October 16, 2018

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

RE: CMS-1701-P, Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success; Proposed Rule (Vol. 83, No. 160), August 17, 2018

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. We greatly appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success Proposed Rule. In general, the FAH appreciates the efforts proposed by CMS to improve the Medicare Shared Savings Program (MSSP). We are very concerned, however, about the potential impact of certain proposals that if implemented would divert CMS from its goal of achieving a “pathway of success” for many ACOs.

After providing a brief introduction and analysis of the 2017 MSSP financial results, this comment letter addresses the following topic areas:

- Eliminating the low and high revenue distinction for determining participation options
- Revising definitions of experience and inexperience with Medicare ACO initiatives
• Providing adequate and timely data
• Using regional factors when establishing and resetting ACO’s benchmarks
• Monitoring for financial performance
• Supporting consistent data-sharing transparency for beneficiaries
• Improving the processes for voluntary alignment
• Incorporating stability and/or flexibility where appropriate, and
• Addressing interactions between the MSSP and other CMS models.

Introduction and Analysis of 2017 MSSP Financial Results

Over the last several years, Medicare accountable care organizations (ACOs) in the MSSP have grown as a model for health care delivery and reform—approximately 561 individual Medicare ACOs as of early 2018 serving over 10.5 million Medicare Fee-for-Service (FFS) beneficiaries. Under the MSSP, providers of services and suppliers that participate in an ACO continue to receive traditional FFS payments under Parts A and B, but the ACO can receive a shared savings payment if it meets specified quality and savings requirements. CMS notes that of the 561 ACOs that participate in MSSP, the vast majority (82 percent) continue to operate under a one-sided, shared savings-only model (Track 1). There is limited participation in its traditional two-sided risk models (Track 2 and Track 3). The Innovation Center designed an additional option (Track 1+ Model) that is a lower-risk two-sided model.

CMS proposals in this rule would, among other things, require a greatly accelerated transition to acceptance of downside financial risk by all ACOs. CMS proposes to retire Track 1 and Track 2, and retain Track 3; Track 3 would be renamed as the ENHANCED track. CMS also proposes to create a new BASIC track, in which participants could begin participation in a one-sided risk model and phase-in risk over the course of a single agreement (referred to as a glide path). CMS also proposes refining its benchmarking methodology (spending is compared to this benchmark to determine ACO savings or losses). In particular, CMS proposes to accelerate the use of regional FFS expenditures in establishing benchmarks, but modify the maximum weight in calculating the regional adjustment, lengthen agreement periods to at least 5 years (instead of the current 3 years), and modify how trend factors are calculated. CMS would also greatly reduce the shared savings rates for some tracks compared to their current configurations.

CMS also proposes limitations on what participation options would be available to each ACO based on two seemingly arbitrary distinctions: (1) whether the ACO is a “low revenue” ACO or a “high revenue” ACO; and (2) the level of risk with which the ACO or its ACO participants has prior experience through recent participation in Medicare ACO initiatives. These proposals appear to be grounded in the 2016 financial results of the MSSP program. As noted in the proposed rule (and reproduced below), the 410 Track 1 ACOs on average overspent relative to their financial benchmarks, resulting in a net loss of $49 million, while Track 2 and Track 3 participants produced net savings for Medicare. CMS also showed results that Track 1 ACO composition (being classified as low revenue) produced net savings, whereas high revenue ACOs produced net losses.
The 2017 financial results for the MSSP program, however, paint a much different picture and call into question the necessity of many of CMS’s proposals. Our analysis of the 2017 financial results (shown above) in fact demonstrates that the 433 Track 1 ACOs on average spent less relative to their financial benchmarks, resulting in a net savings to Medicare of almost $310 million. These more recent results are driven in large part by the financial turnaround of the 2014 Track 1 cohort, which reversed its financial results from a net loss of $77 million in 2016 to a net savings of $167 million in 2017. This very significant turnaround is likely a result of ACOs voluntarily dropping out of the program while ACOs continuing in the program benefited from additional time for their clinical improvement and operational activities to generate program savings. These results clearly show that ACOs in one-sided risk models, given sufficient time, can generate Medicare savings. It is also not surprising that low revenue ACOs (generally physician group led) ACOs would generate savings faster than high revenue ACOs (generally hospital-integrated ACOs), as high revenue ACOs are more complex organizations requiring additional time to implement the clinical improvement activities and operational efficiencies necessary to generate savings under the MSSP. Results from 2017 argue that high revenue ACOs need more rather than less time in one-sided risk models to be successful moving forward. Limiting participation options using the seemingly arbitrary high/low revenue distinction likely would drive out the ACOs that CMS most likely wants to attract and retain for their increased potential to generate significant savings to the program over time.

Our detailed comments below highlight a number of aspects of the proposed rule that could undermine the ability of ACO participants to achieve long-term success in the program,
and which CMS needs to address prior to implementation. Without such changes, we are afraid that these proposals would lead not to a “pathway for success” but instead to a “pathway of failure” for many ACOs.

**Eliminating the low and high revenue distinction for determining participation options**

CMS proposes to define participation options by making a distinction between low revenue ACOs and high revenue ACOs. CMS notes in its proposed rule that high revenue ACOs, (i.e., a proxy for ACOs that typically include a hospital billing through an ACO participant TIN), generally are more capable of accepting higher risk compared to low revenue ACOs (i.e., a proxy for physician group ACOs). As a result of this proposed policy, the participation options are severely limited for high revenue ACOs. For example, 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. In addition, high revenue ACOs with “experience” can only participate in the ENHANCED track regardless of whether they are new, renewing, or re-entering the program.

The FAH strongly opposes this proposal and urges CMS to eliminate the low/high revenue distinction for purposes of determining participation options. As the 2017 MSSP financial results demonstrate, ACOs given sufficient time can generate program savings even under a one-sided risk model. This low/high revenue distinction serves no purpose, other than punitive, given the steep structure of the glide path CMS proposes that would sharply limit time in the one-sided risk model options. This arbitrary distinction also discourages participation by the type of ACOs CMS most wants to attract; those, we believe, that can best coordinate acute and ambulatory care and are more likely to generate substantial savings to the Medicare program over the long-term. This proposal would also endanger the substantial indirect savings to Medicare that accrue due to spillover effect of delivery system changes made by successful ACOs. CMS’s own estimates show that total combined Medicare ACO efforts potentially reduced total FFS Medicare Parts A and B spending in 2016 by about 1.2 percent or $4.2 billion.

In addition, this proposed Medicare revenue-based bifurcation of ACO types creates an unnecessary, unequal playing field in this very competitive marketplace and ignores other sources of capital that may be available to physician led groups. By limiting the bifurcation to Medicare revenues, CMS is making critical program distinctions without a full view of the varied financial resources available to ACOs, outside of the stream of Medicare revenues. Research shows that insurers and venture funds are investing millions of dollars in physician-led ACOs and yet CMS’s rule does not attempt to recognize these investments and the clear advantage they provide. Given CMS’s limited view into all sources of funding available to ACOs, it should not attempt to make distinctions based on an incomplete view of ACO capitalization.

**Revising definitions of experience and inexperience with Medicare ACO initiatives**

CMS also proposes to limit participation options by categorizing ACOs as “experienced” or “inexperienced” with performance-based risk Medicare ACO initiatives then forcing so-called experienced ACOs to more quickly assume risk. A performance-based risk initiative is defined
by CMS as an initiative that requires an ACO to participate under a two-sided model during its agreement period. Specifically, CMS defines as experienced, an 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 5 most recent performance years prior to the agreement start date.

The FAH is concerned that CMS is defining experience too broadly, and that experience defined by these criteria assumes transferability of experience across population and geography. The validity of this assumption is not evident to us nor detailed by CMS in the rule. An ACO could meet CMS’s definition of an “experienced ACO” based on previous experience managing, for example, 4000 lives, yet that ACO may subsequently manage, for example, 30,000 lives in a different geographic region, and therefore would have little comparative experience. Therefore, we instead recommend that the threshold for experience be raised and take into account whether the ACO has previously managed a majority of lives covered by the ACO. We also recommend that the look-back period for determining the threshold should be shortened from 5 years. These changes would help ensure that ACOs are appropriately classified as experienced across populations and geographic locations.

**Provide adequate and timely data**

Under the program’s current regulations in 42 C.F.R. §425.702, CMS shares aggregate data with ACOs during the agreement period. This includes providing data at the beginning of each performance year and quarterly during the agreement period. For beneficiary-identifiable claims data, CMS regulations at 42 C.F.R. §425.704 specify that if an ACO wishes to receive beneficiary identifiable claims data, it must sign a Data Use Agreement (DUA) and submit a formal request for data. After doing so, the ACO may access requested data as often as once per month.

In practice, our members have experienced delays in receiving timely data, and in some instances, the first report for the performance year has occurred not on a quarterly basis, but six months into the performance year. This makes it difficult, and almost impossible, for these ACOs to use this information to make any changes to care management activities or other clinical improvement activities that would have any impact on performance year one results. The frequency of the aggregate data provided also is not sufficient. The FAH recommends that aggregate reports and data be provided routinely to ACOs at least once a month. There also have been quality and usability problems with the data provided including missing data elements. Many of our members, at considerable expense, have had to hire outside consultants to help convert the “raw” data provided by CMS into a more useable format that could help the ACO make more informed actionable decisions.

We encourage CMS to make a concerted effort to improve the quality and timelines of the data provided. As CMS seeks to move ACOs to downside risk more quickly, it is imperative that participants have data in hand to make informed decisions about how to manage patient care.
Use of regional factors when establishing and resetting ACO’s benchmarks

We generally support CMS’s proposals to incorporate the use of regional factors when establishing and resetting ACOs’ benchmarks. This includes incorporating regional factors into the benchmarking methodology for ACOs in the first agreement period, limiting the magnitude of the regional adjustment, and incorporating the national-regional blend trend factors. This helps alleviate concerns that more efficient ACOs operating in low-cost markets could potentially have a lower benchmark and reduced opportunity for shared savings than a less efficient ACO with a higher benchmark operating in a high cost area. With the incorporation of regional blends, ACO benchmarks would be more reflective of broader regional fee-for-service (FFS) spending in each ACO’s market. Gradually incorporating regional data into benchmarks would better account for the patient population characteristics of a specific ACO. We also support the approach CMS proposes to phase-in the regional adjustment based on the agreement period.

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 under 42. C.F.R. §425.216, including a request for corrective action by the ACO, or termination of the ACO’s participation agreement under 42 C.F.R. §425.218. CMS appears to be particularly concerned about one-sided risk ACOs that continue to participate in the program and generate net losses to Medicare.

The FAH disagrees with the necessity of these additional provisions that, if implemented, would provide CMS with too much discretion to terminate ACO participation in the program. The 2017 MSSP financials results suggest that ACOs that are performing poorly drop out of the program voluntarily so that poor financial performance is a self-correcting issue, even for participants in the one-sided risk tracks. This broad authority being claimed by CMS would further discourage ACOs (particularly those with complex organizational structures, including hospitals) from participating in the MSSP, as this would create even more financial uncertainty for participants and make it more difficult to establish collaborative relationships 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 sufficient savings that would help them recoup the substantial investments needed to be successful in this program.

Supporting consistent data-sharing transparency for beneficiaries

CMS has discussed sharing of beneficiary-identifiable claims data in nearly every MSSP ACO rulemaking cycle since the MSSP’s inception, as well as in addenda to several Physician Fee Schedule rules. CMS has consistently asserted that the Agency’s data sharing complies with all relevant privacy laws (including HIPAA) and that beneficiary consent is actually not needed. Simultaneously, however, CMS also has consistently stated a belief that beneficiaries should be afforded some control over the release of their data, resulting in regulations for beneficiary notification and beneficiary opt-out processes. Unfortunately, inconsistency has been the hallmark of
the applicable regulations, and changes have been made with each rulemaking cycle, mixing and matching process elements such as methods of notification (e.g., posters in primary care offices, written notices) and ways to opt out (e.g., mail reply to the ACO, calls to 1-800-MEDICARE). In the proposed rule, CMS has come nearly full circle, reinstating a previously deleted requirement for providing written notice during each ACO beneficiary’s first primary care visit of each performance year, in addition to the currently-required notices posted in each ACO’s primary care facilities. CMS adds to the proposed increased burden by expanding the CMS-template content of the notice to include unrelated information about another beneficiary option — voluntary alignment — and by requiring separate full data-sharing notification for the 6-month cycle beginning July 1, 2019 to beneficiaries that would have already been informed about data-sharing and opting out earlier in the same calendar year.

The FAH opposes the beneficiary data-sharing notification and opt-out processes as proposed. Our members vividly recall the burden imposed by earlier regulatory iterations that mandated written notices provided at the time of primary care visits. Members also recall the associated beneficiary confusion (e.g., some beneficiaries believed that the notices were really intended to allow ACOs to steal their identities) and the negative impact on clinical workflow efficiency. Additionally, substantial numbers of confused beneficiaries opting out of data sharing has the potential to adversely impact ACO operations by degrading the data available to ACOs on which they base their care coordination initiatives, resulting in a suboptimal clinical experience for the patient. The FAH strongly encourages CMS to separate data-sharing notification and opt out from communication with beneficiaries about voluntary alignment, as mixing two disparate and complicated subjects is destined to take beneficiary confusion to even higher levels. The FAH supports maintaining data sharing notification through posters in primary care facilities and providing written notices upon beneficiary request, along with maintaining 1-800-MEDICARE as the vehicle through which beneficiaries convey data-sharing opt-out decisions to CMS. Finally, the FAH urges CMS to promptly develop and implement electronic options for interacting with beneficiaries about data sharing.

Improving processes for voluntary alignment by beneficiaries to ACO professionals

Based upon Section 50331 of the Bipartisan Budget Act (BBA) of 2018, CMS proposes to make two modifications for performance year beginning with 2019 to existing policies on voluntary alignment by a beneficiary to an ACO professional. Voluntary alignment is triggered when a beneficiary accesses MyMedicare.gov and designates an ACO professional as his or her primary clinician (“main doctor”), causing the beneficiary to be treated as prospectively aligned to that ACO, and superseding all other assignment methodologies. CMS proposes to allow voluntary alignment to any ACO professional rather than being restricted to primary care practitioners, and alignment would no longer be contingent upon receipt by the beneficiary of at least one primary care service from the ACO in which the designated professional participates.

Our members remain very concerned about the substantial burden for ACOs associated with the voluntary alignment process, such as responsibility for beneficiary notification about the process to designate a primary clinician and to revoke that designation. The burden appears to far outweigh the reward of voluntary alignment for the ACO, since CMS notes that available data show an increase of only 0.2 to 2.7 percent in prospectively assigned beneficiaries as a direct result of voluntary alignment. The Federation strongly encourages CMS to focus future voluntary
alignment policy changes on burden reduction, such as CMS directly providing notification about voluntary alignment to beneficiaries rather than requiring ACOs to do so. The Federation also encourages CMS to allow primary clinician designation and revocation through 1-800-MEDICARE to provide a user-friendly option for beneficiaries with limited computer literacy or with conditions that impair their access to MyMedicare.gov (e.g., low vision, arthritis of hands and fingers).

Finally, the FAH strongly recommends that CMS focus equivalent attention on improving the utility of the far more commonly used preliminary prospective assignment methodology by exploring approaches to increase its predictive power for final beneficiary assignment at reconciliation, such as exploring a shorter assignment window (e.g., the first two quarters of the performance year).

Appropriately incorporating stability and/or flexibility

The FAH appreciates efforts by CMS to incorporate either stability or flexibility, as contextually appropriate, in some of the proposed regulations. We agree with CMS’s focus on enhanced stability for ACOs through a longer agreement period. The Federation believes that extending the ACO agreement period to five years from the current three years would enhance the fiscal stability of ACOs. We have previously commented on the substantial upfront infrastructure and personnel investments required to effectively coordinate care for ACO beneficiaries; these investments are more fiscally prudent and more easily sustained when they can be made over a longer time horizon. Alternatively, the FAH agrees with CMS’s emphasis on flexibility related to beneficiary assignment methodology. Our members view quite positively the proposed policy to annually elect either prospective or preliminary prospective (with retrospective reconciliation) assignment, regardless of the track in which an ACO is currently participating. The flexibility to change assignment methodology as often as annually could aid ACO participants in adjusting their operations for unexpected events such as an acute shortage of certain specialists. FAH members also appreciate the proposed flexibility for their ACOs to incorporate swing bed operators as potential SNF affiliates. This change could allow ACOs to improve their services to underserved and rural beneficiaries, enhancing the patient experience of care and improving ACO quality ratings.

However, the FAH believes that neither stability nor flexibility is served by the proposed shared savings rate of only 25 percent for Levels A and B ACOs. Levels A and B, like their predecessor Track 1, carry only upside risk, and are designed to introduce new or very inexperienced organizations to the Shared Savings Program. The 50 percent shared savings rate of Track 1 successfully supported many fledgling ACOs through their initial years, when assigned beneficiaries -- and their associated expenditures -- are least predictable. The FAH understands CMS’s intent to accelerate the transition to risk bearing by ACOs, but we regard the proposed 25 percent shared savings rate as destabilizing for Levels A and B ACOs and highly likely to discourage MSSP entry by new groups. The FAH opposes the proposed 25 percent shared savings rate for Levels A and B ACOs and strongly recommends implementing instead the 50 percent rate that currently apply to the analogous Level 1 ACOs.

Addressing interactions between MSSP ACOs and other CMS alternative payment initiatives

FAH members have welcomed the opportunity to participate in a number of CMS-sponsored initiatives designed to accelerate Medicare’s transition from volume-to-value. However, as those initiatives have multiplied, the Federation has grown increasingly concerned about the potential
interactions across the various alternative payment models, especially when population/total cost-of-care programs overlap with more narrowly-focused, bundled payment episodes. Entities providing bundled episodes are incentivized to keep single beneficiary episode costs low but not to limit episode volumes per beneficiary, while the ACO to which that beneficiary is assigned would be accountable for all of the episodes while reaping only part, if any, of the single episode savings. CMS has created precedence rules for some of its overlapping initiatives (e.g., BPCI-Original episodes took precedence over similar CJR episodes), but many overlap scenarios remain unaddressed. Few data are available about the extent of model overlap and its impact upon model success. Precedence guidance is scattered across the various rules addressing specific models rather than available in a single user-friendly source. No set of overarching principles to guide decisions about handling overlaps has been explicitly articulated. Inconsistent, unpredictable, and hard-to-find precedence guidance disproportionately affects ACOs compared to other models, since ACO assigned beneficiaries can be eligible for inclusion in multiple models simultaneously. Identifying and managing overlap scenarios is burdensome for ACOs and impedes efficient operations. The FAH recommends that CMS provide in the final MSSP ACO rule a comprehensive table of precedence rules for Shared Savings Program ACO interactions with all of CMS’s bundled payment episode programs; articulate a set of principles applicable to decision-making about existing and future overlap situations; and create a webpage on which all overlap situations and their relevant precedence materials are easily located and regularly updated.

Recognizing the value in assisting beneficiaries in identifying and choosing high quality care

In recent years, CMS has increasingly recognized the importance and value of preferred provider networks in care coordinated models. Yet, and within all coordinated care models, CMS is continuing to require that participants develop preferred provider networks within the constraints created by current law. The FAH urges that such patient choice constraints be waived to truly effect change under care coordination models, like the MSSP.

While we believe that patient choice must continue to be respected, we also believe that MSSP participants simply require additional flexibility above and beyond that currently permitted. Current patient choice requirements may not only serve to confuse beneficiaries, they also limit the ability of, in the case of MSSP, an ACO to assist a beneficiary in identifying the highest quality care or providers actively engaged in care coordination efforts.

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Thank you for the opportunity to comment. Should you have any questions, please feel free to contact me or my staff at (202) 624-1500.

Sincerely,