October 16, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1701–P
Submitted electronically to: http://www.regulations.gov

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

Dear Administrator Verma:

On behalf of the Premier healthcare alliance serving approximately 4,000 leading hospitals and health systems, hundreds of thousands of clinicians and 165,000 other provider organizations, we appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) Medicare Shared Savings Program (MSSP) Pathways to Success proposed rule. Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our hospitals and health systems, their employed physicians and independent physicians aligned with them. Premier runs the largest population health collaboratives in the country, the Population Health Management Collaborative, has worked with well over 200 ACOs and is currently comprised of more than 70 ACOs.

Premier collaborative participants have demonstrated the power of the ACO model. Since 2012, Medicare accountable care organizations (ACOs) that participate in the Premier Inc. Population Health Management Collaborative (PHMC) have outperformed their peers in achieving cost and quality improvements. Nearly half of PHMC Medicare ACO participants received shared savings payments in performance year 2016 compared to 33 percent of all Medicare ACOs. In addition, since 2012 PHMC Medicare ACOs have performed 57 percent better on average in achieving shared savings.

PHMC Medicare ACOs make up 6 percent of all Medicare ACO program participants but have generated 20 percent of the savings since 2012. In a recent analysis, Premier projects that Medicare could have doubled the $2 billion in savings it has achieved across its ACO programs since 2012 if all participants performed at the average level of PHMC members. Additionally, in performance year 2016 nearly 75 percent of PHMC Medicare ACOs achieved savings for Medicare, compared to 57 percent achieving savings for Medicare across all Medicare ACOs.

The Premier healthcare alliance appreciates CMS' continued commitment to accountable care organizations (ACOs). Medicare ACOs have been successful in reducing healthcare costs and improving quality. The recent MSSP Pathways to Success proposed rule estimates that the overall impact of ACOs, including "spillover effects" on Medicare spending outside of the ACO program, lowered spending by $1.8 – $4.2 billion (0.5 – 1.2 percent) in 2016 alone. Additionally, when assessing the counterfactual, comparing ACOs performance in comparison to what Medicare spending would have otherwise been,

13034 Ballantyne Corporate Place
Charlotte, NC 28277
T 704.357.0022
F 704.357.6611

444 North Capitol Street, N.W.
Suite 625, Washington, DC 20001
T 202.393.0860
F 202.393.6499

PREMIERINC.COM

ACOs estimate savings are approximately 2 percent higher[1]. For example, peer-reviewed studies found that the MSSP saved more than $200 million in 2013 and 2014 and $144.6 million in 2015 after accounting for shared savings bonuses earned by ACOs[2]. A similar study found that ACOs saved $1.84 billion from 2013 through 2015 and reduced Medicare spending by $542 million after accounting for shared savings bonuses[3]. **Premier firmly believes that the ACO model is a successful approach for encouraging providers to work together to reduce costs and improve the quality of healthcare for Medicare beneficiaries.**

Supporting the movement to these value-based payment models goes beyond the quality and financial results of ACOs. From a market perspective, we will never achieve innovation in healthcare except through the creative power of healthcare providers seeking to innovate the care delivery process. Models in which payers seek to achieve savings and quality improvement will always fall short until healthcare providers themselves are held accountable for the results. We have seen firsthand the remarkable innovations that are spurred by this accountability such as those in telehealth, the hospital in the home, special care centers, organizing community support organizations and systematically addressing the social determinates of health**.**

The Pathways to Success establishes a step-wise approach for ACOs increasingly taking on more downside risk. Premier agrees that it is imperative that over time providers become increasingly responsible for total cost of care through risk-bearing agreements; however, CMS must ensure providers have proper tools and experience to achieve this vision. We believe that with proper incentives and improvements in the program organizations will take on risk, seeing the quality, clinical innovation and business benefit from doing so. Specifically, CMS should consider the following within the context of MSSP and any new payment models:

Sufficient time in an upside-only model prior to moving to downside risk. ACOs are more likely to achieve shared savings with time. Specifically, studies show that the shared savings rate doubles with three years of experience from 21 percent for ACOs in the first year to over 40 percent for ACOs in the third of fourth year[4]. Accordingly, *Premier recommends at least 3 years in an upside only model for new ACOs entering the MSSP.* Beyond the MSSP program, *Premier believes it is imperative for CMS to provide a long-term vision and roadmap for the transition to value-based and risk-based models.* In the absence of a clear timeline, some providers are reluctant to embark on new models. When providers have a clear plan for moving to new models (e.g. the Maryland All-Payer model), providers work aggressively to succeed in the model and more rapidly advance to the risk-bearing model.

High performers should be encouraged to participate in models regardless of provider type. The MSSP performance data summarizes average ACO performance, masking differences among high and low performers within each category. We strongly discourage the application of policies targeting provider types that are intended to modify the behavior of the lowest performers; these policies impact high and low performers, thereby disincentivizing high performers from continuing in the model and producing savings. *Specifically, we request that CMS eliminate the distinction of high and low revenue ACOs and avoid creating new blunt tools to define ACOs (e.g. physician-led and hospital-led).* In any payment model CMS should create a level competitive playing field and let those that perform best succeed most. CMS should find non-provider defined approaches to eliminate poor performers.

---

[1] https://www.healthaffairs.org/do/10.1377/hblog20180918.957502/full/?utm_term=Half+A+Decade+In%2C+Medicare+Accountable+Care+Organizatio%E2%80%A6

[22] https://www.nejm.org/doi/full/10.1056/NEJMsa1803388?query=featured_home

[3] https://www.naacos.com/studyofMSSPsavings2012-2015

[4] https://www.healthaffairs.org/do/10.1377/hblog20180918.957502/full/?utm_term=Half+A+Decade+In%2C+Medicare+Accountable+Care+Organizatio%E2%80%A6

Ensure a business case for taking on risk. CMS must ensure that ACOs and new payment models, particularly voluntary models, provide incentives for taking on risk. The existing models to date have ignored the significant investment costs required to start or continue participation in a model. Even when these costs are not incorporated into the payment model, providers will consider potential return on investment when determining whether to enter a new model. CMS must recognize this dynamic and ensure that ACOs and other models will attract providers. Specifically, CMS should:

- *Increase the shared savings rate for ACOs to at least 50 percent.* As discussed below reducing the savings rate prevents ACOs from recouping initial investments, reinvesting savings into population health activities, and recruiting providers with the use of gainsharing agreements.

- *Provide additional flexibility in the models for ACOs taking on risk.* To be best suited to take on more risk, within an ACO or any payment mode, and effectively manage the care of populations providers require flexibility. While beneficial, the current approaches to providing flexibility (e.g. SNF and telehealth waivers, beneficiary incentive program) represent limited portions of Medicare benefits and thus limited opportunities for transforming care. Within the Next Generation ACO model CMS incorporated several options that provide flexibility and should be considered for inclusion in the MSSP—choice on enrolling TIN or NPI, infrastructure payment, prepayment of shared savings and primary capitation. Similarly, CMS should consider aspects of Medicare Advantage that could be incorporated into ACOs. While MA is a capitated full-risk model, providers would benefit from the flexibilities in performance-based risk models. Specifically, CMS should consider incorporating utilization management into ACOs and expanding on the beneficiary incentive payment by incorporating aspects of the MA Value-Based Insurance Design (VBID) Model, allowing ACOs to offer supplemental benefits or reduced cost sharing to aligned beneficiaries with specified chronic conditions, focused on the services that are of highest clinical value to them.

REDESIGNING PARTICIPATION OPTIONS TO FACILITATE PERFORMANCE-BASED RISK

Phase-in of Performance-based Risk in the BASIC Track

CMS proposes to redesign the MSSP's performance-based risk tracks by retiring Track 1 (no risk, upside only) and Track 2 and creating a new BASIC track. In the BASIC track, participants could begin participation in a one-sided risk model and phase-in risk over the course of a single agreement period; the highest level of risk is comparable to the current Track 1+. Additionally, the proposed rule retains Track 3, renaming it as the ENHANCED track. Eligible ACOs would enter into these two tracks for an agreement period of 5 years (the first agreement period, if stated in July 2019 would be 5 years and 6 months). Within the BASIC track, CMS proposes a glide path that includes 5 levels: a one-sided risk model available only for the first two consecutive performance years (Levels A & B), and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Levels C, D, and E). ACOs would automatically advance at the start of each participation years along this glide path until they reach the track's maximum level of risk/reward (designed to be the same as the Track 1+ Model).

Premier supports an agreement period of at least 5 years, as we believe that this adds stability to the program. We have serious concerns, however, that the progression CMS proposes to two-sided risk in the BASIC track is far too aggressive and will deter participation in the MSSP. We believe that the two years in a one-sided risk model is insufficient for ACOs to prepare for moving to

downside risk. Numerous studies show that ACOs require about 3-4 years to become successful.[5] This is not surprising given that ACOs receive feedback on their performance several months into their first agreement period—any initiatives designed to improve performance always take more time than anticipated, and this is particularly true for the complex organizations and agreements that comprise an ACO. Under the current proposal, ACOs would have only one year of performance data before being required to move to a risk-based model. Organizations need time to make the structural, cultural, and practice changes required to successfully manage and assume financial risk for a population. In recognition of the time required for ACOs to be successful, **CMS should allow at least three years of no-downside risk within the BASIC track to ensure the success of participating ACOs and encourage future participation.** CMS should extend an optional fourth year in a one-sided track for ACOs that achieve savings, not necessarily shared savings, across three performance periods and have high quality.

Shared Savings Rate

Premier strongly urges CMS to set the entry-level risk for the BASIC track at 50 percent with gradual increases in the shared-savings rate as ACOs progress through the various levels. Lowering the shared-savings rate for ACOs with no downside risk from 50 percent to 25 percent provides little incentive for new ACOs to join the program. The low shared-savings rate also does not consider the substantial investment needed on the part of ACOs. According to an analysis by the AHA, the investment required to put in place and sustain the elements necessary for a successful ACO has been $11.6 to $26.1 million higher than previous estimates by CMS. These costs, coupled with the cost of having a repayment mechanism in place to cover losses, creates a high hurdle for organizations who are transitioning to accountable care.

The proposed shared savings rate is a significant decrease for existing ACOs, which will be unable to reinvest savings back into population management and care coordination. Shared savings payments are critical as part of an ACO's transformation toward value-based care and are necessary to incentivize providers to make the infrastructure investments needed to transform care delivery and processes. Without them, ACOs will struggle to provide care and services needed to appropriately manage the health of the population and move more rapidly to risk, undermining the overall goal of the program. Reducing shared savings also produces problems with provider participation and ACO buy-in, as some organizations already find this difficult at current shared savings level. **To incentivize ACOS to take on risk, CMS should increase the shared-savings rates as ACOs take on additional risk. We recommend increasing the shared savings by 5 percent with each step: Levels A/B: 50 percent; Levels C/D: 55 percent; and Level E: 60 percent.**

Calculation of Loss Sharing Limit

Premier supports using the lower of the revenue-based or historical benchmark for calculation of the loss sharing limit. However, we recommend that CMS align the risk level for Track E with the nominal risk threshold for APM models established under the QPP, which is 3 percent of the historical benchmark, rather than the 4 percent CMS proposes. CMS provides no rationale for setting the benchmark-based loss limit at the nominal risk standard plus one percentage point. The purpose of Track E is to provide ACO entities with a more gradual pathway to risk, while also meeting the requirements of an AAPM. Setting the historical-benchmark at a higher level would disproportionately affect ACOs with hospital participants and subject them to additional risk as they will always use the historical-based benchmark since Medicare Part A and B revenue will far exceed the historic-based

[5] https://www.healthaffairs.org/do/10.1377/hblog20180918.957502/full/?utm_term=Half+A+Decade+In%2C+Medicare+Accountable+Care+Organizatio%E2%80%A6

benchmark. Accordingly, increasing the benchmark-based loss limit creates an unlevel playing field for ACOs that include hospital participants This proposed policy is counter to the goal of ACOs to encourage providers to work together to improve care for beneficiaries and discourages both health-system led and physician-led ACOs from recruiting hospital participants.

CMS should allow ALL ACOs to remain in Track E or whatever track meets the nominal risk requirements under QPP. If CMS increases the QPP AAPM nominal risk threshold, CMS should create a glidepath in MSSP for ACOs to transition to the new standard of risk.

Transition from Level E to ENHANCED Track

Premier urges CMS to create additional levels within the ENHANCED track to build a more gradual transition from Level E to Enhanced. As proposed, many ACOs would not be eligible for the BASIC track or able to renew within the BASIC track for a second agreement period and would only have the option to enroll in the ENHANCED track. CMS should either build a glide path to the highest risk level within the ENHANCED track or offer an additional track to help bridge the gap between the BASIC and ENHANCED tracks. To further maximize interest in ACOs transitioning to the ENHACNED track, CMS should start the shared savings rate at 80 percent (same as the Next Generation ACO program) and increase the maximum shared savings and losses rate over the agreement period.

Permitting Annual Participation Elections

Annual Risk Election

CMS proposes to allow ACOs in the BASIC track to more rapidly transition (i.e., skip a level or levels) during the agreement period, but Level E must be entered into no later than the ACO's fifth performance year under CMS' proposal. **Premier encourages CMS to provide ACOs with more flexibility in their annual participation elections. If an ACO selects a higher level of risk than it would have been automatically assigned, it should not be required to automatically advance the following year (i.e. an ACO is not required to advance beyond the track they would have been assigned if they did not choose to advance to a higher track).** As noted earlier, ACOs require additional time moving to risk. This option would provide ACOs the option to gain experience in a limited risk track for more than one year. Additionally, we ask that CMS consider allowing high performing ACOs more than one year in limited risk tracks (i.e. Level C and D). CMS could set parameters for successful ACOs to continue in a particular track prior to automatic advancing (i.e. achieving savings, not necessarily shared savings, and high quality).

Annual Election of Beneficiary Assignment

In alignment with the Bipartisan Budget Act of 2018, CMS proposes to allow all ACOs with a choice of prospective assignment for the agreement periods beginning July 1, 2019 and in subsequent years. As proposed, ACOs would also be able to change its beneficiary assignment methodology through the annual election process. **Premier strongly supports this change that would allow ACOs the option of choosing prospective beneficiary assignment or prospective assignment with retrospective reconciliation.** This would provide ACOs with flexibility to better manage their patient populations based on their unique circumstances. Certain ACOs, such as a small ACO that is worried about dropping below the 5,000-beneficiary threshold, may favor a model where the ACO can add beneficiaries throughout the year, and would thus prefer the retrospective assignment model. Other ACOs would likely prefer a prospective model, which would help them stabilize their beneficiary population. The prospective approach also allows more advanced ACOs to employ data analysis and beneficiary engagement

techniques from the start of the performance period on a population for whom they know they are responsible.

Determining Participation Options based on Medicare FFS Revenue and Prior Participation

CMS proposes to define participation options by making a distinction between low revenue ACOs and high revenue ACOs. High revenue ACOs are a proxy for ACOs that typically include a hospital billing through an ACO participant TIN; CMS defines this as an ACO whose total Part A and B revenue for ACO participants is greater than the total Parts A and B expenditures for ACO assigned beneficiaries. ACOs falling below this threshold are considered low-revenue ACOs, a proxy for physician group ACOs. CMS believes that high revenue ACOs are more capable of accepting higher risk than low revenue ACOs. CMS provides fewer participation options for high revenue ACOs. High revenue ACOs with "experience" can only participate in the ENHANCED track regardless of whether they are "new", "renewing", or "re-entering" the program. In addition, low revenue (and inexperienced) ACOs may operate under the BASIC track for a maximum of two agreement periods, whereas high revenue ACOs are limited to one agreement period.

Premier strongly opposes this proposal and urges CMS to eliminate the low/high revenue distinction for determining participation options. We firmly believe that ALL ACOs should the treated the same. This proposed distinction is unnecessary and harmful, as it would discourage ACOs that have the potential to generate substantial savings to the program from participating. The premise CMS uses for hospital-led versus physician-led distinction is also flawed. CMS argues that this policy decision is due in part to low revenue ACOs producing 2 percent of savings compared to 0.2 percent for high-revenue ACOs. A Premier analysis of hospital-led vs. physician-led ACOs revealed two-major findings that refute this assumption: Our analysis of CMS' definition of hospital-led (the ACO includes a hospital TIN participant) found that it is inaccurate with at least 20 percent of health system-led ACOs being designated as "physician led." *Some of the highest performing individual ACOs are hospital-led ACOs. Twenty-one Premier ACOs in MSSP Track 1 have achieved savings in multiple years of the program while also maintain quality higher than the national average. Should they, therefore, be advantaged over physician-led ACOs?*

CMS argues that many low-revenue ACOs are not well-capitalized and therefore unable to absorb losses as well as high-revenue ACOs. Regardless of structure, significant investments are needed in population health platforms and care process changes for ACOs to bear risk. Medicare revenue is also not indicative of ability to bear risk. CMS is unable to identify if an ACO is well capitalized through sources outside of Medicare revenue (i.e., insurer or investor backed ACOs). Accordingly, CMS is unable to truly identify whether an ACO is well capitalized and thus should not create distinctions based on assumptions about capital. Setting up a system that disadvantages hospital-led ACOs limits the types of innovations needed to build a high performing healthcare system for the range of communities across the nation.

CMS makes a flawed assumption that ACOs, in some cases, encourage harmful consolidation in the marketplace. The biggest driver of consolidation is the incessant payment cuts on providers by public payers. Hospitals need to consolidate to manage against these cuts and improve efficiency. Moreover, consolidation is occurring across the healthcare industry for many reasons and is not necessarily negative. Providers and other healthcare entities are seeking to develop high-value care networks that break down the artificial silos that cause duplicative, fragmented patient care. ACOs do not drive physician employment, but rather, ACOs support greater clinical integration and collaboration among doctors, hospitals and other care providers and align the payment system to incent coordination and cost savings across these silos. This alignment accomplishes what the model is designed to do, and what providers need out of high-value networks, without necessitating employment of physicians. Some of the most effective ACOs in Premier's population health collaborative engage a majority of independent

clinicians. The greatest fear related to consolidation is its potential to lead to higher prices. Ultimately, the only way to protect against escalating costs is to advance these alternative payment models that hold providers accountable and give them the opportunity to improve care and reduce costs for an entire population.

Premier believes that the goal of ACOs is to incent all providers to work collaboratively to benefit patients. The best way to drive high quality care for patients is to create incentives that drive all the providers in a system to collaborate, to innovate, and deliver high quality, cost effective healthcare. Including a hospital is an effective way to balance the need for access to specialty care while increasing the focus on primary care. One might argue that an ACO should require a hospital participant and other providers across the care continuum to ensure that ACOs do not simply keep patients away from a particular setting but ensure patients receive care in the least restrictive setting. While it would be absurd to define what providers an ACO must include, it is equally absurd to say that ACOs that work to include multiple provider types should be forced to risk sooner.

Premier believes that healthy market competition relies on a level playing field. This administration has been outspoken in advocating for market solutions and level playing fields among competitors. This proposed policy, however, is contrary to a market-based approach whereby all competitors have similar opportunities for success. Whenever there is an uneven playing field, one competitor will use it to their advantage over another. Alternatively, competitors can take steps to game the system. Advantaging one group over another can also create perverse incentives to undermine a competitor overall.

Defining Participation Options by "Experience"

CMS also proposes to limit participations options by categorizing ACOs as "experienced" or "inexperienced" with performance-based risk Medicare ACO initiatives and determining participation options based on prior participation of ACO legal entities and ACO participants. CMS defines a "re-entering ACO" as (1) the same legal entity as an ACO, identified by TIN, or a (2) new legal entity that has never participated in the MSSP and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list. CMS defines an experienced ACO that meets either of the following criteria: (1) The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative, or that deferred its entry into a second MSSP agreement period under Track 2 or Track 3; or (2) 40 percent or more of the ACO's participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a MSSP agreement period under Track 2 or Track 3, in any of the five most recent performance years prior to the agreement start date.

Premier supports the participation options based on prior participation and definitions of renewing/re-entering ACOs and the 50 percent threshold. We generally support the CMS definition of experienced but urge CMS to increase the threshold from 40 percent to 50 percent to align with the new/re-entering definition. We also encourage CMS to monitor the impact of this policy and consider creating an appeals process. For example, it is possible that two separate ACOs discontinue operation in a region then a new entity, completely unaffiliated with either prior entity, forms in the region and recruits participants involved in the prior organization. The intent of the policy is to avoid gaming of the options for the glidepath not to discourage new entities. To balance this potential outcome, CMS should also consider a second criteria, setting a threshold for a percentage of participants that previously were in the same entity. For example, CMS would first identify if 50 percent of participants would qualify an ACO to be reentering or experienced; then, if less than 30 percent of participants were part of the same legal entity, the ACO could appeal the label of reentering or experienced.

Monitoring for Financial Performance

CMS proposes additional provisions to address an ACO's financial performance when an ACO may otherwise be in compliance with program requirements. CMS states that just as poor quality performance can subject an ACO to remedial action or termination, an ACO's failure to lower growth in Medicare FFS expenditures should be the basis for CMS to take pre-termination actions. These actions could include a request for corrective action by the ACO, or termination of the ACO's participation agreement. Specifically, CMS proposes to terminate ACOs if it is negative outside corridor for two agreement periods. CMS appears to be particularly concerned about one-sided risk ACOs that continue to participate in the program and generate net losses to Medicare.

Premier opposes the CMS proposal to terminate ACOs if negative outside corridor for two agreement periods. We believe that these additional provisions, if implemented, would provide CMS with too much discretion to terminate ACO participation in the program. We are concerned that such unchecked authority provided to CMS would further discourage ACOs participating in the MSSP, as this would create additional uncertainty for participants and would also make it difficult to establish agreements with other organizations. Moreover, CMS proposals with respect to the glide path that would limit participation in one-sided risk models would also provide ACOs with incentives to leave the program if they were not able to generate savings.

Election of Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR) by ACOs

CMS proposes that ACOs under the BASIC track would have the same MSR/MLR options that are currently available to ACOs under one-sided and two-side models of the MSSP. ACOs under the BASIC track's glide path in Level A or Level B would choose the MSR/MLR to be applied before the start of their first performance year in a two-sided model. CMS also proposes to use a variable MSR/MLR when performing shared savings and shared losses if an ACO's assigned beneficiary population falls below 5,000 for the performance year, regardless of whether the ACO selected a fixed or variable MSR/MLR. **Premier supports these proposals and appreciates the flexibility these options provide to meet ACOs' needs.**

Participation Options for Agreement Periods Beginning in 2019

CMS proposes to offer a July 1, 2019 start date as the initial opportunity for ACOs to enter an agreement period under the BASIC or ENHANCED track. As proposed, ACOs that entered a first or second agreement period with a start date of January 1, 2016, may elect to extend their agreement period for an optional fourth performance year, defined as the six-month period from January 1, 2019 through June 30, 2019. CMS notes that this election to extend the agreement period is voluntary and an ACO could therefore conclude its participation in the program with the expiration of its current agreement period on December 31, 2018.

Premier is concerned that this policy will result in an ACO managing the costs and quality of two separate beneficiary populations. Each six-month performance period has two distinct assignment windows and methodologies. Moreover, if an ACO changes its participant lists between the six-month extension and the start of the new model, the ACO's aligned beneficiaries could be significantly different. While some beneficiaries will be attributed to the ACO for both performance periods, there will be a portion of an ACO's beneficiaries that are attributed for only one performance period. For beneficiaries attributed for only the first performance period, the ACO will have to continue to deploy resources to manage this population after they are no longer aligned with the ACO and the ACO is unable to take advantage of the waivers available in the program. For beneficiaries attributed only in the second performance period, the ACO will be responsible for costs incurred in the first half of the year when the ACO had no ability to manage the beneficiaries' care.

Managing two distinct patient populations will require the ACO to be responsible for the beneficiaries' cost and quality during a time in which the ACO is unable to manage the patient. As a result, ACOs will have to scale up resources and infrastructure for one performance period in order to mitigate the quality and cost impact. Moreover, with little influence over beneficiaries' expenditures outside of the performance period, ACOs could potentially be at risk for exceeding their benchmark. To mitigate this impact, **CMS should provide an option to allow ACOs in current models to extend their agreements for one year, resulting in a start date of January 1, 2020 for entering the new model.** CMS could still provide a July 1, 2019 start date option for new and existing ACOs. **At a minimum, CMS should use a singular assignment window and methodology to determine the assigned population for the entire calendar year 2019, regardless of whether they are in an extended agreement or the new model.**

Finally, we are concerned that implementation issues could arise if CMS rushes the application process, so we urge CMS to ensure that there is enough time for CMS and participants to prepare for an application cycle after the final rule. Premier asks that CMS delay the July 1, 2019 start and offer a one-year extension to all current ACOs who are ending their agreements if CMS is not ready to implement a new model.

BENCHMARKING METHODOLOGY REFINEMENTS

Calculating Growth Rates Used in Establishing, Resetting and Updating the Benchmark

CMS proposes to use what it refers to as a national-regional blend or a blend of national and regional growth rates to trend forward BY1 and BY2 to BY3 when establishing or resetting an ACO's historical benchmark. CMS would also use this approach to update the historical benchmark to the performance year – this would be calendar year 2019 for ACOs within the six-month performance period from July 1, 2019 to December 31, 2019. To calculate the national-regional blend, CMS would calculate a weighted average of national FFS and regional trend factors, where the weight assigned to the national component would represent the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO. The weight assigned to the regional component would be equal to 1 minus the national weight. As an ACO's penetration in its region increases, a higher weight would be placed on the national component of the national-regional blend and a lower weight on the regional component, reducing the extent to which the trend factors reflect the ACO's own expenditure history.

Premier appreciates that CMS has responded to our previous concerns with solely a regional trend factor; however, we urge CMS to adopt a policy Premier and others have long recommended. **That is, ACO beneficiaries should be removed from the regional reference population.** Including the ACO population in the reference population causes the ACO to be compared to itself rather than the FFS Medicare spending in the region. By including ACO beneficiaries, the regional cost data incorporates efforts ACOs have made to reduce spending. As a result, benchmarks may diverge from the counterfactual spending, making it increasingly difficult for ACOs to achieve savings in comparison to the benchmark.

Use of Regional Factors When Establishing and Resetting ACOs' Benchmarks

CMS proposes to incorporate regional expenditures into the benchmarking methodology for ACOs in a first agreement period for all ACOs entering the program beginning on July 1, 2019 and in subsequent years. Under current policy, the maximum weight applied to the regional adjustment is 70 percent. CMS proposes policies that would limit the magnitude of the adjustment by reducing the weight (to a maximum of 50 percent) and imposing an absolute dollar limit on the adjustment (capped at 5 percent of the

national per capita expenditures for Parts A and B services in Baseline Year 3 for assignable beneficiaries).

Premier supports the CMS proposal to incorporate the regional adjustment into the initial agreement period. We do not support lowering the regional contribution to below 50 percent and urge CMS to maintain the current maximum contribution of 70 percent. As such we recommend the following schedule of weights to be applied:

Schedule of Weights for Regional Adjustment		
Timing when subject to regional adjustment	**ACO's historical spending is lower than its region**	**ACO's historical spending is higher than its region**
First time	30%	25%
Second time	50%	35%
Third	70%	50%
All subsequent periods	70%	70%

Premier also supports CMS' proposed policy to cap regional adjustment at 5 percent of national expenditures to control for outliers. CMS should, however, provide additional flexibility to incentivize ACOs to take on more risk. CMS should provide an option for ACOs to use national benchmarks (in lieu of regional) for risk-bearing ACOs. This would be more desirable for ACOs in historically low spend regions that believe their targets are too low to take on downside risk.

Risk Adjustment Methodology

Premier appreciates the risk adjustment refinements CMS proposes that would eliminate the distinction of newly and continuously aligned beneficiaries for purposes of risk adjustment. This appropriately recognizes that risk scores should increase or decrease during the course of the agreement period and that the beneficiary population underlying health changes with time. **We urge CMS, however, to raise the cap as +/- 3 percent is too restrictive; +/- 5 percent would more accurately account for changes in risk over a performance period**. Ideally, CMS should provide additional incentives for ACOs to move to higher risk levels by providing additional flexibility in accounting for the risk of the population. This could be accomplished by allowing the cap to increase as ACOs take on additional risk. Level E in the BASIC track, for example, would have a higher cap than Levels C and D. We also believe that the cap for the ENHANCED track should align with the percentage change in risk scores for MA plans.

FEE-FOR-SERVICE BENEFIT ENHANCEMENTS

Skilled Nursing Facility (SNF) 3-Day Rule Waiver Expansion

Currently, the SNF 3-Day Rule waiver can be requested only by those MSSP ACOs that bear performance-based risk and to whom beneficiaries are prospectively assigned. CMS proposes to expand the waiver's applicability beginning July 1, 2019, to include performance-risk bearing ACOs that utilize preliminary prospective beneficiary assignment. In all cases, the SNF must be an eligible affiliate of the ACO and, in most cases, have a rating of 3 stars or better in the CMS Five-Star SNF Quality Rating System. (CMS also is proposing to allow swing bed operators, who are not included in the Star Rating system, to become eligible SNF affiliates.) The waiver is available currently to Track 3 and Track 1+ ACOs; the proposed expansion would include Track 2, BASIC track Levels C, D, and E and the ENHANCED track. **Premier strongly supports the proposed expansion of SNF 3-Day Rule waiver applicability as another important tool with which ACOs can more effectively coordinate care while increasing quality and reducing unnecessary costs.**

Telehealth Waiver Expansion

In keeping with the provisions of the Bipartisan Budget Act of 2018 (BBA 2018), CMS proposes that existing originating site and geographic restrictions would be waived when Medicare-approved telehealth services are furnished to FFS beneficiaries by MSSP ACO professionals. The waiver would take effect beginning with performance year 2020 and be limited to those ACOs that bear performance-based risk and to whom beneficiaries are prospectively assigned. The services must be billed through the ACO's TIN and may not be designated as inpatient-only. The expanded telehealth policy would apply to Track 3 and to Track 1+ ACOs as well as to those on the newly proposed ENHANCED track and on Levels C, D, and E of the BASIC track. **Premier strongly supports the telehealth expansion as proposed, particularly when combined with the increased flexibility that would occur with the proposed ability for ACOs to annually elect either prospective or preliminary prospective beneficiary assignment.**

Other Needed Waivers

Premier notes once again that additional waivers are critical to removing persistent legal and regulatory barriers that inhibit MSSP ACO providers from working together to provide better-coordinated, high-quality care, most notably pertaining to the applicable fraud and abuse laws (e.g., the Stark and Anti-kickback statutes and the Beneficiary Inducements Civil Monetary Penalty (CMP) provisions). Premier continues to recommend that CMS should issue:

- An ACO "pre-participation" waiver to protect ACO-related start-up arrangements, in anticipation of new MSSP participants and the proposed redesigned tracks;
- An ACO participation waiver that applies broadly to ACO-related arrangements during the term of the participation agreement; and
- A shared savings distributions waiver that applies to distributions and uses of any earned shared savings payments or internal costs savings.

TOOLS TO STRENGTHEN BENEFICIARY ENGAGEMENT

Beneficiary Incentive Program Implementation

Beneficiaries assigned to MSSP ACOs, regardless of assignment methodology, retain their rights to seek care outside of the ACO without penalty. Therefore, to effectively deliver value-based care, ACOs must seek to actively engage the beneficiaries for whom they will be held accountable for quality and cost; yet MSSP ACOs are prohibited from marketing activities, such as those permitted for Medicare Advantage (MA) plans. Current regulations do allow ACOs to provide in-kind items or services as incentives, the majority of which are judged on a case-by-case basis, but ACOs are inhibited by the simultaneously applicable statutes (e.g., anti-kickback and CMP provisions). The BBA 2018 enables performance-based risk-bearing ACOs to establish incentive payment programs to encourage their assigned beneficiaries to obtain medically necessary primary care services, beginning no later than January 1, 2020. CMS proposes implementing regulations, including ACO eligibility and incentive program application and certification processes, with a start date of July 1, 2019 (coinciding with the first agreement period of the redesigned ACO tracks). CMS also addresses beneficiary eligibility, primary care services that would qualify for incentive payments, and incentive program recordkeeping, along with payment amount, timing, and distribution method.

Premier appreciates that the regulations proposed by CMS to implement the beneficiary incentive payment program as directed by BBA 2018 are not overly restrictive and are attentive to minimizing

provider and beneficiary burden. **Given longstanding concerns about compliance of ACO incentive programs with applicable fraud and abuse laws, Premier requests that CMS provide template language for use by ACOs to notify beneficiaries about their new incentive programs. Finally, since establishing a primary care incentive payment program is optional for ACOs, Premier recommends that CMS make available summary information about the uptake of beneficiary incentive programs when reporting overall MSSP results.** Information from early adopters of incentive programs would be valuable to the remaining ACOs when making their decisions about applying to establish incentive programs.

Beneficiary Notifications

CMS requires that MSSP ACOs notify beneficiaries that their care is being furnished under a shared savings payment model and that they may opt out of having identifiable, claims-level data about themselves shared with their ACOs. CMS has modified the content, frequency and delivery mechanisms for beneficiary notification multiple times since the MSSP's inception. Currently, notices must be posted in ACOs' primary care delivery sites and a written Beneficiary Information Notice must be provided upon beneficiary request. CMS proposes to expand the requirements beginning July 1, 2019, creating a CMS template Notice, designed to be a comprehensive single source of MSSP information that must be given to beneficiaries during their first primary care visit of each performance year. CMS further proposes to add material to the revised Notice informing beneficiaries of their option to voluntarily designate an ACO professional to coordinate their care (i.e., "primary clinician" or" main doctor"), thereby implementing the voluntary alignment provisions of BBA 2018.

Premier respects CMS' intention to provide beneficiaries with sufficient information to make thoughtful and well-informed decisions about their healthcare, and we understand that CMS must implement the BBA 2018 statutory mandate for informing beneficiaries about voluntary alignment. **Premier, however, firmly opposes the proposed changes to provide beneficiary notification during the first primary care visit of each performance year.** Reasons for our opposition include the following:

- A comprehensive written notice at the time of a planned primary care visit is likely to overwhelm beneficiaries with information about myriad topics only distantly related to that visit. The clinical efficacy and experience of care for that visit are likely to be impaired and the information needed only for future use is unlikely either to be retained or to be readily retrieved later when needed.
- Prior similar requirements for expanded notifications during primary care visits led to considerable confusion among beneficiaries; for example, some beneficiaries believed that the data-sharing notification was in reality an attempt by the ACO to steal their identities. Many ACOs had to reassign staff members from clinical duties to answering beneficiary questions about various notification provisions.
- Clinical workflows and electronic record systems would require reconfiguration (e.g., scheduling additional visit time, incorporating reminder prompts and documentation of notification delivery) to assure that the required notifications occurred at the time of the initial primary care visit of each performance year.
- Beneficiaries should be able to specify how information is most effectively exchanged with them by CMS and by their ACOs (e.g., hard copy, 1-800-MEDICARE, electronic mail).

Premier strongly recommends that no changes be made to the current notification processes regarding the shared savings payment model, ACO participation by a beneficiary's practitioners, and opting out of beneficiary identifiable, claims-level data-sharing. Premier also recommends that notification about voluntary alignment be presented separately, in keeping with the BBA 2018 provisions designed to support access to this choice by beneficiaries and the potential of this option to directly increase beneficiary engagement. Premier further recommends that MSSP ACO beneficiary user groups be created and that no new or revised notifications be implemented

without input from those groups; their input should also guide delivery method choices made available to beneficiaries for various notifications.

Opt-In Assignment Methodology

CMS discusses at length and invites comments about all aspects of a hybrid assignment methodology that would include direct ACO opt in (a beneficiary chooses assignment to a specific ACO); voluntary alignment with an ACO professional (with resulting assignment to the ACO in which that professional participates); and a modification of the current claims-based assignment methodology (incorporating a minimum level of primary care visits furnished to a beneficiary). CMS does not make any formal proposal about the hybrid methodology nor indicate a timeline for further consideration of its implementation.

Premier appreciates that CMS is exploring the potential for opt-in assignment to increase ACO beneficiary engagement that then could lead to more effective care coordination with improved quality and decreased costs. **Premier does not support implementation of the hybrid opt-in methodology as discussed in the rule at this time. Instead, Premier recommends that CMS do the following:**

- Maintain the existing claims-based methodology combined with the voluntary alignment option (and minimizing the notification burden related to that option).
- Expeditiously test an option for beneficiary opt-in directly to an ACO (in parallel to the existing beneficiary voluntary alignment directly to an ACO professional). Testing should explore appropriate marketing opportunities for ACOs analogous to those for MA plans.
- Explore additional approaches hybrid assignment and choose one or more for limited-scale testing. Before proposing any program-wide replacement MSSP assignment methodology, CMS should explore rules for rejecting opt-in or voluntary assignment (e.g. when a beneficiary resides outside the geographic region, when a beneficiary does not receive at least one service from a participating provider in the ACO).

UPDATING PROGRAM POLICIES

Voluntary Alignment Policy Revisions

Medicare FFS beneficiaries may choose to designate an ACO professional as their primary clinician for coordinating their care, and the beneficiary who does so becomes voluntarily aligned to the designated professional's ACO. Currently, a primary clinician must be either a primary care practitioner or practice one of a limited list of specialties (e.g., cardiology), and the beneficiary must have received at least one primary care service from a professional who practices primary care or a listed specialty in the aligned ACO. As part of BBA 2018 implementation, CMS proposes policy revisions to begin with performance year 2019 including removing the specialty restrictions to primary clinician eligibility and no longer requiring the voluntarily aligned beneficiary to have received any services from a professional in the aligned ACO during the applicable beneficiary assignment window. **Premier supports the removal of specialty restrictions for primary clinicians but recommends retention of the requirement for a beneficiary to receive at least one primary care service from an ACO participant.**

Revised Definitions of Primary Care for Use in Beneficiary Assignment

In accordance with provisions of the 21st Century Cures Act and BBA 2018, for performance years 2019 and thereafter CMS proposes to update the definition of primary care services that is used when assigning beneficiaries to ACOs (in combination with the applicable MSSP track's assignment methodology). Services that would satisfy the revised definition include some existing Current Procedural Terminology (CPT) codes (e.g., advance care planning) and Healthcare Common Procedure Coding

System (HCPCS) G-codes (e.g., depression screening) along with new G-codes proposed elsewhere in the rule (e.g., complexity inherent in office visits for certain specialties). CMS also proposes to more accurately distinguish short-term, rehabilitation-related evaluation and management services provided in nursing facilities from ongoing primary care services furnished to longer-term nursing facility residents. CMS would identify the former services by linking the appropriate CPT codes to nursing facility claims for the same dates of service rather than relying on the place of service code for SNFs (code 31) as listed on the professional claim. **Premier supports the changes as proposed and agrees with CMS that linking SNF facility claims by date of service to professional claims will better identify short-term, rehabilitation-focused care that should not be counted as primary care services that contribute to beneficiary assignment to ACOs.**

Extreme and Uncontrollable Circumstances

In December 2017, CMS issued an interim final rule with comment period that established policies to address quality performance scoring and shared loss determinations for MSSP ACOs impacted by extreme and uncontrollable circumstances occurring in performance year 2017 (e.g., hurricanes and widespread wildfires). CMS proposes some limited changes to update the existing policies for use in performance year 2018 and subsequent years, including revisions to align the performance scoring and shared loss determination processes with the proposed redesigned ACO tracks. **Premier supports continuation of the extreme and uncontrollable circumstances policies as applied in 2017 with the proposed revisions.**

Program Data and Quality Measures

Premier agrees with CMS that the existing ACO quality measure set appropriately emphasizes outcomes over process. Premier also supports the goals of the Meaningful Measures initiative in general as well as the streamlined ACO measure set for 2019 as proposed in the Medicare Physician Fee Schedule proposed rule. **Premier recommends that CMS seek input from the Measures Application Partnership to enhance the ACO measure set by identifying measures that best reflect the focus of alternative payment models such as ACOs on care coordination and population health and that CMS commit funding to development of such measures.**

CMS states that the Medicare program has become the largest payer for prescription opioids in the United States. As a result, Medicare drug event records now constitute a substantial and critically important repository of substance use disorder data. CMS currently provides Part D prescription drug event data to each ACO on a monthly basis, but items potentially related to substance use disorders are routinely de-identified, provided only in aggregate, or both. ACOs are held accountable for the total health of their beneficiary populations, but the ability of ACOs to most effectively manage population health is being increasingly constrained by the limited and non-specific substance disorder data with which they are provided. Many beneficiaries are taking multiple medications and are at high risk for adverse drug interactions when opioids are prescribed for them. **Premier believes that it is unfair to hold ACOs accountable for measures of substance use disorder management until CMS provides ACOs with access to the data necessary for instituting appropriate treatment (i.e., complete and identifiable data for all prescribed medications and their related diagnoses).**

In support of optimizing population health management by MSSP ACOs, including substance use disorders, Premier continues to advocate for statutory reform of 42 CFR Part 2 (Confidentiality of substance use disorder patient records) to make substance use data more readily available to providers who are already subject to HIPAA patient privacy protection regulations. **Until Part 2 reform is enacted, Premier again strongly recommends that providers who are engaged in population health management (e.g. ACOs) and that are bound by a data use agreement with CMS, receive complete**

and identifiable data from CMS about substance use disorder--related diagnoses and services furnished to their assigned beneficiaries by providers to whom Part 2 does not apply.

CMS further states that over one-third of beneficiaries assigned to MSSP ACOs with continuous Part D coverage have at least one opioid prescription but that rates vary substantially across ACOs (10-60%). Premier firmly believes that such variability strongly suggests opportunities to improve the quality of care for substance use disorders in many ACOs. **Assuming that CMS makes sufficient beneficiary medication data available, Premier generally supports consideration by CMS of adding opioid use measures to the MSSP measure set. In particular, however, Premier opposes addition of measures that focus primarily on opioid dosing (e.g., NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer).** Premier is concerned that rigid adherence to dosing guidelines (e.g., the Centers for Disease Control & Prevention Guideline for Prescribing Opioids for Chronic Pain) may cause serious adverse outcomes (e.g., depression, suicide) for patients being successfully managed on long-term opioid analgesics whose dosing regimens are abruptly changed to achieve guideline compliance.

Promoting Interoperability (PI)

CMS seeks to harmonize MSSP quality and health IT activities with the Quality Payment Program (QPP) through two actions that would become effective January 1, 2019: 1) retiring the ACO-11 measure (Use of Certified Electronic Health Record Technology (CEHRT)); and 2) requiring instead certification by each ACO that the level of CEHRT usage by the ACO's clinicians meets or exceeds the Advanced APM CEHRT threshold under the QPP. The latter requirement would become a condition of participation for all MSSP tracks, and all payment models within those tracks, that also meet the financial risk standard required of Advanced APMs. **Premier supports both of these proposed actions regarding ACO CEHRT usage and appreciates the associated burden reduction for ACOs and their clinicians.** However, the first change as proposed could potentially create disparate scoring standards for the Promoting Interoperability category in MIPS for ACO clinicians that are not an Advanced APM or do not meet the thresholds to be considered a Qualifying Participant. While the ACO requirement is that clinicians would only have to certify CEHRT usage, the MIPS requirement would require clinicians to actually submit PI data for scoring using MIPS-APM scoring standard. **Premier requests that CMS avoid creating confusion by confirming that clinicians in ACOs that are MIPS APMs would not be subject to full PI category reporting and scoring but instead could simply certify their CEHRT usage. The PI category weight for such clinicians would then be redistributed equally to the Quality and Clinical Practice Improvement Activities performance categories.**

Pharmacy Care Coordination: Request for Comments

Premier supports exploration by CMS of approaches that could facilitate collaboration between ACOs and Part D stand-alone prescription drug plan sponsors and lead to improved outcomes, such as more widespread use of medication therapy management. **CMS should investigate ways to make complete pharmacy data more readily available to MSSP ACOs and their clinicians.** Particular attention should be given to enabling technology methods (e.g., secure data access portals, data sets accessible using Application Programming Interfaces) that could provide ACOs with real-time access to claims data (prior to or synchronous with claims processing) for their aligned beneficiaries. Real-time access would allow ACOs to build provider alert processes that would improve care by triggering rapid clinical interventions when needed, as is being done already by some MA and commercial plans.

CMS should develop one or more voluntary MSSP demonstrations that incorporate ACO accountability for Part D costs. Doing so would allow those ACOs who are ready and interested to participate, would accelerate progress towards readiness by the remaining ACOs, and would provide a

platform for testing multiple approaches, the most effective of which could be expanded to all ACOs. Maximizing flexibility should be a guiding principle in designing such demonstrations; for example, allowing ACOs to select patient cohorts for whom to be responsible (e.g., high-risk patients with diabetes or patients with multiple chronic conditions)

CONCLUSION

Premier is committed to the success of CMS' alternative payment models and encourages CMS to consider models beyond ACOs. Specifically, we recommend CMS consider:

- Adopting a "layered payment model," a provider-driven ACO model that includes primary care capitation as well as inpatient and outpatient bundles within a global capitated amount along with legal waivers that will allow providers to employ tools similar to MA plans; and
- Testing a provider-driven global capitation models; for example, a model aligned with H.R. 5841 as introduced by Reps. Mike Kelly and Richard Neale in the 114th Congress.

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the Medicare Shared Savings Program Pathways to Success proposed rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, senior director, payment and quality policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance