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October 3, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Mr. Slavitt:

AMGA welcomes the opportunity to comment on the "Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs): Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care or Joint Replacement Model (CJR); Proposed Rule" (CMS-5519-P)." AMGA, founded in 1950, represents more than 450 multi-specialty medical groups and integrated delivery systems representing about 177,000 physicians who care for one-in-three Americans. Beyond fee-for-service and Medicare Advantage (MA), our member medical groups also participate in the two current bundled payment demonstrations, the Bundled Payment for Care Improvement (BPCI) and the Comprehensive Care for Joint Replacement (CJR), as well as in numerous other CMS demonstrations including the Pioneer and Next Generation Accountable Care Organization (ACO) demonstrations. Therefore, recognizing the mandatory nature of this demonstration, AMGA has a strong interest in how seeing the cardiac, cardiac rehabilitation and expansion of the CJR demo via surgical hip/femur fracture treatment (SHFFT) succeed.

AMGA's comments are organized in order of how these subtopics appear in the proposed rule.

Potential Future Condition-Specific Episode Payment Models

The Centers for Medicare and Medicaid Services (CMS) seeks comment on potential future condition specific episode payment models. These may, CMS states, provide for a "transition from hospital-led EPMs to physician-led accountability for episode quality and costs, especially given the importance of care management over long periods of time for beneficiaries with chronic conditions" CMS is also interested in models that interface "with other CMS models and programs responsible for population health and costs, such as ACOs and Primary Care Medical Homes (PCMHs); and other considerations specific to identifying future models as Advanced APMs." As we explain

below under “EPM Collaborations,” AMGA believes perhaps the best way to deliver “care management over long periods of time” and interface “with other CMS models and programs responsible for population health and costs” is to allow ACOs to take the lead or own episode payment model (EPM) arrangements.

Exclusion of Certain MSAs

CMS proposes to randomly select a total of 98 Metropolitan Statistical Areas (MSAs) out of a total of 294 eligible MSAs. CMS proposes to exclude MSAs based on Acute Myocardial Infarction (AMI) episode criteria only. That is, MSAs with potentially no Coronary Artery Bypass Graft (CABG) surgeries will not be excluded. Per the agency's proposed rule the agency will use three criteria for exclusion. One, CMS will exclude MSAs with fewer than 75 AMI episodes. Two, CMS also will exclude MSAs if there are 75 non-BPCI AMI episodes in the MSAs in the reference year. Three, CMS will also exclude MSAs from selection based on whether the number of non-BPCI AMI episodes calculated under rule two is less than 50 percent of total number of AMI episodes calculated under rule one. AMGA has no objections to the use of these criteria.

When an EPM Episode Would be Canceled

CMS proposes to cancel an EPM episode when the beneficiary dies during the anchor hospitalization. This deviates from the CJR policy which cancels the episode if a death occurs at any time during the episode. CMS proposes this alternative policy to further incent hospitals to actively manage EPM beneficiaries because AMI and CABG patients die at a much higher rate than those with Lower Extremity Joint Replacement (LEJR) episodes. CMS will also cancel an AMI episode when the beneficiary is discharged from a final transfer hospital that could not, itself, initiate an AMI or CABG model episode. CMS will not cancel an AMI episode for a CABG readmission during the 90 day post-hospital discharge period. CMS would cancel an EPM episode when the beneficiary initiates any BPCI model episode. AMGA agrees with these provisions.

Method of Setting EPM Episode Prices and Paying EPM Participants

CMS proposes to set EPM episode prices consistent with the CJR model's methodology. CMS will apply a retrospective payment methodology initially using three years of historical data. CMS will allow for two exceptions: CMS will use only regional pricing for EPM participants with low historic EPM episode volume, which is participants with fewer than 75 AMI DRGs across the three historical years; and, for participants that have merged or otherwise reorganized CMS will, as in the CJR demo, use historical EPM episode payments attributed to their predecessor. In trending historical data to the most recent year, CMS proposes to apply a national trend factor to each of the years of

historical EPM episode payments as the agency does in the CJR demo. Like the CJR demo CMS is again proposing to migrate from historical target pricing to regional pricing. Regional pricing will increase from one-third in performance years one and two to two-thirds in performance year three and to 100 percent regional pricing in performance years four and five. CMS proposes to define a region as one of nine US Census divisions.

Unlike the CJR demo in its current form, CMS is proposing to include both reconciliation payments and Medicare repayments when calculating historical EPM episode benchmark and quality-adjusted target prices because, CMS states, these would “more fully recognize the total resource costs of care under an EPM than would their exclusion.” CMS is also proposing to apply this policy to the CJR demo going forward. Respondents to the CJR proposed rule encouraged the inclusion of these payments in part because demo participants otherwise “would be providing care coordination services that would not be paid directly or accounted for under applicable Medicare FFS payment systems and thus might be funded through reconciliation payments.”

CMS also proposes to prorate payments when a service straddles an EPM episode, apply a high payment episode ceiling and have stop loss and stop gain limits. Participants will avoid downside risk for the initial nine months of the demo or from July 1, 2017 through March 31, 2018.

Concerning adjusting target prices for quality, CMS proposes a discount factor of three percent for acceptable and below acceptable quality performance. The discount will be two percent for good performance and 1.5 percent for excellent performance. The discount would effectively not apply in performance year one and the first quarter of performance year two as there are no repayment responsibilities during this period.

AMGA is in general agreement regarding these price setting specifics. However, AMGA recommends the agency reconsider its proposal to update target prices every performance year using previous years' historical data as this creates the same problem ACO's faced in having to continuously improve upon historical performance. AMGA recommends the agency instead consider or adopt trending forward the initial three year historical data for the full five years of the demo.

AMGA is concerned however about the agency's continuing approach to risk setting. CMS is again proposing to not make risk adjustments based on beneficiary specific demographic characteristics or clinical indicators. This is because, CMS states, “the validity of HCC scores for predicting Medicare expenditures for shorter episodes of care or specifically for the AMI, CABG, and SHFFT model of episodes that we are proposing

has not been determined.” CMS is likely aware of research recently published in the September 2016 issue of Health Affairs by Chandy Ellimoottil and colleagues that found there was “no significant association between reconciliation payments and CMS-HCC risk scores when target prices were set using a hospital's historical spending.” “In contrast,” the authors stated, “we found a significant inverse association between reconciliation payments and CMS-HCC risk scores when target prices were set to a regional benchmark.” “These findings suggest,” the authors concluded, “that risk adjustment is important for bundled payment programs that use regional spending benchmarks, including the CJR program” and “even a modest risk-adjustment model would have important implications for reconciliation payments received by hospitals when target prices are based on regional benchmarks.” Finally, “CMS should strongly consider amending the current CJR target pricing strategy to account for participation hospital's patient populations during the second performance year of the CJR program – the year when hospitals begin to face penalties.” In the final cardiac rule, AMGA encourages the agency to reconsider its risk adjustment policy. For example, AMGA recommends the agency review risk adjustment used by Arkansas, Ohio, and Tennessee in their multi-payer bundled payment programs for LEJR surgeries.

Beneficiary Overlap With Shared Savings Models and Programs

CMS recognizes this issue has been particularly difficult to address or address adequately if possible.

For example, under “EPM Collaborators” discussion in the proposed rule, CMS states, “it would be difficult for CMS at this time to provide standard program or model rules that would fairly distribute savings among different models & programs for overlapping periods of beneficiary care.”

As in the CJR demo, CMS will attribute savings achieved during the EPM episode to the EPM participant and include EPM reconciliation payments for ACO aligned beneficiaries as ACO expenditures. If the EPM beneficiary is also an assigned ACO beneficiary CMS will add to any reconciliation payment the discount dollars when it is paid back in shared savings to a hospital that is also an ACO. If the hospital is not aligned with the ACO, CMS will allow the ACO the windfall benefit (in its reconciled expenditures) from the EPM episode discount. CMS admits by doing so the agency is allowing an unrelated ACO full credit for the Medicare savings achieved during the episode.

Under the cardiac demo CMS will allow EPM beneficiaries who are aligned with a Next Generation ACO and with a Comprehensive ESRD Care initiative to be exempted from the cardiac demo. The agency is not proposing blanket exclusion of all ACO aligned

beneficiaries from the demo since this would exclude a large percentage of fee for service beneficiaries from the demo. That is it would, CMS states, dilute the power of the EPM test and generalizability of EPM findings. Per AMGA's "EPM Collaborations" comment below, ACOs should not be excluded but given the option to participate as an entity that bears financial risk under the AMI, CABG and SHFFT models.

EPM Quality Measures, Public Display, and Use of Quality Measures in the EPM Payment Methodology

Similar to CJR, CMS proposes to use a composite quality scoring methodology that will use relative, not absolute, scoring and include a year-over-year improvement component (at 10 percent). CMS admits the measures are hospital-centric, consequently the agency will work to create a more robust set of episode quality measures for this and future bundled payment demonstrations. CMS proposes to display the demo's quality measure results on the Hospital Compare website.

For AMIs, CMS proposes three required measures and one voluntary measure: a hospital 30-day, all-cause risk standardized mortality rate; excess days in acute care after hospitalization for AMI; the HCAHPS survey; and, a voluntary hybrid hospital 30 day all cause, risk standardized mortality rate following AMI hospitalization.

For CABG, CMS proposes two required measures: hospital 30-day all cause, risk standardized mortality rate following CABG surgery; and, the HCAHPS survey.

For SHFFT, CMS proposes the same as those used for the CJR demo, i.e., two required measures and one measure requiring voluntary data submission: hospital level RSCR following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA); the HCAHPS survey; and, total hip arthroplasty/total knee arthroplasty voluntary patient-reported outcome.

AMGA has several quality measurement comments. More specifically, HCAHPS results are of the entire hospital's population, that is they do not accurately or truly reflect the experience of the demo's population. AMGA recommends CMS develop a separate or more targeted survey. It is unclear how the AMI excess days after discharge measure accurately reflects quality since it is unclear whether more or fewer days is the better indicator of care quality. Raising the 50 percent of qualifying admissions to 90 percent between performance year one and two under the voluntary hybrid AMI mortality measure may be too aggressive. CMS notes the only quality measure specific to SHFFT would be the HCAHPS measure and again the HCAHPS covers the hospitals entire

population. For this reason AMGA questions whether SHFFT should be included in the CJR demo at this time.

More generally, AMGA has six comments. CMS should more clearly or exactly define how the agency will differentiate quality performance in assigning quality discount percentages. It appears differentiating observed versus expected performance that is statistically significant is problematic since, for example, over 95 percent of hospital's AMI and CABG mortality rates are statistically the same as the national average. Related to our risk adjustment comment above, CMS should apply a socio-demographic variable to quality measurement. Per our related evaluation comment below, we encourage CMS to develop measures that correlate quality with spending efficiency. AMGA encourages CMS work to quickly identify measures that can productively assess post-hospital discharge quality of (post-acute) care under this demonstration that include patient surveys. AMGA recommends further this demo include BPCI's emergency department use without hospitalization measure. Concerning quality measurement data collection more generally, the IMPACT Act requires standardized patient assessment data across post acute providers. As CMS develops post-acute measures via these 90 day bundled payment episodes, the agency should work toward IMPACT measure alignment or synchronization.

EPM Collaborations

CMS proposes to expand the list of cardiac care collaborators beyond those identified in the CJR demo. CMS proposes add other hospitals including Critical Access Hospitals (CAHs) and ACOs. Concerning ACOs specifically, CMS notes, “we believe it is especially important to further encourage collaborative partnerships between accountable care organizations and EPM participants that maximize their organizational efficiency and effectiveness, given their shared goals.” CMS admits however that the agency is still struggling with “attributing savings and changes in quality of care for beneficiaries simultaneously in the EPMs and the total cost of care models or programs such as accountable care organizations, remain under consideration without full resolution.” Therefore, the agency states further, “it would be difficult for CMS at this time to provide standard program or model rules that would fairly distribute savings among different models and programs for overlapping periods of beneficiary care.”

Because the agency is desirous to:

- improve collaboration between EPM participating hospitals and ACOs;
- better address or resolve “attributing savings” or accounting for overlap that would “fairly distribute savings among different models and programs for overlapping periods of beneficiary care;”



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- see more ACOs succeed under shared savings (since, CMS admits, reductions in post-acute utilization is a significant source of ACO savings)
- incrementally progress ACOs to risk sharing arrangements;
- mitigate the likelihood participating hospitals will not gain share, per evidence from the ACE demonstration;
- mitigate hospital financial risk exposure under this cardiac and the CJR mandatory demo;
- allow ACOs to simultaneously participate in other pay for performance demonstrations as in the CPC+ demonstration; and,
- reduce ACO unstable assignment, systemic silo-ed or fragmented care; unwarranted variation under Medicare and EPM hospital care stinting that would negatively impact ACO financial benchmark performance,

for these reasons and others, CMS should allow willing Track 1, 2 and 3 ACOs, or those that are not also a participating hospital in this, or the CJR demo, to participate in the cardiac and CJR demonstrations. This would mean the ACO would be the entity held accountable for Part A and Part B spending during the 90-day EPM and that the ACO could collaborate and gain share with an acute hospital and post-acute providers.

Among other EPM collaborative issues, CMS states sharing arrangements should not be based on volume or value of past or anticipated referrals, not pose a risk to beneficiaries access, freedom of choice or quality of care. CMS also proposes ACOs must have been “clinically involved in the care of the EPM beneficiary during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment.” AMGA agrees with these proposed provisions.

EPM Collaborators and Sharing Arrangements Under the APM

CMS outlines in substantial detail provisions by which participating hospitals can share savings with collaborators or share EPM reconciliation payments, the EPM participants' internal cost savings and if there are episode moneys owed CMS, the EPM repayment amount. Moneys paid to an EPM collaborator CMS proposes to term a “gain sharing payment” and repayments made by a collaborator to an EPM participant would be termed an “alignment payment.” Unlike the CJR demonstration, CMS proposes to expand the list of EPM collaborators to include hospitals, CAHs, ACOs and Physician Group Practices (PGPs). AMGA also agrees the ACO and PGP, as CMS states, must have contributed to EPM activities. AMGA also supports the proposal that the EPM participant would receive no more than 50 percent in alignment payments, in the aggregate, from its EPM collaborators and specifically no more than 50 percent of the aggregate payment amount from an ACO.

Beneficiary Engagement Incentives Under the EPM and Technology Provided to an EPM Beneficiary

CMS proposes to allow providers to incent beneficiaries via items or services “reasonably connected to medical care provided to an EPM beneficiary during the EPM episode.” These could be post-surgical or cardiac monitoring equipment but not technology that is broadly used such as a smart phone. Also, these incentives cannot be advertised or promoted and costs thereof cannot be shifted to another Medicare program. More specifically, CMS also proposes to allow providers to make available technology-related items or services that do not exceed \$1,000 in value to beneficiaries to help advance a clinical goal of the EPM. CMS also proposes for technology items more than \$100 in retail value be retrieved or that a good faith effort is made to retrieve the item from the EPM beneficiary at the end of the EPM episode. Incentives should support adherence to drug regimens, care plans, reduction in readmissions and complications, and the management of chronic diseases and conditions that may be affected by treatment for the EPM clinical condition. AMGA strongly supports the use of limited incentives.

Proposed Waivers of Medicare Program Requirements

As CMS notes, the proposed quality measures for this demo are the same or similar to the CJR demo. CMS proposes to: waive the direct supervision requirement for certain post discharge home visits; waive the telehealth geographic site requirement; waive certain deductible and coinsurance statutory requirements; and, waive the Skilled Nursing Facility (SNFs) three-day rule beginning April 1, 2018. Specifically for the post discharge home visits waiver, CMS proposes to allow for 13 home visits under AMI care, and up to nine visits for CABG follow-up and SHFFT care. For SNFs to be eligible to participate under the waiver, they must have a three star rating for at least seven of the 12 months based on rolling 12 months of overall star rating. AMGA supports all proposed waivers.

Evaluation Approach

This demonstration is intended, CMS states, “to better understand the effects of episode payments approaches on a broader range of Medicare providers and suppliers than would choose to participate in a voluntary model such as is currently being tested under BPCI.” AMGA recommends this demo be thoroughly and exhaustively evaluated.

CMS proposes to use “a range of analytic methods” including regression and other multivariate methods, difference in difference methods and others. CMS states the agency will take into account the effects of other ongoing interventions such as BPCI, Pioneer ACOs, and the Medicare Shared Savings Program (MSSP). The proposed rule

states key questions CMS intends to answer concern patient experience of care, utilization, outcomes, Medicare expenditures, quality and access. CMS further intends to make known evaluative findings incrementally or annually.

AMGA strongly encourages CMS to include in its evaluation the following issues.

1. The extent to which this demo and the CJR demo cause providers to stint on care. Specifically, the extent to which participating hospitals are matching, or not, SHFFT device selection with lifestyle needs, frequently termed demand matching, particularly since less expensive implants, that hospitals are now incented to buy, typically have lower utility. Are demo hospitals purchasing exclusively, or almost exclusively, less expensive and lower utility implants irrespective of patient needs. We are also concerned utilization rates for arterial procedures may inappropriately shift or increase to lower cost options when not appropriate. One way to address this would be to require participating hospitals to make publicly available on Hospital Compare whether and how participating hospitals are gain sharing with their surgeons.
2. Proper implant selection would be better guaranteed if this demo, along with the CJR demo, included patient shared-decision making criteria and the evaluation thereof. This is, or would be, particularly important since beneficiaries have limited or no choice than to use this demo's, or the CJR demo's, participating hospitals.
3. Further, to avoid care stinting by delaying care beyond the 90 day EPM episode, CMS should examine the prevalence of this behavior in its evaluation.
4. To be successful under this demo, along with the CJR and BPCI demos, as well as under the MSSP requires clinical practice redesign or innovation. Unfortunately, how hospitals, post-acute providers and physician practices redesign care or innovate is not made known. This evaluation should evaluate and make publicly known how hospitals, post-acute providers and physician practices are innovating under this, and CJR, demo.
5. The evaluation should measure the effect this demo, and the CJR demo, have on ACO performance, moreover the extent to which these bundled payment episodes compromise ACO earned shared savings success.
6. Evaluate unwarranted regional variation. As the recent summary of The Lewin Group's year two evaluation of the BPCI demo published in JAMA (online on September 19) showed, hospitals participating in the bundled payment program slightly increased the number of joint replacement episodes while episodes slightly dipped at the hospitals in the control group and there appeared to be a shift toward healthier patients in the BPCI hospitals than in the comparison group. As was noted in numerous CJR comment letters last year, bundled

payments may do nothing to address the current volume-based problem, or as Elliott Fisher recently warned in a September 27 [JAMA](#) editorial, may be simply shifting Medicare from fee-for-service to fee-for-bundles.

7. AMGA encourages CMS to evaluate the frequency of, and reasons for, re-hospitalizations and similar questions related to drug utilization, hospital and post-acute infections and CR/ICR utilization. CMS admits currently quality measures for this, and the CJR demo, are substantially lacking. As noted above AMGA encourages including in the evaluation scope the development of new measures particularly outcomes measures related to spending efficiency or measures that correlate outcomes over spending. In addition, with the recent announcement by the ASC X12 committee to include reporting the (unique) device identifier (UDI) at the claim level for hospitals (and other institutions) for safety reasons, CMS should at least encourage hospitals to track this information particularly since IMPAQ concluded in its 2013 evaluation of the Acute Care Episode (ACE) demonstration that, “vendor negotiations on surgical implants, equipment, and materials in both orthopedic and cardiovascular DRGs produced the greatest cost savings for the ACE sites.”
8. Per our risk adjustment comment above concerning recent findings by Chandy Ellimoottil, et al., AMGA encourages CMS to examine historical versus regional price performance with and without accounting for patient specific risk scores.
9. Lastly, it would be of substantial interest to the provider community to learn how reconciliation and gain sharing payments were used by participating hospitals and EPM collaborators and, if possible, how hospitals budgeted for Medicare repayment moneys.

Cardiac Rehabilitation Incentive Payment Model

AMGA enthusiastically supports including cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) in the proposed demonstration. As CMS recognizes CR and ICR are woefully under-utilized. Only 35 percent of AMI patients receive this indicated treatment, a pattern that has not improved over the past two decades. Among AMI and CABG patients who receive services only 50 and 60 percent receive 25 or more sessions respectively.

CMS proposes to identify two sets of MSAs for participation. The CR/ICR demo will run for the same time period or through 2021. CMS will incent CR/ICR care by providing a \$25 incentive payment for the first 11 CR/ICR services and \$175 for each additional session. CMS will not cap the number of CR/ICR sessions. Incentive payments will be made on a retrospective basis, occur concurrently with EPM reconciliation payments. These funds could be used to offset resource costs to increase utilization, such as



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providing transportation or beneficiary engagement incentives. Moneys will be accounted for separately and distinct from reconciliation payments and Medicare repayments, will not be permitted in sharing arrangements for EPM-CR participants and will be excluded when updating quality-adjusted target prices in years three through five. CMS will select 45 MSAs from the larger pool of 98 cardiac demo MSAs and another 45 MSAs as a comparison group that are not participating in the cardiac demo. These are identified as EPM-CR hospitals and FFS-CR hospitals. AMGA supports all these proposed CR/ICR demo provisions.

Thank you for your consideration of our comments. If you have any questions please do not hesitate to contact David Introcaso, Ph.D., Senior Director of Regulatory and Public Policy, at dintrocaso@amga.org or at 703.842.0774.

Sincerely,

Donald W. Fisher, Ph.D.