

October 16, 2018

Seema Verma Administrator Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services Room 445–G, Hubert H. Humphrey Building 200 Independence Avenue SW Washington, DC 20201

Re: Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations Pathways to Success (CMS-1701-P)

Dear Administrator Verma,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS') proposed rule Medicare Program; *Medicare Shared Savings Program; Accountable Care Organizations Pathways to Success*, as published in the Federal Register on August 17, 2018. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College has been an ardent support of the Medicare Shared Savings Program (MSSP) since its inception because we feel it serves a vital role in the transition to value-based reimbursement. We appreciate the agency's ongoing work to continue to make modifications to improve the design of the program and ensure its viability into the future; goals that ACP shares. We appreciate the opportunity to offer comments in response to this proposed rule. We make the following recommendations in the hopes of helping the MSSP to continue to grow and attract new Accountable Care Organizations (ACOs), better coordinate care and recognize efficiencies to control costs and produce savings for participating ACOs and Medicare alike, and above all else improve patient care for the Medicare beneficiaries these ACOs serve.

Summary of Key Recommendations:

- Limited time in one-sided risk ACP strongly supports the need to create a glide path of more incremental increases in risk but firmly opposes strict limits on the length of time ACOs may remain at each level of risk provided they are meeting quality and financial performance standards. Two years is not a sufficient amount of time for ACOs to give new ACOs in one-sided risk. CMS should give ACOs an opportunity to leverage this new glide path and voluntarily accept more risk.
- **Sharing rates** The proposed shared savings rates are insufficient to warrant the level of risk and would result in a mass exodus from the program. ACP strongly opposes any reduction in the sharing rates below 50%, which has proven profitable.
- **Agreement period** ACP strongly supports increasing the length of agreement periods from three years to five years because it would give ACOs more time to gain experience and implement redesigned care processes and increase predictability.
- **Advanced payment opportunities** ACP urges CMS to reinstate advanced payment opportunities, which provide critical support particularly for small and rural ACOs.
- Regional trend factors ACP supports incorporating regional expenditures into benchmarks earlier but does not support capping it nor reducing its weight relative to the national trend factor. To improve accuracy, CMS should remove an ACO's own beneficiaries from the regional beneficiary population to which it is being compared.
- **Risk adjustment** ACP strongly supports accounting for negative changes in health status among continuously assigned beneficiaries but strongly opposes artificially capping risk adjustment without further study, particularly at 3% as proposed.
- **July 1, 2019 start date** It is important to give new ACOs an opportunity to join the MSSP in 2019, but the College has several logistical concerns about a mid-year start date, particularly proposals to evaluate cost and quality performance based on a full year's worth of data. ACP recommends allowing ACOs whose agreements expire in 2018 to extend up to a full year to minimize disruption.
- Beneficiary assignment ACP strongly supports proposals to allow ACOs to annually select their beneficiary assignment mechanism. Giving ACOs more control over patient assignment increases predictability in their ability to control assigned patient costs and outcomes and therefore builds confidence in accepting more risk.

Detailed Recommendations:

Introduction:

The College agrees with CMS that MSSP ACOs are a critical component of the transition to value-based payment reform. To date, the MSSP is the largest by far of any of the Advanced Alternative Payment Models (APMs), with 377,515 participating clinicians in 561 ACOs that collectively care for 10.5 million Medicare beneficiaries. Therefore, its ongoing success is intrinsically tied to the success of the value-based payment movement as a whole. By a similar token, approximately 82% of MSSP ACOs are in Track 1, 43% of which are currently in their second agreement period, and the significant proportion of the program they comprise should be heavily weighted when it comes to considering any dramatic program changes, including those proposed in this rule.

Because this model is voluntary, to ensure its continued viability, it is absolutely paramount that CMS must balance the need to protect Medicare trust fund dollars with the need to create a viable business model that will attract individual ACOs to participate, which we recognize is a delicate but important balance. We could not agree more with CMS that to this point, steep increases in risk level between the various tracks have prevented ACOs from progressing to higher levels of risk, and that by creating more of a graduated glide path to higher levels of risk, CMS will support ACOs progressing to higher risk models. We also agree that eliminating some of the differences between the tracks including risk adjustment and beneficiary assignment methodologies and allowing ACOs to advance to higher levels of risk within their current agreement period will facilitate ACOs advancing to higher risk models at a quicker pace.

However, we strongly disagree that forcing ACOs into risk-bearing models after just two years would be an effective way to motivate more ACOs to take on more risk sooner. To the contrary, we think this would be likely to have damaging consequences on participation in the program. Moreover, we feel that proposals to simultaneously drastically reduce the sharing rates would further hinder participation in the program, to the detriment of the Medicare trust funds.

CMS' goal with this program is to improve patient care while generating savings to the Medicare trust funds. In this letter, we describe an alternative policy design that we feel better encapsulates both goals while ensuring the future viability and growth of the MSSP. In short, we recommend CMS address concerns about protecting the Medicare trust funds at the individual ACO level by requiring all ACOs perform within the risk corridor (above the Minimum Loss Rate) and meet quality targets in order to continue into a second and subsequent agreement periods. That way, CMS is protected from individual ACOs that remain in the program despite generating losses year after year without having to reduce sharing rates or limiting the time ACOs may remain in one-sided models across the board, averting a likely mass exodus from the program. By instead focusing on establishing a more gradual "glide path" to increasing risk incentivized by corresponding increases in reward and eliminating unnecessary design differences between the various levels, ACOs will voluntarily move into more aggressive risk tracks without being forced, as evidenced by early interest in Track 1+. Moreover, by improving risk-adjustment, benchmarking and patient assignment methodologies, CMS will improve accuracy and participant confidence in program metrics and invite wider participation, which means improving care for more Medicare beneficiaries and generating more savings for Medicare.

Limited time in one-sided risk

CMS proposes to create two separate tracks, known as BASIC and ENHANCED. Under the BASIC track, new ACOs could remain in one-sided risk for a maximum of two years (ACOs identified as having previously participated in the program under Track 1 would be restricted to a single year under a one-sided model) before being automatically moved along a continuum of gradually increasing levels of risk and reward that eventually caps out at a 50% shared savings rate and a minimum level of risk that aligns with the Advanced APM nominal amount standard. The ADVANCED track features consistently high levels of non-symmetric risk and reward. Specific sharing rates for both tracks are discussed in

greater detail later in this letter. ACOs with previous experience would be required to enter the ENHANCED track or the highest level of risk and reward in the BASIC track (Level E). Low-revenue ACOs would be allowed up to two agreement terms in the BASIC track, but high-revenue ACOs would be expected to move to the ADVANCED track by their second agreement period. Proposals concerning high-revenue ACOs and ACOs with previous experience are separately discussed in later sections.

The College agrees that creating a suitable glide path to higher levels of risk is necessary to make more ACOs comfortable taking on risk. However, CMS should not impose strict time limits on the amount of time ACOs can remain at each level of risk. In any case, two years is not a sufficient amount of time for ACOs in one-sided risk. Past performance data shows it is common for ACOs to start generating savings in their third or fourth performance year after gaining experience in the program and allowing time for savings to generate from care delivery reforms. Forcing ACOs into levels of risk before this point will result in massive drop-offs in participation, particularly among small and rural ACOs, and will cause CMS to miss out on savings that may have been generated by these same ACOs in later performance years. ACP urges CMS to instead offer ACOs proper incentives to advance to higher levels of risk, which will achieve CMS' goal of enticing more ACOs to move into higher levels of risk without risking upending its flagship Advanced APM. ACOs will voluntarily advance to higher levels of risk if provided proper incentives, as proven by early interest in Track 1+.

Moreover, based on CMS' proposals to eliminate unnecessary distinctions between the various tracks and levels, and our assertion that there is sufficient incentive for ACOs to voluntarily advance to higher levels of risk, ACP believes that the distinction between the BASIC and ADVANCED tracks is unwarranted and adds unnecessary complexity. We would instead recommend CMS create a unified program with separate tracks that differ simply in the level of risk and reward that they offer. As detailed in our recommendations for sharing rates, the sharing rate should be set at a minimum of 50% for all levels, including one-sided models. From there, CMS should create a series of consistent, gradual increases in both risk and reward, rather than a few inflection points to significantly different levels of risk. This is especially needed between what would be Level E in the basic track and the ADVANCED track. This will both create a smooth glide path to higher levels of risk and reduce complexity within the program.

At a minimum, CMS should finalize a more gradual pathway to risk but delay finalizing an aggressive two-year timeline to give ACOs an opportunity to leverage this new gradual pathway to risk and voluntarily accept more risk. Improving the accuracy of financial benchmarking and risk adjustment methodologies, incorporating flexibility in beneficiary assignment, and increasing the benchmark from three to five years, will inherently "provide more certainty over benchmarks... give ACOs a greater chance to succeed in the program... [and] improve program incentives and support ACOs' transition into performance-based risk," as CMS notes. This, coupled with more options for a gradual path to risk with potential for greater reward in exchange for assuming greater potential responsibility, will inherently encourage ACOs to advance to higher levels of risk without having to choose between advancing before they are ready according to a one-size-fits-all timeline or dropping out of the program.

CMS notes that a major deterrent to electing high risk tracks to date has been a lack of a glide path, adding that the magnitude of potential losses in Tracks 2 or 3 is "very high" and likely "significant issue" that contributes to ACOs' reluctance to participate in these tracks. ACP too is confident that low uptake of Tracks 2 and 3 is largely due to the lack of a gradual pathway that allows ACOs to build confidence in taking on more risk. This is supported by the overwhelming interest to participate in the new Track 1+ model. In the first year it was offered, 55 ACOs started participation agreements, instantly more than doubling participation in performance-based risk models. This suggests that it wasn't the lack of interest in two-sided risk models, but rather a lack of models that offered graduated levels of risk that prevented many ACOs from taking the leap from no risk to significant levels of risk. CMS agrees that availability of a lower-risk, two-sided model "is effective to encourage a large cohort of ACOs to rapidly progress to performance-based risk."

CMS explains that a large driver behind its proposed reorganization of the program are financial and quality results to date that prove "ACOs in two-sided risk models generally perform better than ACOs that participate under a one-sided risk model." However, the opposite is true. In 2017, 433 Track 1 ACOs saved an average of \$47 per beneficiary, 36% more than Track 2 or 3 ACOs. In aggregate, Track 1 ACOs generated more than 12 times the net savings as Track 2 and 3 ACOs combined, even after accounting for shared savings payouts (\$290 million versus \$23 million), thanks in large part to the heavy volume of MSSP ACOs in Track 1. No matter how you look at it, one-sided ACOs are saving Medicare money, and at larger rates on both a per-beneficiary and aggregate basis than their two-sided counterparts. Moreover, this program was profitable to Medicare even after generating over \$800 million in shared savings bonuses to ACOs, which will be reinvested back into infrastructure and new value-based innovations that improve patient care, a triple win for Medicare, ACO participants, and patients alike. Not only does this prove that Track 1 ACOs already have more than sufficient motivation to save money, it proves that forcing ACOs out of this profitable model after two years could cost Medicare money.

The proposed two-year mark at which ACOs would be required to take on risk is all-themore concerning given the fact that CMS agrees that ACOs improve over their tenure in the program because they "need time to understand performance, gain experience and implement redesigned care processes." Additionally, value-based reforms, including a larger focus on preemptive, high-value services, a more team-based approach to care coordination, and a wider variety of patient-centered spectrum of services do result in savings, but this takes years to capture. Under these new proposals, ACOs would be forced to move to risk before positive changes would be realized. According to independent analyses, ¹ slight savings in per beneficiary spending generally do not accrue until the third performance year, and substantial savings not until the fourth performance year. 2017 MSSP performance data mirrors this trend; 2017 and 2016 starters each yielded \$34 million in total losses, 2015 starters yielded a slight aggregate savings of \$5 million, while 2014 and 2012/2013 starters netted a rather substantial \$173 and \$205 million profit respectively, suggesting once again that if given sufficient time, the MSSP can be profitable even with a strong presence of ACOs in one-sided risk tracks.

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 $^{^1\} http://avalere.com/expertise/providers/insights/medicare-accountable-care-organizations-generate-savings-as-experience-grow$

In its regulatory impact analysis, CMS makes the assumption that the proposed BASIC track would "increase participation in performance-based risk by ACOs that may not otherwise take on the higher exposure to risk." To the contrary, studies prove that it is much more likely that after just two years, ACOs that do not feel comfortable with risk will drop out of the program, particularly if coupled with proposed changes to have them be financially accountable for shared losses even if they drop out before the end of a performance year. A May 2018 NAACOs survey found that more than seven in ten ACOs would consider dropping out of the program if forced into higher levels of risk.2 CMS acknowledges as much in the regulatory impact analysis when it says that the proposed faster transition to performance-based risk "can affect broader participation."

One-sided risk models create an important on-ramp for a broad spectrum of clinicians and suppliers who have not participated in a value-based initiative before, but are especially critical to making the model accessible to and attract small, rural, safety net, and/or physician-only ACOs, which CMS acknowledges. These types of ACOs are especially challenged by the upfront costs to forming and operating ACOs and have a much more limited ability to take on financial risk without risking the viability of their ability to stay in practice. Accordingly, forcing these types of ACOs to take on risk after only two years in the program would disproportionately impact the ability of small, rural, safety net, and physician-owned ACOs that are able to continue participating in the program. Often, these types of ACOs have the strongest ability to curb spending and improve quality so finalizing these proposals could hinder success of the MSSP as a whole, as well as be a lost opportunity to improve care for thousands of Medicare beneficiaries, particularly in rural areas. Of note, four out of every ten ACOs in Track 1+ were likely comprised of independent physician practices and/or ACOs that include small rural hospitals, proving that these types of ACOs will progress to two-sided models, but that they cannot practically weather higher levels of risk to the same extent that their larger counterparts may be able to, and forcing them to do so may give many small and rural ACOs no other choice but to exit the program.

The College strongly supports CMS' proposal to allow eligible ACOs the option to elect entry into a higher level of risk and potential reward for each performance year within their agreement period. This is a win-win, both allowing CMS to achieve its goal of shifting more ACOs into higher levels of risk and giving ACOs more flexibility and would be particularly impactful if CMS finalizes its policy to extend the benchmark period from three to five years. The College has previously called on CMS to allow ACOs to progress to higher levels of risk within their agreement period and are pleased to see this proposal.

Sharing rates

CMS proposes to reduce overall sharing rates for savings earned, particularly for one-sided and lower risk models. The potential shared savings rate for one-sided risk models would be cut in half, from 50% to 25%. ACOs in the BASIC track would gradually move along a continuum of increasingly higher levels of risk and reward before capping out at a maximum 50% shared savings rate (depending on quality performance) with a minimum shared losses rate that is tied to the minimum Advanced APM nominal amount standard.

² https://www.naacos.com/press-release-may-2-2018

The ENHANCED track which would feature a shared savings rate of up to a 75% and an inverse shared losses rate that could range from 40% to 75%. The proposed sharing rates for ACOs in the BASIC and ENHANCED tracks are displayed below.

Current:

	Track 1	Track 1+	Track 2	Track 3
Shared	Up to 50%	Up to 50%	Up to 60%	Up to 75%
Savings				
Shared	N/A	30%	30%	Choice of symmetrical
Losses				MSR/MLR: (i) 0%; (ii) 0.5%
				increments between 0.5% -
				2.0%; (iii) varies based on #
				of assigned beneficiaries

Proposed:

	BASIC Levels A/B	BASIC Level C	BASIC Level D	BASIC Level E	ENHANCED
Shared Savings	Up to 25%	Up to 30%	Up to 40%	Up to 50%	Up to 75%
Shared Losses	N/A	30%, not to exceed 2% of revenue or 1% of benchmark	30%, not to exceed 4% of revenue or 2% of benchmark	30%, not to exceed AAPM risk standard	1- sharing rate 40% - 70% not to exceed 15% of benchmark

The College finds that the proposed shared savings rates are insufficient to warrant the corresponding level of risk and would result in a massive decline in participation if finalized. Positively encouraging ACOs to take on more risk by offering higher prospects for reward is a much more effective strategy for the future viability and growth of this voluntary model than reducing incentives to participate in lower risk models. CMS acknowledges that the model must have an appealing "value proposition" and provide "sufficient incentives" for ACOs to volunteer to accept risk. Perhaps no element is more critical to the value proposition than the sharing rate. A 2016 NAACOs study found that the average operating costs for ACOs was well over \$1.5 million, nearly \$2 million for single ACOs (as opposed to multi-ACOs). To justify the substantial financial risk and major cultural shift inherent to starting an ACO, the prospect for a return on investment must be there. There is no question that lowering the sharing rate, much less cutting it in half, will exponentially diminish existing and future participation in the program. CMS still benefits from every dollar in shared savings achieved regardless of the sharing rate, but higher sharing rates would attract a much larger participant pool, which will produce more savings for CMS.

ACP strongly opposes any reduction in the sharing rates below 50%. Track 1 ACOs yielded a net profit of \$131 million in 2017, proving the 50% sharing rate strikes a delicate

balance of incentivizing hundreds of ACOs to participate, while still remaining profitable for CMS, and should not be lowered. In particular, cutting the sharing rate in half to 25% for one-sided ACOs will turn many new ACOs from participation given the substantial upfront costs.

Higher savings rates also directly benefits patient care. ACOs are using the money earned by these shared savings payments to reinvest in value-based based and patient-centered innovations that will benefit patients at the ground level.

Minimum Savings Rate (MSR), Minimum Loss Rate (MLR), and loss sharing limits

CMS proposes to continue existing policies for setting the MSR and MLR (the dollar figure at which ACOs begin sharing in savings or losses based on financial performance relative to their benchmarks), including a variable MSR based on an ACO's number of assigned beneficiaries for one-sided risk tracks and a variable, symmetrical MSR methodology for two-sided risk tracks.

ACP supports continuing to allow ACOs in risk-bearing tracks to select their Minimum Savings Rate (MSR) and Minimum Loss Rate (MLR) because it provides them with the flexibility and autonomy that is critical to building confidence in accepting higher levels of risk. Due to the symmetrical nature of the MSR and MLR, the Medicare trust funds would also be protected. There is a benefit to maintaining some consistency in current requirements with ACO participants already have familiarity, as well as consistency between the various two-sided tracks to both reduce complexity and facilitate a more seamless progression to higher risk models. The College does not believe that allowing ACOs to select their MSR/MLR prior to the start of each performance year would lead to gaming. Performance varies significantly for each ACO from year to year and is hardly predictable due to substantial churn in both assigned beneficiaries and participating practices, evolving benchmarking and risk-adjustment policies, a steep learning curve, and a host of other factors, particularly in an ACO's early years of the program. Moreover, performance data is not released until typically six months after a performance year concludes, so ACOs would have a limited practical ability to game the system up to two years after the fact, at which point past experience proves that performance is likely to have improved considerably.

The College additionally recommends CMS build rewards for outstanding quality performance into sharing rates. As it stands, ACOs can have their MSR and MLR negatively impacted by quality performance that falls below certain standards, but they are not rewarded for superior quality performance. We ask that CMS establish a system where MSRs would increase and MLRs would decrease based on superior performance on quality measures, which would provide further incentive for ACOs to invest in high value services to further improve patient quality outcomes.

ACP urges CMS to set the loss sharing limit at the standard for Advanced APMs, which would be 3%, rather than 4% as proposed. Aligning the loss sharing limit with the MACRA standard would create consistency and give ACOs more confidence in entering into higher risk-bearing tracks.

Forced termination of ACOs with poor performance

CMS proposes a number of new program integrity provisions, including regularly monitoring for financial performance and permitting the forced termination of ACOs with multiple years of poor financial performance.

ACP believes enforcing program integrity at an individual ACO level by expecting ACOs to meet quality and financial performance expectations in order to continue in the program would be more appropriate and effective than forcing all ACOs along a continuum of increasing risk. However, it is critical CMS allow ACOs sufficient time to gain experience in the program before being liable for termination. Accordingly, ACP offers the following specific recommendations. ACOs should be protected from possible termination for one full agreement period. However, ACOs that generate losses beyond their MLR and/or fail to meet quality expectations by the end of their third performance year could be required to submit and implement a corrective action plan for their fourth performance year. Then, as a condition of being approved for a second or subsequent agreement period, ACOs could be expected to meet quality standards and operate within the risk corridor (not generate savings below the MLR).

We believe this timeframe is appropriate given earlier cited findings that ACOs tend to not reach significant savings until their fourth and fifth performance years. In the rule, CMS also notes that of the 14 Track 1 ACOs that started in 2012/2013 and were negative outside the corridor for their first two consecutive performance years, only one was negative outside the corridor in 2016 and together they yielded a net savings. This supports the notion that given time, the majority of ACOs that continue participating have the desire and capacity to succeed and it is to CMS' benefit to give them that opportunity. Our approach balances this need to give ACOs adequate time to adjust to program requirements and expectations while holding ACOs accountable for cost and quality performance and protecting the integrity of the MSSP and Medicare trust funds.

Availability of advance payment funds

Despite previously acknowledging in past rulemaking that ACOs must make significant upfront investments in enhanced services and care management infrastructure, CMS does not propose in this rule to reinstate any advance funding opportunities for new ACOs.

ACP strongly urges CMS to reinstate permanent advance payment funding opportunities. Operational costs for ACOs average \$1.5 million and can often be a barrier to participating in the MSSP. Additionally, ACOs may lose revenue in the short run from reducing billable services and may struggle financially until shared savings payments are made. These struggles can be felt particularly profoundly on smaller, rural, or physician-led ACOs that often have a more limited financial reserves. The Advanced Payment ACO Model and the ACO Investment Model were both widely considered successful, but are no longer available to new applicants. Reinstating advancing funding opportunities would facilitate the growth of ACOs, particularly small, rural and physician-led ACOs, with no risk to CMS because the money would all be owed back.

Extending length of agreement period to five years

ACP strongly supports CMS' proposal to increase the length of agreement periods from three to five years. Longer agreement periods give ACOs more time to understand their performance, gain experience, and implement redesigned care processes before their benchmarks are rebased, which allows more time for improved quality and financial outcomes to be realized from care process improvements. This contributes to greater predictability of benchmarks and therefore builds ACO confidence and increase their ability and propensity to take on risk, which is also a win for CMS.

Distinguishing between low-revenue and high-revenue ACOs

CMS explains in the proposed rule that it believes "high-revenue" ACOs "have a greater opportunity to control expenditures...and have the potential to perform better" than they do currently. As added incentive to boost performance, CMS proposes to limit high-revenue ACOs to one performance period in the BASIC track before being required to advance to the ENHANCED track. Low-revenue ACOs would be allowed to continue in the BASIC track at the highest level of risk (Level E) for a second agreement period. CMS proposes to define high-revenue ACOs as those whose total Medicare Parts A and B fee for service revenue for their participant Tax Identification Numbers (TINs) is at least 25% of total Parts A and B total expenditures for the ACO's assigned beneficiaries.

Given the College's proposal that all ACOs should be permitted to remain in each track for an indeterminate amount of time and gradually advance to higher levels of risk, the distinction between "low" and "high" revenue ACOs would not be necessary. However, ACP does have concerns with this distinction between "high-revenue" and "low-revenue" ACOs as described by CMS. While we appreciate CMS' intent to provide "low revenue ACOs," which tend to be smaller or rural ACOs, with risk track options that are more consistent with their ability to take on risk, the College is concerned that the way CMS proposes to distinguish high-revenue ACOs is not appropriate because it would be confusing, operationally burdensome, and most importantly, result in unintended consequences.

While we appreciate CMS' intent in allowing smaller, physician-led ACOs more time in lower-risk models, we find that CMS' reasoning to be fundamentally flawed that high-revenue ACOs have a greater capacity to control costs and are simply not motivated enough. ACOs want to succeed in the program so they can share in the savings; they already have sufficient motivation. Singling out a specific subset of ACOs that are already struggling to meet savings targets and forcing them along an even more aggressive timeline to risk as a way to further incentivize will only result in more of these ACOs dropping out of the program. To the contrary, larger systems often already operate at more maximized efficiencies before entering the program, and as a result may often have less spending to trim, which is a commonly cited concern of historic benchmarks. Moreover, in recent rulemaking including in this proposed rule, there were major changes to benchmark methodology that could drastically alter the current discrepancy in performance between "low-revenue" and "high-revenue" ACOs. CMS should not rush with multiple major changes

to the program simultaneously, and should instead wait and see if adjustments to benchmarking, risk adjustment, and other design elements help to address other discrepancies, such as high-revenue ACOs traditionally not performing as well.

ACP has concerns about the methodology CMS used to arrive at the 25% figure, which appears to be more a line drawn in the sand than a significant inflection point of an ACO's ability to control costs. 25% of expenditures hardly signifies a significant ability to control costs. There is also no accounting for a number of factors beyond the control of ACOs that could artificially inflate this number. For example, infusion drugs, are expensive to Medicare but are a set price with little to no opportunity to reduce spending. ACOs should not be penalized for providing critical services like these and others, or worse, to be perversely incentivized not to administer them to patients.

Executing this policy would be operationally difficult and create unnecessary complexity in the program. As CMS itself acknowledges, "it would be difficult for ACOs to determine at the time of application submission whether they would be identified as a low-revenue or high-revenue ACO." Additionally, CMS would have to consistently monitor to ensure ACO participant changes did not alter an ACO's status as a low-revenue or high-revenue ACO and for those that did, the Agency would have to issue correction notices and require corrective action plans—more unnecessary complication and burden on both ACOs and CMS.

The College recommends CMS instead adopt its alternate proposal to give small, rural, and/or physician-led ACOs opportunities for increased savings through a lower MSR or higher shared savings rate. Given the voluntary nature of the program, positive incentives for participation will be a much more effective long-term strategy than making the program more stringent for particular subclasses of ACOs. This approach would also more directly achieve the results CMS wants and would be far easier to monitor. These types of ACOs face unique challenges to participation in APMs, including a more limited financial reserves, and additional flexibilities including but not limited to lower-risk options would encourage small, rural, and physician-led ACOs to participate in the program. Low-revenue ACOs have typically outperformed high-revenue ACOs, so their ongoing participation is particularly critical to the financial success of the program. Additionally, these types of ACOs often serve underserved patient populations so their participation in the program would have a particularly profound impact on patient outcomes and quality of care. The College would strongly support either of CMS' proposals to offer these ACOs either a lower MSR or higher shared savings rate. Based on feedback from our members, we feel that lowering the MSR would be more persuasive in motivating more low-revenue ACOs to participate.

Experienced and reentering ACOs

CMS proposes to limit the amount of time ACOs have in lower-risk tracks based on their previous experience in Medicare ACO initiatives. An ACO would be considered "experienced" if at least 40% of its participants previously participated in any risk-bearing Medicare ACO model, such as the current MSSP Tracks 1+, 2 or 3. Experienced ACOs would be restricted to participating in either the highest risk level in the BASIC track (Level E), or

the ENHANCED track. Reentering ACOs would be those that reenter the program after a break in participation. New legal entities in which 50% or more of participants most recently participated in the same ACO would be considered reentering ACOs and eligibility to participate on the BASIC track would be based on participation of this original entity.

Based on ACP's earlier recommendation to allow ACOs to remain in a particular track for an unspecified duration of time, the need for distinctions between experienced and reentering ACOs would be eliminated. However, should CMS advance these proposals, ACP recommends at a minimum, CMS set a higher threshold to designate experienced ACOs and restrict the definition of an experienced ACO to those with prior experience specifically in the MSSP. Setting the threshold for experienced ACOs at 40% and the threshold for reentering ACO entities at 50% is confusing. In addition, 40% leaves a majority of participants who would have no prior experience with this type of model and would require more time to familiarize themselves with program requirements and the type of system reforms inherent to participating in a population-based APM. Moreover, the rules of every individual APM are complex and can vary significantly from model to model, so the definition of an "experienced" ACO in this model should be limited to experience in the MSSP. CMS acknowledges that an ACO "may need time to gain experience with the [MSSP]'s policies" even if it previously participated in another Medicare ACO initiative.

ACP agrees there is sound reasoning in establishing a clear definition for initial entrants, renewing ACOs (including ACOs immediately enter a new agreement period after terminating), and reentering ACOs to protect against program integrity concerns. We believe a five-year lookback period would be appropriate if the benchmark is extended to five years as proposed. The College also appreciates and supports the clarification that the 50% threshold would not be cumulative based on experience in any ACO over the past five years, but rather, based on 50% or more participants most recently participating in the same ACO. We agree this will serve CMS' goal of identifying ACOs with "significant participant overlap" while minimizing complexity that could easily arise from using other methods and therefore improve transparency.

The College takes issue with CMS' characterization that ACOs would invest substantial upfront start-up costs and undergo a major organizational shift or undergo the burdensome process of dissolving and re-forming under a different legal entity, much less voluntarily subject itself to shared losses, simply to "game" the system. The number of ACOs that drop out of the program after sustaining losses should prove that waivers for certain service billing requirements or fraud and abuse restrictions is not enough to warrant continued participation in the program without the prospect of earning shared savings. However, we appreciate the importance of program integrity and understand that particularly if CMS elects to move forward with proposals to shorten the time an ACO may remain in a one-sided risk track and extend the contract term to five years which affects how often benchmarks are rebased, the incentives to participate in "gaming" could rise, therefore certain, well-defined precautionary measures may be warranted.

The College supports discontinuing the required "sit out period" that currently exists for ACOs that voluntarily terminate participation in the program. We agree that this

would no longer be necessary to protect program integrity given these new definitions and rules for returning ACOs and if left in place, would only service to diminish participation in the program and restrict the ability of ACOs in current agreement periods to transition to the proposed participation options under new agreements.

Benchmarks changes

To improve the accuracy of financial benchmarks, CMS proposes to make several refinements to the methodology regarding the proportion of national verses regional trend factors. Specifically, the Agency proposes to begin phasing in regional fee-for-service (FFS) expenditures during an ACO's first agreement period, rather than waiting to second and subsequent agreement periods. However, CMS proposes to minimize the impact of regional adjustments overall by reducing the maximum weight of the regional adjustment from 70% to 50% and capping the regional adjustment amount to 5% of national Medicare fee-for-service per capita expenditures. CMS also proposes to increase the weight of national trend factors relative to an ACO's penetration in the regional service area in an attempt to prevent ACOs from being too positively or negatively impacted by changes to its own beneficiary population when trending benchmarks based on regional spending.

ACP supports CMS' proposal to incorporate regional expenditures into the benchmarking methodology for ACOs earlier, in the first agreement period. The College appreciates CMS being receptive to past comments by ACP and many other stakeholders to incorporate regional expenditures into financial benchmarks because they capture trends specific to the regional service market and are more accurate than benchmarks based solely on national FFS spending. Incorporating regional trend factors also allows CMS to more accurately capture the impact of the regional population's health status and socioeconomic factors. Given that in 2017, 80% of ACOs receiving a rebased benchmark benefitted from receiving a regional adjustment, it is no surprise that ACO performance has continuously improved to the point where the program generated a net savings for the first time.

However, the College does not support CMS' proposals to reduce the impact of the regional trend factor by capping it at 5% of national per capita expenditures and by lowering its weight relatively to the national trend factor from 70% to 50%. While we appreciate CMS' interest in consistency with the current weighting schedule, this is hardly reason to cap the regional trend factor artificially low when it is widely accepted to be more a more accurate indicator of costs, including by CMS. ACOs in expensive markets are already contending with a number of challenges to keep costs low. Establishing an artificial cap based on national expenditures has little mathematical justification and would only make it more difficult for ACOs in high-spending regions to participate in the program, which are the very ACOs Medicare should want participating. Weighting the regional trend factor at 50% so as to weight it evenly with the national trend factor is equally problematic. CMS agrees that the regional trend factor has been proven to be a more accurate indicator of market dynamics. Therefore, it rightfully should be weighted higher than the national trend factor. We disagree with the assertion that current regional adjustments provide "overly inflated" benchmarks, since they are based on the regional market that the ACO is operating within.

To improve the accuracy of regional benchmarking, ACP reiterates our past recommendation that the Agency remove an ACO's own beneficiaries from the **regional comparison pool against which it is being evaluated.** While we appreciate CMS' concern about small sample sizes, comparing an ACO's population against itself is no way to conduct a difference of difference analysis. It would be more statistically accurate to compare the ACO's population against a small population that is not tainted with its own beneficiaries to isolate the effect that the ACO is having on its own beneficiaries versus the regional market as a control group. The proposed alternative of varying the proportion of national and regional trend factors based on an ACO's size relative to its regional population would be operationally difficult, lack transparency, would not be budget-neutral on a national scale, and most importantly, it would not solve the problem it is intending to address. It would be inequitable to differ benchmarks in this way and the policy would disproportionally impact rural ACOs which are more likely to comprise a large share of their regional beneficiary population. These ACOs would be held accountable to national trend factors that CMS admits itself are less accurate than regional trend factors and accordingly, benchmarks would not adequately recognize the impact they make in their beneficiary populations relative to their regional markets, rendering them less likely to generate shared savings and disproportionately more likely to drop out of the program.

ACP urges CMS to exclude Merit-Based Incentive Payment System (MIPS) bonuses as ACO expenditures when calculating benchmarks. CMS currently excludes Advanced APM bonuses from ACO expenditures and we reiterate our request for CMS do the same for MIPS expenditures. This will be increasingly important over time as MIPS bonuses are projected to rise in future program years and will count against the ACO when assessing performance relative to the benchmark. The better an ACO performs in MIPS, the greater they will be penalized when calculating shared savings/losses for the ACO, undermining one of the founding principles of the MSSP to incentivize high-value care.

Risk adjustment

CMS proposes to allow risk adjustments to reflect positive, as well as negative changes in the health status of continuous, assigned beneficiaries over the length of an agreement period. However, the Agency proposes to cap the total adjustment to 3% over the course of an agreement period.

ACP strongly supports CMS' proposal to account for both positive and negative changes in health status among continuously assigned beneficiaries over the course of an agreement period. This will help to ensure ACOs are not negatively impacted by natural changes in a patient's health status over time and give ACOs more confidence to move into higher levels of risk. We appreciate CMS being receptive to past concerns raised by stakeholders including ACP that the current risk adjustment methodology does not adequately adjust for changes in health status among continuously assigned beneficiaries.

The College recommends CMS study the net impact of these changes before finalizing any artificial cap on risk adjustment. If the Agency does elect to move forward with banding risk adjustment, we urge a cap of no less than 5%, one percentage point per

performance year in the proposed agreement period. Properly risk adjusting is critical to avert patient cherry picking and to assure ACOs that they will not be negatively impacted for changes in health acuity that are out of their control, thus giving them the confidence to take on more risk. The 3% cap would be especially concerning if CMS finalizes plans to extend the agreement period to five years, which ACP supports. Any cap should be intended to capture strictly outliers, not nearly one-third of ACOs as CMS estimates the proposed 3% cap would. The proposed 3% cap is far too low and should not be finalized.

July 1, 2019 start date

Given the timing of this proposed rule, CMS does not expect ACOs would be able to reasonably apply and implement an ACO under new rules starting Jan. 1, 2019. Therefore, the Agency proposes a one-time start date of July 1, 2019 for new agreements under the new policies proposed in this rule. ACOs that apply for this start date would have an initial agreement period of 5.5 years. To prevent disruption, current ACOs would be able to complete the remainder of their current agreement under existing model rules and requirements. For ACOs agreements that expire at the end of 2018, ACOs would have an opportunity to extend their current agreement periods for an additional six months under current program rules and apply for a July 1, 2019 start date under new rules. The usual annual application cycle would resume on Jan. 1, 2020 and in future performance years.

While ACP believes it is important to give new ACOs an opportunity to join the MSSP in 2019, we have several logistical concerns about a mid-year start date that would need to be resolved, particularly regarding CMS' proposal to evaluate cost and quality performance based on a full year's worth of data and prorate it based on the **number of months of active participation.** ACP agrees that unfortunately due to the timing of the release of this rule, a Jan. 1, 2019 start date would be difficult. We appreciate CMS recognizing that ACOs will need time to consider new participation options, prepare for program changes, make any investment, repayment, and restructuring decisions, obtain buy-in from their governing bodies and executives, and complete and submit applications. However, we agree that it is important not to completely forego an opportunity to join the MSSP in 2019. Additionally, given the timing of Qualified Participant (QP) snapshot calculations. July 1 is the final date an APM can begin in order for its participants to qualify for QP status in an Advanced APM for that performance year, which we also agree is an important consideration. Accordingly, a July 1, 2019 start date could an appropriate option for new ACOs. However, there are several logistical concerns regarding the proposed six month performance periods in 2019 that would need to be resolved and may be difficult to finalize in such a short timeframe, particularly with sufficient stakeholder feedback. Moreover, changing program rules midvear would create unnecessary confusion during what would already be a major period of transition for this program.

To prevent total upheaval and avert mass confusion for ACOs whose agreement periods are ending in 2018 by changing critical program details midyear, ACP urges CMS to allow these ACOs to extend current agreement periods up to a full year. This will drastically reduce confusion that would come with changing the rules midperformance year and will help to mitigate total upheaval for these ACOs during what would already be a period of major transition for the program.

The College also urges CMS to give ACOs the option to combine data from the abbreviated 2019 reporting periods with 2020 performance data to provide for a **longer**, **18-month performance period**. Longer performance periods yield more predictable and accurate outcomes. This added stabilization would be particularly helpful for the first six-months under new program rules and could entice more ACOs to apply. ACOs tend to take multiple years to in the program to gain experience and allow time for positive care transformations to culminate in actual quality and savings results. Six months would be an extremely short turn-around for this. Moreover, we feel the concerns CMS gives for not proposing longer agreement period could be mitigated and that ACOs should have the option to decide for themselves which tradeoffs to make. For instance, we appreciate CMS' concern about delaying shared savings payments, but given the Agency also notes it could reconcile 2018 shared savings/losses owed with those during the January – June 2019 performance period, it does not appear that shared savings payments would be significantly delayed if the six month performance period were absorbed with 2018 data. Some ACOs may prefer to delay shared savings payments for the option of having performance spread out over a longer period of time and should be given the option. Regarding CMS' concern about burdening ACOs by requiring a longer reimbursement mechanism coverage period, we do not feel this would be substantially prohibitive either if CMS finalizes its proposal to allow ACOs to secure funding in segments.

Reconciling shared savings/losses for ACOs with less than 12 months of performance

CMS proposes to base financial and quality calculations based on an entire years' worth of data, and prorate shared savings/losses based on the number of active months, both for ACOs that voluntarily terminate prior to the end of a 12-month performance year and for all ACOs that participate in one of the special 2019 six-month performance periods.

ACP has major logistical concerns with CMS' proposed methodologies for basing financial and quality calculations on 12 months of data and prorating shared savings/losses, particularly for ACOs that would start July 1 under new program rules and urges CMS not to move forward with these policies at this time. It remains unclear how CMS plans to evaluate an ACO based on quality and cost data that predates that ACO's participation in the program, much less even forming, assuming contracts and participations lists will not be solicited, submitted, approved and signed all by January 1. Because ACOs are required to submit ACO-specific quality measures through the CMS Web Interface, ACOs would be expected to collect and report this data from participating TINs before participation lists are finalized, which is impractical. While the concerns are not as profound for continuing ACOs that would participate in a January 1- June 30 contract period, it still raises questions about the realistic expectation for ACOs to continue reporting quality data on behalf of participating TINs after the contract period has ended. Our alternative proposal to allow current ACOs whose contracts are expiring to extend for a full year and new ACOs that join July 1, 2019 the option to combine 2019 with 2020 data would help to alleviate these logistical concerns, since CMS would have more than enough data to analyze without counting data from time outside the actual performance period.

Regarding ACOs in traditional 12-month performance periods that voluntarily terminate early, the College understands the logic behind CMS' proposal to base financial reconciliation for prorated losses based on a full 12 months of data that is then prorated based on the number of months the ACO was in the program, because it could incent ACOs to continue to control expenditure growth, as it could potentially reduce the amount of shared losses owed. However, we have similar concerns regarding expectations for ACOs to continue reporting quality data on behalf of participating TINs after the contract has terminated that would need to be addressed before moving forward with any such policy.

We support CMS' proposal not to assess prorated shared losses for ACOs who voluntarily terminate prior to the end of a six-month performance period in 2019, as imposing an earlier deadline would not allow adequate time for ACOs to acquire the necessary information to make their participation decision. Additionally, this would encourage ACOs to extend and/or sign a new agreement and continue participating.

The College supports CMS' proposal to shorten the minimum notification of termination period from 60 to 30 days because ACOs could base this decision on three quarters of feedback reports, as opposed to only two. However, we recommend CMS set the deadline for notification at 30 days following the release of the second quarter financial report, rather than June 30, as proposed. The timing of release of data varies year to year, so this approach would better ensure ACOs have a reasonable window of time to interpret data from their third quarterly report, as CMS intends.

The College calls on CMS to apply the same prorated policy to shared savings for ACOs that voluntarily terminate. While we agree that ACOs expecting to generate savings will realistically be less likely to terminate in the first place, CMS should apply the same policy to shared savings and losses. This consistency helps to ensure program integrity and transparency, while the practical impact would be minimal so the Medicare trust funds would be not be at substantial risk.

Repayment mechanisms

CMS proposes several changes to the repayment mechanisms, including using more recent data to calculate repayment mechanism estimates and periodically recalculating the amount of repayment arrangements based on TIN or beneficiary population changes. The Agency proposes to potentially require ACOs to demonstrate an ability to pay back a higher amount in the event of a "substantial" increase, which would be defined as the lesser of 10% or \$100,000.

To lessen the burden of securing repayment mechanism funding for longer periods of time given proposals to increase agreement periods to five years, CMS proposes to allow a preliminary four to five year extension to cover the first two or three performance years of the new agreement period plus a 24-month tail period that would be followed by later extensions. CMS also proposes to permit early termination of a repayment mechanism and release of the arrangement's remaining funds to the ACO under certain conditions, such as it being determined that the ACO does not owe losses.

The College supports CMS' proposal to use more recent data to calculate repayment mechanism estimates and agree this will help to improve the accuracy of such estimates. We agree it could be appropriate to periodically recalculate the amount of a repayment arrangement based on TIN composition or beneficiary population changes and to possibly require the ACO to demonstrate an ability to pay back this higher amount but want to emphasize the importance of minimizing burden on ACOs by limiting such requests to "substantial" increases and providing ACOs with adequate notice and time to secure additional funding if necessary. While CMS' proposed thresholds of the lesser of 10% or \$100,000 seem reasonable, we seek more information about how many ACOs this would impact before CMS finalizes such a policy.

ACP supports allowing a preliminary four to five year extension followed by a later extension to balance the need to protect the integrity of the program while not unnecessarily inhibiting participation. We appreciate CMS recognizing that it may be difficult for ACOs that are completing the term of their current agreement period to extend an existing repayment mechanism by seven years (a five-year agreement term plus 24 months). We agree that achieving a seven-year extension, particularly on top of an existing repayment term, may be prohibitively difficult to secure and therefore threaten to hinder participation in the program among willing ACOs. We appreciate CMS' preemptive recognition of this potential hardship and willingness to incorporate additional flexibilities to improve the feasibility of an ACO's ability to secure repayment funding resources. The College also supports CMS' proposal to permit early termination of a repayment mechanism and release of the arrangement's remaining funds to the ACO under certain conditions, such as it being determined that the ACO does not owe losses.

ACP calls on CMS to reinstate alternative repayment mechanisms. While we appreciate CMS' concern over ACOs contracting with non-vetted organizations, having this alternative option is an important way to accommodate ACOs, particularly smaller ACOs, and facilitate their ability to participate in the program. It is important CMS maintain this flexibility and work with those handful of ACOs on an individual basis to ensure that they have flexible options. While we understand that in some cases this can add administrative complexity, we feel that the number of ACOs who partake in this option to be minimal so the burden on CMS would be limited.

Waivers

CMS proposes to expand several existing waivers related to telehealth service requirements, including waiving certain geographic and site of service requirements, and Skilled Nursing Facility (SNF) 3-day rule requirements, including expanding them to ACOs in two-sided models under prospective assignment with retrospective reconciliation and adding more types of eligible SNF affiliates. The agency also proposes waivers to allow two-sided models to establish CMS-approved beneficiary incentive programs.

ACP supports waivers to waive certain restrictions for billing telehealth services and eligible SNF stays. Waivers that lift statutory and regulatory requirements can provide ACOs with more flexibility to be even more innovative in driving new strategies for value-based, patient-centric standards of care. We encourage CMS to finalize the waiver-related

proposals in this rule and urge the agency to continue to look for additional ways to exercise its wavier authority to reduce barriers to care coordination and high-value services.

ACP strongly supports proposals to allow two-sided models to establish CMS-approved beneficiary incentive programs. We would additionally encourage CMS to lift certain restrictions including not expecting ACOs to bear the sole expense and expanding these waivers to one-sided ACOs. Strengthening beneficiary incentives are a critical way to get patients more actively involved in their own care, which results in better health outcomes and smarter spending. Moreover, beneficiary incentives can be designed to inherently direct patients to high-value services, such as rewards for fulfilling primary care visits. However, we feel that by proposing such restrictive and burdensome requirements, CMS is limiting the effectiveness of such programs. For instance, ACOs should not be expected to bear the sole expense. CMS should consider passing additional waivers for proven cost saving services, such as transportation to patient care visits and reduced or waived copays for primary care visits. CMS should consider expanding the beneficiary incentive programs waiver to one-sided ACOs. Because these waivers are already conditional on CMS approval, the risk to CMS would be minimal and would empower ACOs to further innovate and improve patient care.

Beneficiary notification and assignment

CMS proposes to give all ACOs the opportunity to elect between beneficiary assignment methodologies on an annual basis. The assignment methodology that an ACO selects in its initial application would remain in effect unless the ACO voluntarily elects to change it through an annual election process. CMS proposes a "hybrid" beneficiary assignment approach which would give ACOs the option to incorporate voluntary beneficiary alignment to a primary care clinician or opting-into an ACO in addition to claims-based assignment.

CMS proposes to use a beneficiary's designation to supersede claims based assignment even if the beneficiary does not receive primary care services from an ACO professional in that ACO. Moreover, a beneficiary would be assigned to an ACO based upon his or her selection of any ACO professional, regardless of specialty, as his or her primary clinician.

CMS proposes to provide a template notice with information related to the MSSP and patient responsibilities including voluntary assignment and their option to opt out of sharing personal data. The Agency would require ACOs to provide this documentation to ACO beneficiaries during their first primary care appointment during each performance year. ACOs would be banned from advertising any existing beneficiary incentive programs with these materials out of concern that it may "inappropriately steer" beneficiaries to align under a certain ACO. ACOs would be responsible for collecting information related to voluntary patient alignment and submitting it to CMS to be updated on an annual basis.

CMS proposes to designate additional services as primary care service codes, including advance care planning codes, administration of health risk assessment, prolonged E/M or psychotherapy services, annual depression screening, alcohol misuse screening and

counseling, and additional complexity add-on codes for existing primary care service codes proposed in this year's Medicare Physician Fee Schedule.

ACP has long supported flexible beneficiary assignment policies because it affords ACOs more flexibility in patient assignment, which is critical to building confidence and predictability in their ability to control patient outcomes and succeed in the program. We appreciate CMS being responsive to these concerns raised by ACP and other stakeholder groups. Creating consistency between the various tracks also allows CMS to streamline the program and would make it easier for ACOs to more quickly and seamlessly transition to higher levels of risk and reward. We additionally support the proposal to allow the assignment methodology indicated on an ACO's application to remain in effect for the duration of the agreement period unless an ACO voluntarily elects to change it through an annual election process, which maximizes flexibility while minimizing burden on ACOs.

ACP supports the proposed "hybrid" beneficiary assignment approach which entails giving ACOs the option to incorporate voluntary beneficiary alignment in addition to claims-based assignment. We appreciate CMS' concerns that relying solely on voluntary assignment or opting-in, especially in the early years of inception, could lead to small patient populations that do not meet the minimum required 5,000 patient lives and could thus weaken participation in the program, as well as lead to possible cherry picking of patients, and would be premature at this time. Giving ACOs the option to incorporate voluntarily beneficiary assignment and opting-in strikes the right balance of putting patients more at the center of their care without inciting possibly damaging downstream consequences to individual ACOs and the MSSP as a whole.

The College does not support CMS' proposal to assign a beneficiary to an ACO based on their selection of any ACO professional, regardless of specialty. At a minimum, patients should not be attributed to a specialist unless he/she has received a minimum quota of primary care service from a professional within the same ACO. The policy as proposed would undercut the care coordination and primary care focus that is central to the program.

ACP strongly supports the concept of establishing a minimum threshold of primary care visits that a patient would have to be administered from one or more ACO professionals during an applicable assignment window. However, we feel that the proposed threshold of seven services is too high and could result in unintended consequences that negatively impact ability to participate in the program. We recommend CMS apply a lower threshold and study the impact on beneficiary population before increasing it further. Establishing a higher threshold of primary services, combined with voluntary alignment, would allow ACOs to focus their efforts on beneficiaries who have either voluntarily chosen to align with the ACO, or who are receiving a high number of primary care services from the ACO, and whose behaviors the ACO stands a far better chance at controlling. However, based on CMS' own estimates that this could result in an elimination of up to 75% of assigned beneficiaries compared to the current methodology, we feel the proposed seven condition minimum would risk limiting the beneficiary population below the required 5,000 lives for too many ACOs that would be difficult to compensate for with voluntary alignment alone, particularly in the early years of

this new option. In 2018, only 4,314 of 12.3 million beneficiaries voluntarily aligned themselves to an ACO, a fraction of one percent.

ACP agrees that supplying ACOs with a template notice could help to minimize burden and we support requiring ACOs to dispense this information to patients during their first primary care appointment after a TIN has joined the ACO. However, we recommend that after the initial visit, an oral reminder at subsequent visits supplemented by an automatic email would keep patients sufficiently informed while minimizing burden on ACOs. Additionally, ACP urges CMS to reconsider its proposed ban on allowing ACOs to include beneficial additional information, such as available beneficiary incentive programs, along with these notices. ACP agrees with CMS that patient education about the MSSP, their physician's role in it, and particularly their own role regarding the options to align with a clinician or opt-into an ACO and refuse to share their health data is critical, especially initially. However, requiring primary care clinicians to dispel this information annually is burdensome and would yield little benefit after the initial visit. Our proposed alternative approach would reduce burden on practices without sacrificing patient education. While we do not feel it should be required, ACOs should be permitted to include pertinent information about any beneficiary incentive programs as supplemental materials with this notice. Banning this this would inherently undercut the success of such programs and educating patients about the availability of such programs only benefits them. We disagree that informing patients about available benefit programs would "inappropriately steer" beneficiaries; it simply entails providing them with all the information to make an informed decision. These programs do not restrict a patient's ability to seek care outside the ACO, but may incentivize a beneficiary to receive services within that ACO, which minimizes patient churn while providing that patient with services or benefits he/she may not otherwise receive that also improve health outcomes.

We urge CMS to attribute patients on a more frequent, ideally rolling basis, by leveraging its QPP website as a portal that beneficiaries may log into and align themselves with an ACO or clinician. The proposed timeline for officially assigning a patient to an ACO after he/she aligns with a clinician or opts-into an ACO is both confusing and would cause unnecessary delays. To CMS' point, ACOs tend to have high patient churn, so waiting up to a year to be attributed to an ACO makes little sense and would throw off benchmarking, risk adjustment, and other critical calculations. CMS could also screen for program integrity by prompting beneficiaries to answer whether or not they had received any gifts or were improperly coerced in any way, as well as connect patients to quality data about his/her clinician and ACO, creating a seamless and educational point of care experience for the patient while giving CMS direct access to real-time beneficiary assignment and other relevant patient data that could improve program evaluation. The College supports efforts such as the eHealth Initiative that aims to place the patient at the center of their own care and we feel this approach would better support these efforts, give CMS more direct access to real-time data, and reduce expense and administrative burden for practices. This would also drastically lessen, if not eliminate altogether the need for CMS to audit such records. It would be important to reconcile financial benchmarks accordingly based on the attribution methodology so that the two patient populations would match.

Finally, the College supports CMS' proposal to designate additional services as primary care service codes. We agree that these codes are reflective of the robust range of services that are offered in the primary care setting and that adding these to the list of approved primary care service codes would lead to more accurate patient assignment.

More meaningful quality measurement

As iterated in previous comments, the College urges CMS to reconsider the proposal to remove several at-risk population-based measures and to ensure that vulnerable patient populations would not be adversely impacted by the removal of these measures before proceeding. ACP has always been a vocal advocate for prioritizing the study of social determinants of health and the role they play in individual and community health. We feel strongly that social determinants of health are currently underrepresented in quality measurement despite having a profound impact on risk factors and therefore patient health outcomes. Care coordination across settings and incorporating behavioral and mental health services into a patient's total care plan are also critical elements of improving overall patient care that are under-emphasized and under-represented in current quality measurement. ACP recently published a position paper³ with several policy recommendations for ways to better address social determinants to improve patient care and health equity. We encourage the Agency to review and consider these recommendations in future rulemaking for the MSSP and the Medicare program at large.

ACP strongly recommends CMS look to recommendations⁴ made by our Performance Measurement Committee (PMC) when considering what measures to use for reporting by internal medicine specialists. The College further recommends that any measures CMS proposes to use outside of the ACP recommendations and core sets identified by the Core Quality Measures Collaborative be those recommended by the Measure Application Partnership (MAP). The College has been a strong supporter of CMS' Meaningful Measures Initiative, as well as other efforts to reduce burdens on clinicians and practices to improve the accuracy of quality measurement so that it can be better leveraged to improve patient care. We appreciate recent efforts to reduce the total number of quality measures, including for ACOs in the MSSP, and to focus on outcomes and other high impact measures that maximize improved health outcomes while minimizing reporting burden on clinicians. ACP's Performance Measurement Committee (PMC) assessed and provided detailed recommendations on numerous MIPS performance measures, with a focus on those that are particularly applicable to internal medicine.

CMS seeks comment on ways to improve information to combat opioid addiction and opioid-related measures that would support effective measurement of alignment of substance use disorders across programs, settings, and varying interventions.

ACP recommends CMS: remove barriers to evidence-based non-opioid pain management services, improve Medicare and Medicaid patient access to medication-assisted treatment (MAT) and overdose medications including naloxone, and work with states to increase clinician participation in Prescription Drug Monitoring

³ Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An ACP Position Paper.

⁴ Time Out - Charting a Path for Improving Performance Measurement

Programs by making them less burdensome. CMS also should also leverage this valuable data to study factors or demographics that predispose individuals to SUD, including social determinants of health, as well as to better understand which treatment options or combinations of treatment options are most effective. However, the College wishes to issue a word of caution against imposing strict dosage caps, prior authorization requirements, and other hard cutoffs that could hinder access to critical pain treatments for patients who need them while placing an undue burden on practices.

The College supports CMS efforts to include more quality measures related to opioid use and has been an active leader in helping to address the nation's opioid epidemic.⁵ ACP and other private sector stakeholders have been actively engaged in robust initiatives to educate and train clinicians on safe prescribing practices and there are positive signs these efforts are working. Over a four-year period (2013-2017) opioid prescriptions fell by 22 percent nation-wide.⁶ Over the eighteen months we have initiated programs to educate physicians on safe prescribing practices and how to prevent and treat substance use disorders (SUDs), published papers on how to facilitate effective prevention and treatment of SUDs, and addressed letters to Congress and the administration with specific suggestions on how to combat this crisis. We urge the administration to review our past comments⁷ for a more robust discussion of our specific suggestions of strategies to address the opioid crisis, which we summarize briefly below. We also urge the administration to look to better integrate behavior health, including screening for possible SUD in the primary care setting to catch SUD in its earliest stages, and taking precautionary measures to prevent SUD.

We encourage the Agency to continue adding more information to quarterly ACO performance reports, dispensing this information on a more frequent, ideally real-time basis, and to make data more widely available so that all clinicians and practices, including non-ACO participants, can leverage this data to improve patient care, address social inequities in health, correct inefficiencies to drive down costs, and help to address the nation's opioid epidemic and other pressing health crises.

Use of Certified EHR Technology (CEHRT)

CMS proposes to require that ACOs in all tracks, including those that do not meet risk criteria to be considered Advanced APMs, certify that at least 50% of participating eligible clinicians use Certified EHR Technology (CEHRT).

ACP urges CMS to reconsider finalizing its proposed policy to require all MSSP ACOs, including those that are not considered Advanced APMs, to certify that at least 50% of participating eligible clinicians use CEHRT, particularly at the same time CMS proposes to require a transition to 2015 edition CEHRT. The College fully supports efforts to increase use of CEHRT and promote interoperability of different CEHRT systems. However, these systems can often be prohibitively expensive and administratively burdensome to implement, particularly for rural, small, and physician-led ACOs. We fear that this proposal could prohibit participation in the program, disproportionately so for

⁵ ACP Calls for Continued Action in Fighting Opioid Crisis After Encouraging White House Summit

⁶ Progress in Declining Opioid Prescriptions

⁷ ACP Policy Recommendations to Senate Finance Committee on Opioid Use Disorder Treatment

smaller ACOs. In 2017, 34 ACOs would not have met this requirement and of those, roughly two-thirds (62.9%) had less than 10,000 beneficiaries. Should the Agency move forward with this policy in the future, we urge CMS to provide ACOs with adequate financial assistance to support the purchasing and upgrading of EHR technology to meet CEHRT standards, which can often cost hundreds of thousands of dollars.

Hardship exceptions

CMS proposes to extend extreme and uncontrollable exceptions for 2018 and subsequent years and to reduce shared losses based on the percentage of total months in the performance year affected by an extreme and uncontrollable circumstance.

ACP supports proposals to extend extreme and uncontrollable exceptions for 2018 an subsequent years. However, we have concerns over CMS' one-size-fits all approach for determining the time period that ACOs would be exempted and we encourage CMS to allow ACOs an opportunity to request relief from shared losses and negative quality adjustments over a longer period of time up to a full performance year, to be evaluated by CMS on a case-by-case basis. The impact on an ACO's ability to collect and report data would be drastically different if that event occurs in the beginning months of a performance year, as opposed to the final months because this may interrupt systems or cause other long-lasting effects that would make it difficult to hold ACOs accountable for cost and quality long after the initial disaster has struck. Further, while we appreciate CMS recognizing that in certain circumstances ACOs may need more time to report quality data, in some cases, quality data may not be recoverable or may have not been collected during a period of crisis, and ACOs should not have this counted against them. Because CMS would approve of these on a situational basis, there is little risk in terms of the Medicare trust funds, however, we feel it would be important to the integrity of the program for ACOs to have a formal process in place for making these requests based on extenuating circumstances.

Conclusion

ACP sincerely appreciates the opportunity to provide feedback on CMS' proposed changes to the MSSP and thanks you for considering our comments. The College looks forward to continuing to work with CMS to improve the MSSP to ensure it remains a viable model long into the future and can continue to serve as a critical component of the transition to value-based reimbursement. Please contact Suzanne Falk, Senior Associate, Regulatory Affairs at 202-261-4553 or sfalk@acponline.org with any questions or for more information.

Sincerely,

Jacqueline W. Fincher, MD, MACP

Jacqueline W Lincher pro

Chair, Medical Practice and Quality Committee

American College of Physicians