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October 3, 2016

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS – 5519 - P

Submitted Online

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 30 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments on the Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) proposed rule.

Since 1924, the AHA has dedicated itself to reducing disability and death from cardiovascular disease and stroke—the #1 and #5 leading causes of death in the United States—through research, education, community-based programs, and advocacy. One of our approaches to achieving this mission is to continually raise the bar on quality patient care by advocating for, and creating systems, programs, and partnerships that ensure the effective translation of evidence-based clinical guidelines into standard patient care. We have also convened a number of administrators, clinicians and economists with specific expertise and practical real-world experience to inform and advise the AHA on the impact of new payment methods and trends as potentially powerful levers to support our shared goals of improved health, health care quality, and value. With the benefit of the combined expertise of this panel, we submit these comments for consideration by CMS.

While the Association recognizes and supports the movement towards value-based payment and the role of bundled payments to achieve our ultimate goals for health care, we have several concerns related to the way in which the proposed EPM is structured. We must acknowledge and consider the significant time and resources stakeholders will direct towards this program and it is imperative that it is thoughtfully and carefully designed from the outset so as not to undermine advances in quality improvement and reductions in health disparities that we have achieved through the initiatives of this Association and many others. If we are not careful, the emphasis of providers, hospitals, and systems could shift their attention to ensuring they prevail in the new payment scheme, rather than focusing on improved patient outcomes.

We are concerned that as presently designed, the EPMs will lead to unintended consequences for the most sick and complex patients. We appeal to CMS to strengthen the protections against cherry-picking of healthier patients; incorporate risk adjustment learnings as soon as possible; and adjust the quality measures to more directly encourage high-quality patient care.

At the same time, we were very gratified to see the inclusion of the Cardiac Rehabilitation Incentive Payment Model. While we've made significant progress in the prevention and treatment of cardiovascular disease, the participation gap for cardiac rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) is unacceptable with fewer than 20% of eligible patients participating in these programs.¹ There are a number of reasons why patients choose not to utilize these services and we believe that an episode payment model, combined with incentive payments that encourage the use of CR and ICR for beneficiaries hospitalized for a heart attack or bypass surgery will help hospitals better coordinate cardiac rehabilitation and support beneficiary adherence. Below, the Association offers comments on the specific questions posed by CMS focused on the Physician Supervision Waiver, Determination of the CR Incentive Payment, Beneficiary Engagement Incentives, and Regulatory Impact Analysis sections.

Our comments on both areas follow the ordering of the proposed rule.

Episode Payment Model

C.4.a(5) Special Policies for Hospital Transfer of Beneficiaries With AMI

CMS proposes a system by which an “anchor” hospitalization initiates the episode timeline to include all services related to the hospitalization and 90 days post hospital discharge. The anchor hospital is responsible for the quality and cost of the episode. To support this approach, CMS lays out a series of patient transfer scenarios, identifying the hospital that is held accountable under each. CMS

¹ Boyden T, et al. 2010. Will increasing referral to cardiac rehabilitation improve participation? *Prev Cardiol*;13:198-202.

proposes that for situations when a patient is seen in the emergency department (ED), but not admitted, and then transferred to an EPM-participating hospital, that the transfer hospital be the “anchor.” CMS justifies the design by pointing out the operational complexities of accounting for care when there isn’t an initiating hospitalization to use as an administrative marker.

The Association recognizes these data collection barriers, but is concerned about the patient selection that it could enable. Since the anchor hospital designation occurs when the patient is actually admitted, the model seems to allow for transfers out of the ED and to another hospital to be justified as those to so-called “higher level of care” in order to avoid the financial risks associated with these patients. We encourage CMS to look into ways that the operational concerns could be mitigated or bypassed in order to avoid this potential unintended consequence of unnecessary and medically inappropriate patient transfers.

D.4.b. EPM-Episode Benchmark and Quality-Adjusted Target Price Features

We are also concerned by CMS’ declaration that “no standard risk adjustment approach that is widely accepted throughout the nation exists for the proposed EPM episodes. Thus [CMS is] not proposing to make risk adjustment based on beneficiary-specific demographic characteristics or clinical indicators.” CMS makes this statement soon before proposing that it will use a blended hospital-specific and regional benchmark to determine target prices against which hospitals will be compared for years one through three and starting in year four, to use only regional historical data. We are concerned that the use of solely regional data for benchmarking without any risk adjustment mechanism will create a perverse incentive to hospitals to avoid sicker patients out of concern for the financial penalty that could result from treating them.

As Ellimoottil, et al noted recently in *Health Affairs* after modelling the impact of the joint replacement EPM, an expansion of which CMS also proposes in this notice, “our findings suggest that without sufficient risk adjustment, hospitals will be financially penalized for treating medically complex patient populations.”² While this study examines patients with a different condition in a single state (Michigan), other analysts have modelled the impact of the cardiac model, noting that “one reason these hospitals have higher spending could be that they are treating sicker patients, many of whom lack the necessary support systems to prevent them from bouncing back to the hospital for costly follow-up care.”³ If their hypotheses are correct and CMS moves forward without an episode risk adjuster, the potential loophole generated by the transfer scenario that we highlighted above, would be exacerbated.

² Ellimoottil, C, et al. Medicare’s New Bundled Payment For Joint Replacement May Penalize Hospitals That Treat Medically Complex Patients. *Health Affairs*. 35, No. 9 (2016): 1651-1657.

³ New Cardiac Bundles Could Produce Some Big Winners and Losers. Avalere Health Press Release. August 11, 2016.

In this way, we believe that CMS must either adjust its benchmarking approach or begin to test methods by which it can address this unintended consequence now.

While we certainly recognize and actively monitor the work being done under the IMPACT Act to better understand socio-economic factors in risk adjustment, and note CMS' indication that it will incorporate learnings from this work as it becomes available, we still feel that there is sufficient initial evidence to suggest that CMS must begin to examine this issue and devise adjustments immediately.

E. EPM quality measures, public display, and use of quality measures in the EPM payment methodology

We are also concerned by the metrics that will be used to assess the quality of the care delivered in the EPM episode; we feel they are inadequate and ask that CMS reconsider its approach. First, we feel that CMS relies too heavily on the 30 day-mortality measure to represent outcomes. While we recognize CMS's desire to move to performance-based payment based on outcomes, we feel that there is nuance lost in the heavy use of this measure. We would like to see more emphasis on a few critical process measures that can better serve as a gauge as to whether care coordination and collaborative care were conducted on behalf of patients. Without these, we do not feel that the model will drive the needed improvements in quality and cost for the system.

To this end, data sources such as the Association's Get With the Guidelines registries or the National Cardiovascular Disease Registry should be leveraged to inform a series of measures that more adequately assess quality of care and ensure alignment with clinical guideline-based care. Evaluation of the data contained in these registries, as compared to that which can be derived from administrative claims data and which severely restricts CMS' ability to develop meaningful, common-sense measures, will reveal the process factors related to coordination of care and transitions that should be the basis of evaluating these models. Measuring and tracking elements such as phone calls to families, scheduling of follow-up appointments, reconciliation of medications, and follow up of care will go a long ways to ensuring the delivery of high quality care for patients. The Association's staff and network of expert volunteers stand ready to be partners with CMS in making sure the model is best structured and evaluated to meet both its patient care and health system reform goals.

We are also concerned that there are no patient reported outcomes (PRO) measures used to evaluate the care. While we recognize that there is not a standard measurement set used to determine the clinical outcome of patients with AMI or CABG treatment, as there are for the joint replacement or surgical hip/femur fracture treatment, we suggest CMS consider PRO survey SAQ-7, PHQ-2, and the Rose Dyspnea score to evaluate patient outcomes. We additionally suggest that CMS

use the same quality metric composite score benefit of two points for the inclusion of PRO data.

Cardiac Rehabilitation Incentive Payment Model

VI. C. Physician Supervision Waiver

Under current law, CR and ICR programs must have a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs. There is also a requirement for physician-prescribed exercise, and an individualized treatment plan must be reviewed and signed by a physician every 30 days. A CR/ICR program must also be overseen by a Medical Director.

In the proposed rule, CMS provides a waiver to the definition of a physician to include a non-physician practitioner (a physician assistant, nurse practitioner, or clinical nurse specialist) except that a physician must continue to fill the role of Medical Director. The objective is to provide additional flexibility that may increase the availability of CR and ICR services furnished to episode payment model (EPM-CR) or fee-for-service (FFS-CR) beneficiaries who participate in these programs.

- *CMS is soliciting comments on approaches they may take to monitor this waiver to ensure this program flexibility does not have a negative effect on how beneficiaries receive CR and ICR services, which then may affect the outcome of the beneficiary's care.*

The Association strongly supports the physician supervision waiver included in the proposed rule, and supports two bills currently under consideration by the Congress (HR 3355/S. 488) that would allow physicians assistants, nurse practitioners and clinical nurse specialists to meet the “direct supervision” requirement for cardiac, intensive cardiac and pulmonary rehabilitation programs. We also support allowing non-physician practitioners to prescribe exercise and individual treatment plans but concur that the waiver should not alter the requirement for medical direction of CR programs.

We do not believe the waiver will jeopardize patient care. The safety of CR/ICR in a medically supervised, community-based program is well established.^{4,5} Additionally, NPPs are already utilized in a number of critical care environments, including Critical Access Hospital emergency departments, hospitals and hospital clinics, emergency rooms, intensive care units, recovery rooms, cardiac catheterization

⁴ Chul Kim, Chang Jin Moon, Min Ho Lim. Safety of Monitoring Exercise for Early Hospital-based Cardiac Rehabilitation. *Ann Rehabil Med.* 2012 April; 36(2): 262–267.

⁵ Scheinowitz M, Harpaz D. Safety of cardiac rehabilitation in a medically supervised, community-based program. *Cardiology.* 2005;103(3):111-7. Epub 2005, Jan 19.

laboratories, heart failure and arrhythmia clinics, community clinics, health centers, urgent care centers, walk-in clinics, and many other sites. NPPs are highly trained to respond should emergencies arise. In many if not most cases, the supervising physicians are not involved in patient care in CR/ICR programs but merely available (within the prescribed criteria) to fulfill the Medicare requirement for reimbursement.

We strongly believe that the waiver would be far more effective and have a greater impact on utilization if it were *site* rather than *condition* specific. Unless the waiver was applied to the entire CR site, the program would be required to have a physician immediately available and accessible at all times for beneficiaries with other qualifying cardiovascular conditions (chronic stable angina, stable, chronic heart failure, cardiac transplantation and valvular heart disease). This limitation would make it difficult for programs to expand capacity by extending hours of operation, opening new programs in rural areas (where physicians are not available to provide direct supervision), and would in some cases absorb resources that could be used to augment existing programs.

We also strongly support waiving the physician definition for writing the exercise prescription and to establish, review, and sign individualized treatment plans. Allowing non-physician practitioners to order CR/ICR, as state scope of practice laws generally allow, would help facilitate a timely referral to CR and facilitate coordination between hospital discharge, referral and enrollment into CR/ICR. Extending the proposed flexibility in the prescribing of exercise and establishing, reviewing, and signing an individualized treatment plan will improve program productivity and staff/cost efficiency. It would, however, be far more impactful to apply this flexibility to the CR/ICR program site rather than for specific cardiovascular conditions (AMI and CABG.)

- *CMS is also reviewing other program requirements, such as waiving beneficiary cost-sharing, but did not find clinical data and literature that they believed sufficient to support proposing any additional waivers to the CR/ICR program requirements in this proposed rule.*

Although there is ample anecdotal evidence that copays can be a significant barrier to participation in CR/ICR, these observations are supported by few published studies. That's due in part to the fact that program costs may often preclude participants from enrolling in the first place or becomes a reason for discontinuing CR/ICR (although the reasons may not be disclosed to program staff). One recent study did find that in a multiracial population, low socioeconomic status, lack of insurance, and copayment were independent risk factors of poor adherence to CR after adjusting for race. The study concluded that increased medical insurance coverage and the elimination of copayment may improve CR adherence.⁶ Additional

⁶ Lili Zhang; Maria Sobolev; David Prince; Cynthia Taub Socioeconomic Status, Medical Insurance and Copayment are Associated with Adherence to Cardiac Rehabilitation in a Multi-Racial Population, Poster

research in this area would be extremely helpful in addressing cost as a barrier to participation in CR/ICR.

VI.E Determination of the CR incentive payment

CMS proposes a two-tiered incentive for CR/ICR participants to encourage them to increase clinically appropriate service referrals for beneficiaries, reduce barriers to beneficiary adherence to a CR/ICR service treatment plan by making additional resources available for transportation to and from CR/ICR services, and incentivize CR/ICR participant monitoring and support of beneficiary adherence to all prescribed sessions.

The initial level of the per-service CR incentive amount is \$25 per CR/ICR service for each of up to 11 CR/ICR services paid for by Medicare. For those CR/ICR services in an AMI or CABG model episode or AMI care period or CABG care period that exceed 11, the per-service CR incentive amount increases to \$175 per CR/ICR service for each additional CR/ICR service paid for by Medicare. This higher payment would account for the additional resources that CR participants expend to reduce beneficiary barriers to CR/ICR service utilization and also would reward CR participants for AMI or CABG model episodes or AMI care periods or CABG care periods in which beneficiaries meet or exceed the service utilization benchmark of 12 CR/ICR services.

CMS contends that the higher per-service CR incentive amount would strengthen the financial incentive for CR participants to ensure beneficiary adherence to all prescribed CR/ICR services beyond the initial \$25 per-service CR incentive amount for the first 11 CR/ICR services. Moreover, the higher level of the per-service CR incentive amount when a beneficiary completes at least 12 CR/ICR services provides a strong incentive for CR participants to expand CR referrals and to increase the likelihood that beneficiaries complete a clinically meaningful number of CR services.

The CR incentive payment could offset resource costs incurred by CR participants that successfully increase utilization of CR/ICR services, such as FFS-CR participants providing transportation or participants (EPM-CR) providing beneficiary engagement incentives.

- *CMS seeks comments on the proposed timing for making CR incentive payments.*

The Association contends that the incentive payments are in the right amounts and appropriately tiered for the initial demonstration program. CMS notes that they

expect to revisit the levels of the CR incentive payment and the service utilization benchmark over the CR performance years as they observe the effects of the model policies on CR/ICR service utilization and the long-term outcomes and Medicare expenditures for CR incentive payment model beneficiaries under the EPM-CR and FFS-CR program payment methodologies for overall care. We agree the levels and tiered structure should be reevaluated and adjustments made if they are not sufficiently motivating or if they are unnecessary in the context of an episodic payment model.

Presuming that the 90 day period starts with the qualifying event, there are some concerns that this time frame may not be long enough to fully accommodate some post-surgical patients. However at the same time, the timing of the payments may serve as an incentive to enroll patients as soon as possible and make program adjustments to allow for more active participation during the 90 day time period. It would be incumbent on the CR/ICR programs to implement strategies that would result in immediate referral to get patients enrolled within seven days and removing barriers to more active participation to fully complete the 36 sessions during the 90 day period. If they are unable to enroll and engage patients quickly, the time frame may also need to be extended.

VI.F. 6 Beneficiary engagement incentives

EPM participants may provide beneficiary engagement incentives to improve EPM episode quality and efficiency. These include the provision of beneficiary transportation to CR/ICR services.

CMS proposes to allow FFS-CR participants to provide transportation to CR/ICR services as a beneficiary engagement incentive during AMI care periods and CABG care periods to allow these participants similar use of beneficiary engagement incentives as would be available to EPM-CR participants.

- *CMS seeks comment on proposed provisions for beneficiary engagement incentives for FFS-CR participants and welcomes comment on additional or alternative program integrity safeguards.*
- *CMS also seek comments about beneficiary engagement incentives other than transportation that could advance the CR incentive payment model goals of increased CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI care periods and CABG care periods.*

We concur that transportation issues are a significant barrier to participation but it's not clear how this incentive would be operationalized. Making the programs physically accessible is crucial for patient and program success, however, providing transportation to CR/ICR programs could become very expensive and complicated. For example, what would this look like for a patient coming from a rural area to a city? Would the program pay for gas? What if the beneficiary doesn't have a car and

there is no bus transportation? Would the program pay for a taxi? Our presumption is that each program would devise a solution that works for their patient population. However, if the demonstration program eliminated the direct physician supervision requirement for sites rather than simply for conditions, it would be far easier for programs to expand into rural and less populated areas that would be more accessible to patients and reduce transportation issues.

Based on reports from CR/ICR program staff to the Association, a significant barrier to program participation is beneficiary cost-sharing. Lowering or eliminating copays could have a positive effect on adherence, although as stated earlier, the published evidence is limited. One option would be a tiered co-pay structure for beneficiaries that would provide successive reductions the longer the beneficiary remains in the program. For example, the first six sessions would be a full copay followed by a percentage reduction for the next six and an additional percentage reduction for the remaining sessions. Another option would be to allow programs to offer rebates for program progression/completion. Either way, we strongly recommend that CMS consider a patient financial incentive.

Another beneficiary incentive that could be considered for both the EPM and FFS programs is the utilization of smart technology. A variety of devices can track patients and motivate them when they are not at a CR center. We suggest that perhaps CMS may fund proposals from individual centers that are customized to their center and support innovative methods to increase beneficiary adherence.

IX. Regulatory Impact Analysis

CMS included an economic analysis of the effects of the proposed rule including the impact of the cardiac rehabilitation model. The analysis points out that when CMS actuaries reviewed final action Medicare claims data from January 1, 2012 through December 31, 2015 to identify CR and ICR services that count towards CR incentive payments - and compared total Medicare spending over 3 years post hospital discharge for AMI and CABG for patients that received cardiac rehabilitation services within 90 days of discharge, to patients that did not receive cardiac rehabilitation services within 90 days of discharge – they found that among patients continuously enrolled over 3 years in FFS Medicare Part A and B those receiving cardiac rehabilitation services within 90 days of discharge from an AMI and or CABG hospitalization had lower Medicare spending relative to patients whom did not receive cardiac rehabilitation services post discharge from an AMI and or CABG hospitalization, even after adjusting for differences in age, sex, and case-mix between the two populations.

- *CMS solicits comments on the assumptions and analysis presented.*

It would be very helpful to have the costs and savings disaggregated to show the estimate of savings only from expanding CR/ICR. In addition, we strongly recommend that CMS utilize both outcome metrics (mortality, re-hospitalization

rates, and Medicare expenditures) as well as well-established and evidence-based process metrics (referral to CR, statin use) to test the effects of the CR incentive payment. Certain process may not affect the outcomes measured within the time constraints of the demonstration and may diminish the perceived value of the measures.

Thank you again for the opportunity to review the proposed rule and your consideration of our comments. If you have any questions or need any additional information, please do not hesitate to contact Madeleine Konig, Senior Policy Analyst, at (202) 785-7930 or madeleine.konig@heart.org.

Sincerely,



Steven R. Houser, PhD
President
American Heart Association