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Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW,
Washington, DC 20201

RE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 [CMS-3310-FC and CMS-3311-FC]

Dear Acting Administrator Slavitt:

The American College of Cardiology (ACC) is pleased to submit comments on the final rule regarding the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Stage 3 dated October 16, 2015. The ACC is a 49,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, promotes cardiovascular research and bestows credentials on cardiovascular specialists who meet stringent qualifications. The *Journal of the American College of Cardiology* (JACC), which publishes peer-reviewed research on all aspects of cardiovascular disease, is the most widely read cardiovascular journal worldwide. JACC is ranked No. 1 among cardiovascular journals worldwide for its scientific impact. We appreciate the opportunity to comment on this item.

Key recommendations:
The ACC is a long-time supporter of EHR adoption as a driver of improved patient care quality. Because impeded health information exchange and the subpar usability of EHRs can negatively affect the quality of patient care as much as continued reliance on paper records, the ACC recommends that the Centers for Medicare and Medicaid Services (CMS):
• *Refocus the program on interoperability, usability, and outcomes rather than the processes of capturing and reporting data;*
• *Discontinue the pass-fail approach of the EHR Program and transition to assessing achievement on a sliding scale so participants can be provided credit for partially meeting performance thresholds;*
• *Reestablish 90-day reporting periods for all first time meaningful users in 2018 and beyond, along with a 90-day reporting period for all providers reporting to Stage 3 for the first time;*

• Reassess the finalized thresholds for the measures of objectives 4-7 to provide more realistic benchmarks;
• Remove requirements that hold physicians accountable for actions beyond their control;
• Adopt a standard that will ease the movement of data from EHRs to registries; and
• Grant participants as much flexibility as is feasible by expanding hardship exemptions.

General Comments

The ACC appreciates the focus on easing the constraints and complexities established in Stages 1 and 2 of the Meaningful Use (MU) Incentive program and the further clarification of the confusing path to EHR certification provided in the 2015 Edition Health Information Technology (Health IT) Certification Criteria. **Overall, the ACC believes the finalized requirements for Stage 3 set the bar for success too high. The Meaningful Use criteria should encourage the appropriate, purposeful and accurate use of health IT solutions, rather than mandate completion of tasks based on a particular timeline.** Currently, there is too much emphasis on achieving specific objective metrics when the focus should be placed on the exchange of health information, increased usability of EHRs, and the appropriate realignment of clinical workflows to leverage health IT most effectively resulting in improved patient care. The metrics do little to acknowledge that often times diagnostic and treatment strategies are dependent upon observations, findings, results, discussion with colleagues and study, rather than navigating a rigid clinical decision-making tree only to post findings to the portal as soon as possible – a process that is not so subtly enforced.

In addition to setting the bar too high, CMS also places too heavy a burden on physicians and hospitals with the reporting requirements finalized in this rule. The amount of time needed for attestation is only a small sliver of the total operational burden imparted by the rule. While unacknowledged by CMS in the rule, the overall operational burden on both physicians and hospitals substantially increases from Stage 1 or 2 to Stage 3. While CMS estimates that participation in Stage 3 will require 6 hours and 52 minutes per physician participant (down from Stage 2's proposed 10 hours and 33 minutes despite increasing thresholds), we strongly disagree. In fact, we estimate that the operational burden to both physicians and hospitals will dramatically increased amounting to multiple minutes per patient. CMS grossly underestimates the actual amount of work required. After a full office day, clinicians using EHRs today find it necessary to spend several additional hours above and beyond the normal amount of time they spend seeing the same number of patients prior to the implementation of the EHR, leading to frustration. CMS also fails to acknowledge the higher cognitive load or the amount of time required for additional training. These fundamental changes in workflow incrementally increase the amount of time required to document each and every patient encounter. The need to collect clinical data to report on clinical quality measures specifically requires further deviation from current documentation practices. Furthermore, the quality of documentation potentially deteriorates as physician time is diverted to the capture of data, rather than the synthesis of thought. Even with the usability and efficiency requirements described in the finalized rule, the EHR vendor community will err on the side of systems that emphasize compliance rather than clinical utility. **When the additional workload is coupled with new and constantly changing requirements, it is clear that the burden imposed by CMS through this**

final rule for Stage 3 goes above and beyond what providers and vendors are capable of addressing before 2018.

CMS also fails to recognize the unanticipated costs of many of the finalized requirements for which physicians and hospitals are not reimbursed. Interfaces continue to be required for communication between physician and hospital EHRs and individual laboratories, imaging centers and other such parties. Stage 3, as finalized, continues to require a certain level of electronic interactions with outside vendors, which translates to the development and use of numerous interfaces. The implementation of interfaces generally requires upgrades to, replacements of or mergers of subsystems to allow for those interfaces. Additionally, the exchange of information electronically requires a universal patient identifier within and between entities. Practice and health system workflows must also be redesigned, affecting efficiency at least on a long-term, temporary basis. These workflow redesigns may also require the purchase and implementation of new hardware. Added to this are the costs associated with the new staff needed to manage the capturing of discrete data or expansion of the organization's capacity to do so. New staff and new technologies mean training for staff to interact with and use technology to leverage its full potential, as well as to avoid potential errors and to manage increase risks. Lastly, the agencies fail to adequately account for the costs to practices and hospitals associated with interacting with new and additional vendors pertaining to formularies, e-prescribing, IT support and others.

The reality is that most new programs encounter difficulties in the beginning, and adjustments will need to be made for these challenges. As physicians adopt EHRs, we should expect this to be the case and allow for some modifications in Stage 3 to address these difficulties. If implemented as finalized, the Meaningful Use requirements further force physicians into a robotic workflow or rigid clinical decision-making tree that eliminates any nuances of the physician-patient relationship. Dictating physician workflow and decision-making will filter away the documentation of individual variations in patient behavior, perceptions and illness that are needed for good care and communication. These nuances are what differentiate between standard care and high quality care. They describe why individual patients are treated in different manners, despite suffering from the same disease or condition. The final rule is an obvious attempt to use Meaningful Use to alter clinical behavior, a task best left to the professional societies. **The ACC would welcome the opportunity to work with CMS to develop a program that would do just that. First and foremost, the program must be reconstructed to focus on interoperability, EHR usability, and improved outcomes rather than the processes of capturing and reporting data.**

The final rule is unclear with respect to how the Meaningful Use program will move forward if further rulemaking continues to use quality metrics to remove topped out measures to keep the objectives and measures "challenging." If you remove items that have become standards of care, workflows will need to continually evolve enough to accommodate the more demanding objectives and measures, which places an insurmountable burden upon program participants. Furthermore, as innovative approaches to medicine evolve the current outline of the future of Meaningful Use does not provide guidance on addressing these emerging issues. **The College requests**

further guidance on the future path of the program so reasonable expectations can be set and vendors can plan accordingly.

Interoperability

Given there are significant interoperability issues in the current Meaningful Use program, CMS must ensure EHR systems address these challenges and resolve basic cornerstones necessary for data exchange, such as identity management, provider directories, standards and privacy and security. CMS should focus on increasing the functional interoperability between vendors and among vendors and registries to ensure Meaningful Use is a program that improves healthcare, and not another unnecessary regulatory burden on providers. Well-documented issues with certain measures, such as sharing summaries of care, must be resolved before physicians are held accountable for these actions.

Interoperability is fundamental to fulfilling the promise of electronic data exchange and improved patient care. The ACC appreciates efforts to advance this issue in the Stage 3 final rule along with the additional support on this issue in the recently enacted Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA sets a goal of achieving "widespread interoperability" nationwide of EHR systems (across certified EHR systems employed by meaningful users, clinicians, and other health care providers) by December 31, 2018. If the goal is not achieved by that date, the Secretary can seek to adjust MU penalties and/or decertify EHRs. By July 1, 2016, the Secretary must establish, in consultation with stakeholders, the metrics to determine if this goal has been achieved. The Secretary must submit a report to Congress by April 16, 2016, on mechanisms that would assist physicians in comparing and selecting among certified EHR products. Information blocking by MU professionals and hospitals is prohibited, effective April 16, 2016.**The College recommends that CMS examine the requirements of MACRA and the timeline it provides as it addresses the barriers to interoperability and adapt the Meaningful Use program accordingly.**

As a means to counteract data blocking and to effective exchange information, the final rule relies heavily upon application program interfaces as a solution. **The ACC does caution the continued explicit references to application program interfaces (APIs).** Naming this technology will require that it be mandated as part of the program both now in the future. This has the potential to require technology that may become outdated over time and restrict the use of newer and more innovative solutions.

The College urges CMS to consider how interoperability can be improved in the short-term and how to leverage technology beyond EHRs to transmit and access data. The final rule fails to adequately integrate mobile applications and other tools that can facilitate data exchange and are likely to play a more prominent role in accessing information in the future. **In order to be forward thinking, the College urges consideration of these other tools when discussing interoperability**. Further, coordination of standard terminologies and vocabularies is required to achieve meaningful data exchange**.** A common understanding of what is being sent and how it is formatted constitute prerequisites for interoperability. The standardizing of clinical data definitions should be driven by a multi-stakeholder physician-led organization that is a leader in quality improvement, outcomes, and performance measurement with

coordination and support provided by relevant government agencies. In the absence of standardized vocabulary sets, it will be difficult to compare one physician's list of patients with high-priority health conditions, for example, to another's. The ACC has a series of data element and definition publications of terminologies to standardize the lexicon of cardiovascular medicine. The use of limited subsets of these terminologies should be required. One specific example of these datasets is the cardiovascular vocabulary for EHRs, described earlier. This dataset defines fewer than 100 terms that the cardiovascular community feels should be used by all practitioners and recognition of it and similar such data sets is one way the federal government could assist in increasing the value of EHRs to both patients and physicians.

Because the main barriers to interoperability are technology and costs, factors outside of the physician's control, we believe enforcement tools directed at health care providers are misguided and do not address the main obstacles to interoperability. Imposing penalties on physicians is duplicative and unnecessary. Physicians are already held accountable for the performance of EHRs, including requirements on interoperability through the Meaningful Use program. Failure to meet measures specifically focused on data exchange, such as the requirement to provide a summary of care when transferring or referring patients, result in penalties that can be as high as five percent of their Medicare reimbursement. We see no need to impose separate, additional attestation requirements and penalties on physicians when they are not currently blocking data exchange and already face statutory payment reductions if they are unable to promote interoperability. **The ACC strongly opposes the enactment of additional penalties on physicians**.

MU in the Merit-Based Incentives Payment System (MIPS)

Since MU is one component of the MIPS program, it is extremely important that, prior to its implementation, CMS make changes to the program to ensure that MU is achievable and meaningful for all physicians. Therefore, CMS should reopen Stage 3 Meaningful Use to realign the program and take time to evaluate whether providers are successful under the Stage 2 Modifications rule. Without taking the time to review where physicians are currently excelling and where they may be struggling in such an important program and thus incorporating Stage 3 as finalized by CMS into the MIPS program, physicians will not be empowered to achieve the success the program moves towards, and therefore, will jeopardize their ultimate MIPS composite score. If providers are attesting for Meaningful Use and meet a certain percentage of the measures, there should be an option for them to get credit for the percentage they were able to complete. The scoring should not be an all or nothing system and thus CMS needs to eliminate the pass/fail approach.

Sliding Scale / Tiered Approach

Using the modified Stage 2 objectives, as an example, to achieve a prorated compensation percentage for Meaningful Use, CMS could establish a tiered approach in the following way: In order to measure participation in MU on a sliding scale, objectives should score in an accumulative fashion toward the total 25 percent of the MIPS program allotted to the MU category. In other words, if an eligible professional (EP) fails to satisfy an individual measure, and does not meet the prerequisites of any available exclusion(s) from the failed measure, that EP should only lose a smaller, proportional

percentage—not the full 25 percent of the MU category within MIPS. This tiered methodology would continue the requirement that program participants report on and attest to all 10 objectives as well as meet the electronic clinical quality measures (eCQM) reporting requirements. The current exclusions, alternate exclusions, and current hardship exemptions must and would be carried into MU under the MIPS umbrella with an increased focus on flexibility. Meeting these exclusions would qualify as fully meeting the measure and not result in a lower score for the MU component. CMS must also review the current hardship exemptions and expand them as needed.

Three tiers, numbered 1 through 3, must be established and objectives would fall within the three as outlined below. Participants must meet the requirements of each objective within a tier as outlined in the final rule and must meet all objectives to achieve the tier. Participants must move up through the tiers in sequential order – meaning you must achieve tier 1 before you can achieve tier 2 or 3. The tiers would be established as follows in the below table.

General Requirements	Report on and attest to all 10 objectives – or provide the information needed to meet the exclusions Fulfill the eCQM reporting requirements
Tier 1 – 50%	Objective 1 - Protect Electronic Health Information Objective 2 - Clinical Decision Support Objective 3 - Computerized Provider Order Entry (CPOE) Objective 4 - Electronic Prescribing (eRx)
Tier 2 – 25%	Objective 6 – Patient Specific Education Objective 8 - Patient Electronic Access (VDT) Objective 9 - Secure Messaging
Tier 3 – 25%	Objective 5 - Health Information Exchange Objective 7 – Medication Reconciliation Objective 10 - Public Health Reporting

Tier 1 focuses on CMS' programmatic goal to improve patient safety by highlighting electronic prescribing; clinical decision support, and computerized provider order entry. It also prioritizes security in an effort to protect the onslaught of information that has become digitized through the Meaningful Use program.

Tier 2 focuses on the role of patients in embracing and engaging in their health records and thus their health. It includes Patient Specific Education, Patient Electronic Access (VDT) and Secure Messaging objectives.

Tier 3 focuses on improved outcomes and where health IT can lead in reducing costs and improving care through health information exchange, medication reconciliation, and public health reporting.

Redesigning Stage 3

While the Modified Stage 2 objectives were provided in the example to outline a proposed tiered methodology, the Meaningful Use program must be redesigned to focus on the core issues facing the health IT industry: a lack of interoperability and EHR usability. In order to achieve this, CMS should return to the statutory intent and focus

Stage 3 on the three categories outlined in the HITECH law: electronic prescribing, information exchange, and quality reporting. The measures of the program must prioritize outcomes and use cases rather than processes and data entry. Therefore, redesigned measures would focus on if data is accessible and usable and move away from emphasizing counting and thresholds. In order to effective achieve this, CMS should collaborate with national specialty societies when they work to reenvision Stage 3 and beyond to develop health IT-enabled alternatives or pilots that could be optionally used to satisfy the MU component of the composite score. Including reducing the thresholds required to reasonable levels and develop measures that are appropriate and meaningful. Additionally, CMS must reconsider allowing first time meaningful users and participants who are at a new stage for the first year to have a reduced continuous 90 day reporting period. CMS should also utilize the appropriate national specialty societies to review all of the measures and assess them to determine their relevance to all specialties and the conditions they treat; their cost-benefit analysis, including the cost of lost productivity and interfaces; and if actions are controlled by the physician and not by patients, technology, or other factors over which providers have little influence.

Usability

The College recognizes the time and energy dedicated to improving the functionality of certified EHR technology (CEHRT). Given the perpetual advancement of technology, this aspect will continuously require updating. **However, with each new vendor development cycle, the ACC requests there be an ample and thorough testing period.** As finalized, the rule could require vendors and providers to implement untested technology at a time when physicians are fed up with Meaningful Use and other federal regulations. Although 60 new criteria and 25 revised criteria for certification have been finalized, it is hazardous to mix such new guidelines into technology that is rolled out to market before it may be ready. While the vast number of new criteria accounts for various functional needs across specialties or healthcare settings (inpatient versus ambulatory) it instead manifests as overwhelming and muddles the path to certification.

In addition, there needs to be further prioritizing of user-centered design, not simply tweaking EHRs designed around charge capture. EHRs need to be adapted to the clinical environment because it is dreadfully apparent that emergency room physicians want different functionality than cardiologists. To date, the requirements for Meaningful Use, as well as the certification standards, have focused on ensuring that specific functionalities are included in EHRs and are actually being used. However, these functionalities are meaningless without ensuring that they and the EHRs are actually usable and safe. Recently, the Joint Commission provided a comprehensive review of its sentinel events related to health IT, finding that between January 1, 2010, and June 30, 2013, over 120 events occurred. The report found that the vast majority of these problems were caused by usability, workflow, and design or decision support issues and concluded that health IT-related harm will likely increase unless risk-reducing measures are put in place. If we do not focus on improving usability and the design of EHRs, harm to patients will result. Part of the problem is that the necessary solutions to mitigate against patient safety events are still unknown. Moreover, contract clauses continue to preclude physicians from speaking freely about patient safety issues, further concealing these problems. **The College calls upon CMS to work to promote transparency of vendor contracts by making "gag" or "non-disclosure" clauses illegal.**

The College is equally concerned that the vast number of MU requirements has rushed products into the marketplace without the proper considerations for patient safety and that the certification program continues to solely follow the MU requirements without evaluating the safety and security of these systems. The final rule, nonetheless, continues to expand the amount of data collected and stored in EHRs, heightens decision support requirements, and creates new workflow challenges without addressing these growing safety problems. Additional study and evaluation of patient safety is greatly needed before further expanding the program. **The ACC urges CMS to advance standards in these areas to assist physicians and hospitals in determining which EHRs constitute the small subset that are truly high-quality and will assist them in improving the quality of patient care while minimizing the administrative burden of EHR adoption, implementation and use on physicians and hospitals.** Ensuring usability is the key to successful physician adoption of EHRs. Instead, the rule as finalized gives no consideration as to the clinician decision-making process or practice workflow. To ensure that EHR system vendors take these concerns into account, the ACC urges ONC to continue the advancement of standards for usability testing, including requiring that EHRs produced be reviewed by a 15 person panel (consisting of clinicians) and establishing effective, clinically relevant EHR standards created with specialty medical societies

The ACC believes data portability between EHRs and clinical databases such as specialized registries is critical. It is equally critical that physicians and hospitals have the ability to port data between EHRs. To do otherwise restricts physicians and hospitals to the EHRs they adopt at the outset. Today vendors employ methodologies for restricting access to the data that make it challenging to change EHRs. This is made even more challenging by the market consolidation that has begun to occur and that we expect to continue. Physicians and hospitals that adopt EHRs created by vendors that later go out of business or are purchased by others that elect to cease providing the necessary updates and support for those products need solutions to this dilemma that are cost-effective, create as little burden as possible and have minimal effects on the quality of patient care.

Medical record retention laws, as well as those governing fraud and abuse investigations, largely determine the amount and type of information that must be retained, and therefore, needs to be portable. However, there also may be other reasons for retaining longitudinal information on patient care, such as clinical trial participation, post approval study requirements and others. As such, the ACC believes that it should be left to physicians and hospitals to determine the type and amount of information that should be ported from one EHR to another. **For these reasons, the College urges CMS to refocus the MU program to prioritize the portability of data stored within an EHR and allow physicians and hospitals to determine what information and the amount of it that needs to be ported to another EHR or clinical database.** CMS in turn needs to hold the appropriate parties accountable for health IT to be able to perform these functionalities and not punish the most common end users, physicians and care team members, for actions and functionalities beyond their control.

Payment Adjustments and Hardship Exceptions

The EHR Incentive Program is driven by the requirements set forth by CMS rather than the needs of clinicians and patients, and without regard to vendor development cycles. This has created significant difficulties for stakeholders and delayed the promise of EHRs. As a result, physician adoption of EHRs and participation in the program remains low, despite the penalties that are imposed on non-participants and unsuccessful participants. Those that have adopted and implemented EHRs have high levels of dissatisfaction with them because of their focus on the program requirements, rather than the needs of the end users. In fact, many physicians have consciously chosen to accept the financial penalties, rather than invest in EHR adoption and implementation of the federal EHR Program requirements, despite the fiscal challenges physicians and medical practices face in today's economic climate. **Therefore, the College calls for an expansion of current hardship exemptions by including more specialties and by allowing more flexibility on the lack of infrastructure and lack of control over the availability of Certified EHR Technology.**

Reporting Periods

The College's providers who are program participants have continued to struggle when navigating the complex program structure and requirements. The College portends that the establishment of a single, aligned reporting period for providers based on the calendar year, can indeed assist the providers somewhat in understanding which reporting period pertains to them (the federal fiscal year versus the calendar year) and can allow the participants to more easily consult with others and to receive applicable guidance when progressing through the program. However, this alignment does not simplify the program enough to justify a required 12 month reporting period for all participants (since only Medicaid eligible professionals (EPs) and hospitals demonstrating meaningful use for the first time are provided exceptions) beginning in 2018. Throughout Stage 1 and Stage 2 stakeholders have continuously called for a 90-day reporting period at various points in the program such as for first time EP meaningful users and for the 2015 reporting year, which CMS finalized. While we do recognize the government's response to our previous comments calling for a shortened reporting period in Stage 2, additional flexibility is necessary for Stage 3 participants to be successful. This is needed in part due to health IT continuing to be burdensome to adopt, implement, and upgrade, and we do not foresee achievable transitions to the finalized 2015 Edition criteria across a 12 month reporting period. **The College calls for a continuation of 90-day reporting periods for all first time meaningful users in 2018 and beyond, along with a 90-day reporting period for all providers reporting to Stage 3 for the first time.** While there are no planned updates to the health IT certification criteria or MU objectives, when further updates are finalized, 90-day reporting periods should be provided to allow program participants the needed time to adopt and implement new health IT along with the corresponding modifications to workflow and necessary training.

Program Structure

When reviewing the Stage 2 proposed rule, the ACC had recommended that the actual total number of objectives should remain the same (or preferably) be reduced. Combining of multiple objectives into a single complex objective would be disingenuous and should be rethought, since the burden is the sum of the individual components that

comprise an objective, and not a simple count of the number of (compound) objectives. The reality for physicians is that the objectives themselves are largely irrelevant. This is not because they do not care about improvements to the system as a whole, but because it is ultimately the measures that they must implement and thresholds that they must achieve rather than the objectives. The irony is that CMS expends a great deal of time expounding on the objectives, while spending little time discussing the actual thresholds and whether they accurately capture the information that will ultimately improve the quality of patient care. For physicians, the focus is on the individual patient and providing the highest quality of care to each individual patient. **The ACC recommends that CMS adopt measures that allow physicians to maintain this focus, while still working to improve the quality of the overall healthcare system.**

That being said, it is of exceptional concern to the College that the final rule further requires all program participants to meet the advanced Stage 3 objectives come 2018 regardless of past participation in the program. Combining single objectives into consolidated objectives with multiple measures feels disingenuous and leads to underestimation of the burden imposed by various requirements. Consolidation of previously individual objectives ignores the multiplier effect that occurs when combining requirements. The operational burden of a given objective is not equal to the sum of the individual components of that objective. Instead, it is a compounded burden – the burden related to each of the individual components, plus the effect of the compound objective. A compound objective does not eliminate the burden associated with the individual components. While the program structure has long been overly complex, combining all participants onto the same stage will not result in continued program success and will further discourage provider participation and perpetuate frustrations with the Meaningful Use program. **Because of the increased demands finalized in Stage 3, the College urges CMS to discontinue the pass-fail approach of the EHR Program and transition to assessing achievement on a sliding scale so participants can be provided credit for partially meeting performance thresholds.**

Additionally, the College has previously called for the alignment of quality data reporting via a single submission method for multiple CMS programs and applauds the response to these requests; however, the increased call for reporting of certain numerators in the rule continues to increase the provider reporting burden. Despite having been shown to improve patient safety, reduce medication errors, and allow for better coordination of care, incorporating health information technology (IT) into a physician practice and adjusting workflows to allow for proper reporting continues to provide issues in the healthcare setting. Furthermore, the finalized mandatory reporting of eCQMs by 2018 is far too aggressive. **Given the current state of available eCQMs, the ACC recommends that CMS provides additional time to further develop the quality measures and to allow for a period where participants can transition from their current clinical quality measures to eCQMs. The ACC also strongly recommends that CMS re-examine the time and burden estimates associated with the transition to eCQM reporting and at the very least, accurately reflect the actual time and burden imposed by the finalized clinical quality measure requirements.** These are critical and reliable information sources for information pertaining to quality measurement. The certification criteria and standards included in the final rule fail to address this issue.

Additional Hurdles for Specialties

That said, specialists are continually forced to adjust therapies and technologies approved for a broader demographic to apply to a subset, for example adult therapies being used for pediatric patients, which leads to less-than-optimal treatment. These specialties also struggle when it comes to meeting program objectives or quality measures for a lack of relevant equivalent measures to their specialties. For EHRs in particular some key areas to modify are vaccinations, child development, physiologic medication dosing, disease management, and the relationship between patients and their caregivers, including appropriate privacy safeguards. By augmenting the EHR incentive program to create the flexibility to accommodate appropriate interventions that are meaningful to specialists, CMS will create a more robust and clinically relevant program.

Objectives and Measures

The College recognizes that the finalized set of 8 objectives are designed to align with national health care quality improvement efforts and promote interoperability and health information exchange. The College has long been supportive of the creation of a nationwide health information structure; however, the final rule changes reporting options to requirements and increases reporting thresholds for objectives that few early participants elected to adopt without thoroughly understanding why those objectives were not chosen from among the options. 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 rule 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, a result which no one wants, least of all those who believe that a more digital approach to healthcare will ultimately improve care. **The College urges CMS to provide timely (such as quarterly) confidential feedback on physicians' performance on quality and resource use, along with solid performance targets.**

Protect Patient Health Information

The ACC supports the call for performing security risk analyses annually upon installation or upgrade and throughout use of EHRs. **The College suggests that CMS establish an educational campaign to help physicians better secure and protect patient information in a digital world to reduce the likelihood of breaches.** This would help program participants to better understand the importance and utility of the administrative, physical, and technical safeguards which are required to be implemented, along with items such as audit logs. Additionally, the College suggests that CMS provide additional insight into the audit requirements of this objective, given the difficulties program participants have had in meeting and supporting their work towards this objective.

Electronic Prescribing (eRx)

The ACC has long acknowledged the benefits of e-prescribing and encouraged cardiovascular specialists to adopt this technology. In order to continuously advance the MU program's goals, ACC members have voiced that it would be ideal to have medications prescribed flow automatically to clinical data registry fields that correspond to the medication in question. For example, a patient that is discharged after a myocardial infarction (with coronary artery disease) on aspirin, a P2Y12 inhibitor, beta blocker, angiotensin-converting enzyme (ACE) inhibitor, and high intensity statin, it would be highly beneficial to have data fields automatically populated.

Clinical Decision Support

Clinical decision support (CDS) can assist physicians in many ways. Good CDS can parallel integration of clinical variables and patient preferences that are more continuous. However, the ACC is concerned by the parameters finalized by CMS. It is important to significantly increase CDS in EHRs as it relates to clinical data registry reporting. Not only is it important to give prompts to providers about appropriate lack of compliance with performance measures, but also to give them the functionality to order or change medications, laboratory tests, and diagnostic imaging studies within that same tool.

Furthermore, cardiologists face an additional hurdle when incorporating CDS tools into their clinical workflow given the addition of appropriate use criteria (AUC) requirements for advanced imaging services in the Protecting Access to Medicare Act of 2014. Given CMS' stated focus on aligning the various quality data reporting mechanisms with this finalized Stage 3 rule, the ACC would encourage further opportunities to align quality data reporting with respect to AUC and CDS. For example, the ACC's FOCUS is a decision support tool and registry to guide and improve appropriate ordering of cardiovascular imaging and tests. FOCUS includes a Decision Support Tool, Performance Improvement Module, and access to Webinars and a listserv for members to exchange ideas on appropriate use of cardiac imaging. The opportunity to integrate this tool into EHRs, while lofty, is a necessary progression in the health IT system and can relieve reporting burdens on physicians. Additionally, as AUC reporting requirements flesh out, an opportunity exists for registries to aid in navigating these requirements presents itself. In our comments on the Public Health / Clinical Data Registry Reporting objective we further discuss the need to adopt a standard that will ease the movement of data from EHRs to registries and the need to further integrate registry data into EHRs.

Moreover, the use of evidence-based medicine is critical, and EHR vendors should be encouraged to incorporate technology that enables its use. However, the College is concerned that the technology to connect checking of drug-drug interactions and drug allergies with appropriate evidence-based interactions does not exist in an easy-to-use fashion. Today's systems alert physicians through the use of pop-up windows. The problem is that these pop-ups generate frustration on the part of physicians because of a perceived overabundance of them. The next generation of systems must be better able to distinguish between true drug-drug interaction concerns and those that are not of real concern. **The ACC urges CMS to provide data on this objective and any reports of difficulties experienced by physicians in implementing this requirement in a way that truly improves patient care.**

Computerized Provider Order Entry

As was the case when the ACC provided comments to the Stage 2 proposed rule, the difference between computerized provider order entry (CPOE) for orders for medications, lab tests and imaging and e-prescribing is simple: the absence of a need for interfaces. E-prescribing has developed in such a way that there is a centralized hub through which all prescription transactions flow. No such entity has evolved or been developed for medication orders, lab tests, or imaging. Instead, ambulatory practices and hospitals must develop and implement interfaces with each lab, resource-intensive processes for both providers and labs, pharmacies and imaging centers. The ACC urges the Administration to work with the vendor community to develop a solution that is easy for providers, labs, pharmacies, and imaging centers to implement, rather than the current solution requiring the development of individual interfaces for each pathway. **Additionally, to assist in the transition to CPOE, the ACC urges CMS to work with the healthcare provider and vendor communities to create standards for orders and results interfaces, similar to the standardization of business transactions achieved with HIPAA.**

The ACC also encourages CMS to recognize the increased burden of CPOE implementation on physician practices as compared to hospitals. While standardized and formatted orders are reasonable to encourage, physicians are more likely than hospitals to deal with non-standardized ways to requisition or order outside services. Hospitals may have multiple departments, but at least they are a part of the same institution that can mandate standard ordering protocols. Physicians would not only need to change workflows, but also know how the orders were formatted and placed with multiple vendors and institutions. As such, the threshold should be much lower for the eligible professional. **The ACC urges CMS to provide an additional exclusion for an EP in such a situation presenting a barrier to successfully implementing the technology required to meet this objective.**

In the finalized rule the Agency clearly recognizes that medical orders are frequently given verbally by physicians, rather than directly entered into a patient's medical record. This, in many ways, is due to the need for a direct action to occur as a result of the order. Left alone in the medical record, it may end up ignored or forgotten. When given verbally to another individual, the physician can be assured that a follow-up action will occur. The individual who receives the order is the one who takes those next steps and would be in the best position to enter the order into the medical record, whether the record is on paper or electronic. Additionally, there are many demands on a physician's time, and the patient is not always best served if the physician has to stop what he or she is doing to physically enter the order into the electronic record, especially if it will have to also be handwritten or called in to someone else. In some settings, CPOE may not easily fit into the workflow, especially as the first record of the order in the patient's medical record. CPOE may interfere with the ability of patients to conduct price comparisons for imaging or lab tests ordered by physicians if they are required to immediately inform the physician where they intend to have those tests performed. **Given this, the ACC urges CMS to allow scribes and other non-licensed personnel to physically enter an order into the EHR, rather than requiring it be done by licensed personnel.**

With respect to Measure 3, CMS not only increased the threshold from 30 percent to 60 percent but also expanded the objective to include diagnostic imaging, which is a broader category including other imaging tests such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology. The College finds this expansion worrisome since the previously provided description is the only information provided to outline the expanded imaging orders to be included in the measure. CMS explained that this change addressed the needs of specialists and allowed for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement but leaves these same specialists to figure out which orders are included in the numerator of this measure on their own in hopes that they are correct and do not receive a payment adjustment following an audit. **Therefore, the ACC calls for further clarity for Objective 4, Measure 3 to outline what orders are to be included in the expanded definition of this measure.**

Patient Electronic Access to Health Information

The ACC strongly supports the right of patients to have access to their health information in a timely fashion and understands the importance of ensuring that patients understand their diagnoses and conditions. However, the finalized time requirements here are unreasonable. It is essential that an EP have the opportunity to review, correct and verify the accuracy of the information in order to prevent further harm to the patient. Instead, a more reasonable time requirement must be imposed to allow for this work to occur. CMS finalized requiring physicians to provide patients access to their health information within 48 hours of its availability for more than 80 percent of unique patients seen. The ACC contends that the 48-hour timeframe is inadequate since many who have adopted certified EHRs are now finding it necessary to spend more and more time after hours (typically one or two hours per day) just to try to keep up. There are numerous extenuating circumstances where a 48-hour turnaround might not be possible. Additionally, this further worsens the patient-physician disconnect as more and more clinicians are using what should be face-to-face time to try to complete documentation work in the EHR. Instead, CMS should continue to rely upon the business day construct. The Stage 2 measure requires this information be furnished to patients within four business days. CMS provides no explanation as to why they finalized decreasing this requirement to 48 hours other than a patient's right to access their information, a right which the College fully supports. As discussed during the development of Stages 1 and 2, there are many reasons for retaining a four business day requirement. **The ACC is concerned that the finalized 48-hour requirement may ultimately detract from the quality of care physicians furnish patients, rather than the other way around as is intended. Thus, the College recommends that CMS retain the four-business day rule from Stage 2.**

Additionally, it is critical that the Agency consider the time commitment required from physicians before electronic health information is made available to patients. Information must be viewed for accuracy and sensitivity. It would be poor care quality for a patient to learn of a potentially devastating diagnosis from a patient portal, personal health record (PHR), or any other form of health IT. While there is no "good" way to receive bad news, it is certainly more compassionate and better for the patient-physician relationship that such information be conveyed directly and personally to the

patient by the physician. Thus, it is essential that time be allowed for physician review and screening of information before it is accessible to patients. Before this information exchange can occur in a meaningful way with patients, physicians must be comfortable using EHRs and information exchanges to share information amongst themselves.

The ACC recognizes that there are some patients who may be interested in obtaining electronic access to their medical records. However, rather than focusing their resources on patient care and improvements to that care, the program as finalized will force physicians to shift those resources where they will not have the level of impact they would have if spent on direct patient care. Physicians will be unduly confined to their patients' interest in accessing their medical information online for this objective. Again, the finalized decrease in the patient wait time for the availability of information online from Stage 2's 4 business days to within 48 hours is too aggressive.

Although the objective states that "This objective should not require the provider to make extraordinary efforts to assist patients in use or access of the information, but the provider must inform patients of these options, and provide sufficient guidance so that all patients could leverage this access." CMS is refusing to accept the realities of the situation. As finalized, physicians will be required to provide timely information to patients online. Physicians cannot force patients to enroll in their online portal and they are provided very few alternative options to transmit a patient's information electronically until the patient has enrolled in the portal. Those who already have portals have experienced difficulties enticing patients to enroll in them. Thus, what will occur is that organizations that can afford to do so will hire staff whose sole job will be to sit in the lobby or waiting room and sign patients into their electronic records. This will allow them to meet their physicians to meet their 80 percent requirement without really accomplishing much toward the intended goal of this EHR Incentive Program: improvements in patient care. Physicians and physician practices that cannot afford to do so will be left to the mercy of their patients' comfort with using technology to access their confidential and private medical records, something with which a large majority of patients are clearly still uncomfortable. Of course, if patients will not even enroll in the portal, the likelihood of them actually using it to access their information is fairly slim.

There are those who are of the opinion that all patients need to access their information electronically for education. These same individuals believe that the education should be furnished by physicians, so these measures are intended to be incentive for physicians to conduct that education. Physicians who have implemented patient portals report that patients typically do not take advantage of them, and those that do are generally not Medicare or Medicaid beneficiaries. In actuality, physicians and their office staff do not have the time required to provide them with individualized, detailed information as to the reasons for them to do so, other than, of course, to allow them to successfully meet the requirements of this program. Instead, physicians and their staff spend their time and resources on patient care and related tasks.

Requiring them to educate their patients on patient portals and similar tools will reduce their available time for patient care, thereby reducing the quality, the exact opposite of the effect intended by the shift to EHRs. **The ACC opposes the program requirements that hold physicians accountable for actions beyond their control,**

such as interest in signing up for the patient portal by patients. Alternatively, this energy could be redirected to focus on improved patient compliance and accountability documentation which holds patients accountable for dietary and lifestyle choices that negatively impact health outcomes, instead of penalizing physicians for factors that they cannot control despite patient counseling. **Not only should physicians not be held accountable for the actions of others, but patients should not be forced to use technology to access their medical information if they are uncomfortable with it simply because the government thinks they ought to access the information this way. The College urges CMS to reduce the threshold for this objective from 80 percent back to 50 percent.** In order to engage a broader audience, the ACC would suggest that CMS expand the opportunities to engage beyond the patient portal and view/download/transmit construct provided; leverage ONC's privacy toolkit to unlock data that was previously difficult to obtain due to unnavigable privacy laws and guidelines; and increase the usability of patient engagement tools. CMS must also recognize the costs – financial and otherwise – to physicians and hospitals as they adopt and implement EHRs when crafting the programs requirements.

Cardiologists are fully committed to the provision of patient-centered care when it comes to factors which they can control. In order to fully participate in making decisions pertaining to their own care, patients must be sufficiently educated regarding their disease or condition and various treatment options. For this requirement to improve patient care, the patient-education resources must be relevant to the individual patient and the specialty of the treating physician. General educational resources, such as information on the importance of annual flu shots, are less helpful and do little to educate patients regarding their own health. It is critical that the materials provided are at appropriate literacy and cultural competency levels for individual patients. **The College urges CMS to work with medical specialty societies such as the ACC and educational material vendors to identify materials appropriate for these purposes.** The ACC is firmly committed to the provision of such materials to assist communications between patients and physicians.

In 2008, as a result of the ACC's commitment to patient-centered care and response to the lack of accurate, authoritative patient resources related to cardiovascular disease, the College launched CardioSmart.org, a patient-facing website providing educational materials on cardiovascular disease and associated conditions along with relevant therapies and treatment options. Cardiovascular specialists are encouraged to direct their patients to these resources, where they can also find mobile apps and online programs to help them live more fully with their condition. The CardioSmart.org website incorporates interactive information and tools to better engage patients in understanding their health and working with their cardiac care team. It is also the primary dissemination point for ACC's shared decision making tools, which offer evidence-based decision aids to help patients better understand their preferences for care in light of the risks and benefits associated with their care options. The ACC has also partnered with a number of patient advocacy organizations to expand its reach for content dissemination so that patients throughout the United States have more effective and higher quality conversations with their physicians and participate more actively in their care.

In addition to the website, the CardioSmart brand also hosts a text messaging service for which patients can register to receive text messages with practical tips, advice and reminders to prevent heart disease and to stop smoking. The ACC has also developed a CardioSmart app, a virtual anatomical model of the heart, available for iPad users, to assist cardiovascular specialists in educating patients about their condition at the point of care. There are a number of medical specialty societies that have developed patient-facing websites and educational materials. **The ACC urges CMS to work with physician organizations and EHR vendors to ensure that patients are receiving accurate educational materials pertaining to their individual needs and concerns.**

With respect to patient specific electronic educational resources, the ACC continues to believe that physicians should have the flexibility to provide these resources in whatever is the most useful format for their patients (e.g., electronic copy, printed copy, electronic link to source materials, through a patient portal or personal health record). Currently there are concerns with availability since EHRs may not include the full spectrum of educational materials which leaves out tools that may be the best sources for patients. Also, the EHR may contain insufficient resources in foreign languages for patients who do not speak English or English is their second language, which can add to existing health disparities based in basic language barriers. Third, the sub-par usability of EHRs leads to an increased focus on documenting a patient encounter rather than focus on the patient and interacting with them. The ACC's members report that they have to hunt and peck for the information in the EHR, which takes longer than providing the patients a handout. What was once a one minute task has now expanded into a process that requires querying, searching, filtering, and printing. **Therefore, the College suggests that CMS not limit educational resources to those identified by Certified EHR Technology and also consider other methods that may be more efficient and reasonable at providing this information.** These revisions would allow patients to become more accustomed to using these tools so that they are then more inclined to use them in the future for clinical purposes.

Coordination of Care through Patient Engagement

CMS' Stage 3 rule continues the strong interest in patient and family engagement. **The ACC agrees that it is critical to involve patients and their families in care decisions.** However, despite combining numerous Stage 2 core and menu objectives to create this objective, it continues to embody the complexities of the early stages of the EHR program. While it does appear that participants are provided flexibility when they have a few options within a measure, this only truly exists if the options actually exist in the market for which participants can leverage them in their healthcare setting. Additionally, the objective should recognize age and cultural gaps that could result in a digital divide if physicians do not have explicit exceptions to ensure these patients can be included in the MU measure. **Measure 1, which requires patients to actively engage with the electronic health record made accessible by the provider, therefore, should be expanded to include a broader set of actions, such as convenience tools (billing/appointment scheduling) to better meet patients' needs and increase the likelihood that physicians will meet this measure.**

As with the requirement for patients to access their information online, the requirement that at least 25 percent of patients send or receive a secure message is still an

aspiration and not a reasonably achievable goal. With respect to those eligible to send or receive secure messages, the term “care team” or “team member” is never defined within the finalized rule and is unclear as to whether this is limited only to physicians or those practitioners required to enroll in the Medicare program or if it extends to nurses and other clinical personnel. **The College requests that the Agency provide clarification pertaining to this requirement in further rulemaking.** Furthermore, physicians cannot continue to be held responsible for their patients’ decisions regarding preferred methods of communicating with their physicians and their office staff. Many of the secure messaging programs continue to be cumbersome to use, even for those patients who are technologically inclined. Therefore, the fact that the objective’s rigidity has been eased through the inclusion of communications from the providers and relevant communications amongst the care team doesn’t entirely alleviate the overly ambitious hurdle this objective provides. The College continues to remind CMS that controlling physicians through the actions of their patients is inappropriate and urges CMS to instead redirect this focus onto vendors so they can bring more effective options to market within a timeframe that provides for adequate improvements and testing so the product can fit the needs of a broader range of providers. **Until then, the ACC requests that CMS provide further flexibility on this objective, to allow time for technological advancements and patient engagement opportunities to grow, by requiring that EPs meet only 1 of the 3 measures.**

The College is perturbed that CMS would finalize the collection of patient generated data (PGD) as an option when there have been ongoing discussions about the lack of standardized data capture abilities for such data. Given that the rule includes the collection of input on how to capture, standardize, and input this PGD into an EHR reaffirms that this requirement has been instituted prematurely. If you then remove that possible measure from the three listed, you are now required to meet the other two measures, leaving providers with absolutely no flexibility on this objective. Further, the requirement that providers must attest to the numerator and denominator for all three measures of this objective, along with the Health Information Exchange objective, when they are only required to meet the threshold for 2 out of the 3 measures, places further reporting burdens on already overtaxed providers. **Therefore, the College recommends that in addition to lowering the requirement to meeting only 1 of the 3 objectives, CMS should also reduce the objective’s thresholds to: 1 unique patient for Measure 1, 1 unique patient for Measure 2, and the capability for patient generated health data or data from a non-clinical setting can be incorporated into the certified EHR technology was fully enabled during the EHR reporting period for Measure 3.**

Health Information Exchange (HIE)

For physicians, this objective introduces another element of uncertainty. They frequently conduct histories and physical examinations when a patient is hospitalized. However, this information may or may not be entered into their practice’s EHR, making it difficult to track as a transition of care. Additionally, patients may be sent to the emergency room outside of business hours, so physicians may not know that their patients have experienced a transition of care, requiring them to provide a summary of care record. The rule finalizes that providers would need to actively seek, as a recipient of a transition or referral, an electronic summary of care document in a patient’s record when

a patient is referred to them or otherwise transferred to them for care. All of this makes it difficult to track these transitions electronically for measurement purposes in addition to the difficulties experienced when providers are required to actively seek the various records. Given the current definitions of transitions of care and referrals, physicians will have a difficult time distinguishing when these records must be furnished. **Until industry solutions to these issues have reached an adequate level of adoption, CMS must revise this objective to allow providers a chance to meet the requirements by requiring providers to meet only 1 of the 3 measures**. Rather than focusing efforts on moving more data, the College strongly recommends that the focus remain on furthering functional interoperability, that is, the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner.

An additional component of this objective is that the physician or hospital transitioning or referring their patient to another setting or provider electronically transmit a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different EHR vendor than the sender for more than 40 percent of transitions or referrals**. This threshold is extremely high given the state of interoperability and data blocking which occurs and needs to be reassessed**. While the College understands CMS' intention to help drive the electronic exchange of information, this measure is outside the control of physicians or hospitals. Recent changes in reimbursement have led to resulting changes in the ownership structure of ambulatory practices. More and more private practices have merged with hospitals. This means that many physicians are employed by integrated health systems or hospitals, have little to no control over the EHR they use, and may use the exact same EHR as virtually every other physician with which they typically interact.

Even where physicians are not part of the same health system or employed by the same hospital, they may use the same EHR as the other physicians in their geographic region or have no idea as to the particular EHR used by the physicians with whom they frequently interact. Requiring providers to transmit summaries of care to recipients with no organizational affiliation and a different EHR requires physicians and hospitals to perform activities they do not control and have no ability to track. **At a minimum, the ACC urges CMS to provide exclusions for physicians and hospitals that do not transition care or refer patients to a minimum number of physicians or hospitals with different organization affiliations and/or different EHRs.**

Transitioning from the ability to transfer data to tackling the cost of transferring it, given that most practices and hospitals are required to interface with more than one clinical laboratory, this measure is infinitely more difficult to implement than it would appear at first glance. Physicians generally have privileges at multiple hospitals that each have their own laboratories or require the use of a particular laboratory. Additionally, health insurance companies have different requirements when it comes to the use of particular laboratories. Thus, the costs and ability of physician practices to develop interfaces with multiple labs are really out of their control. One lab interface alone can take six months to a year to implement, and practices and hospitals pay for each interface that they implement. The costs and resources needed to develop the multitude of interfaces necessary to accomplish this measure are beyond the current Stage 3 implementation timeline. Health information exchanges (HIEs) may assist physician practices and

hospitals in meeting these requirements, but they either do not yet exist in many states or they may not be functioning at the levels necessary to remedy this situation. **Until industry solutions to these issues have reached an adequate level of adoption, CMS must revise this objective to allow providers a chance to meet the requirements by lowering Measure 2's threshold to 20 percent and Measure 3's threshold to 50 percent**.

CMS sought comments on whether "utilization alerts" received by a provider when a patient is admitted, seen in an emergency room, or discharged from a hospital should have been included in measure two or as a separate measure. Such alerts are ideal when a patient remains in the same health system for all of their interactions and EHR vendors across the system remain homogenous. However, if either of these elements is missing, quality patient care could be compromised due to the lack of a unique patient identifier. Without the assurance that patients across varying health systems and varying EHRs have been matched appropriately, sending a utilization alert could become detrimental to a patient's health. The integration of health IT into care settings drives us towards the goal of providing the right information at the right time to the right patient, but only if those items are correct. **The ACC strongly cautions CMS on integrating any required utilization alerts into the program unless an effective patient matching plan is outlined alongside it. By the next certification cycle, the Administration needs to begin development of provider directories and facilitate patient matching.** Developing these tools will ensure that when exchanging information among records that the intended recipient and patient are easily and correctly identified.

Public Health and Clinical Data Registry Reporting

Registry reporting remains challenging in 2015. There is a scarcity of specialty registries available for EPs to report to and their number and affordability needs to increase. While several vendors willingly export files with sufficient data for registry participation, others refuse to export more than the "minimum government standard", put in place artificial technical barriers, or attempt to charge excessive fees. **Although the ACC is encouraged by CMS' finalized removal of the prior "ongoing submission" requirement and replacing it with an "active engagement" requirement, we seek further clarity in how to prove active engagement.** Given that three active engagement options are outlined, if there is an expectation upon being audited, that the participant must prove they are currently participating in the production option of active engagement (option 3), the language should clearly stipulate what is needed to support proving participation at this level.

We would caution CMS on the timeline for this required objective. Given that reporting remains challenging and can act as a barrier to participation, mandating participation can cause an unprecedented surge in registry enrollment which on the surface seems like a good problem to have. However, the time necessary from engaging an appropriate registry, to executing a contract, to achieving active engagement, is by no means an expeditious process. Before finalizing this requirement **we would strongly urge CMS to consider the many months it can take to finalize agreements and the time it will take for registries to adapt to this influx, again, preventing providers from being penalized for actions outside of their control**. CMS also requires in Option 1 that participants complete registration with a CDR but does not outline what

registration entails, how it might be proven, or how participants will attest to this. CMS must continue to release FAQs and provide other educational opportunities so program participants are provided the clarity needed to meet the requirements of this option. The driving mission towards increased health information exchange and improved outcomes can quickly unravel if providers sign up for registries and await testing only to find out that their proof of registration does not meet the documentation requirements provided to CMS auditors. **In lieu of this, the ACC suggests that CMS alter the definition of "Active Engagement" in Option 1 to "contact was initiated by the physician to the CDR or PHA via email or written notice within the EHR reporting period."**

While the College supports population and public health activities, we believe the expanded mandate is premature and the exclusions are insufficient. There is now a burden on states and physicians to register and engage in PHA reporting when there is no guarantee that state and local PHA will neither comply with the standards, nor be able to meet the standards in time. We are also concerned that many vendors will charge to connect with each physician's desired PHA or CDR due to our awareness of vendors erecting technical and financial barriers to connect to a physician's desired PHA or CDR or otherwise limit choice of connections. Several widely used EHR vendors charge into the thousands of dollars to connect and some outright refuse to connect. Ultimately this may limit options, especially for certain specialties. Furthermore, ONC's 2015 Certified EHR Technology final rule only addresses standards with EHRs and PHA. Essentially, vendors do not have to be accountable to meet the CDR measure option. In addition, the exclusion provided for this measure is jurisdiction based, but the vast majority of CDRs, specifically qualified clinical data registries (QCDR) within the PQRS program are national. **Accordingly, the College believes the exclusion for Measure 5 should be expanded to include the fact that a vendor may not connect or make it cost prohibitive to connect to a physician's preferred CDR.**

Immunization Registry Reporting: Many cardiology practices today are still not set up to submit data to an immunization registry or immunization information system. This will continue to be a hurdle for these practices to achieve between now and 2018. **While the ACC agrees testing a physician practice's ability to transmit information to an immunization registry or immunization information system may not be an adequate measure, successful active engagement of the information for the entire EHR reporting period is too extreme in the other direction. Instead, the ACC urges CMS to set a threshold, as it has done for the majority of other measures which would allow a physician to receive credit when submitting to an immunization registry in the method expected by their state or local agency.** This will allow for any problems that may occur early in the reporting period. Successful active engagement of the information is too vague as to allow for any problems that may occur through no fault of the physician, physician practice or hospital. It also does not allow for difficulties that may occur in the implementation of the necessary interfaces and testing of those interfaces.

Syndromic Surveillance Reporting: Many physician practices continue to be perplexed by the term electronic syndromic surveillance. If the term itself still incites confusion, they certainly cannot be prepared to implement it effectively in their practices. Given this

state of education and understanding, successful active engagement of electronic syndromic surveillance data from a certified EHR to a public health agency is not an achievable measure option for this objective. **The ACC urges CMS to remove this measure or to provide physicians with true choices for objectives and measures that can be achieved both when the rule takes effect and beyond. If this issue remains unaddressed come 2018, CMS should modify this objective to require EPs to meet only 2 of the 4 remaining measures.**

Case /Public Health / Clinical Data Registry Reporting: The ACC and its members are committed to furnishing high quality care to patients diagnosed with cardiovascular diseases and conditions. One of the best ways to do this is through the collection of data using specialized registries. **The ACC applauds CMS for including reporting to public health and/or clinical data registries in an objective**. We believe this objective should seek to ensure that physicians participate in registries that are truly committed to increasing the quality of patient care. **To that end, the ACC recommends that CMS include registries that meet the following specifics in the finalized centralized repository of national, state, and local PHA and CDR readiness:**

- 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; and
- Offer timely support services and training to participating sites, including best practices on incorporating data collection into their workflow.

Cardiovascular specialists have been among the most prominent supporters of registries. Through the use of registries, much has been learned about cardiovascular care. 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® focuses on what has long been recognized as the missing component of the NCDR: the ambulatory setting. With data on more than 20 million patient encounters involving close to 5 million 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.

In 1997 the ACC launched the NCDR as a result of its exploration of various strategies for collecting and implementing clinical data to improve cardiovascular care. The outgrowth of this effort focused on quality patient care through standardized measurement of clinical practice and patient outcomes. That first registry encompassed cardiac catheterization and percutaneous coronary intervention activities and was designed to help healthcare provider groups and institutions respond to increasing requirements to document their processes and outcomes of care. Then, as now, NCDR was committed to including clinicians and care providers in its leadership and to using standardized, clinically relevant data elements and scientifically appropriate methods to collect, analyze and report clinical outcomes. Today, more than 2,400 hospitals nationwide participate in the NCDR. As the US' preeminent cardiovascular data repository, the NCDR provides evidence-based quality improvement solutions for cardiologists and other medical professionals who are committed to measurement, improvement and excellence in cardiovascular care. As a trusted, patient-centered resource, the NCDR has developed clinical modules, programs and information solutions that support the areas of cardiovascular care where quality can be measured, benchmarked and improved to make a difference in patients' lives.

The NCDR suite of cardiovascular data registries has expanded to include:

- ACTION Registry®-GWTG™ for high-risk STEMI/NSTEMI myocardial infarction patients
- AFib Ablation Registry™ for atrial fibrillation (AFib) ablation procedures
- CathPCI® for cardiac catheterization & percutaneous coronary intervention procedures
- Diabetes Collaborative Registry® for diabetes and cardiometabolic care
- ICD Registry™ for tracking implantable cardioverter defibrillator procedures
- IMPACT Registry® for adult and pediatric congenital heart conditions
- LAAO Registry™ for left atrial appendage occlusion (LAAO) procedures
- PINNACLE Registry for physician practices to capture data on coronary artery disease, hypertension, heart failure and atrial fibrillation
- PVI Registry™ for lower extremity peripheral arterial catheter-based interventions
- STS/ACC TVT Registry™ for transcatheter valve therapies

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. Currently, HIEs vary immensely by state and by exchanges and they continue to fall short when demonstrating technical capability or expressed willingness to connect directly with registries.

Regardless of ACC's support for the use of specialized registries, data collection directly from EHRs remains hampered by the lack of data standards and technical interfaces to IT systems. Different EHRs and applications use different clinical and technical definitions, so it can be challenging to determine what information is needed. To overcome this barrier, the PINNACLE Registry works with an application that performs back end "system integration" data mapping. Additionally, clinical staff helps to identify key terms and phrases that may be used to describe critical elements. As cited earlier in our comments, to ultimately solve this problem, the ACC has been working with the

AHA to attempt to ultimately solve this problem. Through these efforts we have identified the key data elements and definitions of a base cardiovascular vocabulary for EHRs. The subsequently generated document contains less than 100 terms that are commonly used in cardiovascular care. The ACC is now in the process of building out those terms and the necessary specifications for them; however, this ultimately takes time and will not be ready immediately for use. **As such, the ACC urges the Administration to adopt a standard that will ease the movement of data from EHRs to registries for these purposes.**

Electronic Reportable Laboratory Result Reporting: In today's modern practice of medicine, physicians rely heavily on imaging for diagnosis and treatment. Yet, CMS fails to work towards encouraging the development of standards for transmission of images and information pertaining to those images. For instance, standards for the transmission of 3-D echocardiography images continue to lag behind in this area. Additionally, most EHRs remain incapable of handling images. Images embedded in reports such as Microsoft Word documents may be difficult to view with adequate resolution on some systems and with some hardware such as smart phones. Physicians continue to receive studies on disk that cannot be read by a PACS system, let alone an EHR.

The incorporation of scanned images into EHR records is generally ineffective at improving patient care. When images are scanned into EHRs, physicians cannot manipulate the data, which may prevent them from truly seeing the images or from understanding what the images represent. Additionally, it represents an additional burden imposed by CMS on physicians, one that will not improve the quality of patient care. Many vendors of cardiovascular imaging equipment claim that the format of stored files is DICOM compliant; however, the reality is that this is frequently not the case. Specifically, it is the ability to view a "DICOM compliant" study created by one vendor with a second vendor's DICOM viewer that is not guaranteed. This problem permeates the market, and failure to specify conformance to the DICOM format for storage and retrieval as a least common denominator functionality will only serve to exacerbate this situation. To execute successfully, the specific components of DICOM compliance need to be specified. Requiring DICOM standards as a component of EHR certification will galvanize industry towards adoption and implementation of the standard. After this has occurred, then CMS can consider requiring electronic transmission of images as a component of the EHR Incentive Program.

Overall, what CMS fails to grasp is that a number of the measures apply to so few physicians or hospitals that the ability of physicians or hospitals to select from the measures that they prefer to report on is so low as to not really be a true choice. The College believes that CMS should be providing physicians with a legitimate selection of measures from which to choose. **Additionally, the College recommends that CMS either reduce the number of measures upon which physicians must report or provide physicians with real choice among the objectives by adding workable measures.**

Provider Education

A critical component to the success of the EHR incentive program is physician participation. CMS has launched extensive physician education campaigns to

encourage physician adoption of EHRs, and the ACC applauds the administration for their efforts. However, this process is not complete. CMS will need to continue physician outreach and education programs as they unveil this critical phase of the program. The administration must be prepared to provide continuous education on the earlier stages and Modified Stage 2, as well, recognizing that physicians will choose to adopt and implement EHRs at different points in time. Additionally, come 2018 the rule finalizes that new physicians will begin their participation in the program with Stage 3. Thus, the ACC believes that it will be important that educational materials and programs pertaining to the earlier stages of the EHR Incentive Program remain available. **The ACC urges CMS to work closely with the physician community to ensure that the educational materials address all of the potential questions and concerns.** As representatives of the parties directly affected by the incentive program, physician organizations such as the ACC are best suited for assisting CMS in preparing these materials and disseminating them to physicians.

As part of this continuous education campaign, the ACC recommends that CMS continue to develop a series of frequently asked questions documents, hold webinars and Special Open Door Forums, issue MLN Matters articles, and draft articles that can be used in physician organization publications. Additionally, the ACC urges CMS to publish editorials in major newspapers and trade publications to alert physicians to the program and its requirements. While CMS currently has a website containing all of the current information on the EHR Incentive Program the site is difficult to locate and cumbersome to use. **The ACC urges CMS to streamline the website to make it easily accessible, understandable, and navigable by physicians, physician practice staff, and hospital personnel. The ACC further recommends that the website combined with the respective ONC website on the EHR program to reflect the nature of the integration between the work performed by CMS and ONC in this area.** The development of one combined website will allow for a reduction in the resources needed overall for the development and maintenance of the two websites devoted to this topic.

Conclusion

The ACC believes that CMS should be commended on the efforts to develop the EHR Incentive Program. This is not an easy feat and while the final rule addressed here is far from perfect, the College recognizes the amount of thought and work that went into its development. However, the College has substantive concerns about the practicability, adaptability, deliverability, and ability of physicians to comply with the finalized Stage 3 requirements as described above. The College appreciates the opportunity to furnish input on this important issue and looks forward to the prompt issuance of additional guidance and modifications. We would welcome the opportunity to discuss this and other relevant issues with CMS. Please direct any questions or concerns to Julie Brown at (202) 375-6351 or jbrown@acc.org.

Sincerely,

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President