

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244 –1816

Re: Comments on CMS-1751-P: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

The Society for Vascular Surgery (SVS) is a professional medical society composed of 5,800 specialty trained vascular surgeons and other medical professionals who are dedicated to the prevention and cure of vascular disease. We appreciate the opportunity to provide the following comments on the proposed Quality Payment Program provisions contained in the CY 2022 Medicare Physician Fee Schedule proposed rule. (CMS-1751-P).

CY 2022 Updates to the Quality Payment Program

Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs)

MVP Development Criteria

Proposed Rule: CMS proposes the following additions to the MVP development criteria beginning with the 2022 performance year/2024 payment year: 1) MVPs must include at least one outcome measure that is relevant to the MVP topic, so MVP participants are measured on outcomes that are meaningful to the care they provide. 2) Each MVP that is applicable to more than one clinician specialty should include at least one outcome measure that is relevant to each clinician specialty included. 3) In instances when outcome measures are not available, each MVP must include at least one high priority measure that is relevant to the MVP topic, so MVP participants are measured on high-priority measures that are meaningful to the care they provide. 4) Allow the inclusion of outcomes-based administrative claims measures within the quality component of an MVP. 5) Each MVP must include at least one high priority measure that is relevant to each clinician specialty included. 6) To be included in an MVP, a qualified clinical data registry (QCDR) measure must be fully tested at the clinician level.

SVS Response

The SVS appreciated CMS' outreach regarding its creation of an MVP for Stroke Care, one of the initial seven MVPs that are proposed for the 2023 performance period. However, we are concerned regarding the seemingly random nature of the outreach and the lack of structure for submission of comments. Also, it is unclear from these seven (7) proposed MVPs if CMS is looking to develop MVPs that are condition-related, or procedure related and if the MVPs are for one specialty or for multiple specialties working in "patient-care teams." It was also unclear why vascular surgeons were being consulted when the measures that were proposed to be included in stroke care were not a complete set of at least 4 quality measures that would be reported by vascular surgeons. Using the Stroke MVP as an example, SVS would also urge CMS to include more measures under each MVP if they are condition specific to allow physicians regardless of practice patterns or care pathways followed to report on an MVP.

For these reasons, we urge CMS to establish a formal process for soliciting feedback on MVP concepts, including specifics with deadlines for submitting written comments, to ensure transparency and coordination among the relevant specialty societies in the early development of an MVP.

Additionally, SVS would recommend that CMS alert specialties regarding which clinical areas CMS is considering working on for condition-focused MVPs (e.g., stroke), versus areas that will be based on "specialty," specific MVPs or areas that will be "procedure," based MVPs. This would help physicians and medical societies who may want to be part of efforts regarding MVP development to know how and when to formulate their ideas regarding potential MVPs which might be of interest to their members.

We understand that CMS may not be aware of all the physicians who are engaged in potential MVP development; therefore, SVS would offer several suggestions to ensure all clinically appropriate stakeholders receive notices about MVPs that are under development:

- First, CMS should publish and update on a quarterly basis a list of MVPs under consideration on the QPP website along with the MVP developer to contact for coordination.
- Second, CMS should also publish a list of its MVP priority areas, also on a quarterly basis, to alert specialty societies that they should begin to collaborate and engage with CMS to build out those MVPs and provide specific timeframes whereby CMS would open a formal notice and comment period on a specific priority area. This could mirror the process that CMS uses when it opens a concept for potential consideration for a national coverage determination.
- Third, CMS should require that all MVPs submitted around a condition or other broad clinical topic be subjected to a 60-day comment period to allow MVP developers a guaranteed opportunity for public feedback and input outside of the annual proposed rule notice and comment period. MVP developers would then be given the opportunity to revise their MVP submission during a subsequent 60-day period and then provide any needed updates to CMS.

Finally, when CMS decides not to propose a candidate MVP for implementation that was developed by a medical specialty society, SVS urges the Agency to provide clear and timely feedback about why CMS is not moving forward with the MVP. MVP creation is a resource intensive process and developers would surely appreciate the feedback. This process for clear and timely feedback should be articulated and published so that medical societies that are spending the time and resources to develop MVPs are

aware of this process and also understand the criteria for MVP selection and what their options will be for re-submission if they choose to incorporate CMS' feedback.

MVP Implementation Timeline

Proposed Rule: CMS proposes an implementation timeline for the MVPs in the 2023 performance period. CMS proposes seven MVPs to be available with the beginning of the 2023 performance period, including rheumatology, stroke care and prevention, heart disease, chronic disease management, lower extremity joint repair, emergency medicine, and anesthesia. CMS requests comment on potentially phasing out traditional MIPS after the 2027 performance year, and mandating MVP participation for all MIPS clinicians beginning in 2028.

SVS Response

Given the current status of the COVID-19 Public Health Emergency (PHE) and the lack of information and articulated process for MVP development and review by CMS, SVS recommends that CMS extend its gradual implementation timeline for MVPs such that they would first become an option in 2024, with 2023 being used by CMS as a "pilot year," where a small number of interested medical practices could apply to test out an MVP for that reporting year. Seven MVPs is an exceptionally small number of MVPs given the number of physicians that participate in the Medicare program, and it does not come close to covering all specialties. In addition, none of the seven are vascular care specific or even include a primary vascular component.

Furthermore, the SVS does not support CMS' proposal to make MVP participation mandatory beginning in 2028. We strongly urge CMS to have MVP participation as a voluntary option that physicians, group practices, and subgroups can participate in, in addition to the traditional MIPS pathway. SVS believes there remain several outstanding questions and issues that CMS must get right in order to attract participation in MVPs, including the process for enrolling in an MVP as well as the process for those employed in larger multi-specialty practice groups to be able to enroll as a subgroup.

Also, SVS is concerned that CMS is only thinking about MVPs being created by using existing MIPS measures instead of testing and adopting new, innovative approaches to measuring quality, cost, and health information technology, such as aligning with clinical pathways and patient-reported outcome measures. CMS must get these policy decisions right before considering a time horizon in which all eligible clinicians could participate in an MVP.

Further, we have logistical concerns about CMS' ability to adopt and implement an applicable MVP for all eligible clinicians. We believe CMS' analysis estimating that approximately 10 percent of eligible clinicians will participate in an MVP in 2023 is overly ambitious. There remain many questions regarding whether employed physicians will be able to participate in an MVP that is specialty or condition specific and how CMS will be able to align NPIs and TINs to identify individual physicians and have them be assigned to specific MVPs. Also, it is unclear what the process will be if a physician misses the date to sign up for an MVP. Will they be contacted by CMS? Will CMS automatically assign them to an MVP? What happens to providers who join at or just after the enrollment period? Most physicians have been participating in MIPS as part of a much larger multi-specialty practice group and are neither familiar with nor versed in the paperwork and processes for participating in MIPS. Their

employer, the practice plan or hospital, has been performing these functions. Shifting this burden to the employed physician is counter to CMS' goal of reducing reporting burdens and paperwork.

As required by statute, every eligible clinician must participate in MIPS or be subject to a penalty of up to 9 percent of Medicare reimbursement. It would be extremely unfair and unreasonable to subject any physicians to an automatic penalty because there is no clinically relevant MVP option available to them. We believe this may be particularly true for subspecialists. For example, even though CMS proposed a stroke MVP, most vascular surgeons would not select to participate given the low volume of stroke care and the lack of 4 quality measures for them to report. Again, at a time when CMS is looking to reduce reporting burden this policy would act in direct opposition to that CMS directive.

We also strongly urge CMS to create and maintain the subgroup option as a voluntary participation pathway in MIPS. The SVS has always supported a subgroup reporting option in MIPS, and we applaud CMS for tackling the operational and implementation hurdles to make this an option for MIPS and MVP participation. We are concerned that 2023 may be too ambitious of a timeframe for implementation. Therefore, SVS does not support requiring multispecialty groups to form single specialty subgroups to participate in MVPs starting as soon as 2025. We again believe that CMS should start this as a pilot program, first, in 2023 and post the pilot determine a date for full implementation.

MVP Reporting and Scoring

Proposed Rule: CMS proposes to require MVP participants select four, rather than six, quality measures; two medium-weighted or one high-weighted improvement activity; and be scored on only the cost measures included in the MVP. CMS maintains many of the same traditional MIPS reporting and scoring requirements, including requiring reporting on the same Promoting Interoperability measures required under traditional MIPS. Additionally, CMS proposes to require MVP participants to select one population health measure, on which they will be scored.

SVS Response

Instead of using only what is currently available under the MIPS program, CMS should work with medical specialty societies, like the SVS, to develop quality and cost measures based on clinical pathways that could be a viable MVP. SVS has already worked with CMS on the development of two, episode specific cost measures for specific conditions and while we still have concerns regarding the specifications in those cost measures, we do believe that we could use the ischemic limb cost measure as the basis for a vascular disease MVP and have been working on its development. This MVP could be a more comprehensive method of measuring the quality of care than current MIPS quality measures and could allow the SVS Vascular Quality Initiative to again participate as a qualified clinical data registry in the QPP, if CMS had a more streamlined process for the development of quality measures for use in the development of an MVP.

In addition, SVS' journal has recently accepted for publication a review paper on the use of PROMs in the case of patients with vascular disease. SVS would like to include a PROM in our MVP, but it is unclear how such a measure would be reviewed by CMS for use in MVPs. The expanded use of PROMs could help to reduce current inequities in care delivery and outcomes for patients with vascular disease.

Also, requiring a population health measure to be included in an MVP appears to be a “make work,” project. Not all MVPs may be related to population health. Measures need to be relevant to the care pathway of the condition or procedure that is the subject of the MVP. If MVPs are going to be successful, all elements in an MVP need to be activities that when performed will increase the quality of the patient’s care and reduce its overall cost.

MVP Subgroup Reporting Option and Composition

Proposed Rule: CMS proposes to establish a subgroup reporting option for MVP participation by a subset of clinicians in a multispecialty group. To form a subgroup, interested clinicians must identify the MVP the subgroup will report on, identify the clinicians in the subgroup by TIN/NPI, and provide a plain language name for the subgroup for purposes of public reporting. Registration for both MVPs and subgroups would take place between April 1 and Nov. 30 of the performance period. Subgroups would be scored at the subgroup level on Quality, Cost, and Improvement Activities and would receive the group level Promoting Interoperability score. CMS proposes to use performance period benchmarks, or a different baseline period, such as calendar year 2019, for scoring quality measures in the 2022 performance period. Clinicians in a subgroup would continue to be included in group-level reporting if the practice also chooses to participate in traditional MIPS as a group. CMS requests comment on moving to mandatory subgroup reporting beginning in 2025 for multispecialty groups interested in MVP participation.

SVS Response

SVS believes that MVPs should be organized around specialties and sub- specialty areas of practice and should, at a minimum, be voluntary until such time as CMS has conducted a “pilot,” and tested that it can accurately connect TINs and NPI numbers to create subgroups. This must occur, first before any medical society can agree with CMS on a specific year for implementation and even then, it should still only be a voluntary option with CMS defining which specialties the available MVPs could be applied to.

We appreciate CMS’ recognition of the importance of subgroup reporting. Consistent with our previous comments, we continue to believe subgroup reporting will be crucial to MVPs as it would facilitate participation by specialists who may be practicing within multispecialty groups.

SVS has heard from its members who are part of a group practice that they would like to report separately from the larger group and instead partner with their colleagues in the same or similar specialty. However, we have questions, similarly to those noted above, regarding how physicians that are employed by a large group would be able to sign up for an MVP under CMS’ proposed timelines. What will the process be if a physician misses the date to sign up for an MVP? Will they be contacted by CMS? Will CMS automatically assign them to an MVP? What happens to providers who join at or just after the enrollment period? Most physicians have been participating in MIPS as part of a much larger multi-specialty practice group and have not been dealing with any of the paperwork or processes for participating in MIPS. Their employer has been coordinating all of this for them.

CMS needs to provide more complete proposed instructions on how the deadlines for signing up as a subgroup would work, what happens if a subgroup is not allowed to sign up by their employer and whether there would be an option to sign up later in the year if they were able to convince their employer to allow a subgroup to form for the purposes of reporting a specific MVP.

MIPS Performance Categories

Quality Performance Category

Proposed Rule: As required by statute, CMS proposes to reduce the weight of Quality Performance Category from 40 percent to 30 percent of the final MIPS score in 2022 and beyond. CMS proposes to update quality measure scoring to remove end-to-end electronic reporting and high-priority measure bonus points as well as the 3-point floor for scoring measures (with some exceptions for small practices). Additionally, CMS proposes to extend the CMS Web Interface as a quality reporting option for registered groups, virtual groups, or other APM Entities for the 2022 performance period, as well as update the quality measure inventory (a total of 195 proposed for the 2022 performance period). CMS also proposes to increase the data completeness requirement to 80 percent beginning with the 2023 performance period.

SVS Response

CMS was granted increased flexibility in the Bipartisan Budget Act of 2018 (BBA) to set the performance threshold and category weights, and the SVS urges CMS to work with medical specialty societies and Congress to be granted continued flexibility as least through 2023 due to the current PHE. Altering the category weights during the PHE when the cost category is potentially not valid because the PHE has led to under- representation of many procedures causing volatility in the claims data is not appropriate. The episodes-based measures under the cost category are still new. In addition, many have questionable reliability, and it is unknown how the COVID-19 PHE will impact the physicians' claims data used to calculate these cost measures. Therefore, SVS urges CMS to work with the medical society community and Congress to extend the period for flexibility, allowing the quality performance category final score weight to be 45% in 2022 and the cost performance category to be 15%.

The SVS urges CMS to continue to postpone transitioning away from the GPRO web-interface and associated measures until at least 2023. While only about 20 percent of users of the GPRO Web-Interface participate in MIPS, the SVS asks CMS to continue to evaluate its current timeline to eliminate this collection type for large groups.

Also, SVS believes that the cost to a practice of reporting any quality measures should be recognized by maintaining at least a 3-point floor regardless of practice size for each quality measure that a physician reports.

SVS does not support CMS' proposal to remove bonus points on additional outcome measures. Physicians should continue to be recognized and compensated for this increased effort through bonus points. Therefore, the SVS does not support CMS' proposal to remove bonus points for reporting on additional outcome measures.

Also, to promote the infrastructure needed to eventually allow a subgroup to report an MVP, CMS needs to continue to award bonus points for end-to-end reporting.

The SVS appreciates CMS' proposal to continue the data completeness criteria at 70 percent for the upcoming 2022 performance period and urges CMS to reconsider increasing it to 80 percent beginning in the 2023 MIPS performance period.

As we have stated in previous comments, the increased reporting requirement is counter to CMS' goals of reducing administrative burden within the MIPS program. Annual program changes such as this proposal increase the administrative burden and complexity of the MIPS program. Physicians do not stop complying with quality protocol once they hit minimum threshold requirements. However, they may just stop submitting data to CMS due to the administrative burden of data collection and reporting, especially if reporting on patient reported outcome measures and all-payer data.

Therefore, until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings, and providers, the SVS believes it is premature to increase the data completeness requirement to 80% for 2023.

Cost Performance Category

Proposed Rule: As required by statute, CMS proposes to increase the weight of the Cost Performance Category from 20 to 30 percent of the final MIPS score in 2022 and beyond. CMS proposes to add five new episode-based cost measures, including the first chronic condition cost measures. The proposed measures include Melanoma Resection, Colon and Rectal Resection, Sepsis, Asthma/Chronic Obstructive Pulmonary Disease, and Diabetes. CMS also proposes a new process for stakeholders to develop cost measures for MIPS beginning in 2022 for earliest adoption in MIPS in 2024. CMS proposes criteria for determining whether a cost measure change is considered substantive and thus must be proposed through notice-and-comment rulemaking before it is implemented in MIPS.

SVS Response

Following three years of unprecedented and significant disruptions to the health care system and MIPS due to the COVID-19 PHE, we urge CMS to exercise every lever under its Extreme and Uncontrollable Circumstances hardship exception policy and related authorities to reweight the Cost Performance Category to the weight that it was prior to the PHE in 2019, which was 15 percent. At a minimum, CMS should maintain the weight of the Cost Performance Category at 20 percent.

The COVID-19 pandemic has interrupted MIPS participation across three performance years so far, and the program is not even five years old. So, for more than 60 percent of the existence of the program, MIPS has been curtailed by the COVID-19 pandemic that is now in its fourth surge with cases, hospitalizations, and deaths increasing across the United States with continued uncertainty about the impact of future waves and new variants that may arise, essentially an ongoing crisis with an unclear future at this time. The SVS greatly appreciates the flexibilities that CMS has put in place to hold physicians harmless from undue MIPS penalties during this time as physicians care for patients diagnosed with COVID-19. We ask that CMS continue to allow for hardship exemptions at least through 2023. We urge CMS not to move forward with policy changes in 2022 as if the past three years have been business as usual.

Moreover, the Cost Performance Category has been severely impacted by the COVID-19 pandemic, to the extent that CMS reweighted the category to zero percent of MIPS final scores in 2020. The SVS

strongly supported this decision as we were very concerned that physicians would not be reliably and fairly scored on Medicare administrative claims-based cost measures due to geographic variation and changes in patient case mix. This means, however, that physicians have had one fewer year of reliable performance data to prepare for an increase in the weight of the Cost Performance Category. Physicians need more time to understand this new category and the new measures, especially those developed in Waves 2 and 3, which have not yet been scored due to either the COVID-19 reweighting or because they are being proposed for the first time for 2022.

SVS continues to disagree with CMS that a 0.4 threshold for mean reliability is appropriate. Prior to the implementation of the Wave 1 episode cost measures, SVS urged CMS to include more cases in the minimum calculation of a cost measure, given our experience in review data as part of working on the Acumen TEPs to develop the Wave 1 and 2 cost measures.

The minimum case thresholds should be set at the level needed for reliability and CMS and Acumen, LLC should accept the fact that this will lead to fewer clinicians being attributed the measure. We strongly urge CMS to increase the case minimums for these measures to improve reliability. At a minimum, CMS should increase reliability in the first few years that a measure is introduced into the program to ensure that it is reliably and consistently measuring resource use during an episode of care.

Improvement Activities Category

Proposed Rule: CMS states that the weight of the Improvement Activities (IA) category will be 15 percent of the final MIPS score in the 2022 performance year based on statute. CMS proposes several changes for the IA Performance Category for the 2022 performance year and beyond, including a proposal around group reporting requirements to address subgroup participation. Essentially, each IA for which groups and virtual groups attest to performing must be performed by at least 50 percent of the NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable. The NPIs must perform the same activity during any continuous 90-day period within the same performance year. CMS proposes to add seven new IAs, modify 15 existing IAs, and remove six existing IAs. The proposed new IAs include activities about health equity and standardizing language related to equity across IAs. CMS also proposes a process to suspend IAs that raise possible safety concerns or become obsolete from the program when this occurrence happens outside of the rulemaking process.

SVS Response

SVS supports CMS' proposal for revised group reporting requirements for the 50 percent participation threshold to address subgroup reporting of IAs that may differ from the "parent" group.

We continue to encourage CMS to develop ways to automatically award IA credit to eligible clinicians performing activities that overlap with similar Quality, Cost, and PI measures.

SVS would also encourage CMS to outline the process for suspending and/or retiring IAs due to safety concerns or activities becoming obsolete to allow for IA activities to be developed that are MVP specific.

MIPS Performance Thresholds

The SVS strongly urges CMS to automatically apply the Extreme and Uncontrollable Circumstances Hardship Exception for the 2021 MIPS Performance Period, so that physicians are held harmless from the 9 percent MIPS penalty due to the significant, ongoing disruptions that the COVID-19 PHE is having on physician practices.

The COVID-19 PHE was in effect prior to January 1, 2021 and is expected to remain in effect through at least the end of the calendar year. Although the rate of COVID-19 cases, hospitalizations, and deaths decreased in the early summer, those numbers are again surging in part due to the Delta variant and lack of sufficient vaccine uptake to allow for herd immunity. As in 2020, clinicians on the front lines still do not have time to focus on MIPS, their patient case mix is different, and their utilization has and will continue to vary geographically as physicians in hot spots once again delay or cancel non-essential procedures.

We think all eligible clinicians and groups should be held harmless from a MIPS penalty in 2021 as they continue to confront this PHE. We urge CMS to make this determination sooner rather than later so physicians can focus on caring for patients during this crisis.

MIPS Threshold Score

Proposed Rule: As required by statute, beginning with the 2022 performance year/2024 payment year, the performance threshold must be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period. CMS proposes to increase the MIPS performance threshold, which must be achieved to avoid a penalty, from 60 to 75 points based on the mean final score from the 2017 performance period/2019 MIPS payment year.

SVS Response

While CMS states that the statute would otherwise march onward toward full MIPS implementation and use of a prior year's mean or median as the performance threshold in 2022, we believe the extraordinary circumstances of the COVID-19 pandemic warrant a change in course. Specifically, the SVS urges CMS to exercise every lever under its Extreme and Uncontrollable Circumstances hardship exception policy and related authorities to lower the performance threshold from the proposed 75 points. At a minimum, the performance threshold should remain at 60 points and the Extreme and Uncontrollable Circumstances exception should be applied for 2021 reporting.

The COVID-19 pandemic, which is now in its fourth surge with cases, hospitalizations, and deaths increasing across the United States, has again interrupted MIPS participation for 2021 reporting. SVS greatly appreciates the flexibilities that CMS has put in place to hold physicians harmless from undue MIPS penalties during this time as physicians care for patients diagnosed with COVID-19. We urge CMS to continue these flexibilities until COVID cases are markedly reduced and more Americans have been vaccinated. It is unfortunately reasonable to anticipate the PHE will extend into 2022.

Advanced Alternative Payment Models (Advance APMs)

Proposed Rule: CMS proposes some changes in how it accesses the TIN information for a Qualifying APM Participant (QP) to increase the likelihood of paying incentive payments in a timely manner. Advanced APMs for 2022 are: Bundled Payments for Care Improvement Advanced; Comprehensive Care for Joint Replacement; Global and Professional Direct Contracting; Kidney Care Choices; Maryland Total Cost of Care; Medicare Shared Savings Program; Oncology Care Model; Primary Care First; Radiation Oncology model; and Vermont All-Payer ACO Model.

SVS Response

The SVS supports the proposal to take additional actions to identify changes that may occur in APM participants' organization affiliations so that their incentive payments may be correctly paid.

CMS should consider developing a process that would allow physicians to notify CMS of changes in these affiliations earlier and to allow for verification of APM participation. The SVS also recommends that CMS work collaboratively with the physician community to improve payment model design and implementation so that more physicians have opportunities to voluntarily participate in APMs that support the delivery of high-quality care to their patients.

CMS recognizes that under the Quality Payment Program, Qualifying APM Participants (QPs) eligible to receive an APM Incentive Payment from performance 2 years prior are sometimes disassociated from the practice where the payment was earned. The APM Incentive Payment is sent to the organization based on the Tax Identification Number (TIN) in CMS' system. The lag time between earning and paying the APM Incentive Payment should not cause a QP who has changed practices to be denied what they have rightfully earned. Many SVS members whose QPP participation is through an APM are unsure if they have received any of the 5% incentive money that was paid to the APM.

SVS supports the clarifications CMS is making for the APM Incentive Payments to QPs. CMS should carry out its proposal to expand the search at each step to identify potential payee TINs that are so associated with the QP so that their incentive payments can be sent to them, directly.

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The SVS appreciates the opportunity to provide comments on this Proposed Rule. If you have any questions or need additional information, please contact Kenneth M. Slaw, PhD, Executive Director of the SVS at KSlaw@vascularsociety.org or 312-334-2301.

Sincerely,

Evan Lipsitz, MD, MBA
Chair, SVS Performance Measures Committee