

October 15, 2018

Seema Verma, Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1701-P P.O. Box 8016 Baltimore, MD 21244-8016

Dear Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the proposed rule titled, "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success" published by the Centers for Medicare & Medicaid Services (CMS) in the August, 17, 2018 Federal Register.

The AAFP welcomes and appreciates the continued opportunity to work with CMS to identify and implement policies that improve the Medicare program. We believe that the movement to value-based care and payment is critical to improving quality and outcomes for Medicare beneficiaries, as well as to reduce costs for the program. This is especially critical given the 2018 Medicare Trustees report, which projects that the Hospital Insurance (HI) Trust Fund will be depleted in 2026—three years earlier than in the previous year's report. The AAFP believes that a commitment and investment in physician-led models that support advanced primary care practices are necessary to strengthen the long-term solvency of the Medicare program and to deliver patient-centered care to beneficiaries.

Our members offer a unique and important perspective as family physicians. They provide care in more than 90 percent of U.S. counties working in diverse settings as employed physicians, in large practices, and as owners of small independent practices. Family physicians participate in the Medicare Shared Savings Program (MSSP) accountable care organizations (ACOs) providing preventive and wellness services, chronic disease management, and leading care teams that also offer linkages to services that address the social determinants of health, which research has shown affect health outcomes. We are committed to working with CMS to further develop and implement physician-led, primary care focused models that increase participation in value-based care and payment models.

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¹ The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. (2018). 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.

AAFP Member Commitment to Value-Based Care and Payment

The AAFP has been committed to the transition away from fee-for-service (FFS) to value-based payment, which aligns with and supports CMS' shared goal of the delivery of high-quality, efficient, patient-centered care. Our annual surveys indicate that among our members:

- 41% are in Patient-Centered Medical Homes (PCMHs),
- 54% are in value-based payment models or contracts,
- 38% of CPC+ participants are AAFP members
- Of physicians in an ACO (and knowledgeable of the type), more than half are in the Medicare Shared Savings program (55%)

The AAFP has been working the past two years to develop the Advanced Primary Care Alternative Payment Model (APC-APM), a next generation, advanced primary care model that would empower family physicians—especially those in small, independent practices—to move away from FFS payment systems and in to population-based, predictable revenue streams that support comprehensive, longitudinal, and high-quality primary care. The AAFP has appreciated CMS and the Innovation Center's engagement on moving this model forward.

MSSP ACO Program Important APM Opportunity for Family Physicians

ACO success is related to at least two factors—being physician-led and having a strong primary care foundation. A September 2018 <u>New England Journal of Medicine</u> article found that physician-led ACOs generated savings that increased over a three-year study period compared to hospital-led ACOs.² In addition, a review by the <u>Patient-Centered Primary Care Collaborative (PCPCC)</u> found that Medicare ACOs with primary care physicians practicing in PCMH models were more likely to generate savings and demonstrated higher quality scores on a significant number of both process and outcome measures.³

These findings show that CMS should advance policies that encourage the formation of ACOs that are physician-led; can sustain participation across risk-bearing tracks; and support primary care transformation to generate greater savings for Medicare and improve quality for beneficiaries.

The AAFP believes that the MSSP ACO program is an important opportunity for family physicians to participate in APMs. The recommendations we offer are based on our members' experiences participating in ACOs and primary care transformation.

II.A.3.b(2) – Levels of Risk and Reward in the BASIC Track's Glide Path Summary

CMS proposes the BASIC track's glide path will have an incremental approach to higher levels of risk and potential reward. The glide path has five levels. Levels A and B, which do not have downside risk, and Levels C-E, which have progressively higher levels of upside and downside risk. ACOs would be automatically advanced at the start of each participation year. The maximum allowed time in Levels A-D would be one performance year. Once ACOs reach Level

² McWilliams J, Hatfield L, Landon B, Hamed P, Chernew ME. Medicare spending after 3 years of the Medicare Shared Savings Program. *N Engl J Med.* 2018;379:1139-1149.

³ Jabbarpour Y, Coffman M, Habib A, et al. Advanced primary care: a key contributor to successful ACOs. Patient-Centered Primary Care Collaborative. Robert Graham Center. 2018. https://www.pcpcc.org/sites/default/files/resources/PCPCC%202018%20Evidence%20Report.pdf. Accessed October 8, 2018.

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E, ACOs would be required to remain in that level for all subsequent years of participation in the BASIC track, which includes all years of a subsequent agreement period in the BASIC track.

Participation the BASIC track will depend on an ACO's experience with the MSSP.

CMS proposes that the BASIC track's highest level (Level E) may be elected for any performance year by ACOs in the glide path but will be required no later than the ACO's fifth performance year in the glide path.

Level A and Level B: A final sharing rate not to exceed 25 percent based on quality performance would apply to the first dollar shared savings for ACOs that meet or exceed their minimum savings rate (MSR). This is half of the maximum shared savings rate available under Track 1. Savings would be shared at this rate not to exceed 10 percent of the ACO's updated benchmark.

Level C: A final sharing rate not to exceed 30 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark.

A loss sharing rate of 30 percent regardless of the quality performance would apply to the first dollar shared losses for ACOs with losses meeting or exceeding their minimum loss rate (MLR), not to exceed two percent of total Medicare Parts A and B revenue for ACO participants. If the loss sharing limit as a percentage of total Medicare Parts A and B FFS revenue for ACO participants exceeds the amount that is one percent of the ACO's updated benchmark, then the loss sharing limit would be capped at one percent of the ACO's updated historical benchmark for the applicable performance year.

Level D: A final sharing rate not to exceed 40 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark.

A loss sharing rate of 30 percent, regardless of the quality performance would apply to the first dollar shared losses for ACOs with losses meeting or exceeding their MLR, not to exceed four percent of total Medicare Parts A and B revenue for ACO participants. If the loss sharing limit as a percentage of total Medicare Parts A and B FFS revenue for ACO participants exceeds the amount that is two percent of the ACO's updated benchmark, then the loss sharing limit would be capped at two percent of the ACO's updated historical benchmark for the applicable performance year.

Level E: The levels of risk and potential reward would match the levels in Track 1+. This level would qualify as an AAPM. A final sharing rate not to exceed 50 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark.

A loss sharing rate of 30 percent regardless of the quality performance would apply to the first dollar shared losses for ACOs with losses meeting or exceeding their MLR. The percentage of ACO participants' total Medicare Parts A and B FFS revenue used to determine the revenue-based loss sharing limit would be set for each year consistent with the generally applicable nominal amount standard for an Advanced Alternative Payment Model (AAPM). However, if the loss sharing limit, as a percentage of the ACO participant's total Medicare Parts A and B FFS revenue exceeds the expenditure-based nominal amount standard, as a percentage of the

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ACO's updated historical benchmark, then the loss sharing limit would be capped at one percent point higher than the expenditure-based nominal amount standard.

AAFP Response

The AAFP supports the creation of more APMs for practices of all sizes to participate. We firmly implore CMS to increase the glide path for new, low-revenue ACOs in the one-sided levels of the BASIC track to three years. As cited above, we believe this is supported by a recent study published by the *New England Journal of Medicine*, which found that, after three years in the MSSP, physician-led ACOs were able to generate shared savings that grew over the study period.⁴ It is imperative to allow ACOs, particularly physician-led and low-revenue ACOs, enough time to generate sufficient shared savings to offset startup costs and support sustained transformation.

We strongly encourage CMS to maintain the current shared savings rate at 50 percent for BASIC Levels A-D. CMS must offer a higher shared savings rate to support ACOs—especially physician-led and low-revenue ACOs with more limited capital reserves—in their efforts to improve quality and decrease costs. In addition, the MSR ensures ACOs in one-sided only tracks are not earning shared savings due to chance. We believe that the proposed shared savings rates for Levels A-D are not adequate to support or incentivize participation and ask that CMS consider maintaining current shared savings and MSR levels.

II.A.3.b(3) – Calculation of Loss Sharing Limit

Summary

CMS is proposing an approach where the loss-sharing limit for BASIC track ACOs would be determined as a percentage of ACO participants' total Medicare Parts A and B FFS revenue that is capped at a percentage of the ACO's updated historical benchmark expenditures when the amount that is a certain percentage of ACO participant FFS revenue (depending on track) exceeds the specified percentage of the ACO's updated historical benchmark expenditures for the relevant risk/reward level. CMS expects this approach would tend to place ACOs that include hospitals under a benchmark-based loss-sharing limit.

CMS is proposing to establish the revenue-based loss sharing limit as the default for ACOs in the BASIC track and to phase-in the percentage of ACO participants' total Medicare Parts A and B FFS revenue. However, if the amount that is the applicable percentage of ACO participants' total Medicare Parts A and B FFS revenue exceeds the amount that is the applicable percentage of the ACO's updated benchmark, then the ACO's loss sharing limit would be capped and set at this percentage of the ACO's updated historical benchmark.

For the BASIC track, CMS proposes that the percentage of ACO participants' FFS revenue to determine the revenue-based loss sharing limit for Level E would be set for each performance year consistent with the generally applicable nominal amount standard for an AAPM.

AAFP Response

The AAFP supports the CMS proposal to use a revenue-based approach to calculate ACO loss sharing rates. The AAFP also supports the proposal to cap and set the loss sharing rate at the percentage of an ACO's updated historical benchmark expenditures, if the revenue-based amount exceeds the applicable percentage of the ACO's updated benchmark.

⁴ McWilliams J, Hatfield L, Landon B, Hamed P, Chernew ME. Medicare spending after 3 years of the Medicare Shared Savings Program. *New Engl J Med.* 2018;379:1139-1149.

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The AAFP supports the CMS proposal to set the revenue-based loss sharing limit for the BASIC track's Level E consistent with the generally applicable nominal amount standard required for AAPMs. The AAFP suggests CMS maintain the eight percent generally applicable nominal amount standard at least through the QP Performance Period 2024. We believe this will support the ability of low-revenue ACOs to bear risk; whereas risk based on benchmarks is challenging for low-revenue ACOs operating on thin margins. To enable participation and set ACOs up for success, CMS should rely on a revenue-based risk structure. Any expenditure-based nominal risk amount should be kept low to avoid placing physician-led and low revenue ACOs at a disadvantage. We ask CMS to maintain the three percent expenditure-based nominal amount standard through at least QP Performance Period 2024. This should provide program stability in both the Quality Payment Program and the Medicare Shared Savings Program, while also allowing CMS to gain a better understanding of how the risk levels will affect low-revenue ACOs.

II.A.4.c – Proposals for Permitting Annual Election of Beneficiary Assignment Methodology Summary

CMS is proposing to offer ACOs entering the BASIC or ENHANCED tracks, beginning July 1, 2019, and in subsequent years, the option to choose either prospective assignment or preliminary assignment with retrospective reconciliation, prior to the start of their agreement period. They also propose to provide an opportunity for ACOs to switch their selection of beneficiary assignment methodology on an annual basis. An ACO's beneficiary assignment methodology would have no effect on the voluntary alignment process.

AAFP Response

The AAFP supports the CMS proposal to allow ACOs to choose either prospective assignment or preliminary assignment with retrospective reconciliation. We also support CMS' proposal to allow ACOs to update their beneficiary assignment methodology on an annual basis. As we discuss elsewhere, we ask CMS to delay implementation of the BASIC and ENHANCED tracks and any applicable policies until January 1, 2020.

II.A.5.b(1) – Identifying Low-revenue ACOs and High-revenue ACOs *Summary*

CMS proposes that if an ACO participants' total Medicare Parts A and B FFS revenue exceeds a specified threshold of total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO would be considered high revenue. ACOs with a percentage less than the threshold amount would be considered low revenue.

The proposed approach generally would categorize ACOs that include hospitals, health systems, or other providers and suppliers that furnish Part A services as ACO participants or ACO providers/suppliers as high revenue. ACOs with participants and providers/suppliers that mostly furnish Part B services would generally be categorized as low revenue. CMS proposes a threshold of 25 percent to determine low revenue versus high revenue. CMS will make revenue and expenditure calculations using the most recent calendar year for which 12 months of data are available.

CMS considered a lower threshold of 15 or 20 percent, and a higher threshold of 30 percent. CMS also considered an alternative that would use multiple years of revenue and expenditure data.

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AAFP Response

The AAFP is supportive of the CMS definition of high-revenue and low-revenue ACOs. We believe it is appropriate to generally define low-revenue ACOs as those whose providers and suppliers mostly provide Part B services, which are likely to be physician-led ACOs. As previously noted, physician-led ACOs have consistently shown their ability to produce savings. The AAFP supports and appreciates the additional flexibilities included throughout this proposed rule for low-revenue ACOs and we urge CMS to finalize these provisions. We also ask CMS to allow new low-revenue ACOs to remain in the BASIC track's Levels A and B for three years before being required to assume downside risk given their more limited capital reserves compared to high-revenue, hospital-led ACOs.

II.A.5.b(2) – Restricting ACOs' Participation in the BASIC Track Prior to Transitioning to Participation in the ENHANCED Track

Summary

CMS proposes to limit high-revenue ACOs to, at most, a single agreement period under the BASIC track prior to transitioning to the ENHANCED track. CMS proposes to limit low-revenue ACOs to, at most, two agreement periods under the BASIC track. The agreements would not be required to be sequential, which would allow low-revenue ACOs to transition to the ENHANCED track after a single agreement period under the BASIC track, and the opportunity to return to the BASIC track if the ENHANCED track initially proves too high of risk. Once an ACO has participated under the BASIC track's glide path, a subsequent agreement period under the BASIC track would be required at Level E.

CMS considered and seeks comment on an approach that would allow low-revenue ACOs to gradually transition from the BASIC track's Level E up to the full levels of risk and potential reward of the ENHANCED track. For example, CMS seeks comment on whether it would be helpful to devise a glide path that would be available to low-revenue ACOs entering the ENHANCED track. CMS also considered and seeks comment on whether such a glide path under the ENHANCED track should be available to all ACOs.

AAFP Response

The AAFP is concerned about the steep increase in risk between the BASIC track's Level E and the ENHANCED track. We support the ability of low-revenue ACOs to stay in the BASIC track for two agreement periods. We encourage CMS to continue to assess the ability of low-revenue ACOs to assume higher levels of downside risk. CMS should also evaluate the success rates of low-revenue ACOs that moved to the ENHANCED track and monitor the number of ACOs that returned to the BASIC track, particularly due to inability to assume higher levels of risk.

II.A.5.b(3) – Allowing Greater Potential for Reward for Low-revenue ACOs Summary

CMS is seeking comment, but not making specific proposals, on approaches to allow for greater access to shared savings for low-revenue ACOs.

CMS considered an approach that would allow for low-revenue ACOs to have a lower MSR in the one-sided levels of the BASIC track. CMS considered a fixed one percent, fixed two percent, or zero percent MSR. They would apply a variable MSR based on the number of assigned beneficiaries in the event the ACO's assigned beneficiaries falls below 5,000 for the performance year.

CMS also considered an approach that would allow for a higher final sharing rate under the first four levels of the BASIC track for low-revenue ACOs. For example, allowing a maximum 50

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percent sharing rate based on quality performance for all levels within the BASIC track for low revenue ACOs.

AAFP Response

The AAFP supports a MSR of one percent for ACOs in one-sided levels of the BASIC track. We also support a higher final sharing rate of 50 percent for low-revenue ACOs in the first four levels (A-D) of the BASIC track. While one-sided models (Levels A-B) do not carry downside financial risk, they are not without risk. The startup investments for ACOs are substantial and should be considered a significant financial risk in themselves. To succeed, practices must make organizational and operational changes as they work to improve quality and reduce cost, with no guaranteed return on investment. ACOs and practices typically do not receive their shared savings until 18-24 months after the performance year, making their commitment even riskier.

ACOs generate more shared savings the longer they are in the program. By combining a lower MSR and higher final shared savings rate, ACOs should be able to continue to invest in new and innovative ways to improve their performance. As existing and new ACOs progress through the BASIC track, CMS needs to ensure there are sufficient and attainable incentives to support the transformation efforts required to improve quality and lower cost. A lower MSR and higher sharing rate will provide predictability of savings and the financial support ACOs need to ensure successful participation.

II.A.5.c(5) – Proposed Evaluation Criteria for Determining Participation Options Summary

CMS proposes to identify available participation options for ACOs by considering: (1) whether the ACO is a low-revenue ACO or a high-revenue ACO; and (2) the level of risk with which the ACO or its ACO participants has experienced based on participation in the Medicare ACO initiatives in recent years.

CMS proposes to define a "performance-based risk Medicare ACO initiative" to include MSSP Tracks 2 and 3, the ENHANCED track, and the proposed BASIC track (including Levels A through E). It will also include the: Pioneer ACO Model, Next Generation ACO Model, the performance-based risk tracks of the Comprehensive End Stage Renal Disease Care (CEC) Model, Track 1+, and other models that may be specified by CMS.

To determine if an ACO qualifies as "inexperienced with performance-based risk Medicare ACO initiatives," there are two requirements that must be met:

- (1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO, as defined under §425.20, and has not deferred its entry into a second MSSP agreement period under Track 1 or 2; and
- (2) Less than 40 percent of the ACO's participants participated in a performance-based risk Medicare ACO initiative, as defined under §425.20, or in an ACO that deferred its entry into a second MSSP agreement under Track 2 or 3 in each of the five most recent performance years prior to the agreement start date.

CMS will determine cumulatively what percentage of ACO participants were in any performance-based risk Medicare ACO initiative in each of the five most recent performance years prior to the agreement start date.

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CMS proposes to define an ACO as "experienced with performance-based risk Medicare ACO initiatives" if it meets either of the following criteria:

- (1) The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in a performance-based risk Medicare ACO initiative, as defined under §425.20, or that has deferred its entry into a second MSSP agreement period under Track 2 or 3; OR
- (2) Forty percent or more of the ACO's participants participated in a performance-based risk Medicare ACO initiative, as defined under §425.20, or in an ACO that deferred its entry into a second MSSP agreement period under Track 2 or 3 in any of the five most recent performance years prior to the agreement start date.

All Track 1 ACOs that deferred their renewal will be considered experienced with performance-based risk Medicare ACO initiatives.

CMS considered an alternative that would restrict ACOs with Track 1 experience from participating in any of the one-sided models of the BASIC track (Level A and B).

AAFP Response

The AAFP supports CMS' proposal to define participation options based on prior experience with performance-based risk. Offering ACOs with previous Track 1 experience an additional year in a one-sided model before transitioning to downside risk is appropriate.

However, we ask CMS to raise the final sharing rate for low revenue ACOs in the Levels A-D of the BASIC track to at least 50 percent. Without an increase, ACOs with previous Track 1 experience that enter the BASIC track's Levels B-D will experience a significant decrease in their sharing rate that will not increase to the current Track 1 level for three years. Such a decrease could disadvantage ACOs with Track 1 experience that have made operational and infrastructure investments based on the current structure of the program. We are concerned that not only could this reduce participation in the program, but it could also jeopardize ACO ability to support the initiatives that drive improved quality and decreased cost. One of the goals of the Medicare Access and CHIP Reauthorization Act (MACRA) legislation was to transition physicians from FFS to alternative payment models. In the absence of sufficient incentives, practice that can perform well in the Merit-Based Incentive Payment System (MIPS) will not have reason to transition to an APM. Since the program does not offer adequate rewards, the program could drive practices back to FFS.

II.A.5.d – Monitoring for Financial Performance

Summary

CMS is proposing to add a provision to allow them to monitor an ACO's financial performance. Specifically, CMS will monitor for whether the expenditures for the ACO's assigned beneficiary population are "negative outside corridor," meaning the expenditures for the assigned beneficiaries exceed the ACO's updated benchmark by an amount equal to or exceeding either the ACO's negative MSR under a one-sided model, or the ACO's MLR under a two-sided model. CMS proposes that they may take any of the pre-termination actions specified in §425.216 if the ACO is "negative outside corridor" for a performance year. If the ACO is "negative outside corridor" for another performance year, CMS may immediately or with advance notice terminate the ACO's participation agreement.

CMS is concerned that ACOs may obtain reinsurance to offset their liability for shared losses as a way of enabling their continued participation. CMS considered prohibiting ACOs from obtaining reinsurance to mitigate their performance-based risk but felt this was overly restrictive.

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CMS seeks comment on this issue, and on ACOs' use of reinsurance, including their ability to obtain viable reinsurance products covering a Medicare FFS population.

AAFP Response

Since the proposed design of the program transitions all ACOs to assume downside risk, the AAFP believes this will automatically mitigate the risk of ACOs with poor performance from continuing participation in the program. Therefore, we do not feel it is necessary for CMS to terminate ACOs that are "negative outside corridor" after two years.

As we discuss in other sections of this letter, we ask CMS to allow new, low-revenue ACOs to participate without downside risk for three years. Analyses have shown that savings increase as ACOs become more familiar with the program. New ACOs need time to adjust to the program requirements. Removing new ACOs that are "negative outside corridor" after two years is punitive. CMS should assess an ACO's performance for the entire agreement period before considering any termination action. In addition, we believe ACOs that are underperforming will voluntarily terminate as they are required to assume downside risk under the new glide path in the proposed rule.

II.A.6.c(4) – Proposal for Repayment Mechanism Duration

Summary

CMS is proposing revisions to §425.204(f)(6). CMS proposes to specify that a repayment mechanism must be in effect for the duration of the ACO's participation in a two-sided model, plus 24 months after the conclusion of the agreement period. CMS proposes three exceptions to this rule.

CMS recognizes that it might be difficult for renewing ACOs that are completing the term of their current agreement period to extend an existing repayment mechanism for seven years (full five-year agreement period, plus the 24-month tail period). CMS is considering whether they should allow the existing payment mechanism to be extended long enough to cover the first two or three performance year of the new agreement period. This would equate to four or five years (two or three years, plus the 24-month tail period). CMS seeks comment on whether they should require a shorter or longer extension.

CMS notes that the repayment mechanism may terminate earlier than 24 months after the agreement period if it is no longer needed. CMS proposes that a repayment mechanism may be terminated at the earliest of the following conditions:

- The ACO has fully repaid any shared losses owed for each performance year of the agreement period under a two-sided model;
- CMS has exhausted the amount reserved by the ACO's repayment mechanism and the arrangement does not need to be maintained to support the ACO's participation in the MSSP; or
- CMS determines the ACO does not owe any shared losses under the MSSP for any of the performance years of the agreement period.

CMS seeks comment on whether these proposed provisions at §425.204(f)(6) are adequate to protect the financial integrity of the MSSP, to provide greater certainty to ACOs and financial institutions, and to facilitate the establishment of repayment mechanism arrangements.

AAFP Response

The AAFP believes CMS should only require an extension of 12-18 months. We believe this is a sufficient period for CMS to determine if an ACO has incurred shared losses and for ACOs to

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repay any shared losses, as repayments are due within 90 days of notification. A 24-month tail period would place an undue burden on small- and low-revenue ACOs that operate on thin margins.

II.A.6.c(5) – Proposals for Regarding Institutions Issuing Repayment Mechanism Arrangements Summary

CMS is proposing to revise its policy to specify that an ACO may demonstrate its ability to repay shared losses by placing funds in escrow with an insured institution, obtaining a surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies, or establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon) at an insured institution. CMS will update the Repayment Mechanism Arrangements Guidance to specify the types of institutions that would meet these requirements.

AAFP Response

The AAFP supports CMS' proposed issuing institutions for repayment mechanisms. Small and rural ACOs may be more likely to select surety bonds. We appreciate any policies that alleviate burden and reduce barriers to participation for small and rural ACOs.

II.A.6.d(3) – Proposals for Payment Consequences of Termination Summary

CMS is concerned that the updates to the required termination notification period could allow for gaming. An ACO facing losses could wait until the end of the year to terminate and would not be liable for any losses. CMS is proposing to conduct a financial reconciliation for all ACOs in two-sided models that voluntarily terminate after June 30. CMS will use the full 12 months of performance year expenditure data in performing the reconciliation. For ACOs that generate losses, CMS will prorate the shared loss amount by the number of months during the year in which the ACO was in the program. CMS considered whether to allow ACOs to voluntarily terminate after June 30 to share in portion of any shared savings. However, they decided to limit the proposal to shared losses.

CMS is also proposing to prorate any shared losses for ACOs in two-sided models that are involuntarily terminated by CMS.

AAFP Response

The AAFP is supportive of CMS' proposal to prorate shared losses for ACOs that voluntarily terminate or are terminated by CMS after June 30. We support CMS' proposed methodology to prorate shared losses. We support allowing ACOs that terminate early to continue to share in savings provided they meet the criteria in §425.221.

II.A.7.a – Participation Options for Agreement Periods Beginning in 2019 (Overview) Summary

CMS is proposing to offer a July 1, 2019 start date as the initial opportunity for ACOs to enter an agreement period under the BASIC track or the ENHANCED track. CMS anticipates the application cycle would begin in early 2019. Aside from the ACOs that entered initial agreements beginning in 2015 and deferred renewal into a second agreement period, CMS will not be accepting applications from other ACOs for a new agreement period beginning on January 1, 2019. The July 1, 2019, start date is a one-time opportunity and CMS expects to offer a 2019 application cycle for a January 1, 2020, start date for new five-year participation agreements.

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Based on an ACO's agreement period start date, an ACO would have the following options for a July 1, 2019, start date:

- ACOs entering an agreement period beginning on July 1, 2019, would have an agreement period of five years and six months, of which the first performance year would be July 1, 2019, through December 31, 2019.
- ACOs that entered a first or second agreement period that started in 2016 may elect to
 extend their agreement period for an optional fourth performance period (January 1,
 2019, through June 30, 2019). This option is voluntary—an ACO that does not choose to
 extend their agreement period would conclude its participation in the program with the
 expiration of its current agreement (December 31, 2018).

CMS also considered forgoing an application cycle for a 2019 start date entirely. Under this alternative, ACOs would enter agreement periods for the BASIC or ENHANCED track for the first time beginning January 1, 2020. CMS would allow ACOs that started a first or second agreement period on January 1, 2016, to elect a 12-month extension of their current agreement period to cover the duration of calendar year 2019.

AAFP Response

The AAFP strongly encourages CMS to delay the implementation of all proposed policies until January 1, 2020. We ask that CMS extend the existing agreements for calendar year 2019 and begin agreement periods under the BASIC or ENHANCED track no earlier than January 1, 2020. The proposed changes are complex. As the final rule will likely not be released until early 2019, practices will need sufficient time to assess the changes and make participation decisions. CMS and medical societies, such as the AAFP, will need time to disseminate information to physicians.

With a proposed July 1, 2019, start date, CMS is creating two six-month performance years, which adds an additional layer of complexity and confusion. Delaying the start until 2020 will give new ACOs adequate time to form and review the participation criteria. We add that the significant proposed changes will also require an adjustment period for CMS staff. A later implementation will give CMS additional time to ensure a smooth and effective transition. Moreover, we encourage and are hopeful CMS will implement new APMs for small practices by 2020 to provide equal APM opportunities for all practice sizes.

<u>II.B.2.b – Billing and Payment for Telehealth Services</u> Summary

To comply with the *Bipartisan Budget Act* (BBA) of 2018, CMS is proposing to treat a beneficiary's home as an originating site and not to apply the originating site geographic restrictions for telehealth services furnished by a physician or practitioner participating in an applicable ACO. CMS proposes to apply these policies to ACOs under a two-sided model that participate under the prospective assignment method.

CMS proposes that these policies would go into effect beginning with performance year 2020 and subsequent years for physicians or practitioners participating in ACOs that are operating under a two-sided model with a prospective assignment methodology for the applicable performance year. Participants of ACO Track 1+ would be able to furnish and be paid for telehealth services in accordance with section 1899(1) of the Act.

For applicable ACOs, CMS proposes that a beneficiary's home would be a permissible originating site. CMS would not pay a facility fee when the originating site is the beneficiary's home. CMS also proposes that the geographic limitations under section 1834(m)(4)(C)(i) would not apply to any originating site.

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CMS proposes that ACO participants must not submit claims for services specified as inpatient only when the service is furnished as a telehealth services and the beneficiary's home is the originating site. Example codes include CPT codes: G0406, G0407, G0408, G0425, G0426, and G0427.

To provide protection to a beneficiary when they are prospectively assigned to an ACO, but subsequently excluded from assignment, CMS is proposing to provide a 90-day grace period for payment of otherwise covered telehealth services to allow sufficient time for CMS to notify an applicable ACO of any beneficiary exclusions, and for the ACO to then inform its participants and providers/suppliers of those exclusions. CMS would make payments for telehealth services provided to such a beneficiary as if they were telehealth services authorized under section 1899(1) if the following conditions are met:

- The beneficiary was prospectively assigned to an applicable ACO at the beginning of the relevant performance year, but was excluded in the most recent quarterly update
- The telehealth services are furnished to the beneficiary by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO within 90 days following the date that CMS delivers the quarterly exclusion list to the applicable ACO.
- Except for the beneficiary's exclusion from the applicable ACO's assignment list, CMS would have made payment to the ACO for such services under section 1899(1).

In the event that CMS makes no payment for telehealth services and the only reason the claim was non-covered is because the beneficiary was not prospectively assigned to the ACO or was not in the 90-day grace period, the following beneficiary protections would apply:

- The ACO participant must not charge the beneficiary for the expenses incurred for such services;
- The ACO participant must return to the beneficiary any monies collected for such service; and
- The ACO may be subject to compliance actions, including being required to submit a correction action plan (CAP) under §425.216(b) for CMS approval.

CMS welcomes comments on these proposals for implementing the requirements of section 1899(1), as added by the Bipartisan Budget Act, and related issues.

AAFP Response

The AAFP supports the proposal to allow a patient's home to be an originating site, and believe all originating site restrictions should be removed to reduce regulatory burden and to facilitate patient-centered care. Patients should be able to receive care wherever they are located, such as a work or vacation site. We also support CMS' proposal not to include a facility fee.

However, we have concerns regarding the administrative burden of determining beneficiary eligibility for telehealth services and ask CMS to transition to a real-time benefit eligibility confirmation system for physician offices.

II.C.2.c – Proposals for Beneficiary Incentive Programs

Summary

To comply with sections 1899(b)(2) and (m) of the Bipartisan Budget Act, CMS is proposing to allow ACOs participating under certain two-sided models to establish incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying services.

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Beneficiaries would be eligible to receive an incentive payment if they are prospectively or assigned through the preliminary prospective methodology. Beneficiaries that voluntarily align with an ACO are considered prospectively assigned. Therefore, any beneficiary assigned to an ACO participating under Track 2; Levels C, D, or E of the BASIC track; or the ENANCED track may receive an incentive payment.

CMS proposes to mirror language from the section 1899(m)(2)(C) so that "a qualifying service is a primary care service" as defined in §425.20 "to which coinsurance applies under Part B," and is furnished through an ACO by "an ACO professional who has a primary care specialty designation included in the definition of primary care physician" under §425.20; or a physician assistant, nurse practitioner, clinical nurse specialist, Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC).

CMS proposes to limit the incentive payment maximum of \$20. The incentive amount must be the same for all eligible Medicare FFS beneficiaries, regardless of the beneficiary's enrollment in a Medicare supplemental policy, state Medicaid plan, or a waiver of such a plan, or in any other health insurance policy or health plan. The incentive payment may be made in different forms (e.g., gift card, check) depending on the beneficiary's preference. ACOs would be prohibited from distributing incentive payments in the form of cash and must be made in the form a cash equivalent, which includes instruments convertible to cash or widely accepted on the same bases as cash, such as checks and debit cards.

The ACO must furnish an incentive payment to an eligible beneficiary each time the beneficiary receives a qualifying service. The incentive payment must be made no later than 30 days following a qualifying service.

CMS is proposing that the ACO legal entity, and not the ACO participants or ACO providers/suppliers, furnish the incentive payments directly to beneficiaries. CMS seeks comment on other potential methods for distributing an incentive payment.

CMS proposes that an ACO would be required to fully fund the costs associated with an incentive program. The ACO would be prohibited from accepting or using funds furnished by an outside entity, including, but not limited to, an insurance company, pharmaceutical company, or any other entity outside of the ACO, to finance its beneficiary incentive program.

CMS also proposes that the Secretary will not make separate payments to an ACO for a beneficiary incentive program. However, the ACO is not prohibited from using shared savings to fund its program. CMS proposes that the policy regarding the use of shared savings would apply to both in-kind items and services, as well as incentive payments. CMS proposes to prohibit ACOs from shifting the cost of establishing or operating an incentive program to a federal health care program, as defined at section 1128B(f).

AAFP Response

There are opportunities for several waivers that would both help MSSP ACOs improve care delivery and encourage beneficiary health-seeking behavior. **Our strongest recommendation is waiving certain primary care co-pays for all ACO tracks.** We offer this proposal for four reasons.

First, by waiving the co-pays for primary care services, the ACO can encourage patients to get the most appropriate care. The waiver offers the possibility of further engaging beneficiaries in their health and their health care by helping ensure necessary preventive screenings are Administrator Verma Page 14 of 25 October 15, 2018

provided, chronic conditions are kept from unduly progressing, and new conditions or exacerbations of existing conditions are prevented.

Second, unstable beneficiary assignment is a well-recognized MSSP problem. In one <u>study</u>, unstable assignment was as high as 33 percent and "much of the outpatient specialty care for patients assigned to ACOs, particularly higher-cost patients with more office visits and chronic conditions, was provided by specialists outside of patients' assigned organizations, even among more specialty-oriented ACOs." We believe a co-pay waiver would reduce unstable assignment and "leakage," where ACO-assigned patients' office visits occur outside their ACO.

Third, because we propose to limit the co-pay waiver to five specific primary care evaluation and management (E/M) codes (99211-99215) and the chronic care management (CCM) code (CPT code 99490), we believe this will produce the greatest benefit for the least cost to the ACO. Without an out-of-pocket (OOP) cost, the ACO patient can seek care without having to decide presumptively whether care is essential or not. For the ACO provider, the waiver will help reduce year-over-year assignment instability and leakage. The co-pay waiver would also serve the ACO provider and patient equally well since more timely appointments and greater adherence to care would minimize the possibility of greater downstream costs due to higher intensity care. The waiver would both motivate and reinforce beneficiary-provider attestation. Voluntary alignment of a patient with his/her primary care provider is recognized by CMS as inherent in improving the goal of patient-centered care.

Fourth, we recognize the concern that waiving OOP costs can drive over or unnecessary utilization (i.e., the concern over the "offset effect"). Here again we are limiting the waiver to a discrete number of primary care codes delivered by primary care physicians. The waiver would also only benefit a discrete number of ACO patients since about 25 percent of Medicare beneficiaries have Medigap insurance and a much larger percentage have supplemental coverage via employer-sponsored plans and other polices that typically provide first dollar coverage. We also know beneficiaries without secondary coverage have poorer health, lower incomes, higher out-of-pocket costs, and, as a result, underutilize medically-necessary care.

In sum, we believe waiving a discrete list of primary care service co-pays for all three ACO tracks would encourage the use of primary care services, improve patient outcomes over time, and further enhance patient-centered care. This recommendation is consistent with the Medicare Payment Advisory Commission's (MedPAC's) 2010 technical panel's finding that lowering cost sharing services for preventive services is an effective way to encourage the use of high-value, high-quality health care.

II.C.3.a(2) – Proposed Revisions (Beneficiary Notification) Summary

To comply with the BBA, CMS is proposing, beginning July 1, 2019, that an ACO participant must notify beneficiaries at the point of care about voluntary alignment, in addition to notifying beneficiaries that its ACO providers/suppliers are participating in the MSSP and the beneficiary has the opportunity to decline claims data sharing. The notification must include the process by which a beneficiary can identify or change identification of a primary care provider for purposes of voluntary alignment.

CMS is proposing that this information must be provided to all Medicare FFS beneficiaries at the first primary care visit of each performance year. Notification of voluntary alignment would be in addition to the existing requirement that ACO participants must post signs in its facilities and make standardized written notices available upon request.

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CMS proposes that ACOs must use a template prepared by CMS. The template would include details about how a beneficiary may select his or her primary care provider on Medicare.gov, and the step-by-step process by which a beneficiary could designate an ACO professional as his/her primary care provider, and how a beneficiary could change such designation.

AAFP Response

The AAFP adamantly believes that proactive beneficiary notification of participation in an APM is critical to engaging patients in their care. CMS must maintain current ACO requirements for beneficiary notification. We are concerned the CMS proposal adds undue burden on ACO participants. CMS goals are already satisfied through the existing requirements for ACO participants to post signs in its facilities. Patients are already inundated with information at their visits, including reviewing and signing privacy agreements, verifying or updating addresses and insurance information, etc. Any new requirements will increase burden for staff and could overwhelm patients. As an alternative, we suggest CMS include information on voluntary alignment as part of its "Medicare and You" educational materials.

Should CMS move forward with this, we support CMS' proposal to provide templates that contain all required information. The template should be made available to ACO participants immediately upon entering the program. To ensure the information is relevant and easily understood, CMS should include stakeholders and beneficiaries in the development of the template. Any additional information (such as ACO quality reporting, financial incentives, etc.) can be added by ACO participants as they see appropriate. While there can be multiple methods for sharing the information, the format of dissemination should be left up to the ACO participants. If required, there should not be restrictions on when the information is provided to beneficiaries, so long as its provided annually. For example, an ACO participant could send an email notice to its beneficiaries at the beginning of the year.

II.C.3.b – Beneficiary Opt-In Based Assignment Methodology Summary

CMS is exploring ways to implement a beneficiary opt-in based assignment methodology. Opt-in differs from voluntary alignment. Voluntary alignment is based on the relationship between the beneficiary and a single practitioner in the ACO. An opt in based on assignment methodology would be an affirmative recognition of the relationship between the beneficiary and the ACO itself.

CMS believes an opt-in methodology would be similar to enrollment in a Medicare Advantage (MA) plan.

CMS would need to determine how frequently beneficiaries would be able to opt in or withdraw an opt in to an ACO, and whether there should be limits on the ability to change an opt in after the end of the opt-in window, in order to reduce possible beneficiary assignment "churn." ACOs would be responsible for providing the list of beneficiaries who have opted in to assignment, along with each beneficiary's Medicare number, address, and certain other demographic information. ACOs may need to acquire new information technology and additional support staff to track, monitor, and transmit opt-in data to CMS. CMS believes it would be critical for ACOs to inform beneficiaries of their option to withdraw their opt in to the ACO.

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ACOs would still be required to have at least 5,000 FFS beneficiaries assigned to the ACO at the time of application and for the entirety of the ACO's agreement period.

CMS could allow beneficiaries to opt in before they have received a primary care service from a physician in the ACO, or any service from an ACO provider/supplier. This means a beneficiary could be assigned to an ACO based on opting in to the ACO, and the ACO would be accountable for total cost and quality of care for the beneficiary, including care from providers that are not in the ACO. To comply with section 1899(c), CMS is considering whether they would need to continue to require that a beneficiary receive at least one primary care service from an ACO professional in the ACO who is a primary care physician or a physician with a specialty used in assignment for the beneficiary to be eligible to opt in to assignment to the ACO.

CMS would allow, but not require, ACOs to elect an opt-in methodology. When entering or renewing its participation in the MSSP, an ACO could elect an opt in based on assignment methodology that would apply for the length of the agreement period.

An ACO that does not elect an opt-in methodology would continue to be assigned beneficiaries using the existing methodology. CMS is considering discontinuing the existing methodologies and applying an opt-in methodology program wide as a hybrid assignment approach, which includes a beneficiary opt in, modified claims-based assignment, and voluntary alignment.

Hybrid assignment would be used for ACOs that elect to participate under an opt in methodology. Beneficiaries who opt in to assignment or who voluntarily align with the ACO would be prospectively assigned. If a beneficiary was not prospectively assigned using either of these two methods, the beneficiary would be assigned to such ACO only if the beneficiary received the plurality of their primary care services from the ACO and received at least seven primary care services from one or more ACO professionals in the ACO during the applicable assignment window. Beneficiaries that did not receive at least seven primary care services would not be assigned to the ACO based on claims—even if they received the plurality of their primary care services from the ACO. CMS seeks comment on whether to use a higher- or lower-minimum threshold for determining beneficiaries assigned to the ACO under a modified claims-based assignment approach.

CMS does not anticipate that it would establish restrictions on the geographic locations of the ACOs from which a beneficiary could select.

CMS anticipates that beneficiaries who opt in would likely be a subset of beneficiaries who would have been assigned under the existing claims-based methodology. Based on CMS' experience, 75 percent of ACO's assigned beneficiaries receive six or fewer primary care service visits annually.

AAFP Response

The AAFP urges CMS to continue to monitor the effectiveness of voluntary alignment before implementing an opt-in policy. Further, the benefits of beneficiary opt in versus beneficiary voluntary alignment are not clear. While CMS states that an opt in is based on a relationship with the ACO as opposed to a relationship to a single provider, the beneficiary joins the ACO under either option. In the 2017 Medicare Physician Fee Schedule (MPFS) final rule, CMS states, "...if a beneficiary designates an ACO professional that they believe is responsible for coordinating their overall care as their 'main doctor," the beneficiary will be assigned to the ACO in which that ACO professional is participating..." CMS also declined to implement an opt-

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in policy because, based on their experience with the Pioneer ACO Model, beneficiaries are less likely to identify with an ACO than with an individual physician. We agree. Beneficiaries should be encouraged to align and develop a relationship with a primary care physician. The relationship between a patient and the primary care physician is vital, will drive better patient outcomes, and lower costs. Primary care helps prevent illness and death, and it is associated with a more equitable distribution of health in populations. Primary care is also associated with enhanced access to health care services and better health outcomes, as well as lower costs through changes in utilization, such as lower rates of hospitalization and emergency department visits.

CMS explains that an opt-in approach could create a stronger economic incentive for ACOs to compete against other ACOs and non-ACO providers. We are not clear how an opt-in approach encourages this any more than a voluntary alignment approach. In either instance, for the purposes of improving quality and managing cost, the beneficiary is aligned with the ACO.

CMS is proposing to allow beneficiaries to align with an ACO even if they have not received any services from a physician within the ACO. In previous rulemaking, when discussing voluntary alignment policies, CMS stated it would not be fair to hold an ACO accountable for the quality and costs of a beneficiary with whom they do not have a relationship. To prevent this, CMS decided beneficiaries must have received at least one primary care service to be assigned to an ACO through voluntary alignment. Allowing beneficiaries to align with an ACO even if they do not have a relationship with any provider within the ACO is inconsistent. Under any opt-in or voluntary alignment policy, a beneficiary should only be assigned to the ACO if he or she has received at least one primary care service from a physician within the ACO.

CMS is proposing to allow ACOs to elect an opt-in approach. For these ACOs, beneficiaries may be assigned to the ACO based on opt-in, voluntarily alignment, or claims-based assignment. As part of this proposal, CMS would only assign a beneficiary to an ACO using claims if the beneficiary received the plurality of his or her primary care services from the ACO AND received at least seven primary care services from one or more ACO professionals in the ACO. CMS states that about 75 percent of beneficiaries receive six or fewer primary care service visits annually. Such policies may prevent many ACOs from reaching the 5,000-beneficiary threshold and create barriers to participation. Further, CMS is creating unnecessary complexities by introducing multiple claims-based attribution methodologies. Claims-based attribution should remain based upon plurality of primary care services.

Patient attribution methodology is critical to payment, quality, and cost performance measurement, and defining accountability. Physicians are assured they know for whom they are accountable in terms of quality and cost. Accurate attribution may also help patients understand the importance of their relationship with their primary care physician, and the need to include the physician in major and minor decisions that impact their health, such as when and how to seek medical care or lifestyle choices.

In 2016, the Health Care Payment Learning and Action Network (HCPLAN) released a <u>white</u> <u>paper on patient attribution</u>, in which they deemed patient attestation as the gold standard for attribution for population-based payments that rely on primary care as the starting point to

⁵ Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. *Milbank Q*. 2005;83(3):457-502.

⁶ Shi L. The impact of primary care: a focused review. *Scientifica*. 2012;Epub.

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coordinate care across the continuum. Some private payers already use self-attestation in patient attribution.

In our Advanced Primary Care Alternative Payment Model (APC-APM) proposal to the Physician Focused Payment Model Technical Advisory Committee (PTAC), the AAFP recommended an attribution methodology that uses beneficiary alignment and prospective patient attribution. We offer it as an alternative to CMS' proposed policies.

The AAFP recommends a patient-based, prospective, four-step process that includes a 24-month look-back period for attribution. Patients attributed through this process should be the focus of payment and performance measurement. A prospective methodology allows physicians to know for whom they are responsible in advance and facilitates proactive care planning and management. Like the CPC+ initiative, patients should be attributed on a quarterly basis. For attribution purposes, a primary care physician should be defined as a physician who is in a family medicine, general internal medicine, geriatric medicine, general pediatrics, or general practice specialty.

The Four-Step Attribution Process

1. Patient Selection of Primary Care Physician and Team

• This is the acknowledgement that patient selection is the best choice in attribution and should be prioritized as such. While the patient is attributed to a specific physician, their attribution within the model will be to the ACO.

2. Primary Care Visit Events: Wellness Visits

 If a patient is not attributed by self-selection of a primary care physician, Medicare should use well visits, including Welcome to Medicare (IPPE), physicals, and Annual Wellness Visits (AWV) provided by the patient's primary care physician or the practice team, as the next step in the attribution process.

3. Primary Care Visit Events: All Other E/M Visits

• If a patient is not attributed by a wellness visit, the next incremental step is to include all other evaluation and management (E/M) visits to a primary care physician. Medicare should attribute the patient to the primary care physician who provides the plurality of E/M visits.

4. Primary Care Prescription and Order Events

 If the patient is not attributed by a wellness visits or any other E/M services, Medicare should consider claims related to medication prescriptions, durable medical equipment prescriptions, and lab and other referral orders made by primary care physicians. Medicare should require a minimum of three such events before attributing a patient on this basis.

Step in the Process	Event Type	Eligible Procedure or Event	Look-back Period	Assignment Criteria	Minimum Threshold for Assignment	In Event of a Tie
Step 1	Patient selection of primary care physician	N/A	N/A	N/A	N/A	N/A
Step 2	Primary care visits: wellness visits	Well visit E/M and select G codes only	24 months	Plurality	One visit	Most recent visit
Step 3	Primary care visits: all other E/M visits	Any E/M codes	24 months	Plurality	One visit	Most recent visit
Step 4	Primary care prescriptions and order events	Any Rx code; claims related to medication prescriptions, durable medical equipment, and lab and referral orders	24 months	Plurality	Three events	Most recent event

Review and Reconciliation of Attributed Patients

No patient attribution methodology is perfect. The four-step methodology recommended above may still produce errors in assignment. Physicians should have the option to engage in a reconciliation process in which they can review and recommend the addition and removal of patients (with supporting rationale) from the formal list Medicare supplies to them. Like the attribution process, review and reconciliation should occur quarterly and include enough time to adequately review the list.

II.E.2.b – Proposals – Revisions to Policies on Voluntary Alignment Summary

Section 1899(c), as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the secretary to permit Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO.

CMS is proposing to modify their current policies, such that CMS will assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. If the beneficiary selects any provider or supplier outside of the ACO, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year.

CMS proposes to remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in §425.402(c) within the 12-month assignment window to be assigned to the ACO. A beneficiary who selects an ACO professional but does not receive any services from an ACO participant during the assignment window will remain eligible for assignment to the ACO.

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If a beneficiary does not change their primary care clinician designation, they will remain assigned to the ACO in which that practitioner participates during the ACO's entire agreement period and any subsequent agreement periods under the MSSP, even if the beneficiary no longer seeks care from any ACO professionals.

CMS proposes that ACOs must use a CMS-developed template notice that encourages beneficiaries to check their designation regularly and update it when they change providers or move.

AAFP Response

The AAFP strongly opposes CMS' proposal to remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation to be assigned to the ACO. CMS cites the *Bipartisan Budget Act* of 2018 as reasons for removing this requirement. However, we believe the BBA only specifies that beneficiaries must be notified of their ability and informed of the process to make a voluntary alignment, and any voluntary alignment supersedes any claims-based assignment. We believe requiring a beneficiary to have at least one primary care service to be eligible for assignment to the ACO through voluntary alignment still complies with the BBA's requirements and that such a requirement does not supersede a beneficiary's voluntary alignment.

We disagree with CMS' rationale that their approach "reduces burden on beneficiaries and their practitioners by not requiring practitioners to provide unnecessary care..." as this implies as little as one primary care service a year is unnecessary. This sends an incorrect and inappropriate message to both beneficiaries and physicians.

We are supportive of voluntary alignment and believe it is heading in the right direction in terms of attribution. We offer CMS an alternative approach that incorporates beneficiary attribution as the primary form of attribution. As detailed in the previous section, the AAFP recommends a patient-based, prospective, four-step process that includes a 24-month look-back period for attribution

<u>II.E.3.b – Proposals – Revisions to the Definition of Primary Care Services Used in Beneficiary</u> Assignment

Summary

CMS proposes to revise the definition of primary care services to include: (1) advance care planning codes (CPT 99497 and 99498); (2) administration of health risk assessment service codes (CPT 96160 and 96161); (3) prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT 99354 and 99355); (4) annual depression screening service code (HCPCS G0444), alcohol misuse screening service codes (HCPCS G0442); and (6) alcohol misuse counseling service code (HCPCS G0443). CMS also proposes to include: (1) GPC1X add-on code, for the visit complexity inherent to evaluation and management associated with certain primary care services; (2) GCG0X add-on code for visit complexity inherent to evaluation and management associated with certain specialties; and (3) GPRO1, an additional add-on code for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure.

CMS proposes to update its policy to exclude services furnished in a skilled nursing facility (SNF). Rather than excluding claims based on place of service (POS) 31, CMS will exclude

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services billed under CPT 99304-99318 when the service is furnished in a SNF by analyzing facility claims data files.

CMS welcomes comment on the new codes they are proposing to add to the definition of primary care services used for the purposes of assigning beneficiaries to MSSP ACOs. In addition, CMS seeks comments on their proposal to revise the method for excluding services identified by CPT 99304-99318 when furnished in a SNF.

AAFP Response

In general, the AAFP is supportive of CMS' proposed changes to the definition of primary care services. In our comments on the 2019 Medicare PFS proposed rule, we oppose the creation of GPC1X, GCG0X, and GPRO1. However, should CMS finalize those codes, we would only support the inclusion of GPC1X and GPRO1.

The AAFP agrees it is appropriate to exclude services billed at a SNF and supports the proposed updated policy.

II.E.4.b(1) – Modification of Quality Performance Scores for All ACOs in Affected Areas Summary

CMS proposes to apply determinations made under the Quality Payment Program (QPP) with respect to whether an extreme and uncontrollable circumstance has occurred and the identification of the affected geographic areas and applicable time periods. CMS would have the sole discretion to determine the time period, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity. CMS will determine an ACO's legal entity location using the address on file in the CMS ACO application and management system.

CMS proposes to use the following approach when 25 percent of beneficiaries reside in an area affected by an extreme and uncontrollable circumstance or the ACO legal entity is located in such an area:

- The ACO's minimum quality score would be set equal to the mean quality score for all MSSP ACOs for the applicable performance year.
- If the ACO completely and accurately reports all quality measures, CMS would use the higher of the ACO's quality performance score or the mean quality performance score.
- If the ACO receives the mean MSSP quality performance score, the ACO would not be eligible for bonus points.
- For ACOs that receive the mean quality score, the next year the ACO submits data, CMS would measure quality improvement based on the comparison between the ACO's performance and in the most recently available prior performance year in which the ACO reported data.

CMS would use the alternative scoring methodology for ACOs affected by a disaster in any month in 2019.

AAFP Response

The AAFP appreciates and supports CMS' policy efforts that recognize extreme and uncontrollable circumstances pertaining to ACOs. We concur with CMS that extreme and uncontrollable circumstances pertaining to hurricanes and wildfires warrant new policies for assessing quality and financial performance of MSSP ACOs in affected areas for performance year 2017. We agree with CMS that, if 25 percent or more of an ACO's assigned beneficiaries

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reside in an area identified under QPP as being affected by an extreme and uncontrollable circumstance or if the ACO's legal entity is in such area, it is reasonable to conclude an ACO's quality performance has been adversely affected. The AAFP encourages CMS to continue measuring this 25 percent threshold and other percentage thresholds as test cases. For instance, CMS might test whether 5 or 10 percent is also as likely to cause an impact on quality scores.

Disasters can also affect health care providers billing under the tax identification number (TIN) of the ACO, and as a result, can disrupt routine operations related to participation in MSSP and achievement of program goals. The AAFP encourages CMS to include physicians and other health clinicians as an additional method to identify if the ACO's quality performance has been affected. To help CMS develop this policy, if 50 percent of the national provider identifiers (NPIs) billing under the TIN are in an impacted area, based on the practice location listed in the Provider Enrollment, Chain and Ownership System (PECOS), CMS should automatically apply the extreme and uncontrollable circumstance policy.

In the event CMS determines an ACO is being affected by extreme and uncontrollable circumstances, the AAFP believes the quality performance score could be set to the mean, but should not be used to calculate future benchmarks or subsequent year thresholds until complete and accurate reporting can be achieved. Setting quality benchmarks to an artificial mean is not a valid approach to determine legitimate savings and losses.

CMS must be transparent regarding the criteria used to determine the time period in which an ACO is identified as being in extreme and uncontrollable circumstances. Furthermore, CMS must work closely with Medicare Administrative Contractors (MACs) and the Federal Emergency Management Agency (FEMA) to communicate these provisions to ACO entities.

II.E.5 - Program Data and Quality Measures

Summary

CMS wishes to align their MSSP policies with the priorities identified in the <u>Opioid Misuse Strategy</u>. CMS is considering what data, including what aggregated Medicare Part D data, could be useful to ACOs to combat opioid misuse in their assigned beneficiary population. ACOs currently receive Part D prescription drug event (PDE) data on prescribed opioids for their assigned beneficiaries who have not opted out of data sharing.

CMS seeks suggestions for other types of aggregate data related to opioid use that could be added for informational purposes to the aggregate quarterly and annual reports CMS provides to ACOs. They are particularly interested in high-impact aggregate data that would reflect gaps in quality of care, patient safety, multiple aspects of care, and drivers of cost.

Types of data CMS has begun considering include filled prescriptions for opioids, number of beneficiaries with a concurrent prescription of opioids and benzodiazepines, and number of beneficiaries with opioid prescriptions above a certain daily morphine equivalent dosage threshold.

CMS is considering the following relevant National Quality Forum (NQF)-endorsed measure:

- NQF #2940 Use of opioids at high dosage in persons without cancer
- NQF #2950 Use of opioids from multiple providers in persons without cancer
- NQF #2951 Use of opioids from multiple providers and at high dosage in persons without cancer

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AAFP Response

Effective state prescription drug monitoring programs (PDMPs) must facilitate the interstate exchange of registry information as called for under the National All Schedules Prescription Electronic Reporting Act. We advocate for physicians to use their state PDMP before prescribing any potentially abused pharmaceutical product. However, the success of this advocacy depends on state reporting systems that are accessible, timely, and interoperable. We urge CMS to work with other sectors at the national and state level to help integrate these systems and improve their effectiveness.

We also support the inclusion of the three proposed measures in the ACO measure set (NQF #2940, NQF #2950, and NQF #2951). However, as new measures are developed, we strongly urge CMS to ensure alignment and harmonization across all CMS quality performance programs. To that end, we would suggest the development of a measure for consultation of the PDMP and outcome measures related to opioid use.

II.E.6 – Promoting Interoperability

Summary

Beginning in performance year 2019 and subsequent performance years, CMS is proposing that any track that does not meet the financial risk standard to be an AAPM must attest and certify at the time of application to the MSSP and with each annual certification, that at least 50 percent of the eligible clinicians (ECs) participate in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers.

For ACOs that meet the AAPM financial risk standard, CMS is proposing to align the proposed CEHRT-use threshold with the criterion on use of CEHRT established for AAPMs. CMS anticipates that this threshold will apply to Track 2, Track 3, and Track 1+ for performance years beginning January 1, 2019. For performance years beginning on July 1, 2019, the threshold would apply to BASIC Level E and the ENHANCED track.

If finalized, CMS believes the new CEHRT thresholds required for MSSP eligibility would replace the need for the current ACO quality measure "Use of CEHRT (ACO-11)." To meet AAPM CEHRT-use criterion under the MSSP, a penalty or reward must be applied to an APM entity based on the degree of CEHRT use among its ECs. CMS believes their proposal to impose specific CEHRT-use requirements on ACOs participating in the MSSP would eliminate the need for the separate CEHRT-use criterion applicable to MSSP APMs.

AAFP Response

The AAFP is supportive of these proposals. We support all efforts to create alignment across programs. CMS has also stated its intentions for BASIC track Level E and the ENHANCED track to qualify as AAPMs. As such, we would support the logical alignment of the CEHRT requirements for those tracks with the CEHRT AAPM criterion in the QPP. To allow for consistency, we believe it would be appropriate to apply this criterion to all MSSP ACOs, including those that do not meet the AAPM financial risk standards.

The AAFP appreciates efforts to reduce complexity and supports the removal of the quality measure ACO-11 from the MSSP measure set.

II.F – Applicability of Proposed Policies to Track 1+ Model ACOs

Summary

If the proposed approach to adding the BASIC track is finalized and made available for agreement periods beginning in 2019, CMS would discontinue future application cycles for the

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Track 1+ Model. Existing Track 1+ Model ACOs would be able to complete the remainder of their current agreement period in the model, or terminate their current participation agreements (for the Track 1+ Model and the MSSP) and apply to enter a new MSSP agreement period under either the BASIC track (Level E) or the ENHANCED track, depending upon whether the ACO is low or high revenue. The SNF three-day rule waiver would be available starting July 1, 2019, for eligible Track 1+ Model ACOs that apply and are approved for the waiver.

There are two ways the proposed policies would become applicable to Track 1+ Model ACOs—through revisions to:

- (1) Existing regulations that currently apply to Track 1+ Model ACOs, and
- (2) ACO's Track 1+ Model Participation Agreement.

CMS seeks comment on these considerations and any other issues they may not have discussed related to the effect of the proposed policies on ACOs that entered the Track 1+ Model beginning in 2018. CMS notes that these ACOs will complete their participation in the Track 1+ Model by no later than December 31, 2020, or sooner in the case of ACOs that entered the model at the start of their second or third performance year within their current three-year agreement period.

AAFP Response

The AAFP is supportive of CMS' application of the proposed policies to those participating in Track 1+ ACOs. Any early termination and transition to the BASIC or ENHANCED tracks should be at the discretion of the Track 1+ participants. **We strongly urge CMS to delay the implementation of all proposed policies until January 1, 2020.**

IV – Regulatory Impact Analysis

Summary

CMS anticipates the average impact of the proposed changes to be approximately \$2.24 billion in lower federal spending over 10 years from 2019 through 2028. CMS expects a drop in participation, mainly because the program will be less likely to attract new ACO formation in future years as the number of risk-free years and maximum sharing rate available to new ACOs would be reduced. The changes are expected to increase continued participation from existing ACOs. CMS requests comment on the aspects of the rule that may incentivize behavior that could affect participation in the program and potential shared savings payments.

AAFP Response

The AAFP concurs with CMS' analysis that the decreased attractiveness of the program's one-sided tracks will deter the formation of new ACOs. We believe this is contrary to the goals of the MACRA legislation and the goals of this administration. CMS also believes the proposed policies will increase participation from existing ACOs. While we appreciate CMS' desire to provide improved incentives for these ACOs, it is unclear how many existing Track 1 ACOs will continue in the program. Under the current proposal, the shared savings rate for existing Track 1 ACOs is significantly reduced and they will be forced to assume downside risk. To address these concerns, we ask CMS to increase the shared savings rate for ACOs in BASIC tracks A-D to 50 percent and allow new ACOs to participate in the upside-only levels for three years.

While this rule aims to address concerns related to low-revenue ACOs, there is still a segment of practices without a viable APM option. Without sufficient opportunities for small and rural ACOs to participate in APMs, practices are forced to remain in a broken FFS environment that places them at a significant disadvantage compared to their peers. The FFS structure does not incent improved quality and decreased costs, which is part of what spurred the transition to

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value-based payment in the first place. Moreover, the MIPS pathway was intentionally designed to be difficult and drive practices to APMs. We strongly urge CMS to make additional pathways available for small and rural practices as soon as possible.

We appreciate the opportunity to make these comments. Please contact Erin Solis, Regulatory Compliance Strategist, at 913-906-6000 or esolis@aafp.org, with any questions or concerns.

Sincerely,

Michael L. Munger, MD, FAAFP

Michael Mungy MD

Board Chair

About Family Medicine

Family physicians conduct approximately one in five of the total medical office visits in the United States per year—more than any other specialty. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families, and communities. Family medicine's cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient's integrated care team. More Americans depend on family physicians than on any other medical specialty.