

Advancing Health in America

October 16, 2018

Washington, D.C. Office 800 10th Street, N.W. Two CityCenter, Suite 400 Washington, DC 20001-4956 (202) 638-1100

Ms. Seema Verma Administrator Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue, S.W., Room 445-G Washington, DC 20201

RE: CMS-1701-P, Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations--Pathways to Success

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Medicare Shared Savings Program (MSSP) proposed rule regarding Pathways to Success for accountable care organizations (ACOs).

Our members are enthusiastic about the MSSP as one pathway to advance their ongoing efforts to transform care delivery through improved care coordination and financial accountability. As such, the AHA appreciates certain steps CMS is taking to improve the stability and flexibility of the MSSP and expand participants' ability to provide care to beneficiaries, for example, via telehealth. However, we are concerned that, as a whole, the proposals in the rule would likely result in significant decrease in MSSP participation. While such an outcome may very well be CMS's expectation, it unfortunately disregards many of the lessons we have learned from the current program. Chief among those is that the longer ACOs of all types remain in the program, the more likely they are to achieve shared savings. Indeed, evidence demonstrates that per beneficiary savings correlate to experience, especially after ACOs' third year in the MSSP. Drastically shortening the length of time in which they can participate in an upside-only model, along with attempting to create arbitrary differentiations between physician- and hospital-led ACOs, does not empower ACOs to maximize their contribution to patient care and is not a pathway for improving the value of the MSSP for beneficiaries. Instead of making it harder for ACOs, particularly those



Ms. Seema Verma October 16, 2018 Page 2 of 25

with hospital participants, to achieve shared savings, we urge CMS to improve program methodology so that it accurately rewards performance for improving quality and reducing costs.

Our key recommendations follow.

DIFFERENTIATION OF PARTICIPATION OPTIONS FOR HIGH- AND LOW-REVENUE ACOS:

- Do not finalize the proposed differentiation of participation options for high- and low-revenue ACOs.
- Instead, improve program methodology to accurately reward performance for improving quality and reducing costs, and offer resources and assistance to all ACOs.

REDUCTION OF TIME IN UPSIDE-ONLY RISK ARRANGEMENTS

- Finalize the proposal to allow inexperienced re-entering and renewing ACOs, including those that are currently participating in Track 1 of the MSSP, an additional year of upside-only risk.
- Allow new, inexperienced ACOs three years in upside-only risk, rather than two, before requiring them to take on downside risk, but maintain the opportunity for ACOs that feel ready to elect to move into downside risk prior to completing three performance years.

LEVELS OF RISK AND REWARD:

- Do not finalize the proposal for a reduction in the shared savings rate for BASIC track ACOs and, instead, maintain a 50 percent shared savings rate for all BASIC levels ACOs.
- Finalize the proposal to create a glide path to risk, but fully align the loss sharing limits in the proposed BASIC Level E with the standards for Advanced Alternative Payment Models (APMs) under the Quality Payment Program (QPP).
- Create a more gradual glide path to risk between the levels of risk in the proposed BASIC Level E and the proposed ENHANCED Track.

EXPANSION OF ACCESS TO WAIVERS

• Finalize proposals to expand access to the Skilled Nursing Facility 3-Day Rule waiver and telehealth coverage via waivers of certain related regulations.

PROPOSED CHANGES TO BENCHMARKING METHODOLOGY

- Increase the proposed 3 percent symmetrical cap on risk scores and apply the increased cap on a year-over-year basis rather than over the entire length of the agreement period.
- Do not finalize the proposal to use the full 12 months of calendar year 2019 to determine the benchmark and assigned beneficiary expenditures for ACOs that participate in one or both of the 2019 six-month performance periods.

Ms. Seema Verma October 16, 2018 Page 3 of 25

ELECTION OF MINIMUM SAVINGS RATE (MSR)/MINIMUM LOSS RATE (MLR)

• Allow ACOs to alter their MSR/MLR throughout the proposed five-year agreement period.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Shira Hollander, senior associate director of policy, at shollander@aha.org.

Sincerely,

/s/

Thomas P. Nickels Executive Vice President Government Relations and Public Policy

Enclosure

American Hospital Association (AHA) Detailed Comments on the Medicare Shared Savings Program (MSSP) Proposed Rule

DIFFERENTIATION OF PARTICIPATION OPTIONS FOR HIGH- AND LOW-REVENUE ACCOUNTABLE CARE ORGANIZATIONS (ACOS)

In order to provide ACOs with "pathways to success" in the MSSP, CMS proposes to redesign the MSSP's participation options. Specifically, the Centers for Medicare & Medicaid Services (CMS) would discontinue Tracks 1 and 2 and the deferred renewal option. Instead, it would offer two tracks – BASIC and ENHANCED – that eligible ACOs could enter for an agreement period of not less than five years. The BASIC Track would include a glide path to risk consisting of five levels, but only certain ACOs would be permitted to enter the program at the start of the glide path with upside-only risk. The ENHANCED Track would mirror the current Track 3.

CMS proposes additional policies to distinguish among ACOs and restrict some ACOs to only certain participation options. One such proposed distinction is between what CMS has termed "low-" and "high-revenue" ACOs. To define low- and high-revenue ACOs, the agency would assess the degree of control an ACO holds over the Medicare expenditures of its assigned beneficiaries in terms of how much of its beneficiaries' revenue it "captures." Specifically, if an ACO's Medicare Part A and B fee-for-service (FFS) revenue is 25 percent or more of the total Medicare Part A and B FFS expenditures for its assigned beneficiaries, CMS would consider that ACO "high-revenue." In addition, CMS proposes to differentiate between "inexperienced" and "experienced" ACOs, based on ACOs' prior experience in "performance-based" (or two-sided) risk Medicare ACOs.

CMS proposes to limit high-revenue ACOs, which the agency states are often hospitalled, to a single agreement period in the BASIC Track. Conversely, it proposes to allow low-revenue ACOs to participate in two agreement periods in the BASIC Track. Additionally, CMS proposes to prohibit experienced, high-revenue ACOs from entering the BASIC Track at any level, and would instead limit them to immediate participation in the proposed ENHANCED Track. CMS would allow experienced, low-revenue ACOs to participate in Level E of the BASIC Track for up to two agreement periods before requiring them to transition to the ENHANCED Track. CMS also considers and seeks comments on proposals to allow low-revenue ACOs to have potentially greater access to shared savings than high-revenue ACOs.

The AHA is deeply concerned about CMS's proposals to create different participation options for high- and low-revenue ACOs, which functionally penalize certain ACOs for the size of their patient population and volume of services. The agency has provided inadequate justification to support its assumption that the Ms. Seema Verma October 16, 2018 Page 5 of 25

degree of an ACO's control over its assigned beneficiaries' Medicare expenditures indicates that it is able to take on more risk, more quickly. As such, we urge CMS not to finalize any proposals that differentiate between high- and low-revenue ACOs, or between ACOs with and without hospital participation, at this time. Such proposals are unwarranted and could have negative effects on patient care, as well as CMS's efforts to transition our nation's health care system to one that pays for value instead of volume. In short:

- The bifurcation of participation options for high- and low-revenue ACOs creates an un-level playing field based on faulty and incomplete definitions, assumptions and data;
- Risk readiness is not determined by ACO composition; and
- The proposal fails to empower ACOs to maximize their contribution to patient care and is a distraction from the goals of ACOs and CMS.

The Bifurcation of Participation Options for High- and Low-revenue ACOs Creates an Un-level Playing Field Based on Faulty and Incomplete Definitions, Assumptions and Data. CMS bases its proposal to differentiate between high- and low-revenue ACOs on incomplete and misguided data that suggest "physician-led" ACOs outperform "hospitalled" ACOs, as well as its assumption that high-revenue ACOs are likely to include hospitals, health systems, and/or other institutional providers. **However, the results of the ACO program cannot be explained simply by dividing the world into high- and low-revenue or hospital- and physician-led. As such, CMS should not base such significant changes to the MSSP on these distinctions. This is especially true given that, in 2017, only approximately one third of ACOs achieved any shared savings at all.¹ Any generalizations about which ACOs are more successful than others would not advance the goals of the MSSP to improve the quality of patient care and reduce costs.**

Under the MSSP as it currently stands, CMS defines an ACO as "hospital-led" only if it includes an inpatient taxpayer identification number (TIN) on the participant list it submits to CMS. This definition misrepresents the wide range of hospitals' involvement in ACOs, including:

- jointly initiating and leading an ACO with a physician group;
- participating in the ACO contract without a leadership role;
- contracting with a physician group for health system services and resources without appearing on the physician group ACO's participant list; or
- participating in another manner.

For example, an academic medical center might have an ACO that is run through its faculty practice; CMS would call this ACO "physician-led" despite the obviously critical

¹ 2017 Shared Savings Program Accountable Care Organizations Public Use File, *available at* <u>https://data.cms.gov/Special-Programs-Initiatives-Medicare-Shared-Savin/2017-Shared-Savings-Program-SSP-Accountable-Care-O/gk7c-vejx/data</u>.

Ms. Seema Verma October 16, 2018 Page 6 of 25

role the academic medical center would play in providing care to the ACO's patients. As another example, a "physician-led" ACO may be truly led by an investor, which would not be reflected in the ACO's participant list. **Indeed, CMS itself recognizes this fallacy of relying on participant lists when it indicated that to move from being a high- to low-revenue ACO, an ACO could simply remove a hospital from its participant list but make no other changes to its care delivery.**

This is even more troubling considering the vagueness with which the specifics of the proposal are presented in the rule. For example, CMS neither sufficiently explains the basis for its proposed threshold of 25 percent to identify high-revenue ACOs, nor provides any indication of which current ACOs would be considered high- or lowrevenue. The agency does not even provide ACOs with the tools to run a calculation themselves to determine whether they are high- or low-revenue and, in fact, recognizes it would be difficult for ACOs to do so. CMS indicates in the rule that it would inform an ACO of whether it is high- or low-revenue only after it has submitted its application for participation in the MSSP. However, by that point, ACOs and their participants would have already had to make several critical participation decisions - all with woefully inadequate information. This is especially true for existing ACOs that have already experienced the long lag time between when they complete their performance years and when they receive their performance data from CMS, as well as fluctuations in their lists of assigned beneficiaries, or those that do not have a team of actuaries that can run necessary calculations for them. If the rule is finalized as proposed, this lack of transparency and resources from CMS would leave ACOs having to make uninformed decisions about a full five years of participation. We strongly recommend CMS release data on which it based these and all other proposals and provide ACOs with significantly more tools and resources to run calculations themselves.

Differentiation Between High- and Low-revenue ACOs Based on Flawed Data. CMS's proposed differentiation of high- and low-revenue ACOs is based on misleading definitions and inaccurate data regarding the performance of physician- and hospital-led ACOs. While some differentiation between participants may be appropriate, favoring a certain provider type or ACO size over another simply incentivizes physicians and hospitals to distrust one another rather than improve care coordination. CMS cannot effectuate sustainable change in care delivery without having all providers of care at the same table.

CMS justifies its proposed differentiation by citing data that suggest physician-led ACOs outperform hospital-led ACOs. Yet, the agency offers no citations or other transparency as to the source of these data. If the data are based on CMS's standard approach of measuring ACO performance as spending relative to benchmarks, then we question its appropriateness. Specifically, researchers have found that this approach – which is not a statistically valid program evaluation but rather simply the model's approach to financial target setting – systematically underestimates the actual savings generated by MSSP ACOs by as much as 39 percent. **Indeed, it provides too simplistic a picture**

Ms. Seema Verma October 16, 2018 Page 7 of 25

of the success of an ACO as it fails to account for not only methodological issues with setting the benchmarks but also the spillover effect on patients who are not participating in an ACO that nonetheless benefit from its integrated care networks, care coordination and other operational infrastructure.

In fact, a methodology that calculates how much shared savings was earned against a benchmark depends equally, if not more, on the benchmark itself (and the market context in which it is set) than on the efforts of the ACO. Two ACOs – regardless of whether or not a hospital participates in them – could be performing exactly the same but have completely different results because their benchmarks are different. No ACO can decline its expenses as quickly as its benchmark declines, which means that no matter how well an ACO may perform, it still may fail to earn shared savings. CMS may not even be able to explain the degree of change in an ACO's benchmark: one of our members' ACOs saw its benchmark decline by \$1000 in a single rebasing and no one, including CMS, could explain why.

The interrelationship between CMS programs can also impact shared savings calculations. For example, the physicians of some of our members participating in ACOs also participate in the Comprehensive Primary Care Plus (CPC+) program, through which participants receive upfront care management fees. In the MSSP, the millions of dollars that these ACOs spent in care coordination, which included those care management fees, were counted as an expense of the ACOs, impacting their benchmarks. In addition, two of our member hospitals that participate in one of these ACOs also began participation in the Bundled Payments for Care Improvement (BPCI) Advanced initiative earlier this month; any savings generated from patients that are assigned to the ACO that trigger a BPCI Advanced episode will be attributed to the hospital as a BPCI Advanced participant, not the ACO.

Other studies performed by external researchers that rely on CMS's definitions of hospital- and physician-led also misstate the difference in savings between the two groups. For example, in a study published in the *New England Journal of Medicine* on Sept. 5, 2018, the authors conclude that physician groups that participated in ACOs saved money for Medicare "whereas hospital-integrated ACOs did not produce savings (on average) during the same period."² However, a closer analysis of the results in the study, using the authors' own methodology of finding significance at the 5 percent level, demonstrates that their conclusion is not supported. The authors base their conclusion on their comparison of the performance of physician-led and hospital-led ACOs over eight years (years one, two and three of the 2013 cohort and years one and two of the 2014 cohort). However, in only two of those eight years were the differences in savings between physician-led and hospital-led ACOs statistically significant. **Therefore, even though they used different methodologies, both CMS and other researchers have**

² J. Michael McWilliams, et al., Medicare Spending after 3 Years of the Medicare Shared Savings Program, 379 N Engl J Med 1139, 1149 (Sept. 5, 2018).

Ms. Seema Verma October 16, 2018 Page 8 of 25

significantly overstated the degree to which the performance of hospital-led ACOs differs from that of physician-led ACOs. CMS should not base a major redesign of the MSSP participation options on a single methodological approach nor on data that lack clarity and conclusiveness.

Moreover, when using more appropriate definitions of ACO composition, our analysis revealed that ACOs with hospital participation actually saved more for the Medicare Trust Fund than those without hospital participation. Specifically, we analyzed CMS's list of the 472 ACOs that participated in the MSSP in 2017 and deemed ACOs with any hospital participation as "hospital-affiliated" ACOs. This methodology captures the important contributions that hospitals make to the care of ACO beneficiaries, regardless of whether they are listed on ACOs' participant lists. Our analysis found that nearly 20 percent of the ACOs that CMS would characterize as physician-led, in fact, have affiliated hospitals contributing to the care of the ACO's assigned beneficiaries. And, our analysis demonstrates that, in 2017, hospital-affiliated ACOs saved a total of approximately \$174 million, while non-hospital-affiliated ACOs saved a total of approximately \$140 million.³ These numbers stand in stark contrast to the calculation of savings using CMS's definitions of ACO leadership; those definitions suggest hospital-led ACOs saved a total of approximately of \$72 million and other ACOs saved a total of approximately \$241 million in 2017. Clearly, hospitals have made significant contributions to the savings to the Medicare program that ACOs have achieved and should not be treated otherwise. Thus, CMS's proposed revisions to the MSSP that rely on results suggesting "hospital-led" ACOs underperform as compared with "physician-led" ACOs are misguided and based upon inaccurate definitions of these ACOs and inconclusive evidence about their performance.

We conducted additional analysis to demonstrate that small changes in definitions can lead to large variations in results. For example, if we define "small" ACOs as those with fewer than 10,000 beneficiaries and those with 10,000 or more beneficiaries as "large" ACOs, our data indicates that larger ACOs save significantly more than smaller ACOs, both in the aggregate and in per beneficiary savings. However, when we compare ACOs with fewer than 25,000 assigned beneficiaries ("small") to those with greater than 25,000 beneficiaries ("large"), the opposite is true.⁴ Perhaps these data also suggests that the larger an ACO is, as defined by number of assigned beneficiaries, the harder it is to achieve shared savings. Large ACOs must manage risk for a greater number of beneficiaries and bring together what is likely a higher number of providers in agreement on how to manage this risk. Due to the magnitude of the total cost of care for these ACOs, prematurely forcing them to take on even a small percentage of risk could result in shared losses that nearly swallow their entire operating margins. **We urge CMS**

³ Data provided by Leavitt Partners Insight, LLC; not for use or re-distribution without approval from the company.

⁴ Id.

Ms. Seema Verma October 16, 2018 Page 9 of 25

to seek ways to support these ACOs, rather than make it harder for them to achieve savings.

Importance of Quality Improvement to Success in the MSSP. In its heightened focus on achieving savings, CMS overlooks the significant improvements in patient experiences, outcomes and quality of care that all providers have achieved through ACO participation. Excluding these achievements from the definition of "success" in the MSSP would render any such definitions incomplete and ill-suited to form the basis of significant program change. In our analysis, ACOs had an average quality score of approximately 92.4 percent in 2017, with a negligible difference between the scores of hospital-affiliated ACOs and ACOs without hospital affiliation. This delivery of high-quality health care across providers should be as important to Medicare as the achievement of shared savings.

Given that managing hospital care is a key component of improving outcomes and reducing cost growth, hospitals are in an ideal position to contribute to the quality of care that ACOs deliver. By engaging providers across the care continuum, managing the coordination of care transitions, and driving data sharing within and among provider settings, hospitals play a vital role in improving the quality of care for ACO and other beneficiaries. What's more, these quality improvements often produce a reduction in health care costs, and thus should be efforts that CMS seeks to support. For example, with hospital participation, an ACO could more carefully manage transitions out of the hospital to minimize post-hospital care and reduce readmissions, improving patient outcomes and reducing costs.

<u>Risk Readiness is Not Determined by ACO Composition</u>. Using the level of "captured" revenue as a proxy for the leadership composition of an ACO belies the true nature of care delivery in today's environment. There is no valid reason to conclude that an ACO's "captured" revenue is an accurate or appropriate predictor of either the amount of "control" it has over its beneficiaries' expenditures or its level of risk preparedness.

Revenue Does Not Predict Control. **CMS's assumption that the Medicare revenue hospitals receive is strictly generated by Medicare expenditures they can control is not appropriate.** Indeed, high levels of "captured" revenue by an ACO can originate from many sources, none of which necessarily predict the amount of "control" it has over its beneficiaries' expenditures. For example, individual providers, not large institutions, make the decision to admit patients to hospitals, controlling where Medicare dollars are spent for that patient. In addition, our research indicates that, relative to patients seen in an independent physician office, Medicare patients, including cancer patients, seen in hospital outpatient departments are more likely to be suffering from more severe chronic conditions, dually eligible for Medicare and Medicaid, previously hospitalized, and under 65 years old (and thus more likely to be individuals with Ms. Seema Verma October 16, 2018 Page 10 of 25

disabilities, end-stage renal disease, and/or amyotrophic lateral sclerosis).⁵ These individuals also are more likely to have been previously cared for in an emergency department, thereby having higher Medicare spending both prior to and during the receipt of ambulatory care. No matter how efficiently hospitals operate, they still have to – and do – provide complete and medically appropriate care to these more complex individuals.

Similarly, the significant rise in Medicare drug spending results in more Medicare dollars being paid to hospitals for beneficiaries in its care. However, it does not indicate "control." According to our research, from 2015 through 2016, Medicare spending on all Medicare Part B separately payable drugs increased more than 7 percent. Approximately 96 percent of the growth was due to increases in drug prices and 4 percent was due to increased utilization. During the same time period, spending on outpatient separately payable drugs grew by approximately 11 percent. The price of outpatient separately payable drugs grew at an even higher rate of about 11.28 percent; thus, over 100 percent of the growth during this time was attributable to price increases of outpatient separately payable drugs. The utilization of these drugs decreased over the same period of time. The increase in drug spending from 2015 to 2016 represents about \$1 billion in additional spending compared to if no change in price had occurred.

Control Does Not Predict Risk Preparedness. CMS offers no convincing argument to support its assumption that an ACO's degree of "control" over the Medicare expenditures for its assigned beneficiaries indicates that it is more prepared to take on more risk, more quickly, with less experience. Indeed, researchers and ACO participants are still working to determine what, in fact, does prepare an ACO to take on risk. In the experience of our members, some factors that determined their own risk preparedness included:

- tight coordination between hospitals and post-acute providers;
- interdisciplinary management of the ACO;
- robust care management in inpatient and outpatient settings;
- significant investment in infrastructure to close gaps in care transitions and coordination;
- investment in data analysis and reporting systems to better target the care each population receives; and
- system-wide incentives to manage the total cost of care.

The amount of time an ACO spends in an accountable care arrangement is also a welldocumented contributor to ACOs' ability to take on risk and share in savings.⁶ The risk

⁵ Berna Demiralp, et al., KNG Health Consulting, LLC, Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices (Sept. 25, 2018), *available at* <u>https://www.aha.org/guidesreports/2018-09-24-care-comparison-reports</u>.

⁶ William Caughey, et al., ACO Maturity Score: A Metric to Assess an Organization's Progress in Accountable Care, Leavitt Partners (Aug. 2018).

Ms. Seema Verma October 16, 2018 Page 11 of 25

preparedness of MSSP ACOs also may be influenced by the accountable care contracts with other payers in which the ACO participates.⁷ We urge CMS to focus its attention on determining accurate predictors for risk preparedness and revise elements of the MSSP based on those factors.

<u>Proposal Fails to Empower ACOs to Maximize their Contribution to Patient Care and</u> <u>Distracts from ACOs' and CMS's Goals</u>. Making participation more challenging for ACOs that would be high-revenue – i.e., those with hospital affiliation, among others – would marginalize these participants. We are concerned that this could lead to their departure and would squander the significant investments they have made in care coordination and data-sharing before they were able to pay off for the Medicare program and its beneficiaries.

While CMS suggests that providers are "waiting in the wings" to sign up for accountable care, in 2018, only 11.8 percent of the nation's hospitals were participating in the MSSP.⁸ If hospital participation falls – as CMS in fact expects it will – it would be to the detriment of both patients and the Medicare program because they would lose the important contributions of ACOs that include hospital participants. Even under CMS's methodology, which systematically underestimates shared savings, net program savings were approximately \$313 million in performance year 2017. Using the more precise methodology of measuring savings against spending that would have occurred had ACOs not existed reveals the MSSP achieved net savings in performance years 2013-2015 of approximately \$542 million. In addition, by using new and stronger partnerships across the care continuum to excel on quality measures, hospitals participating in ACOs also may have impacted the relative quality scores of non-participating hospitals. Should hospitals decline to participate in the MSSP moving forward, these spillover effects also would disappear.

We also are concerned that CMS's proposal essentially communicates to hospital-led ACOs that, although they invested more in their programs, they will, nonetheless, face higher hurdles in order to recoup any of it. Such a message is a counterintuitive one to send, especially to the hospitals that were early adopters of risk and most prepared to demonstrate that the ACO program works. For example, one of our members spent \$1.4 million to set up its ACO in 2015. It spends an additional \$500,000 per year on annual maintenance of the ACO's two electronic medical record systems and \$1.2 million per year to provide health coaching to beneficiaries on site and via telehealth. This brings its total investment to date to \$6.5 million. And, even this ACO relied on donated staff time from an even larger health system that helps run the

⁷ William Caughey, et al., ACO Maturity Score: A Metric to Assess an Organization's Progress in Accountable Care, Leavitt Partners (Aug. 2018).

⁸ Data provided by Leavitt Partners Insight, LLC; not for use or re-distribution without approval from the company. "Hospitals" in this statistic include Alcohol/Drug Hospitals, Children's Hospitals, Critical Access Hospitals, Long-Term Hospitals, Psychiatric Hospitals, Rehabilitation Hospitals, and Short-term (General and Specialty) Hospitals.

Ms. Seema Verma October 16, 2018 Page 12 of 25

ACO. We would expect that larger ACOs with multiple hospitals, hundreds of providers, and thousands of beds, would spend in the tens of millions to set up their ACOs and separately, in annual costs to maintain their ACOs.⁹

Without hospital participation, the MSSP could be left with small pockets of healthy beneficiaries and an overall shift of the Medicare program back to siloed operation. But where would this leave the troves of sicker and more complex patients that require hospital care? Those beneficiaries would receive primary care in physicians' offices, but be sent outside the ACO for hospital-based care, likely facing interruptions in care transitions and delays in receiving care as they attempt to navigate the continuum of care on their own. Non-ACO beneficiaries that receive care in the hospital also would lose the benefit of the spillover effects that result from a hospital redesigning care pathways as part of its ACO participation. Such a result hardly accelerates the system-wide transition to value-based care that CMS is so eager to effectuate.

Instead of making it harder for ACOs with hospital participants to achieve shared savings, and adding complexity to the MSSP with arbitrary distinctions, we urge CMS to "float all boats" by improving program methodology so that it accurately rewards performance for improving quality and reducing costs. We also urge the agency to offer resources and assistance to all ACO participants that are working to redesign care delivery to improve the health of patients. Indeed, the experience of ACOs in other models suggests upfront support increases the likelihood of ACOs' success. For example, ACOs in the ACO Investment Model (AIM), which was created to help rural providers in the MSSP, received \$58 million in loans from CMS, much of it upfront, and achieved \$82 million in net program savings in their first year.

In addition, we urge CMS to conduct in-depth studies of what other practices contribute to success in the MSSP, such as infrastructure arrangements and workforce competencies. This information will be essential as CMS increasingly expects providers to address community and population health. As ACOs continue to lead the field in testing out this type of care, we recommend CMS encourage their learning efforts and provide them with adequate time and resources to make the changes they find are necessary.

The AHA stands ready to work with CMS to identify which program methodologies would enable ACOs to prepare for risk, achieve shared savings and improve patient outcomes. ACOs are building momentum and determining the best ways to manage their patient populations' total cost of care. Stability and clarity in the ACO program could go a long way in empowering them to do so.

⁹ The Work Ahead: Activities and Costs to Develop an Accountable Care Organization (April 2011), *available at* <u>https://www.aha.org/system/files/content/11/aco-white-paper-cost-dev-aco.pdf</u>. This research from the AHA, in conjunction with McManis Consulting, found that a prototypical large ACO-type organization (with 1,200 beds, five hospitals, 250 primary care physicians and 500 specialists) would spend \$12 million in startup costs to establish its ACO and over \$14 million annually to maintain it.

DIFFERENTIATION OF PARTICIPATION OPTIONS FOR INEXPERIENCED AND EXPERIENCED ACOS

In addition to differentiating between high- and low-revenue ACOs, CMS proposes to differentiate between "inexperienced" and "experienced" ACOs in terms of prior participation with performance-based risk. It would make different participation options available to each group. Specifically, CMS would identify an ACO as experienced with performance-based risk Medicare ACO initiatives as those that meet either of the following criteria:

- 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 a two-sided model; or
- Forty 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 second MSSP agreement period under a two-sided model, in any of the five most recent performance years prior to the agreement start date.

As proposed, experienced ACOs would be required to enter the new MSSP at the highest levels of risk (Level E of the BASIC Track for low-revenue ACOs and the Enhanced Track for high-revenue ACOs). Thus, up to 60 percent of participants in a given ACO could be prohibited from entering the BASIC Track's glide path based on the experience of as few as 40 percent of their co-participants. CMS states that this proposal is intended to ensure that ACOs with "significant" experience with performance-based risk are "appropriately placed." But in its own example, CMS envisions an ACO where 20 percent of participants have experience in Track 3 and another 20 in the Next Generation ACO model. This situation hardly represents cohesive and consistent - not to mention significant - experience with a single set of ACO methodologies such that it should drive participation options for all 100 percent of the ACO's participants. Therefore, we recommend CMS define an "experienced" ACO as one in which at least the majority of ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second MSSP agreement period under a two-sided model, in any of the five most recent performance years prior to the agreement start date.

Additionally, as described above, the experience and performance of an ACO in one location has little bearing on how the ACO might perform in another location. Market factors contribute significantly to ACO performance to such a degree that ACOs performing identically could achieve savings in one market but not another. An ACO with participants that have experience in a huge range of different markets could hardly be considered as having one, cohesive experience with performance-based risk. **We therefore recommend that CMS revise its proposed second criterion for**

Ms. Seema Verma October 16, 2018 Page 14 of 25

identifying "experienced" ACOs to require that a majority of the ACO's participants participated in the *same* performance-based risk Medicare ACO initiative.

REDUCTION OF TIME IN UPSIDE-ONLY RISK ARRANGEMENTS

Under the rule, new, inexperienced ACOs would receive two-and-a-half years in upsideonly risk arrangements for agreement periods beginning July 1, 2019, and two years for agreement periods beginning at a later date. Inexperienced re-entering or renewing ACOs would receive a maximum of one-and-a-half years and one year, respectively. Experienced ACOs, as noted above, would be immediately required to take on risk.

The AHA greatly appreciates CMS's proposal to allow inexperienced re-entering and renewing ACOs, which include those that are currently participating in Track 1 of the MSSP, an additional year of upside-only risk. This would allow these ACOs to gain experience and familiarity with CMS's proposed changes to the MSSP, such as changes to benchmarking and risk adjustment, better preparing them to take on risk in a redesigned MSSP. The AHA also supports CMS's proposal to allow ACOs to voluntarily assume more risk and move out of the upside-only levels as they feel prepared to do so.

However, we have serious concerns about limiting of new, inexperienced ACOs to two years in upside-only arrangements. The timing of benchmark notification, data receipt and shared savings determinations under the program render such a short period of time effectively useless to determine if the ACO's care coordination and other redesigns are having the intended effect. In other words, these ACOs are functionally blind to their financial performance for the entire length of a performance year and into the following year. At a time when ACO participants need to determine how to invest any returns or how to alter their care delivery to achieve savings and improve quality, they have no visibility into whether they even have any returns to invest or whether changes they have already made have produced cost reductions or quality gains.

Specifically, before beginning participation in the MSSP, ACOs invest months' or years' worth of finances to make operational and other preparations. They do not receive a preliminary benchmark until after the performance year has begun. They also do not receive historical data on their assigned beneficiaries' health care utilization until after the start of the performance year. They do not receive a final shared savings determination until seven or eight months after the conclusion of a performance year. In other words, ACOs would not have any information on whether and to what degree their interventions have had a positive effect until more than three-quarters of their two-year upside-only time has expired. And even then, they would only have one year's worth of data to rely upon, as well as a few short months to make any changes to their organization and/or care delivery before they were required to take on two-sided risk.

Ms. Seema Verma October 16, 2018 Page 15 of 25

This proposal would force ACOs to take on risk without much-needed information, setting many up for failure.

Taking on risk this quickly could be especially difficult for rural providers with low patient volumes and could imperil their ability to participate in the Merit Based Incentive Payments System (MIPS), another vitally important CMS value program. Participation in any of the current MSSP tracks qualifies clinicians and groups to use the MIPS APM scoring standard in which clinician or group quality and improvement activity scores are tied to their ACO. Rural providers join ACOs to contribute to the overall health of their communities, but as non-ACO clinicians or groups, they would lack sufficient Medicare part B patients or charges to surpass the MIPS low-volume threshold. Without the ability to report MIPS measures via the MIPS-APM scoring standard, these ACOs would likely cease to report MIPS measures altogether.

In addition, contrary to CMS's belief that an upside-only track may be encouraging consolidation in the marketplace, we are concerned that the proposal to shorten the time ACOs can spend in upside-only arrangements would result in the consolidation or departure of ACOs, especially smaller ACOs, which do not feel prepared to take on risk after two performance years and one year of performance data. ACOs allow providers to collaborate without merging to achieve the scale necessary to engage in value-based care. Thus, providers can form and join ACOs to access many benefits they otherwise might have merged to obtain. Upside-only ACOs specifically allow providers that lack the size and sophistication to manage downside risk to engage in value-based care. Shortening the time that ACOs can engage in upside-only arrangements would discourage smaller providers that cannot bear downside risk from joining ACOs. This would likely lead to more provider consolidation, as some providers may choose to merge with or join an organization that can manage the downside risk in order to access value-based care contracts. And, moving ACOs to downside risk before they are ready may cause them to perform poorly, which can put small providers out of business or force them to merge or consolidate to survive.

We recommend that CMS allow new, inexperienced ACOs three years in upsideonly risk before requiring them to take on downside risk, but maintain the opportunity for ACOs that feel ready to elect to move into downside risk prior to completing three performance years. Indeed, our recommended three-year upsideonly term is supported by ACO performance data itself. For example, it is well documented that the longer ACOs remain in the program, the more likely they are to achieve shared savings.¹⁰ Evidence demonstrates that per beneficiary savings correlate to experience, *especially after ACOs' third year in the MSSP*.¹¹ In the experience of one

¹⁰ William Caughey, et al., ACO Maturity Score: A Metric to Assess an Organization's Progress in Accountable Care, Leavitt Partners (Aug. 2018).

¹¹ 2017 Shared Savings Program Accountable Care Organizations Public Use File, *available at* <u>https://data.cms.gov/Special-Programs-Initiatives-Medicare-Shared-Savin/2017-Shared-Savings-Program-SSP-Accountable-Care-O/gk7c-vejx/data</u>.

Ms. Seema Verma October 16, 2018 Page 16 of 25

of our members, whose \$6.5 million investment to set-up and run its ACOs for its first three performance years is described above, it took three years to achieve any savings. This ACO was only able to achieve savings by making regular adjustments to its care delivery as it learned more and more about its beneficiaries over all three years. And, when the ACO did earn savings, it earned \$2.1 million, not even a third of their initial investment. If this and other ACOs had had to take on risk before that crucial third year, they may have declined to participate in the MSSP at the outset.

We also believe that allowing ACOs to remain in upside-only risk arrangements for a longer period of time would result in more – not less – savings to the Medicare program. Contrary to CMS's assertion in the rule that "two-sided models perform better over time than one-sided model ACOs," the 2017 results of the MSSP demonstrate that upside-only ACOs achieved 93 percent of the MSSP savings to Medicare. It is clear that it takes time to achieve shared savings, and spending a meaningful amount of that time in upside-only risk may actually increase, not decrease, the likelihood of achieving savings.

LEVELS OF RISK AND REWARD

Reduction of Shared Savings Rates for ACOs in Upside-only Risk Arrangements. As part of its glide path to risk, CMS proposes to gradually increase the shared savings that ACOs can achieve. The savings rate would be 25 percent in the upside-only levels, Level A and Level B. It would gradually increase to 50 percent in Level E. However, this is a marked decline from the current up-side only savings rate of 50 percent in Track 1 if ACOs meet certain cost and quality targets. In addition, as Figure 1 below illustrates, once CMS makes all the calculations that go into determining a shared savings bonus payment, the 50 percent savings rate ends up yielding much less. In this example, the hypothetical "American ACO" has 60,000 Medicare beneficiaries and saved \$300 per beneficiary, or \$18 million in total. Of the \$18 million saved, CMS would keep \$10.8 million or 60 percent, and the ACO would receive \$7.2 million, or 40 percent. Ms. Seema Verma October 16, 2018 Page 17 of 25

Figure 1



In this example, with a 25 percent shared savings rate American ACO would receive \$3.6 million of the \$18 million it saved, or 20 percent, and CMS would keep \$14.4 million. Reducing the shared savings rate from 50 percent to 25 percent for upside-only ACOs would result in such low shared savings payments to ACOs that participation in the program would not be worthwhile for many of them. This is particularly true given the start-up and ongoing annual operational costs of participation, as described above, as well as other program features for which ACOs carry all of the risk. If ACOs receive far lower shared savings payments, they will have less capital to invest in caring for their beneficiaries, thereby reducing the potential for future savings to Medicare. Inexperienced re-entering and renewing ACOs that established their ACOs on the expectation that they would share in 50 percent of any savings they achieved and those that have already achieved some savings would face a significant cut to any savings they achieve in the future. We expect some of these ACOs would exit the program rather than put into care redesign the same amount of work for significantly less potential reward.

Ms. Seema Verma October 16, 2018 Page 18 of 25

To address these issues, we recommend CMS maintain a 50 percent shared savings rate for not only upside-only ACOs, but also for all levels under the BASIC track. We also recommend CMS continue to allow ACOs to share in first-dollar savings once the minimum savings rate (MSR) is exceeded. Additionally, we recommend CMS treat the achievement of quality scores as something that deserves reward rather than only something that can reduce shared savings. Specifically, we urge CMS to use an ACO's quality score to award additional shared savings up to a maximum sharing rate of 80 percent for upside-only ACOs and 90 percent for ACOs under two-sided risk. Currently, the shared savings rates available to MSSP ACOs function as a ceiling; an ACO's quality score can only reduce, not increase, that rate. However, given that one of the goals of the MSSP is to improve quality and patient outcomes, we urge CMS to modify the shared savings methodology to make the shared savings rates floors upon which quality scores can be used to award additional sharing points.

Degree of Risk in Proposed Level E. While we believe the shared savings available to ACOs on the glide path to risk should begin at a higher rate than as proposed by CMS, we recognize and appreciate CMS's proposal to create such a glide path that allows for a gradual introduction of two-sided risk. We believe, however, that the degree of risk that ACOs in the proposed Level E of the BASIC Track would be required to assume should not be based upon the lopsided calculation that CMS has proposed. Specifically, CMS proposes to make the benchmark-based loss sharing limit in Level E a percentage point higher than the QPP standards while matching the revenue-based loss sharing limit to the QPP. This proposal would leave almost all ACOs with only one choice: the benchmark-based standard. ACOs would have to be extremely low-revenue to make selecting the revenue-based standard worthwhile. Under this proposal, a large percentage of ACO participants in Level E would face a difficult benchmark, which could more intensely disadvantage smaller ACOs by creating larger swings in their results. Thus, we recommend that CMS fully align the loss sharing limits in BASIC Level E with the standards for Advanced APMs under the QPP.

Increase of Risk between Proposed BASIC Level E and ENHANCED Track. Assuming most ACOs in Level E of the BASIC Track would feel compelled to select the benchmark-based loss sharing limit, CMS's proposals would transition ACOs from a 4 percent cap on shared losses in Level E to a 15 percent cap in the EHNHANCED Track. However, CMS states in the rule that creating parity between the BASIC and ENHANCED Tracks would streamline the ACO program and make it easier for CMS to operate the program. To that end, we recommend CMS create a more gradual glide path to shared losses in the ENHANCED Track so that ACOs in both tracks have access to the same opportunities and degree of support from CMS in their transition to two-sided risk. Specifically, we recommend CMS incrementally increase the shared loss risk that ENHANCED Track ACOs would face by 2 percent in each of Ms. Seema Verma October 16, 2018 Page 19 of 25

the first four years of an ENHANCED Track agreement period and 3 percent in the final year to arrive at a total of 15 percent.

EXTENSION OF AGREEMENT PERIOD LENGTH FROM THREE YEARS TO FIVE YEARS

We strongly support CMS's proposal to extend the current three-year agreement periods to five years. This proposal will add predictability and stability to the MSSP and allow ACOs a longer time horizon to redesign care in accordance with their experience in the program. Given the longer agreement periods, we urge CMS to create equally long-term program rules and avoid substantially altering them during the course of ACOs' agreement periods. As ACOs take on more risk and create more innovative care arrangements, they need reassurance that the rules upon which they base their initial investments will be the same rules under which they will participate in the program. To the degree that ACOs base participation on modeling of the MSSP and other ACO programs, midstream changes would potentially leaving them with no option but to exit the programs in which they participate. This became apparent in the Next Generation program, when CMS's unilateral, mid-stream change to the riskadjustment cap resulted in the departure of several Next Generation ACOs, including hospitals and health systems that were prepared to take on the high degree of risk Next Generation requires. As participation in the MSSP would become more difficult under the proposals in this rule, it is essential that CMS not lose participants due to methodological and other rule changes.

EXPANSION OF ACCESS TO WAIVERS

We support CMS's proposals to expand access to and usefulness of waivers of certain Medicare program requirements. We encourage CMS to consider adopting additional waivers to allow, for example, funding for transportation and other social services.

Skilled Nursing Facility (SNF) 3-Day Rule. CMS proposes to extend the availability of the SNF 3-Day rule waiver to ACOs that elect preliminary prospective beneficiary assignment (assuming they are in a two-sided risk model). CMS also proposes that beneficiaries that appear on an ACO's cumulative assignment list (that CMS would create and update quarterly) at any point during the performance year will be eligible for the SNF 3-Day Rule waiver, even though the beneficiary might not appear on any of that ACO's subsequent quarterly list updates or might not be finally assigned to the ACO during retrospective reconciliation for that year. The AHA believes this proposal would address one of the main barriers to using the SNF 3-Day Rule waiver, which is the inability to know who is eligible for it. ACOs have found it challenging to identify to whom the waiver applies and this proposal will make it easier for them to do so, expanding access to treatment for patients.

Ms. Seema Verma October 16, 2018 Page 20 of 25

<u>Billing and Payment for Telehealth Services</u>. CMS proposes regulatory changes for the coverage of approved telehealth services furnished during performance years 2020 and beyond by risk-bearing ACOs with prospectively assigned beneficiaries. **We support these proposals that would expand access to telehealth and protection for beneficiaries receiving care via telehealth, but we continue to urge the agency to more generally and broadly expand Medicare coverage and payment for telehealth services. The AHA will also continue to urge Congress to remove the statutory barriers to increased Medicare coverage of telehealth services, including the geographic and practice setting limitations on where Medicare beneficiaries may receive telehealth services and the limitations on the types of technology that providers may use to deliver services via telehealth.**

PROPOSED CHANGES TO BENCHMARKING METHODOLOGIES

<u>Risk Adjustment of Historical Benchmark</u>. To better account for changes in beneficiary health status between the historical benchmark period and the performance year, CMS proposes to use a single methodology – CMS-HCC prospective risk adjustment – to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, including continuously assigned beneficiaries. **The AHA strongly supports this proposal and believes it would remove unnecessary complexity from the MSSP. Additionally, the proposal would reverse the current approach that does not adequately capture changes in continuously assigned beneficiaries' health status and would improve the accuracy of ACOs' benchmarks by reflecting the increased or decreased costs of treating these beneficiaries.**

In conjunction with this proposal, CMS proposes to place a symmetrical cap of +/- 3 percent on ACOs' risk scores over the course of each agreement period. The AHA appreciates CMS's proposal to allow risk scores to rise and fall in conjunction with beneficiary health status. However, a 3 percent cap is too low and the five-year period over which it would be spread is too long. While we recognize the benefit of having a cap on the decrease in risk scores, we do not believe 3 percent will capture the significant beneficiary turnover and changes in health status that ACO beneficiaries experience. This is especially true as the burden of illness in the Medicare population increases over time. We urge CMS to provide the modeling on which it based this proposal so that ACOs can analyze the same data that CMS used and provide recommendations for a higher cap that would still meet the needs of both CMS and ACOs.

We also recommend that whatever risk score cap CMS chooses, the agency applies it on an annual basis, allowing risk scores to change, for example by +/- 3 percent year-over-year throughout the agreement period. This is especially important for ACOs in high churn areas; the patients with which these ACOs begin a year look very different from the patients it serves the following year. Freezing risk scores at +/- 3 percent over five years could create a situation that is similar to what Ms. Seema Verma October 16, 2018 Page 21 of 25

Track 3 ACOs experience today: a constant struggle against an outdated risk score under which they are at risk for a population whose risk score was calculated several years prior. Such a situation could create a level of risk some ACOs cannot bear, deterring them from entering a redesigned MSSP program. CMS has already recognized the necessity of shorter-term caps on risk and price adjustments; the agency capped trend factor variation in the BPCI program on a quarter-over-quarter basis and risk scores in the Next Generation ACO program at 3 percent over two years.

Limiting risk scores to a three percent increase or decrease over five-year agreement periods could also incentivize ACOs to avoid higher risk patients; this is why insurers that participate in Medicare Advantage (MA) receive annual premium adjustments based on beneficiaries' HCC risk scores. CMS should look to MA and the experience of ACOs in other programs to determine the flexibility necessary in risk scores to ensure high acuity patients receive the care they need.

Benchmarking Methodology for Six-month Performance Years in 2019. For ACOs that participate in the Jan. 1, 2019 to June 30, 2019 performance year, the July 1, 2019 to Dec. 31, 2019 performance year, or both, CMS proposes to use the full 12 months of 2019 to calculate the benchmark and assigned beneficiary expenditures for these ACOs. CMS is concerned that any other approach, including the interim reconciliation approach the agency used with ACOs in the MSSP's initial cohorts, would introduce further complexity into program calculations and interrupt program operations. However, this proposal traps ACOs with a full year's worth of risk for beneficiaries that they may have only cared for six months of the year. CMS has not provided sufficient justification for why it cannot use the relevant six month periods to calculate ACOs' benchmark and assigned beneficiary expenditures. For these reasons, we oppose this policy and urge CMS not to finalize it.

BENEFICIARY NOTIFICATION REQUIREMENTS

Under current regulations, ACOs must post informational signs in participant facilities and primary care service delivery settings, and they must provide upon request a written Beneficiary Information Notice, for both of which CMS provides templates. CMS adopted these requirements in the June 2015 ACO final rule in response to concerns from ACOs that the notification rules in place at the time were too burdensome. However, in this rule, CMS again makes proposals that would increase the beneficiary notification burden that ACO participants would face. Specifically, CMS proposes to require ACO participants to provide additional information to beneficiaries at the first primary care visit of each performance year, including information about voluntary alignment, the provider's participation in the MSSP, and the beneficiary's opportunity to decline claims data sharing. This notice would be in addition to the existing requirements detailed above. Ms. Seema Verma October 16, 2018 Page 22 of 25

This proposal would add to ACOs' regulatory burden as it relates to beneficiary notices and we are concerned it would cause them to divert important resources away from patient care and to ACO operations. We recognize and appreciate the agency's proposal to provide a template for this notice, but we believe its delivery would add unnecessary complexity to ACOs' operations as they would need to expend resources disseminating this notice to providers and ensuring they disseminate it to patients. The requirement could also complicate individual providers' ability to spend as much time as they can focused on patient care. Rather than creating a new notice requirement, we urge CMS to considering how to strengthen the existing notifications that ACOs deliver to beneficiaries.

ELECTION OF MINIMUM SAVINGS RATE (MSR)/MINIMUM LOSS RATE (MLR)

In its efforts to address "gaming" practices by ACOs that have taken advantage of the MSSP, CMS proposes to require ACOs to select their MSR/MLR prior to assuming performance-based risk and to apply this selection for the duration of the agreement period. CMS bases this proposal on its concern that allowing ACOs to change their selection during the course of an agreement period would incentivize ACOs to learn from their experience in the program and select an MSR/MLR that maximizes shared savings or avoid shared losses.

While we appreciate CMS's proposal to allow ACOs in two-sided risk arrangements the flexibility to choose their MSR/MLR, we urge CMS to allow ACOs to alter their MSR/MLR throughout the proposed five-year agreement period. We do not agree that allowing for such changes would leave the MSSP vulnerable to gaming; in fact, we believe it would be just the opposite. Allowing ACOs to alter their MSR/MLR in accordance with their experience in accepting certain levels of risk would allow ACOs to continue to advance in operating under performance-based risk, grow the competencies to be successful in the MSSP, and build an understanding of the benchmark methodology. This flexibility could increase program participation uptake and retention.

Moreover, even experienced ACOs would need time to understand the implication of the benchmarking proposals included in this rule. That knowledge would be essential to informing their MSR/MLR selection and it may take some years in the program to develop it. Additionally, the attributed populations of ACOs can change significantly over time and as an ACO's attributed population changes, so does its risk profile. CMS recognized this need to allow providers to alter their risk thresholds throughout agreement periods when it allowed BPCI participants to change their risk track (or "winsorization") levels on a quarterly basis.

Ms. Seema Verma October 16, 2018 Page 23 of 25

BENEFICIARY ASSIGNMENT

<u>Election of Assignment Methodology</u>. To execute certain provisions of the Bipartisan Budget Act of 2018, CMS proposes to allow all ACOs to choose prospective beneficiary assignment or preliminary prospective assignment with retrospective reconciliation. CMS also proposes to allow ACOs to switch their beneficiary assignment selection on an annual basis. **The AHA strongly supports these proposals and believes they would bring necessary flexibility to the MSSP, especially for ACOs that operate in areas with high patient churn rates.** The ability to choose their assignment methodology would also support ACOs' ability to manage care as they assume greater levels of risk.

Creation of an Opt-In Assignment Methodology. In addition to providing ACOs with a choice of assignment, CMS considers providing beneficiaries the option to opt-in to assignment to a specific ACO. In evaluating possible approaches to operationalizing an opt-in methodology, CMS considers a "hybrid" approach through which beneficiaries that opt-in or voluntarily align with an ACO would be prospectively assigned to that ACO. Other beneficiaries would be assigned to that ACO only if they receive the plurality of their primary care services from the ACO and receive at least seven primary care services from one or more ACO participants in the ACO during the applicable assignment window. CMS explains in the rule that the seven service threshold is based upon "the threshold established by an integrated healthcare system in a prior demonstration." We urge CMS to release additional information on data on the proposed seven-service threshold, as we are concerned that this threshold is too high and could have the unintended consequence of significantly lowering several ACOs' assigned beneficiary counts. Before offering pure opt-in assignment or a hybrid approach, we further urge CMS to continue to explore the potential burdens an ACO could encounter if beneficiaries are permitted to opt-in to ACO assignment and how the option would be explained to beneficiaries.

<u>Definition of Primary Care Used in Beneficiary Assignment</u>. CMS regularly revises the definition of primary care services used to assign beneficiaries to ACOs. In this rule, CMS proposes to include in the definition of primary care services Current Procedural Terminology codes for advance care planning services (99497 and 99498). **Planning for advanced illness care and end-of-life care is an important element of primary care and we support the addition of these codes to the definition of primary care.**

CMS also proposes to add the definition of primary care three new Healthcare Common Procedure Coding System G-codes, or "add-on codes" that the agency proposed to create in the Calendar Year 2019 Physician Fee Schedule Proposed Rule. As detailed in our <u>comments</u> submitted to the agency on Sept. 7, 2018, we oppose CMS's proposed collapse of the payment rates for levels 2 through 5 E/M visits, and do not believe the proposed add-on codes would offset the proposed payment decrease. **We urge CMS** Ms. Seema Verma October 16, 2018 Page 24 of 25

not to finalize the proposed payment collapse or add-on codes and, thus, not to add them to the definition of primary care services.

MONITORING FOR FINANCIAL PERFORMANCE

To address its belief that current regulations are insufficient to monitor ACOs' financial performance, CMS proposes to monitor ACOs' expenditures. CMS proposes that, if expenditures are "negative outside corridor" for a single performance year, the agency could take pre-termination actions. If expenditures are "negative outside corridor" for an additional performance year of the same agreement period, CMS proposes that it may terminate the ACO's participation in the MSSP.

This proposal is not a necessary or appropriate mechanism for protecting the **Medicare Trust Fund.** If ACOs in two-sided models believe they can achieve savings at some point, it would be more protective for the Trust Fund to allow them to remain in the program and pay shared losses to CMS until then. Moreover, CMS's automatic advancement proposal would protect against ACOs who generate losses remaining in the MSSP just to take advantage of waivers and other provisions. As those ACOs are required to take on increasingly more risk, they themselves would incur too many losses to remain in the program indefinitely. As discussed above, it can take several years for ACOs to understand their patient population and providers in order to generate savings and at the end of two years, ACOs barely have a single year of performance data. We do not believe ACOs would want to invest the millions of dollars required to set up and run an ACO if they could be kicked out of the program just 24 months later. There already would be sufficient risk to participants under the proposed redesigned program; the risk of being terminated this guickly could be too much for many ACOs to bear. We recommend CMS consider other approaches for monitoring financial performance, such as the use of corrective action plans, which it already uses as a pre-termination action when an ACO's assigned population falls below 5,000.

PROGRAM DATA AND QUALITY MEASURES

The AHA agrees that ACOs have a unique opportunity to use aggregate Part D data to monitor appropriate use of opioids for their assigned beneficiaries and inform their own and wider opioid misuse prevention efforts. As CMS describes in the proposed rule, polypharmacy (or the simultaneous use of multiple drugs by a single patient) increases the risk of adverse events including over-utilization of opioid medications. Related issues, like patients having prescriptions from multiple practitioners, exacerbate both over-utilization and diversion of opioid medications. With access to aggregate Part D data, ACOs could better monitor their beneficiaries to prevent these risks. In addition, ACOs often serve as proving grounds for value-based care programs that can be scaled larger with evidence of effectiveness; if ACOs are able to stymie opioid misuse through data monitoring, it is possible that non-ACO providers may be able to do the same.

Ms. Seema Verma October 16, 2018 Page 25 of 25

The three opioid use-related measures CMS suggests for inclusion in the ACO quality measure set seem to be appropriately focused on the right patient population. By specifying that patients of interest would be those without cancer or enrolled in hospice, these measures are less likely to harm patients for whom opioid prescriptions are suitable. In addition, these measures address the major risks associated with opioid diversion—high dosages and multiple prescriptions—rather than an overbroad measure of all opioid prescriptions. The AHA appreciates that CMS has recommended measures endorsed by the National Quality Forum (NQF), as NQF-endorsement is an indicator of scientific and statistical validity and reliability.

However, a number of issues with these particular measures should be addressed before they are used as part of the MSSP measure set. First, the measures are NQF-endorsed at the health plan level, and not the ACO level. We encourage CMS to conduct testing to ensure the measures provide accurate, reliable data at the ACO level. The importance of accurate reporting of quality measures is particularly high considering the other proposed changes to the MSSP that emphasize taking on more risk.

Furthermore, the purpose of the MSSP is to "promote accountability for a patient population, foster coordination of items and services under Medicare Parts A and B, encourage investment in infrastructure and redesigned care processes for high-quality and efficient health care service delivery, and promote higher value care." Strictly speaking, the MSSP program's purpose is not to test out new measures or address specific epidemics, even though ACOs provide a logical opportunity to do both. Obviously, addressing the opioid crisis is a top priority and accountability and coordination for a patient population necessarily involves addressing medication and drug use. It is unclear, though, how these specific quality measures would interact with the other measures currently used in the program. With these concerns in mind, the AHA recommends that these measures be first reported on a voluntary or pay-for-reporting basis rather than associated with shared savings outcomes for the first few years.