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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS-1701-P; Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success Proposed Rule

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Medicare Shared Savings Program (MSSP) Pathways to Success proposed rule. The AMA is encouraged by several proposed policies aimed at improving the opportunities for accountable care organizations (ACOs) to succeed, but also recommends some significant changes. Our key comments may be summarized as follows:

- **We are pleased that CMS proposes to extend ACO agreement periods to five years, as this will improve stability and predictability for ACO participants.** Studies of physician experience with payment models have found that constant changes in payment policies and requirements are extremely disruptive to practices.

- **As the AMA has recommended, CMS proposes to better account for changes in ACO patients' health status over time.** We support the proposal to treat newly and continuously assigned beneficiaries the same way for purposes of risk adjustment. We also encourage CMS to consider modifying its policy in the final rule to include adjustments to ACO baseline scores, not just benchmarks, as many conditions that may be newly documented when patients are assigned to an ACO are not new diagnoses for the patient, and to eliminate the proposed limit of three percent in the amount that risk scores may change during a five-year agreement.

- **The AMA agrees with CMS' proposal to integrate the Track 1+ model into the MSSP.** The AMA joined with the National Association of ACOs (NAACOs) and other organizations in proposing to CMS that the Track 1+ model be created following enactment of the Medicare Access and CHIP Reauthorization Act (MACRA) and we are glad that CMS views it as a positive addition to the ACO program.

- **The AMA appreciates that CMS is seeking to better define ACOs' accountability to match their capabilities, as we have long recommended.** Although we continue to strongly support allowing ACOs and other alternative payment models (APMs) to set risk requirements at a percentage of revenues instead of benchmark spending, we recommend an alternative approach for establishing shared savings and risk requirements based on the ACO participants' ability to control key aspects of spending, instead of the proposed low- or high-revenue designations.

- **We urge CMS to retain the Track 1 model, potentially with modifications to encourage greater savings, instead of forcing all ACOs into two-sided risk models.**

- **The AMA recommends that additional upfront payments for services be made available to physicians participating in ACOs, beyond those currently available under the Medicare Physician Fee Schedule.**

- **Instead of focusing on opioid dosage, quality measurement should focus on promotion of preventive strategies such as screening and treatment for substance use, as well as the quality of pain care.** The AMA is actively working to reverse the opioid epidemic, and agrees that performance measurement may be one avenue for tracking progress and improving management of patients' pain and substance use disorders; however, the AMA has several concerns with the opioid-related measures that CMS has proposed for use within the MSSP.

- **The AMA agrees with NAACOs and other stakeholders that the proposed sharing rates for new ACOs are too low and will hurt the business case for organizations contemplating participation.** Surveys conducted by NAACOs have demonstrated that ACOs incur very significant start-up costs. Even under current MSSP policies, it is difficult for many ACOs to recover their initial investments, and a reduced sharing rate will make this even more difficult.

- **The AMA supports the proposed flexibilities for ACOs to choose between prospective and retrospective assignment methods, and the expanded definition of primary care services to be used in claims-based assignment.** We agree with NAACOs that the current voluntary alignment process has been underutilized and that CMS should explore policies to improve this process, such as allowing patients to make their designation by calling 1-800-MEDICARE, instead of adopting a new opt-in process focused on patients choosing ACOs instead of choosing their primary physician.

- **The AMA appreciates the policy proposals regarding waivers of the skilled nursing facility three-day inpatient stay rule and certain telehealth rules.** ACOs in the shared savings-only model have generated more savings for Medicare than those in two-sided models. Accordingly, the AMA recommends that the policy waivers available to ACOs that take downside financial risk also be available to ACOs in the shared savings-only model. These waivers help ACOs to better manage the delivery of patient care and are as likely to improve care for patients assigned to shared savings ACOs as they are to improve care for patients assigned to two-sided ACOs.

- **The AMA strongly recommends that ACO payment incentives under the Merit-based Incentive Payment System (MIPS) be excluded from ACO expenditures for purposes of comparing benchmark to actual spending and calculating each ACO's savings and losses.** This policy unfairly punishes high-performing ACOs that do not meet Advanced APM criteria by

requiring them to participate in MIPS but then counting their MIPS payment incentives against them. It would have the perverse result of linking better MIPS scores to reduced likelihood of earning shared savings. CMS currently excludes Advanced APM bonuses from ACO expenditures and it should do the same for MIPS incentive payments.

- **The AMA has concerns with the proposal allowing CMS to exercise the option to terminate an ACO's participation agreement early if the ACO's expenditures exceed its benchmark by a certain amount.** By potentially terminating ACOs before they have several years of meaningful performance data available, this provision may have the unintended consequence of removing well-intentioned ACOs from the program which may go on to achieve savings and make quality improvements in later years.

- **The AMA encourages CMS to allow individual physicians and subsets of physicians within a practice that has a single taxpayer identification number to align themselves with ACOs as participants.** It should not be necessary for all the physicians within a group practice to participate in an ACO because one or more members of the group wish to participate in the ACO. A taxpayer identification number for a medical group is basically a means of billing Medicare for claims under the fee-for-service system; physicians should have greater flexibility in how they organize themselves for delivering care within ACOs and other APMs.

The remainder of this letter provides a more detailed explanation for several of our key recommended changes in the proposed rule.

The Track 1 ACO Model Should Be Retained

Under the proposed rule, all ACOs would be required to move into a two-sided risk model. This proposal should not be finalized. The Track 1 model should be retained for four reasons:

- Many ACOs have demonstrated that they can reduce Medicare spending without accepting downside risk, and in 2017, Track 1 ACOs achieved greater savings than ACOs with downside risk in Tracks 2 and 3.
- The methodology used by CMS can unfairly penalize ACOs for increases in spending that ACO participants cannot control.
- Many physicians are using their Track 1 participation as a means of participating in the Quality Payment Program.
- CMS does not have statutory authority to retire the shared savings-only model and replace it with the BASIC and ENHANCED Tracks.

ACOs Can Achieve Savings for Medicare Without Downside Risk

In every year since the MSSP was first created, the majority of Track 1 ACOs have reduced Medicare spending relative to CMS benchmarks without being subject to downside risk. In 2017, the savings produced by the Track 1 ACOs that reduced spending were large enough to offset the increase in spending for those that did not generate savings as well as the shared savings payments to those who did.

The premise underlying the proposed policies is that ACOs with downside risk achieve greater savings than those with upside-only risk, but the exact opposite was true in 2017—the 433 Track 1 ACOs saved

an average of $37 per beneficiary, 36 percent more per beneficiary than the Track 2 and 3 ACOs. Because there were so many more Track 1 ACOs, the total net savings they generated for Medicare ($290 million) was more than 12 times the net savings generated by the Track 2 and 3 ACOs ($23 million). Based on the experience to date, terminating the Track 1 program could increase Medicare *spending* rather than increasing *savings*.

The Benchmarking Methodology Can Unfairly Penalize ACOs

CMS indicates that it is continuing to refine its ACO benchmarking methodology. For example, the risk adjustment methodology used to date has failed to account for patient characteristics and changes in those characteristics that can result in the need for more services or more expensive services, which has unfairly penalized ACOs that have more of these patients. Although the current proposal would allow ACOs' risk scores to change over time, the risk adjustment methodology still does not account for important factors in patients' health care needs, such as functional status and severity or stage of illness.

CMS has included some changes to the benchmarking methodology in the proposed rule, such as modifying the use of regional vs. national data and allowing changes in patient health status to be more fully recognized in the risk adjustment system, but there is no evidence yet as to how effective these changes will be, nor does CMS propose adjustments for aspects of spending that ACO providers cannot control, such as Part B drug costs. Requiring ACOs to accept downside risk based on a flawed methodology could penalize them financially for delivering the services their patients need.

Track 1 Offers a Better Way to Measure and Reward Quality for Many Physicians

CMS has recognized physician participation in a Track 1 ACO as a MIPS APM. In section 1899(b)(3)(D), Congress specifically authorized CMS to "use alternative criteria than would otherwise apply" under the MIPS program for making payments to ACOs. Many physicians have found that using ACO quality measures and reporting on other MIPS elements through the ACO is a more efficient and effective way of measuring and improving the quality of care than is possible through the standard MIPS program. CMS has reported that ACOs have significantly improved the quality of care for Medicare patients, so even if a Track 1 ACO has not reduced Medicare spending, it may well have improved the quality of care for Medicare patients and enabled participating physicians to manage quality reporting more efficiently. Terminating the Track 1 option could therefore have negative impacts on both Medicare patients and their physicians.

CMS Cannot Substitute the BASIC and ENHANCED Tracks for the Shared Savings-Only Model

What CMS refers to as "Track 1" is the "shared savings program" that was established by section 1899(d) of the Social Security Act. Under this statutory authority, "ACOs that meet quality performance standards established by the Secretary are eligible to receive payment for shared savings." Although Congress also provides the option for CMS to use "partial capitation" or "other payment models" rather than shared savings to make payments to ACOs, it is not clear that section 1899 allows CMS to replace Track 1 entirely with the BASIC and ENHANCED tracks.

Section IV.E of the Proposed Rule (83 FR 41927) states that the proposed requirements for downside risk and other changes rely on the authority granted in section 1899(i)(3), but it incorrectly states that section 1899(i)(3)(B) "requires that such other payment model must not result in additional program

expenditures." What this section actually says is that "payments to an ACO for items and services…for beneficiaries for a year…shall be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such year if the model were not implemented." In other words, the statute is not referring to a measure of overall program spending, but to the change in spending for *each* ACO.

The current Track 1 model meets the statutory requirements for shared savings payments under section 1899(d). Section 1899(i) permits CMS to use payment models that meet the requirements for partial capitation or other payment models instead of the shared savings approach.[1] However, one of the requirements for both of these other payment models is that spending cannot be more for such an ACO than would otherwise be expended for such ACO if the model were not implemented.[2] In the proposed BASIC and ENHANCED tracks, if Medicare spending exceeds an ACO's benchmark, the ACO would be required to repay a *portion* of the difference but not the full amount. Because the ACO would not be required to repay the *full* increase, Medicare would spend more for that ACO than it would otherwise have spent and this does not satisfy the statutory requirement in section 1899(i).

Clearly, modifying the proposed BASIC and ENHANCED track models to require that each ACO repay any spending above its benchmark in full would be an undesirable policy and unattractive to potential applicants, so CMS cannot use its proposed downside risk models to completely replace the shared-savings only model. Moreover, we believe Congress clearly intended to allow ACOs to participate in a shared savings-only model. Consequently, the AMA recommends that CMS retain Track 1, with potential modifications to improve the model and increase the savings for Medicare, as described below. CMS could use other statutory authorities to implement the other models included in the BASIC and ENHANCED tracks, in addition to retaining Track 1, similarly to how the Track 1+ and Next Generation ACO models were established.

Modify Rather than Retire Track 1

Requiring ACOs to accept downside risk is not the only approach that CMS could use to increase net savings to the Medicare program from the MSSP. For example, one policy expert identified several different options for increasing MSSP savings, including:[3]

- Drop ACOs from the program if they have not achieved savings after several years;
- Reduce shared savings payments to ACOs that incur large losses before generating savings; and
- Allow ACOs to take accountability for the specific types of spending they can control, rather than total Medicare spending.

The information provided in section IV.D of the proposed rule (83 FR 41926-27) does not indicate that these or other options were considered. We recommend that CMS analyze these and other approaches and develop a comparative analysis of their advantages and disadvantages in lieu of retiring Track 1.

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[1] Social Security Act § 1899(i)(1).
[2] Social Security Act § 1899(i)(2)(B) & (3)(B).
[3] Miller HD. *How to Fix the Medicare Shared Savings Program*. Center for Healthcare Quality and Payment Reform, June 2018. Available at: http://www.chqpr.org/downloads/How_to_Fix_the_Medicare_Shared_Savings_Program.pdf

Base Risk Requirements on ACO Participants' Ability to Control Spending

The AMA commends CMS for recognizing that ACOs differ significantly in their ability to accept financial risk and for including limits on downside risk based on a percentage of the ACO participants' revenue, not just a percentage of Medicare spending. This is consistent with the approach that the AMA recommended and CMS adopted in its regulations defining Advanced APMs.

We also commend CMS for recognizing that ACO participants differ in their ability to influence or control total Medicare spending, and that adjustments in financial rewards and penalties are needed based on those differences. We do not believe the proposed distinction between "low revenue" and "high revenue" ACOs is an appropriate or effective way of making those adjustments.

It is true that if 90-100 percent of Medicare spending on the beneficiaries assigned to an ACO represents services delivered by the ACO participants, they will be in a better position to control spending than participants in an ACO where only 10-20 percent of the spending is associated with the participants' services. However, one cannot conclude that an ACO that delivers services representing 30 percent of total spending has significantly greater control over the total than an ACO that only delivers services representing 20 percent of spending. Neither ACO delivers a majority of the services that are driving spending, and the difference in proportion could be entirely due to characteristics of the patients who are assigned to the ACO, not to any difference in factors that the ACO participants can control.

For example, a physician-led ACO whose assigned beneficiaries are younger and less frail is likely to have lower levels of spending on hospitalizations and post-acute care than other ACOs, and therefore the physicians' revenue will represent a higher share of total spending in the ACO. This would not indicate that the physicians have a greater ability to control spending or to accept risk than physicians in other ACOs; indeed, the exact opposite may be true, because the primary way many ACOs have achieved savings has been through reducing the use of expensive post-acute care services. Another example would be that ACO participants who administer expensive infused medications in their offices may have revenues representing a higher share of total spending than in ACOs organized by physicians who do not administer infused drugs. The first set of physicians cannot better control drug prices or pay penalties to Medicare if drug prices increase faster than CMS benchmarks than the second ACO's physicians.

The proposed rule states that the "low revenue/high revenue" distinction is intended to measure differences in the ability of the ACO to control total spending, but the discussion suggests that the real goal is to identify which ACO participants have more financial resources and are less likely to be bankrupted by repaying losses to CMS. We are concerned that the proposed rule is so narrowly focused on "risk" that it overlooks the original intent of the ACO program to enable physicians and other health care providers to deliver patient care in better and more affordable ways.

To actually "measure the degree of control that ACOs have over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries," as stated in the regulation, the AMA recommends that CMS do so directly instead of using problematic proxies such as the proportion of revenues. This could be done by dividing services or spending into several categories reflecting the relative levels of control that ACO participants would be expected to have over services, and then assigning different savings thresholds and sharing levels to each. For example, spending could be divided into the following categories, reflecting decreasing levels of control by the ACO participants:

- Services delivered by the ACO participants;
- Services ordered by the ACO participants;
- Potentially avoidable complications of services delivered or ordered by the ACO participants; and
- All other services.

Under this approach, if a large share of the spending on an ACO's assigned patients is associated with services that are delivered or ordered by the ACO participants, or with potentially avoidable complications of those services, that ACO would be in a much better position to control total spending than in an ACO where most of the services are being delivered or ordered by other providers. Both ACOs could be held accountable for the spending on the services their participants can control, while avoiding penalizing them for decisions made by other providers that the patients have chosen to use.

This approach is consistent with the one payment option Congress authorized in section 1899 that CMS has not implemented—the "Partial Capitation Model." In section 1899(i)(2), Congress specifically gave CMS the authority to place an ACO "at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B." Many physician groups have experience with using this approach in commercial insurance and Medicare Advantage plans.

Allow Additional Upfront Payments to ACO Participants for Patient Services

We were pleased that CMS acknowledged in section IV.C.1.a.(2) (83 FR 41919) that ACOs must make significant upfront investments in enhanced services and care management infrastructure that can only be recovered through shared savings payments. As the AMA has pointed out repeatedly in its comments to CMS on APMs, one of the biggest barriers physicians face in delivering higher-value care is that there is no payment at all in the Medicare Physician Fee Schedule (or inadequate payment) for many high-value services, such as development of treatment plans and employment of nurse care managers. In addition, if participants in the ACO reduce the use of current billable services and substitute unbillable services, they will lose revenues in the short run and may not be able to wait until CMS makes a shared savings payment to recoup those losses.

For ACOs to reduce Medicare spending without harming quality of care for patients, participating physicians need to be paid appropriately for delivering the *right* mix of services to patients, not just receive a financial bonus when fewer services are delivered. Moreover, if an ACO is going to be *accountable* for total Medicare spending, the ACO participants should have the *flexibility* to be paid upfront for the services they need to deliver in order to reduce spending and improve quality.

Ideally, each physician in an ACO would be able to participate in one or more APMs specifically designed to support high-value care for the types of patients they treat. Unfortunately, CMS has only implemented a small number of physician-focused APMs, and most physicians do not have the opportunity to use an APM to improve care delivery. Until more primary and specialty care APMs are available, it is essential that the MSSP provide the opportunity for physicians participating in an ACO to be paid differently. CMS did provide additional resources to some ACOs through the Advanced Payment ACO Model and the ACO Investment Model, but these programs are no longer available to new applicants. The proposed expansion of telehealth services will likely be very helpful to ACOs, but this will address only one aspect of services that are currently undercompensated.

We recommend that CMS create a mechanism whereby physicians in ACOs can receive upfront payments to support services that are currently not paid for under standard Medicare payment systems. Physicians in the ACO would identify what types of payments they need based on the specific ways they plan to change the delivery of patient care. Accountability for spending on these payments could be achieved in two different ways, depending on the ACO's overall accountability for spending:

- Track 1 ACOs would be responsible for repaying all or part of the upfront payments they receive if specific aspects of utilization or spending were not reduced. This is similar to the approach that CMS is currently using in the Comprehensive Primary Care Plus model.
- For ACOs in two-sided models, the upfront payments would be counted toward the overall spending for which the ACO is accountable, so if the additional payments do not result in more than offsetting savings, the ACO would be required to pay back CMS some or all of what they received. This is similar to the approach CMS has defined in the downside risk track of the Oncology Care Model.

Quality Measures Related to Use of Opioids

The AMA is actively working to reverse the opioid epidemic, particularly through the activities of the AMA Opioid Task Force, which was formed in 2014 and includes 26 national medical specialty and state medical associations, the American Osteopathic Association, and the American Dental Association. Performance measurement may be one avenue by which we can track progress and make improvements to reduce the opioid epidemic. The AMA supports every effort underway to meet this need. However, we have concerns with the opioid related measures CMS proposes for use within the MSSP. Quality measurement needs to focus on utilization of preventive strategies such as screening and treatment for substance use, as well as pain management, i.e., how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If ACO patients are receiving appropriate care for substance use disorders and if their pain can be well-controlled and function improved without the need for high doses of opioids over a long period of time, those may be indicators of good patient care, but a reduction in opioid dose alone is not an appropriate goal.

- *NQF #2940: Use of Opioids at High Dosage in Persons Without Cancer*

As the AMA has highlighted in our 2019 Physician Fee Schedule Proposed Rule comments, the AMA does not agree with the fundamental premise of a measure that focuses only on daily dose and duration of therapy involving prescription opioid analgesics because on its own it is not a good indication of quality patient care. In fact, since the Centers for Disease Control & Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time being forced to abruptly reduce or discontinue their medication regimens with sometimes extremely adverse outcomes, including depression, loss of function, and even suicide. There has been considerable discussion of these unintended consequences at meetings of the HHS Interagency Pain Management Best Practices Task Force.

Identifying those patients for whom daily morphine milligram equivalents (MME) prescribed are considered high may serve as an indicator of whether a patient is at risk of overdose and should be co-

prescribed naloxone, but it is not a mark of higher quality care. The CDC recommendations[4] allow physicians to document a clinical rationale or justification when suggested dose levels are exceeded; yet, the existing measures that focus on MME do not capture if a justification exists nor do they provide a well-defined and targeted denominator.

We are also concerned with the feasibility of directly calculating the measure from the electronic health record (EHR). The electronic clinical quality measure (eCQM) is reliant on a function that is not consistently supported by EHR vendors, and participation with the measure would require additional costs or vendor fees placed on the ACO. It is our understanding that the EHR does not uniformly capture MMEs and this calculation would be necessary to populate the measure's numerator. There are also Internet, iOS and Android-based apps that perform this functionality, but to use them the ACO would need to manually enter patient information and calculate the MME, introducing the possibility for human error. In addition, terminology and code mappings play a big role in how well an EHR-based calculator works, but due to the lack of consistency and standardized code mappings the results produced are not very reliable. Many physicians are not yet able to electronically prescribe controlled substances, and those that can do not have seamless integration between their controlled substance e-prescribing and EHR systems, which would present additional problems in capturing the needed eCQM information.

If CMS implements a measure that focuses on MME it must adequately define the patients for whom higher doses of opioids may be appropriate. Otherwise, the measure may provide invalid representations of physician performance and CMS would be sending a signal to physicians that the government does not think physicians should prescribe these medications, and substituting its judgement about the risk-benefit tradeoff for those of physicians. Therefore, CMS should consider and explore alternative measures or ones that provide complementary information on the quality of care in managing substance use disorders and/or pain, for example, NQF #2597 for assessing substance use screening and intervention.

- *NQF #2950: Use of Opioids from Multiple Providers in Persons Without Cancer*

The AMA has concerns with the proposed inclusion of "Use of Opioids from Multiple Providers in Persons Without Cancer" (NQF #2950) in the MSSP as it was developed with the intention of determining the quality of care provided by prescription drug health plans and not for ACOs. The measure as currently specified requires health plan medical and pharmacy claims and member enrollment information and the data may not be readily available across all ACOs given their varying composition and access to pharmacy claims data. Comprehensive assessment of the feasibility of collecting and reporting these data at the ACO level must be determined. For example, for those MSSP participants that provide care across state lines or have patients that receive care from others outside of the ACO, it is unclear whether they can access data to ensure that prescriptions were not received outside of the network. Ensuring that ACOs can collect the data needed to satisfy the measure requirements will inform and allow thorough evaluations of the reliability and the validity of the performance scores. For example, it is not clear what minimum sample sizes are needed to ensure that performance scores could be considered reliable across ACOs. The testing completed by the Pharmacy Quality Alliance included more than 700 Medicare Part D prescription drug plans, eight state-based Medicaid prescription drug plans, and one commercial health plan. The AMA believes that this measure must be adequately specified and tested across ACOs prior to its implementation in MSSP.

[4] Centers for Disease Control & Prevention. Guideline for Prescribing Opioids for Chronic Pain. 2016. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

- *NQF #2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer*

The AMA has the same concerns with the proposed inclusion of "Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer" (NQF #2951), given the dearth of information on the feasibility of collecting and reporting pharmacy claims data and the lack of specifications and testing for the intended level of analysis. In addition, on review of the performance scores provided during the NQF endorsement review, we question whether this measure has adequate variation in scores to enable meaningful comparisons in performance since the testing results showed that there was less than 2.5 percent difference between the minimum and maximum rates for the Medicare population and less than 5.5 percent for the Medicaid population. If similar rates will be found when applied to ACOs, we believe that it will be difficult to distinguish better versus worse care and it also must be adequately specified and tested across ACOs prior to its implementation in MSSP.

Conclusion

The AMA appreciates the opportunity to provide our comments and thanks CMS for considering our views. If you should have any questions regarding this letter, please feel free to contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD