems. This issue of patient matching has long been a challenge for NCDR. Efforts to match patient records across registries within the NCDR suite to ensure data quality have been fraught with difficulties and have required a great deal of time and resources. *For these various reasons, the ACC supports efforts to facilitate patient identity matching that reduce the resources required for these initiatives and can improve care quality.* The College would welcome the opportunity to work with others on this critical issue.

Conclusion

The ACC appreciates the efforts by HITPC to begin the development of Stage 3 of the federal EHR Incentive Program and the standards, implementation specifications and certification criteria

for EHRs. These are not easy feats, and while the proposed recommendations addressed here are far from perfect, the College recognizes the amount of thought and work that went into their development. The ACC supports the staged approach toward increasingly stringent requirements and measures to meet national health outcomes priorities as the most effective method to ensure widespread adoption of health IT and improving patient care. However, the College has substantive concerns about the practicability, adaptability, deliverability, and ability of physicians to comply with the draft recommendations for the Stage 3 requirements and the next iteration of the standards, implementation specifications and certification criteria as described above. The ACC welcomes the opportunity to provide HITPC with further clarification on the comments above, as well as to work with the Committee and HHS on these important priorities. Please contact Lisa P. Goldstein, Associate Director of Regulatory Affairs, at (202) 375-6527 or lgoldstein@acc.org with any questions or concerns.

Sincerely,



William A. Zoghbi, MD, FACC
President