January 16, 2018

Ms. Seema Verma

Administrator

Centers for Medicare and Medicaid Services

7500 Security Boulevard

Baltimore, Maryland 21244-1850

Dear Ms. Verma:

We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS') “Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” (CMS-4182-P) published on November 29, 2017 in the Federal Register.

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. Our member medical groups widely participate in the Medicare Advantage (MA) program, under contract with MA plans and via their own sponsored MA plan offerings, and equally in the Medicare Access and CHIP Reauthorization Act's (MACRA's) Advanced Payment Model (APM) pathway, including the Medicare Shared Savings Program (MSSP) or Accountable Care Organizations (ACOs). AMGA is equally invested in the success of both these programs.

What follows are five comments in order in which the topics appear in the proposed rule. These bullets summarize our principal comments.

* AMGA is concerned about the changes to the MA uniformity requirements will have on the Medicare program more broadly. The proposed change will exacerbate the existing lack of synchronization between Part B and Part C of the Medicare program.
* CMS should maintain a quantifiable meaningful different standard for MA plan bid submissions and review, in part, because CMS provides no evidence that the current meaningful differences evaluation is undermining MA plan innovation.
* AMGA supports CMS’ proposal to address “cross walking” of MA beneficiaries into higher star-rated plans and recommends the proposal be revised to account for geographic variation.
* CMS should explain how it intends to incorporate patient-reported outcome measures into the star rating program. CMS also should align measures among Medicare payment programs.
* AMGA supports CMS’ proposal to provide Part D plan sponsors with the flexibility to implement generic substitutions for therapeutically equivalent brand name prescription drugs.

Flexibility in the Medicare Advantage Uniformity Requirements (FR 56360-61) and Segment Benefits Flexibility (FR 56361)

CMS is “considering issuing guidance clarifying the flexibility MA plans have to offer targeted supplemental benefits for their most medically vulnerable enrollees.” CMS states further, “we believe this flexibility will help MA plans better manage health care services for the most vulnerable enrollees.” For example, CMS notes, reduced “cost sharing flexibility would allow an MA plan to offer diabetic enrollees zero cost sharing for endocrinologist visits. Similarly, with this flexibility, a MA plan may offer diabetic enrollees more frequent foot exams as a tailored, supplemental benefit. In addition, with this flexibility, a MA plan may offer diabetic enrollees a lower deductible.” “Under this example,” CMS states further, “non-diabetic enrollees would not have access to these diabetic-specific tailored cost-sharing or supplemental benefits; however, any enrollee that develops diabetes would then have access to these benefits.” The benefit and cost sharing would apply to Part C, not Part D, benefits. CMS notes flexibility in benefit design is currently being tested under the agency's MA Value-Based Insurance Design (VBID) demonstration. In the discussion immediately following “Flexibility in the Medicare Advantage Uniformity Requirements,” titled “Segment Benefits Flexibility,” CMS is similarly proposing, “to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area.”

AMGA strongly supports the idea of VBID. We have written repeatedly in our comment letters that CMS both improve benefit design to drive value, or outcomes achieved relative to spending, and measure for value or correlate quality and cost performance. Absent such a correlation CMS sacrifices quality for cost efficiency. Currently, both the MSSP and the Hospital Value-Based Purchasing Program (VBP) provide financial rewards to comparatively more spending efficient providers whom also have comparatively lower quality measurement scores.

This point aside, MA beneficiaries that are the most medically vulnerable should receive care that presents comparatively fewer price or out-of-pocket barriers and should enjoy access to appropriate supplemental benefits. We have noted repeatedly in letters to CMS over the past two years that access to supplemental benefits is particularly important for Medicare beneficiaries with any number of chronic conditions combined with functional status limitations because this population of Medicare beneficiaries disproportionately drive Medicare spending. As Harriet Komisar and Judy Feder noted in a related 2011 Georgetown report 15 percent of Medicare enrollees who have chronic conditions and functional limitations account for 32 percent of Medicare spending while the 48 percent of enrollees with three or more chronic conditions and no functional limitations drive 51 percent of spending.1

Our concern with this proposed policy is the effect it has on the Medicare program more broadly. CMS cannot make a change to Part C without it having an effect, unintended or not, on Part B. As we argued in a December 2015 and June 2017 Health Affairs blog post and more recently in a THCB (The Health Care Blog) post, CMS should work towards, using MedPAC's word “synthesizing” Part C with Part B or the agency's Alternative Payment Models (APMs), specifically the MSSP or ACOs. 2 If CMS finalizes this proposed Part C policy change it ought to provide commensurate uniformity flexibility for providers and beneficiaries participating in Part B APMs. As discussed below, CMS via a recently published Request for Information (RFI), desires to increase competition across all health care markets. Making commensurate changes under Part B, or leveling the playing field between Part B and Part C, would present at least six opportunities or advantages. If MA plans had to compete against ACOs, that is if they were designed as comparable programs (currently they are not), they would be more motivated to financially incent their providers. MA providers would then have the opportunity to participate under MACRA as an advanced APM. For Part B, more benefit flexibility would improve chances for ACO participant success. More ACOs earning more shared savings means greater participation and more willingness to take on advanced APM contracts. Assuming CMS continues to make Medicare benefit design and pricing more transparent, competition between Part C and Part B would mean beneficiaries would have more choice and leverage which would translate to decreased premium costs. In sum, Medicare would, finally, become a synergistic, coherent program or one greater than the sum of its parts.

Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (FR 56363-365)

Under current law or as the proposed states, “MA plans may submit bids for multiple plans in the same area under the same contract only if those plans are substantially different from another based on CMS' annual meaningful difference evaluation standards.” However, CMS is proposing “to eliminate this meaningful difference requirement beginning with MA bid submissions for contract year (CY) 2019.” “This proposal,” CMS states, “aims to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation.” CMS argues further the current standard meaningful difference evaluation methodology is currently not sufficiently sensitive to account for certain plan designs. For example, CMS notes, plans that are able to “tier the cost sharing for contracted providers.” “These flexibilities,” CMS states, “allow MA organizations to provide beneficiaries with access to health care benefits that are tailored to individual needs, but make it difficult for CMS to objectively measure meaningful differences between plans.” Consequently, CMS is concerned this “could lead to MA organizations to focus on CMS standards, rather than beneficiary needs, when designing benefit packages,” “The current meaningful difference methodology,” CMS states further, “may force MA organizations to design benefit packages to meet CMS standards rather than beneficiary needs.”

AMGA has at least three concerns regarding this policy change.

First, CMS recognizes beneficiaries already have substantial choice in plan selection. In 2017, the agency states the average number of plans per county was 18. Because of a large number of plan choices and because a substantial percent of Medicare beneficiaries suffer cognitive impairment, per the Kaiser Family Foundation in 2013 over one-third, or 34 percent, had a cognitive or mental impairment, CMS recognizes, “consumers, especially elderly consumers,” CMS states, “may be challenged by a large number of plan choices that may: (1) Result in not making a choice, (2) create a bias to not change plans, and (3) impact MA enrollment growth.” Because of this current reality only a small percentage of MA beneficiaries voluntarily change plans year-over-year. MedPAC estimates approximately 10 percent of MA beneficiaries change plans annually. This compares, for example, to 49 percent of those who switched Affordable Care Act (ACA) marketplace plans between 2014 and 2015 after being re-enrolleed.3

Second, CMS details at some length the limitations of the current meaningful differences evaluation methodology. However, the agency makes no effort at proposing how the methodology could be improved to recognize or account for, as CMS notes, tiered cost sharing, Provider Specific Plans, and the agency's proposal to reinterpret MA uniformity requirements. Improving the meaningful differences evaluation methodology is certainly not an impossible task, or likely no more difficult than the agency's stated commitment to “taking steps to improve information available through MPF [Medicare Plan Finder] and 1-800-MEDICARE to help beneficiaries, caregivers, and family members make informed plan choices.”

Third, though the agency states it “is concerned” the current meaningful differences evaluation may be undermining plan innovation, it presents no evidence that it, in fact, does so. Instead, CMS states “the current meaningful differences methodology **may** force MA organizations to design benefit packages to meet CMS standards,” “CMS **is concerned** that benefits **may** be decreased or cost sharing increased to satisfy the meaningful differences evaluation,” “CMS **expects** that elimination the meaningful differences requirement will improve plan options,” “CMS **does not believe** the number of similar plan options offered by the same MA organization in each county will necessary increase significantly,” “CMS **does not expect** a significant increase in time spent in bid review as a direct result of eliminating meaningful differences,” “new flexibilities in benefit design **may allow** MA organizations to address different beneficiary needs,” and “MA organizations **may be able to** offer a portfolio of plan options with clear difference between benefits, providers, and premiums.”

Because a substantial percent of beneficiaries already have inherent difficulty in making an informed plan selection, because plan offerings are already numerous, because it is reasonable to assume CMS could improve its evaluative methodology (CMS is simply asserting this task should be abandoned because it cannot be improved), and because the agency presents no evidence the proposed change will not result in unintended negative consequences, i.e., more plan choices will effectively paralyze beneficiaries from making a plan choice that is best for them, we are unconvinced this change will result in beneficiaries having “access to innovative plans that meet their unique needs.” AMGA essentially agrees with MedPAC's position that CMS maintain a quantifiable meaningful difference standard for plan bids but allow plans to seek waivers by providing alternative evidence of meaningful differences. For example, if a plan failed to meet the evaluative standard the plan sponsor would have the opportunity to present evidence that beneficiaries would be able to distinguish between the sponsor's offerings.

Contract Consolidations (FR 56380-382)

In citing MedPAC's March 2016 report, CMS recognizes the problem, that MedPAC terms, “cross walking.” As the proposed states, “there has been an increase in the number of enrollees being moved from lower Star Rating contracts that do not receive a QBP [Quality Bonus Payment] to higher Star Rating contracts that do receive a QBP as part of contract consolidations, which increases the size of the QBPs that are made to the MAOs [Medicare Advantage Organizations] due to the large enrollment increase in the higher rated, surviving contract.” CMS proposes to remedy this type of QBP gaming by proposing, “to assign and display on Medicare Plan Finder Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation.” CMS proposes to do this for the first and second plan years following the contract consolidations.” “We believe,” CMS states, “the use of enrollment-weighted means will provide a more accurate snapshot of the performance of the underlying plans in the new consolidated contact, such that both information to beneficiaries and QBPs are not somehow inaccurate or misleading.” Phrased another way, CMS is “worried that this practice results in masking low quality plans under higher rated surviving contracts.” “This,” CMS states, “does not provide beneficiaries with accurate and reliable information for enrollment decisions and it does not truly reward higher quality contracts.”

AMGA applauds the agency's proposal to address this problem. As MedPAC notes in its January 3 comment letter, “at the end of 2017, 1.4 million beneficiaries in consumed contracts will be moved from contracts below four stars to a contract in a bonus status.” AMGA is concerned however that the proposed remedy is flawed in that it still would not account for geographic variation. In its January 3 letter, MedPAC also noted, “the [proposed] average method would only give an accurate picture of quality in a given geographic area if the two or more contracts involved in a given consolidation shared exactly the same service area.” At the end of 2017, MedPAC found that of 17 contract consolidations “in which a contract below 4 stars was consumed by a contract at or above 4 stars,” “in only one case was there any overlap of service areas.” Therefore, proposing to average star ratings would not correct for this problem, that is provide accurate information for a specific geographic areas. Per MedPAC, in 2017 there were 30 MA HMO plans that included 10 or more MSAs, 35 PPO plans with 10 or more MSAs and in 2018 one MA contract will cover care in over 35 states. In addition, current policy would still incent contract consolidation, for example, a 4.5 star plan combining with a 3.5 star plan.

AMGA supports policy reform that would report quality at the local market or at the plan level, not the contract level. Among other things, this approach would align with the agency's interest, per its recent RFI,“Promoting Healthcare Choice and Competition Across the US, in reducing “barriers to choice and competition” and improving “access to and the quality of information that Americans need to make informed healthcare decisions.” Specifically, this approach would allow beneficiaries to evaluate MA versus ACO or other appropriate APM coverage. To this end, we encourage CMS to consider carefully MedPAC's two related recommendations made at its recent January 11 meeting.

Adding, Updating and Removing Measures and Measure Set for Performance Periods Beginning on or After January 1, 2019) (FR 56382-393)

CMS requests comment “regarding the processes to add, update and remove Star Ratings [quality] measures.” We have three inter-related comments.

First, CMS states “For the 2021 Star Ratings, we propose . . . to have measures that encompass . . . patient/consumer experience . . . measures.” We are pleased to see CMS recognizes the importance of patient-reported outcome measures (PROMs) within the MA program. We assume this reflects, in part, the agency's effort to submit an increasing number of PROMs to the National Qualify Forums (NQFs) Measures Applications Partnership (MAP). AMGA is a participant in the annual MAP process. CMS is well aware PROMs or patient-reported outcome performance measures (PRO-PMs) are a “high priority” of the NQF Measure Incubator. In 2015-2016, 11 of 71 measures under MAP consideration were patient-reported. This year's MAP process is considering 32 measures, seven of which are PROMs. However, beyond this one mention of PROMs CMS provides no discussion of how it intends to evolve the MA quality measures set to include PROMs or more specifically when it will introduce a PROM into the measures. None of the Part C and Part D quality measures identified in Table 2 and Table 2B that CMS is proposing for the performance period beginning January 1, 2019 and for 2021 Part C and D Star Ratings are PROMs. We encourage CMS in the final 2019 MA rule to, at minimum, explain how and over what timeframe the agency intends to integrate PROMs into the MA quality Star program.

Second, per our argument under uniformity requirements that Medicare programs should be synthesized or aligned, in part, such that they can compete, the NQF MAP has recently supported two PROM measures under the MACRA Merit-based Incentive Payment System (MIPS). These are: average change in functional status following lumbar spine fusion surgery (MUC17-168); and, average change in functional status following total knee replacement surgery (MUC17-169). The MAP has also conditionally supported three related patient reported measures: functional status following lumbar discectomy laminotomy surgery (MUC17-170); average change in pain following lumbar spinal fusion surgery (MUC17-177); and, the international prostate symptom score change 6-12 months after diagnosis of benign prostatic hyperplasia (MUC17-239). We encourage CMS to work toward aligning measures between and among Medicare payment programs. CMS is well aware disparate quality measurement reporting places a substantial burden on providers that also undermines overall provider performance, makes it impossible for beneficiaries to make informed benefit choices and as noted above undermines the agency's interest in increasing competition that, again, would lower beneficiary premium costs and overall Medicare spending.

CMS states “we will continue to analyze measures to determine if measures scores are “topped out.” CMS is its most recent MACRA final rule outlined a policy to retire topped out measures. Again, in order to synchronize or make comparable Medicare program offerings, we encourage CMS to use the same topped out measure retirement protocol across all payment models.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (FR 56413-416)

CMS is proposing to “permit Part D sponsors meeting all requirements to immediately remove brand name drugs (or to make changes to their preferred or tiered cost-sharing status), when those Part D sponsors replace the brand name drugs with (or add to their formularies) therapeutically equivalent newly approved generics – rather than having to wait until the direct notice and formulary change request requirements have been met.” Generic substitutions therefore could be made “at any time of the year,” CMS states, “rather than wait for them to take effect 2 months after the start of the play year.”

AMGA strongly supports the proposed change to provide Part D sponsors with more flexibility to implement generic substitutions.

Thank you for your consideration of AMGA's 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](mailto:dintrocaso@amga.org) or at 703.842.0774.

Sincerely,



Jerry Penso, M.D., M.B.A.

President and Chief Executive Officer

AMGA

**Notes**

1. Harriet Komisar and Judy Feder's “Transforming Care for Medicare Beneficiaries with Chronic Conditions and Long-Term Care Needs: Coordinating Care Across All Services,” (Georgetown: 2011) at: “<http://www.thescanfoundation.org/sites/default/files/Georgetown_Trnsfrming_Care.pdf>.”

2. David Introcaso, “Synchronizing Medicare Advantage and ACOs,” Health Affairs Blog (December 28, 2015) at: <https://www.healthaffairs.org/do/10.1377/hblog20151228.052406/full/>, David Introcaso, “Medicare's Programs Should Compete,” Health Affairs Blog (June 15, 2017) at: <https://www.healthaffairs.org/do/10.1377/hblog20170615.060627/full/>, and David Introcaso and Scott Hines, “Fixing MACRA Should Mean Fixing the APM Pathway,” THCB (December 18, 2017) at:

<http://thehealthcareblog.com/blog/2017/12/18/fixing-macra-should-mean-fixing-the-apm-pathway/>. See also MedPAC's 2014 Report to the Congress, specifically chapters one through three. At: <http://www.medpac.gov/docs/default-source/reports/jun14_entirereport.pdf?sfvrsn=0>.

3. Paul Shafer and Stacie Dusetzina, “Looking Ahead to 2018: Will a Shorter Open Enrollment Period Reduce Adverse Selection in Exchange Plans,” Health Affairs Blog (April 14, 2017) at: <https://www.healthaffairs.org/do/10.1377/hblog20170414.059663/full/>.