Heart Rhythm Society

June 27, 2016

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

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Administrator Slavitt,

The Heart Rhythm Society (HRS) appreciates the opportunity to provide feedback on proposed policies related to the implementation of the new physician payment system authorized under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). HRS is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Founded in 1979, HRS represents more than 5,100 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists, and their support personnel. Electrophysiology is a distinct specialty of cardiology, and electrophysiologists are board certified in both cardiology and clinical cardiac electrophysiology through the American Board of Internal Medicine. HRS members perform electrophysiology studies and curative catheter ablations to diagnose, treat and prevent cardiac arrhythmias. Electrophysiologists also implant pacemakers, implantable cardioverter defibrillators (ICDs), and cardiac resynchronization devices in patients who are indicated for these life-saving devices.

The discipline of electrophysiology has undergone significant change in recent years, crossing clinical frontiers in the treatment of cardiology's most challenging diseases such as sudden cardiac death, atrial fibrillation and heart failure. As these advancements occur, HRS remains committed to improving the quality, safety, and efficiency of patient care. Unfortunately, federal initiatives aimed at improving quality and the overall value of care have, to date, provided members of our specialty with very few opportunities to demonstrate their commitment to care improvement.

As we noted in our initial comments to the Centers for Medicare & Medicaid Services (CMS), there is great potential in many of the new programs created under MACRA. This represents an opportunity to press the "reset button" on physician-focused quality mandates and to correct misguided policies that have thwarted meaningful engagement among physicians and quantifiable advancements in quality. The complex policies proposed in this rule further emphasize the need for CMS to approach this transition in a thoughtful and deliberate manner that includes substantial investment in technical assistance, thorough and continuous evaluations and ongoing consultation with the clinical stakeholders that will be most directly

impacted by these changes. The physician community was engaged with Congress as it drafted the MACRA legislation. With the potential for significant improvements over the incentive programs in prior law, including reduced penalties, more support for positive incentive payments, simpler requirements, and fewer administrative burdens, HRS are strongly committed to work with the physician community to ensure a successful MACRA launch.

In our comments below, we focus on specific proposals that have the most significant impact on heart rhythm care.

Thoughtful Implementation and Reasonable Timelines

Proposed Start Date

In HRS's response to the Request for Information (RFI), we urged CMS to focus primarily on establishing an effective program rather than adhering to challenging and arbitrary deadlines. New policies should be phased in and carefully analyzed prior to widespread implementation.

HRS strongly opposes CMS's decision to propose January 1 through December 31, 2017, as the initial performance period for the first MIPS payment adjustment in 2019. **We strongly urge CMS to provide a period of transition and stability by delaying the start date of the first MIPS performance period and holding groups harmless from downward payment adjustments or otherwise minimizing the impact of penalties during the initial years of MIPS, as it did under the Value Modifier.** Two delay options for your consideration are: Establishing a performance period that is not based on the calendar year; or establishing a shorter performance reporting period (as was previously done when the Performance Quality Reporting Initiatives was first established in 2007).

Releasing the final rule in November 2016 for implementation on January 1, 2017 ignores the complexity of the proposals set forth in this rule, the time for clinicians to understand how to comply with these new requirements and for professional societies to educate members about their options under this new program. Given the importance of properly launching this new system, a rushed implementation date sets up physicians and CMS for unnecessary confusion. Plus, using reporting data from 2017 for calculating 2019 bonus payments has the potential to discount those bonuses solely based on problems associated with physicians' learning curves.

CMS could consider a performance period that runs from July 1, 2017-June 30, 2018. That would offer more timely data for the 2019 bonus payments. Alternatively, the Agency could utilize a shorter performance period, such as a 9-month reporting period (e.g., March 1-December 31), which is the equivalent amount of time that CMS uses to collect data from Physician Quality Reporting System (PQRS) Web Interface users. CMS also relied on a shortened performance period when the Physician Quality Reporting Initiative (PQRI) was first established (i.e., July 1, 2007 through December 31, 2007).

During this transition period, it is critical that CMS use MACRA-authorized funding to invest more heavily in user-friendly and easily accessible educational tools, technical assistance, and other interactive resources. HRS members report that the current CMS help desk is frustrating to use due to the lack of granular knowledge and limited ability to delve into issues beyond what

is provided to the staff in their script. Given the added level of complexity proposed under MIPS, CMS must ensure that support tools are well-informed, responsive and timely, and understandable. The task of distilling all of this information is arduous and one that professional societies cannot do alone.

Performance-Payment Gap

We also urge CMS to continue to work to close the gap between the performance period and the payment year. Closing this gap will produce more actionable data for both clinicians and patients, and allow CMS to make more timely modifications to the program as necessary.

Public Reporting

Despite comments opposing CMS's current strategy for public reporting, MACRA facilitates the continuation of the phased approach to public reporting by requiring the Secretary to make available on the Physician Compare website, in an easily understandable format, individual and groups performance information, including:

- The MIPS-eligible clinician's Composite Performance Score (CPS);
- The MIPS-eligible clinician's performance under each MIPS performance category;
- Names of eligible clinicians in Advanced APMs and, to the extent feasible, the names of such Advanced APMs and the performance of such models; and
- Periodically post aggregate information on the MIPS, including the range of composite scores for all MIPS-eligible clinicians and the range of the performance of all MIPS-eligible clinicians with respect to each performance category

HRS has long held that public reporting is an area that must be approached thoughtfully. If not carried out appropriately, it could have serious implications for both physicians and patients. It is critical that CMS focus its efforts on carefully designing and gradually implementing the MIPS system prior to making performance data available for public consumption. CMS must first accrue a strong foundation of data under this new system, confidentially share it with impacted clinicians, and simultaneously conduct research into what information and reporting formats are most valuable to consumers and clinicians. Only after this work is complete should CMS transition to the public reporting of performance data.

<u>Minimize Administrative Burden</u>

Participating in MIPS should bolster the practice of medicine, not interfere with it. The administrative complexity of current quality reporting mandates not only discourages participation, often they erode the physician-patient relationship, which contradicts the underlying goals of these programs. **As part of our recommended strategy for providing clinicians with a transition period, we strongly urge CMS to simultaneously adopt policies that further minimize the reporting burden in the initial years of MIPS**.

Performance Measures

We support CMS's focus on the need to measure performance, but we firmly believe that quality improvement efforts should extend beyond developing performance measures to

include a robust assessment of the impact of performance measures on patient care and outcomes. Although numerous performance measures currently exist, to our knowledge very few of these measures have actually been shown to improve patient care and outcomes. Consequently, we believe that when performance measures are requested for renewal for NQF or for use in PQRS, that data on the effectiveness and impact of their performance measures should be assessed before such renewal requests are approved.

Quality Measure Reporting Thresholds

Under the Quality component of MIPS, CMS proposes to lower the number of measures that must be reported from 9 to 6 and to no longer require that reported measures span 3 National Quality Strategy (NQS) domains. Clinicians and groups using any reporting mechanism, including Qualified Clinical Data Registries (QCDRs), also would have to report on one cross-cutting measure, as well as an outcome or other high-priority measure (i.e. patient experience, safety, efficiency, appropriateness, or care coordination). While we appreciate CMS's proposal to reduce the number of required measures and to abandon the NQS requirement, we are very concerned by the proposal to raise the reporting threshold for each measure from 50% to 80% of all applicable Medicare patients for claims and to 90% of all patients (i.e., both Medicare and non-Medicare) for QCDRs, qualified registries, and electronic health records (EHRs). HRS strongly opposes the proposal to increase the reporting threshold this high since it leaves very little room for error and fails to account for the fact that reliable data could be achieved with a much lower sample. The proposal also contradicts CMS's efforts to promote the use of registries by creating a disincentive for clinicians to enter that market by setting a lower bar for claims-based reporting. Finally, the 90% requirement could pose a particularly high burden for hospital-based physicians, who often face barriers gaining access to facility owned or managed data, as well as clinicians who practice at multiple sites since not all sites might be enrolled in a registry.

We recommend that CMS maintain the current 50% reporting requirement for each quality measure. When CMS originally increased the PQRS reporting requirement from 3 to 9 measures in the 2014 Physician Fee Schedule (PFS) final rule, CMS justified its decision to lower the reporting threshold to 50% of patients to compensate for the increased reporting burden. Looking ahead, the reporting threshold for quality measures should reflect the overall increased burden imposed by MIPS, such as the fact that clinicians now have to report on Clinical Practice Improvement Activities (CPIAs), which was not a requirement in the past.

Subspecialty Measure Sets

CMS proposes that clinicians may select quality measures from either a list of all MIPS Measures or subsets of specialty and subspecialty-specific measures. These subsets were designed to address concerns that the quality measure selection process can be confusing for specialists. For example, under PQRS, clinicians were asked to review close to 300 measures to find applicable measures for their specialty. While there is no requirement to report on a specialty set, CMS proposes special accommodations in situations where a specialty set includes less than 6 measures. Clinicians and groups reporting on such sets would only have to report on the measures in the set, as well as a cross-cutting measure.

HRS thanks the Agency for recognizing the hard work of the Society to establish heart-rhythm-

care-specific measures. After 6 years since the inception of the Society's performance measures initiative and the success of developing 4 fully specified measures, we welcome CMS's recognition with great enthusiasm. It is very rewarding to be included in the Agency's examples of subspecialty measures and we thank you for your partnership.

HRS appreciates that this policy is intended to address that highly specialized clinicians only may have a handful of applicable measures. As such, we support allowing clinicians to report on subspecialty-specific measure sets for the quality performance category, including the proposed cardiac electrophysiology set, even if it means that a clinician or group would report on fewer than 6 measures. However, **we urge CMS to ensure that specialties with less than 6 measures are not at a disadvantage for scoring**. Those with less than 6 applicable measures should be able to earn the maximum number of performance points in this category without having to report marginally relevant measures simply for the sake of reporting.

As proposed, the electrophysiology measure set includes the following 3 measures, all of which are outcome measures. Clinicians and groups reporting on this set would be responsible for reporting on all 3 measures, as well as a cross-cutting measure.

- PQRS 348/HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate
- PQRS 392/HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation
- PQRS 393/HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

We continue to urge CMS to consider the following NQF-endorsed measure for inclusion in MIPS. We believe it would be appropriate to add this measure to the cardiac electrophysiology measure set:

- **NQF 2491/HRS-4—In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)** assesses the proportion of adult patients with a new CIED implanted during the reporting period who had an in-person evaluation within 2 to 12 weeks following the procedure—either with the EP or through coordination with another physician or allied professional. http://www.qualityforum.org/QPS/2461

Pediatric Measures

We also urge CMS to take advantage of MIPS as an opportunity to carefully consider the unique health care needs of children. Even though few children are enrolled in Medicare, the program has the potential to greatly impact the pediatric population nationally since Medicare often sets the foundation for other public- and private-payer programs. Given MACRA's increasing reliance on all-payer data, it is an opportunity to incorporate more pediatric-focused specialty and subspecialty measures and activities into MIPS.

Flexibility and Autonomy

Requirements under MIPS should be as flexible as possible to encourage innovative practices and sincere engagement. Physicians in all specialties, practice settings, and geographic areas should have the opportunity to choose the reporting mechanisms and measures that are most

relevant and meaningful to their practice type and patient population. Despite HRS's investment in the development of meaningful measures, current quality reporting programs present few opportunities for our members to take advantage of these more relevant measures. In subspecialties such as cardiac electrophysiology, where physicians tend to practice in larger multispecialty group practices, they have limited control over the selection of measures and reporting mechanisms. As a result, electrophysiologists are unable to be a meaningful participant in these programs and to demonstrate quality in a relevant manner.

Group vs. Individual Participation

CMS proposes to use multiple identifiers that would allow MIPS-eligible clinicians to be measured as an individual or collectively through a group's performance. However, the same identifier would have to be used for all 4 MIPS performance categories (i.e., a clinician cannot report as an individual for some aspects of MIPS and as a group for others). Although CMS proposes to use multiple identifiers for participation and performance, it would use a single identifier (tax ID number [TIN]/ National Provider Identifier [NPI]) for applying the payment adjustment, regardless of how the clinician is assessed. More specifically, if a clinician is identified by TIN only for purposes of performance, CMS would still use the TIN/NPI when applying the payment adjustment.

HRS agrees with this approach since the use of the TIN/NPI combination allows CMS to identify more accurately which TIN/NPIs are still MIPS-eligible clinicians after exclusion criteria have been applied (e.g., clinicians who satisfy the proposed low volume threshold or are determined to be an APM Qualifying Participant, which would occur after the performance period). Similarly, this strategy permits CMS to calculate performance for multiple unique TIN/NPI combinations (i.e., those who practice under more than one TIN), which enables greater accountability for individual clinicians beyond what might be achieved when using the TIN alone. This strategy also provides a safeguard for clinicians who might try to change their identifier simply to avoid payment penalties.

Nevertheless, **we request that CMS provide a more detailed explanation of how it intends to evaluate *group* performance and determine payment adjustments based on group performance for each of the following 4 MIPS performance categories: Quality, Resource Use, Advancing Care Information (ACI, formerly Meaningful Use), and Clinical Practice Improvement Activities.** It is not clear from the rule whether CMS will evaluate each individual within the group and combine those scores into a composite group score, or whether CMS will look at the group's performance as a whole, as it currently does under the PQRS (e.g., in accordance with the proposed quality reporting threshold, did the group as a whole report on 6 measures for 90% *of the group's* applicable patients?). While it might be feasible for CMS to evaluate group-level performance for quality and resource use and then apply that score to everyone in the TIN regardless of whether all individuals in the group contributed to the score, that strategy does not translate as easily to the new ACI and CPIA categories.

HRS appreciates that CMS proposes to maintain and expand the group practice reporting option since it is an important way to reduce the participation burden that could be experienced by larger groups that would otherwise have to report data for each individual. However, we also believe that there needs to be a mechanism to ensure that individuals within a group using the

group reporting option are not held accountable for cases attributed to the group, and only for cases over which they have direct control.

We want to reinforce that the majority of electrophysiologists practice within large multispecialty groups affiliated with large hospital systems and/or academic medical centers. As such, they currently have limited control over the selection of measures and reporting mechanisms that best reflect their care. For instance, despite HRS's investment in the development meaningful measures for the PQRS, our members are limited in their ability to report more focused heart rhythm care measures because their practice administrators independently make the decision to participate in PQRS via the Group Practice Reporting Option (GPRO). While these physicians might avoid a penalty without having to take much action, they are often disengaged from the process and lack the autonomy to demonstrate quality in a manner that is most appropriate and meaningful to their practice. In general, this flawed structure discourages the capture of data on specialty care and promotes the reporting of general measures that lack the granularity needed to understand and improve upon heart rhythm care.

Due to these concerns, we recommend that CMS also give individual clinicians the opportunity to opt out of participating as a group and to instead be evaluated as an individual. Since MIPS represent an unprecedented shift toward pay-for-performance, it is even more critical that individual clinicians have direct control over what they are being held accountable. CMS needs to recognize quality improvement efforts at multiple levels and calculate performance in a manner that is congruent with the varied ways that providers practice and are organized.

Clinical Practice Improvement Activities

To achieve the highest potential score in this category, CMS proposes that individual clinicians and groups must achieve a total of 60 points. Clinical Practice Improvement Activities (CPIAs) are categorized as high-weighted CPIAs (20 points each) and medium-weighted CPIAs (10 points each), and clinicians can choose any combination to achieve the maximum score. Those who select less than the designated number of CPIAs will receive partial credit based on the weighting of the CPIA selected. For clinicians and groups that are small or located in rural areas or geographic Health Professional Shortage Areas, CMS proposes that only two CPIAs would be required (either medium or high) to achieve the highest score of 100% in this category, and that only one CPIA would be required to achieve a 50% score.

HRS thanks CMS for proposing that clinicians simply would have to attest to performing activities on the CPIA Inventory for a minimum of 90 non-consecutive days during the first year of MIPS. **We also support that CMS proposes an inventory of over 90 varied activities from which a clinician could choose from and that CMS has not imposed any minimum requirements in regards to selecting activities from specific CPIA subcategories.** These policies will ensure greater flexibility and permit clinicians to choose activities that are most relevant to their practice. Finally, we appreciate the accommodations to ease the reporting burden for certain types of clinicians. We strongly urge CMS to maintain all of these policies beyond the first year of MIPS.

We recommend that CMS also recognize under this component of MIPS clinicians who have contributed to the development and/or implementation of interoperability standards and

profiles. As described below, many of our members have been involved with the development of an Implantable Device Cardiac Observation (IDCO) profile, which specifies the creation, transmission, and processing of discrete data elements and report attachments associated with implantable pacemaker (PM), ICDs, and cardiac resynchronization therapy device (CRT) interrogations (observations) or messages. These standards are critical for more robust engagement in quality measurement and meaningful use of health information technology to improve the quality of patient care.

Continued Investments in Better Measures and Better Risk Adjustment and Attribution Methodologies

One of our members' biggest barriers to meaningful participation in quality programs and innovative payment models is an insufficient set of relevant measures. MACRA-authorized funding must be used as soon as possible to address these measurement gaps. One area that is particularly in need of work is cost measurement.

Resource Use Measures

In this rule, CMS proposes to maintain the following 2 controversial cost measures used under the Value Modifier for purposes of calculating the MIPS Resource Use performance score: the Medicare Spending Per Beneficiary (MSPB) measure and the total Per Capita Cost measure. In addition, CMS also proposes 41 new episode-based cost measures.

HRS is discouraged that CMS is proposing to maintain the problematic Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Cost measures for the Resource Use component of MIPS. Making matters worse, CMS also proposes to remove the specialty adjustment from the MSPB measure and to reduce the case minimum threshold from 125 to 20 patients. These 2 proposals will weaken an already flawed measure and result in more individual clinicians being held accountable for a measure that was intended to be hospital-level.

While we favor more granular, episode-based cost measures and appreciate the hard work that has gone into developing these to date, we do not believe that the proposed episode-based measures are ready for prime-time yet. Much work remains to be done on these measures in terms of risk adjustment and attribution to ensure that they accurately and comprehensively account for the multiple factors that contribute to the overall cost of caring for a patient. For instance, none of these proposed measures are adjusted yet for socioeconomic status. CMS has also just begun to delve into identifying more accurate ways to attribute care to individual physicians. As authorized by MACRA, CMS is in the process of developing patient condition groups that better describe the patient's clinical history, as well as patient relationship categories and codes that better distinguish the relationship and responsibility of a physician with a patient at the time of furnishing an item or service. However, CMS is collecting public feedback on this newly proposed methodology through mid-August and clinicians will not be required to begin reporting these codes on claims until 2018.

CMS has also not identified ways to better account for less evident things that contribute to the overall value of care, such as upfront investments (e.g., the cost of medical devices) that might accrue long-term savings in regards to better outcomes and avoided costs elsewhere in the

health system. Furthermore, there is an ongoing and major disconnect between what CMS is measuring on the cost side versus what it is measuring on the quality side. Ultimately, appropriateness of care, which accounts for both quality and spending, should be the goal, rather than measuring raw cost data in isolation.

For these reasons, we strongly urge CMS to consider using its authority to re-weight the Resource Use category to zero given the current lack of sufficient measures and re-distribute the excess weight to the quality component**.** As described above, the existing Value Modifier measures incorrectly assume that physicians have control over other physicians' care plans and treatment decisions, are of little value to clinicians, and simply serve to confuse the public. Ideally, **we recommend that CMS shift to more focused, episode-based cost measures, but until it has had the opportunity to develop and implement more granular attribution mechanisms; clinicians should not be held accountable for these measures that lack readiness.**

Reinventing Meaningful Use

In our RFI comments, we noted that the regulatory framework for encouraging meaningful use of EHRs must be adjusted to eliminate obstacles to technological innovation, enable interoperability, and improve usability to improve patient care and reduce the burden of excessive data collection requirements. We do not believe that CMS's proposals for the ACI performance category under MIPS makes the changes necessary to accomplish those goals.

Objectives and Measures

Unfortunately, for the most part, CMS proposes to maintain the current modified Stage 2 and Stage 3 objectives and measures, and to require that clinicians report on all of those measures to be eligible for the base and performance score under this category. While we appreciate CMS's attempt to abandon existing thresholds for each measure, the proposed scoring structure of this category still requires a clinician to report on the entire set of existing measures with no flexibility to demonstrate meaningful use in more innovative ways that account differences in practice size, makeup, resources, and experiences with health information technology (HIT). HRS urges CMS to take more concrete steps to move beyond what is still largely a one-size-fits-all, all-or-nothing approach to meaningful use. To realize the full potential of EHRs, requirements of the program need to be less prescriptive to allow clinicians to creatively incorporate technology into their unique clinical workflows and to respond to their patient's needs.

Clinical Decision Support Systems

Clinical decision support (CDS) is an important and growing component of health information technology systems and EHRs. HRS notes that CDS is on the verge of being more directly incorporated into the systems used by electrophysiologists. In fact, several manufacturers in our industry have started to include advancements, such as clinical indicated-based templates for implantable defibrillator (ICD) programming and electroanatomic mapping systems that provide pattern-matching algorithms to determine the degree of match between QRS morphologies during pace mapping, in their products.

Under CMS's primary proposal for calculating the base score of the ACI category, it proposes to remove the Clinical Decision Support objective and its associated measures from existing

requirements. **We believe that CMS should maintain Clinical Decision Support as an option, but not a requirement, under this category since specialties like ours have long been working towards more innovative solutions on this front and should have the opportunity to demonstrate these effort**s.

Interoperability

It is equally critical that clinicians not be limited by existing technology barriers. For electrophysiologists, the primary challenge with HIT continues to be a lack of interoperability standards. CMS must resolve basic cornerstones necessary for data exchange and focus on increasing the functional interoperability between HIT vendors and among vendors and registries to ensure this aspect of MIPS is actually achievable, meaningful, and not another unnecessary regulatory burden on clinicians.

Since 2005, HRS has partnered with industry and *Integrating the Healthcare Enterprise* (IHE) to identify areas of clinical practice where gaps or "pain points" limit clinicians' abilities to provide optimal care. Working with industry engineers under the construct and guidance of IHE, HRS has sought to develop standards-based solutions to these clinical gaps in care in order to provide industry with the leadership and guidance to implement such solutions. We believe this standards-based approach benefits patients by enabling exchange of data among healthcare providers, provides a mechanism to improve patient safety, and provides the opportunity for industry to devote resources to developing higher level functionality and new products. It also provides the opportunity for data to be aggregated and utilized for registries and quality monitoring and will facilitate the development of new, more efficient workflow patterns.

As part of this effort, HRS is actively developing several IHE interoperability profiles under the Cardiology and Patient Care Devices Domains. The Implantable Device Cardiac Observation (IDCO) profile specifies the creation, transmission, and processing of discrete data elements and report attachments associated with implantable pacemaker (PM), ICDs, and cardiac resynchronization therapy device (CRT) interrogations (observations) or messages. This profile has been developed by HRS in partnership with cardiac rhythm management (CRM) industry (all vendors represented), tested, validated, and certified by the IHE's rigorous standards development process. It contains over 250 data elements identified by HRS clinicians as necessary and sufficient to evaluate and monitor the function of all pacemakers, ICDs, and CRT devices regardless of vendor. Additional interoperability profiles in development include the Electrophysiology Report Content Profile, the National Cardiovascular Device Registry Interoperability Profile, the Retrieve ECGs for Display, and the Resting ECG Work Flow interoperability profiles.

Work on the IDCO profile was initiated in 2005. Prior to its development, clinicians voiced concern that data from ICDs was becoming difficult to manage. Data for an individual patient, which requires a proprietary programmer specific to each vendor, could now be acquired in an office setting, acute care setting, or remotely from the patient's home. The data could be printed on paper or exported electronically. However, the electronic format also was proprietary, creating a high barrier to entry for any vendor who considered creating a product to manage and view the aggregate data. Compounding this challenge was the fact that new PM and ICD models, even from a single vendor, often would export data in new formats. This

created a situation where meaningful aggregation of the data, even for a single patient, was extremely difficult and often virtually impossible.

The IDCO profile was developed in partnership with the CRM industry out of recognition that patient safety, quality, and efficiency of care required an interoperability standard to close this gap. It is now available for implementation and clinical use. Yet we have been unsuccessful in convincing the CRM industry to implement the full IDCO profile in their market release products. This has limited our ability to seek adoption and implementation by the EHR industry and personal health record vendors. It also has limited the ability to encourage utilization of the interoperability profile for data registries, quality monitoring, and post-market approval FDA surveillance studies.

HRS continues to advocate for collaboration with federal agencies to realize the full potential of meaningful interoperability of data acquired from PM's, ICDs, and CRT devices. We recognize MIPS as an important opportunity to incentivize market use of the IDCO profile. **Use of this and other interoperability profiles should be rewarded under both the ACI and the CPIA components of MIPS.**

Hardship Exemptions

Under the EHR Incentive Program, hospital-based clinicians were exempted from being a meaningful EHR user. Under MIPS, these hardship exemptions would not apply to the ACI performance category. However, CMS instead proposes to assign a weight of zero to the ACI performance category for hospital-based clinicians. Similar to the definition of a hospital-based EP CMS established for the EHR Incentive Program, CMS proposes to define a "hospital-based, MIPS-eligible clinician" as a MIPS-eligible clinician who furnishes 90% or more of his or her covered professional services in inpatient hospital or emergency room settings in the year prior to the performance period.

As noted earlier, HRS supports CMS using its authority to reweight a performance category to zero when hardships exist. However, ***we strongly encourage CMS to reduce the threshold of hospital-based services from 90% to no greater than 75% under MIPS***. We also request that CMS clarify how it intends to treat group practices participating in MIPS as such in regards to satisfying the "hospital-based clinician" definition. Would it evaluate the group as a whole, or each individual within the group? And if the latter, would CMS adopt a process for scoring individuals in a group differently than the overall group?

Alternative Payment Models (APMs)

MACRA allows for two types of APMs, Advanced and MIPS APMS. However, the currently proposed Advanced and MIPS APM models apply to a limited population of physicians. In most cases, specialty physicians have no control over the constructs of Advanced APMs and how they apply to their practices, especially in hospital-based practices. CMS should establish a clear approach to approving Physician-Focused Payment Models (PFPMs). Expanding the opportunity develop and implement PFPMs in a timely manner will offer additional incentives for physicians to develop quality-based care payment models for some of Medicare's most costly medical conditions, and could lead to an even greater reduction in reporting burdens. We look forward to working with the Physician-Focused Technology Advisory Committee as we pursue the

applicability of PFPMs for costly conditions such as atrial fibrillation, and device implantation and management. We encourage CMS to develop transparent guidance on how PFPMs will be assessed. In addition, PFPMs should be eligible to be considered an Advanced APM.

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In conclusion, as CMS considers new mechanism to measure quality, attribute resource use, enhance EHR adoption, and recognize engagement in more innovative CPIAs, we urge the agency to think carefully about the need to balance administrative simplicity with a clinician's freedom to select the measures and level of accountability that he/she feels is most appropriate for his/her practice. The current system places too much emphasis on compliance and reporting simply to avoid penalties. The focus should shift to incentivizing investments in more meaningful activities that make sense to the provider and ultimately improve the care of the patient.

HRS appreciates the opportunity to provide CMS with this input and looks forward to working with the Agency to implement these policies going forward. If you have questions regarding HRS's comments or would like to discuss our initiatives, please contact Kimberley Moore, Director of Reimbursement and Regulatory Affairs at kmoore@hrsonline.org.

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