

# Sound Policy. Quality Care.

September 6, 2022

Ms. Chiquita Brooks-LaSure, Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1770-P P.O. Box 8013 Baltimore, MD 21244-8016

Submitted electronically via <a href="www.regulations.gov">www.regulations.gov</a>

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Dear Administrator Brooks-LaSure,

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians across 15 specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care by advancing sound health policy. On behalf of the undersigned members, we write in response to proposals outlined in the CY 2023 Medicare physician fee schedule (PFS).

# PFS Payment Reductions

CMS proposes a steep, **4.5% reduction** in Medicare payments to physicians for 2023 due to statutory requirements and regulatory changes discussed in the rule. In contrast, most other Medicare providers, including Medicare Advantage (MA) plans, anticipate **sizeable increases** in their 2023 payments (e.g., inpatient hospitals (4.3%); inpatient rehabilitation facilities (3.9%); hospices (3.8%); hospital outpatient departments (2.7%); and MA plans (8.5%). **The gross payment disparity between health care facilities, MA plans and physicians** — **those who diagnose, treat and manage Medicare beneficiaries' care** — **is unconscionable and cannot be ignored any longer.** 

#### Inflation

Costs associated with running a physician practice have increased considerably as the price of medical supplies, equipment, and clinical and administrative labor have risen dramatically, outpacing high inflation rates. Unlike other Medicare providers that receive annual payment updates based on an inflation proxy, such as the Consumer Price Index, physician payment updates are prescribed in law — without an inflation adjustment. The increasing downward financial pressure on physicians is forcing many to sell their practices to hospitals, health systems, and private equity groups. Indeed, an <a href="https://example.com/april 2022">April 2022</a> report prepared by Avalere found that nearly 70% of all physicians are now employed — a figure that spiked 19% in 2021 alone.

#### Consolidation

Consolidation in health care systems increases costs to everyone, including taxpayers and Medicare beneficiaries, and is a growing concern of policymakers. As explained by the Medicare Payment Advisory Commission (MedPAC) in its <u>March 2020 Report to the Congress</u>:

Physician—hospital integration, specifically hospital acquisition of physician practices, has caused an increase in Medicare spending and beneficiary cost sharing due to the introduction of hospital facility fees for physician office services that are provided in hospital outpatient departments. Taxpayer and beneficiary costs can double when certain services are provided in a physician office that is deemed part of a hospital outpatient department.

MedPAC further notes that "...[G]overnment policies have played a role in encouraging hospital acquisition of physician practices" and highlights how "[t]he potential for facility fees from Medicare and higher commercial prices encourages hospitals to acquire physician practices and have physicians become hospital employees."

#### Impactful Regulatory Policies

We recognize that CMS is required to implement physician payment updates as outlined in the statute. However, until a long-term solution to the flawed physician payment methodology is addressed by Congress, CMS should be cautious when proposing and finalizing policies that would adversely impact the conversion factor. This includes policies that prompt significant, negative budget-neutrality adjustments that CMS cannot mitigate under its existing authority. Examples of policies discussed in this proposed rule that may put stress on the conversion factor in CY 2023 or a future year include the following:

- Expanding access to dental services;
- Revising payments for skin substitutes;
- Increasing values for inpatient and certain other evaluation and management (E/M) services;
   and
- Ongoing phase-in of the clinical labor pricing updates.

While CMS' goal in these policies is to expand beneficiary access to medically necessary care and improve accuracy in payments to physicians, these gains will be lost if — absent the infusion of new money into the PFS or an expansion of authority that would allow the agency to override budget-neutrality adjustments — these policies further impair physicians' ability to receive fair and reasonable payment updates under the current system.

Medicare payments to physicians are dangerously low. It is no longer a question of if, but rather when, more physicians will sell their practices, retire, or simply leave the practice of medicine altogether. This exodus will put Medicare beneficiaries in a state of crisis that will only serve to limit their ability to seek care. CMS must take steps to prevent/mitigate payment cuts in 2023 and work with Congress to ensure physicians receive fair and reasonable updates to their Medicare payments, similar to other providers, in CY 2023 and beyond.

#### Medicare Economic Index (MEI) and Practice Expense Data Collection Update Strategies

The Alliance recognizes that data currently used for the MEI are sorely out-of-date and should be updated. This is particularly true if, in the future, Congress adopts the MEI as an inflation adjustor in a revised physician payment methodology. However, CMS' proposal continues to rely on outmoded data

(i.e., 2017 inputs) from sources (i.e., Table 5, Estimated Selected Expenses for Employer Firms for NAICS 6211 (Office of Physicians) from the 2017 U.S. Census Bureau's Services Annual Survey (SAS)) that were not designed, and therefore inappropriate, for updating the MEI cost weights. Most importantly, the proposal would significantly redistribute Medicare dollars from "physician work" to "practice expense," diminishing physicians' specific contribution to the health care system.

The American Medical Association (AMA) has shared with you that it is engaged in an extensive effort to collect practice cost data from physician practices, many of which are specialty practices that Alliance members represent. Given the important role that the MEI currently plays (and may potentially play in the future), like the AMA, we urge CMS to pause consideration of other sources of cost data for use in the MEI until the AMA effort is complete.

With regard to CMS' comment solicitation on practice expense data collection strategies, we urge the agency to include direct practice updates when establishing its "roadmap toward more routine PE updates." CMS recently completed its phase-in of updated supply and equipment costs and is in the second year of its 4-year phase-in of clinical labor price updates. However, these direct practice expense updates created significant reimbursement challenges for many specialties. As alluded to above, these policies prompted significant budget-neutrality adjustments and reduced payments for some Alliance specialties by as much as 22.04%. These reductions were exacerbated by the fact that CMS had not updated these inputs in 20 years. As a result, many physicians are being paid less for services that cost them more to deliver. Any "standardized and routine approach to valuation" should include both direct and indirect practice expenses.

#### Valuation of Services

Many Alliance members invest considerable time and resources to participate in the AMA/Specialty Society RVS Update Committee (RUC) and develop work and practice expense relative values for the services they deliver. The RUC process is generally recognized as an open, transparent, and collaborative valuation process, and CMS staff has a long history of attendance and engagement.

Over the years, and amidst scrutiny of this process, CMS has limited its acceptance of RUC recommendations and increasingly employed alternative approaches to derive different — and usually lower — relative values for physician services. While we grant that CMS is under no obligation to accept RUC recommended values, specialties are rightfully frustrated when the agency proposes lower values for their services based on concerns never raised when the values were being vetted at the RUC. Specialties feel blind-sided when they review the annual PFS proposed rule and learn that the value of their services has been diminished. This is also true in the context of the global surgery services, where CMS has failed to apply the 2021 office E/M visit increases — and now the hospital and discharge day management visits — to those same visits when they are included in the global surgery package.

The Alliance urges CMS to meaningfully engage in the RUC process and be forthright about concerns with physician service values as they are being evaluated during the RUC meetings.

#### Telehealth

Generally, the Alliance appreciates CMS' proposals that implement the Consolidated Appropriations Act, 2022 and continue allowing certain telehealth services (that would otherwise not be available via telehealth after the expiration of the public health emergency (PHE)) to remain on the Medicare Telehealth Services List for 151 days after the expiration of the PHE. We also appreciate and *support CMS' proposals to add several codes to the Medicare Telehealth Services List on a Category 3 basis that are currently temporarily included during the PHE.* 

The Alliance has previously expressed support for CMS to extend the availability of audio-only telehealth services, which enables patients who cannot or who are not willing to utilize audiovisual telecommunications technology to continue to receive essential specialty medical care, as clinically appropriate, and regardless of whether such patients have the financial resources, local broadband infrastructure, or technological wherewithal utilize more traditional audiovisual telehealth modalities. For this reason, we are disappointed that CMS is not proposing to continue separate Medicare coverage of telephone E/M services nor to keep these services on the Medicare Telehealth Services List after the 151-day post-PHE extension period. *We urge CMS to reconsider this position.* 

Despite our support, we do recognize that expansions of telehealth will present challenges, including potential increases in utilization and spending and increased program integrity risks. The Alliance is committed to assisting CMS as it works toward establishing policies that balance the value of ongoing access to medically necessary virtual care with CMS' financial stewardship and program integrity responsibilities.

# Quality Payment Program (QPP)

# Merit-Based Incentive Payment System (MIPS) MIPS Value Pathways (MVPs)

As we noted in comments to CMS last year, the Alliance supports CMS' desire to streamline MIPS reporting, reduce clinician burden, focus on metrics that are valuable to clinicians and patients, and provide clinicians with a glide path to alternative payment model (APM) participation. *However, we are* 

very concerned that the MVP framework is not enough of a departure from traditional MIPS and that it fails to resolve foundational issues with the program that some Alliance member specialties believe has limited clinician engagement and hampered meaningful progress towards higher quality care.

MVPs essentially preserve the siloed nature of the four MIPS performance categories and fail to provide cross-category credit or recognize more comprehensive investments in quality improvement. MVPs also continue to rely on problematic MIPS participation options, scoring rules, and qualified clinical data registry (QCDR) policies that disincentivize the development and use of more clinically focused measures and participation pathways that better align with clinical practice.

As CMS implements the MVP framework, particularly as it considers adopting a sub-group reporting mechanism, it is critical to incentivize the ongoing development and use of a diverse inventory of specialty- and sub-specialty-specific measures that are truly meaningful to both physicians and their patients. Current program policies encourage large multispecialty groups and institutions to report on broad measures that are not relevant or meaningful to all specialists in those groups. At the same time, specialty societies that have invested in developing better measures, including through QCDRs, have not been able to invest the significant resources required to maintain those measures or have been forced to water down measures to the point of it not being worth the investment. They also have faced program disincentives for groups and facilities to invest in using those measures. As a result, specialists lack MIPS results that can lead to data-driven improvements in quality. At the same time, their patients are denied the granularity of data needed to make informed health care decisions. While we believe that subgroup reporting has the potential to produce more clinically relevant, actionable and valuable data, it can only do so if paired with policies that simultaneously incentivize the development and use of more meaningful measures and more focused reporting mechanisms. Otherwise, subgroup reporting will only add another layer of complexity and administrative burden to an already unworkable program.

As we stated last year, the Alliance believes it is premature to consider making MVPs mandatory in the future. MVPs should remain a voluntary pathway for clinicians, alongside traditional MIPS, providing clinicians with a choice that best reflects their patient populations and practice needs.

Rather than focus on this single new pathway, we urge CMS to instead continue working with stakeholders and Congress to fundamentally reform the program.

# Development of New MVPs

CMS proposes to modify the MVP development process such that were CMS to receive a new candidate MVP, evaluate it through the MVP development process and determine it "ready" for feedback, CMS would post a draft version of the MVP on the QPP website and solicit feedback from the general public for a 30-day period. CMS would review the feedback received and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If it determines changes should be made, it will not notify the interested parties who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process.

The Alliance believes CMS must work in tandem with relevant clinicians and specialty societies to develop MVPs. This process should be transparent and inclusive of all relevant stakeholders, particularly the clinical experts that could be impacted by the MVP. We appreciate that CMS proposes a more formal process for soliciting public feedback on MVPs. However, we request more clarity on the criteria that CMS would apply to determine that an MVP is "ready" for feedback. We are also very concerned that CMS is proposing that it would not consult with the parties who originally submitted the candidate MVP in advance of rulemaking if changes are made to the MVP. In most cases, the parties who initially submitted the MVP will be the specialties most connected to the procedure, condition, or patient population captured by the MVP. It is critical that CMS recognizes the clinical content experts who developed the MVP by providing them with the opportunity to review whether the revised MVP makes clinical sense before it is formally proposed through rulemaking.

#### MIPS Performance Threshold

Beginning with the 2022 performance year/2024 payment year, section 1848(q)(6)(D)(i) of the Act requires the performance threshold to be the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. In the CY 2022 PFS final rule, CMS selected the mean to determine the performance threshold for the 2022-2025 performance years/2024-2026 MIPS payment years. In this rule, CMS proposes relying on the CY 2019 MIPS payment year as the prior period to determine the performance threshold for the 2023 performance year/2025 MIPS payment year, which would result in a performance threshold of 75 points. *The Alliance appreciates CMS maintaining the performance threshold at the current level and selecting the lowest threshold value possible under statute.* Nevertheless, we remind CMS that 75 points is still a significant increase from the 30-point performance threshold adopted for the 2019 performance year, immediately prior to the COVID-19 pandemic. Many clinicians have not participated in MIPS since that time because they were either automatically exempt from MIPS or applied for a hardship exception due to COVID-19. As these clinicians reintegrate back into MIPS, it will be challenging for them to meet this threshold and avoid a penalty.

**Additionally, we request that CMS release specialty-specific data regarding mean and median performance.** This will help CMS to determine if there are significant differences across specialties that may warrant a more thorough evaluation and potentially consideration of specialty-specific MIPS performance thresholds.

# Complex Patient Bonus

CMS proposes that beginning with the 2023 performance period/2025 MIPS payment year, a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus, even if they do not submit data for at least one MIPS performance category. *The Alliance supports ensuring that facility-based clinicians are eligible for the complex patient bonus*. Many specialists meet the definition of

"facility-based" and rely on those scores rather than submit their own measures. Those with more complex patient populations should be recognized as such, regardless of their participation pathway.

# **Quality Category**

# Data Completeness Threshold

CMS proposes to increase the data completeness criteria from 70 percent to 75 percent for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years. *As the Alliance noted last year, we oppose CMS increasing the data completeness threshold until reporting is more seamlessly integrated across providers and settings.* Specialists often do not have direct control over EHR systems, and revisions to accommodate new measure requirements may take time to design and implement. Additionally, sub-regulatory guidance is usually unavailable until late in the performance year, which could result in a change in reporting strategy that makes it challenging to satisfy data completeness requirements. We also remind CMS that no other federal quality programs at the hospital or health plan level rely on sample sizes as high as MIPS.

Similar to benchmarking, the Alliance also requests that CMS consider setting different data completeness thresholds for different types of measures. For example, clinicians may find it challenging to satisfy a 50 percent data completeness threshold for patient-reported outcome measures. Setting a lower threshold for these types of measures would incentivize the development and use of such measures.

#### **Quality Category**

# Screening for Social Drivers of Health Proposed Measure

As a first step towards addressing determinants of health (DOH) to close health equity gaps among patients served by MIPS-eligible clinicians, CMS proposes adopting an evidence-based DOH measure that would support the identification of specific DOH associated with inadequate health care access and adverse health outcomes among patients. The "Screening for Social Drivers of Health" measure would assess the percent of patients 18 years or older screened for food insecurity, housing instability, transportation problems, utility difficulties, and interpersonal safety.

The Alliance values the importance of systematically addressing social determinants of health affecting individual patients, which can help improve the early identification of risk and/or need and prompt referral to relevant resources. However, we have some concerns about specific aspects of this proposal, which lack clarity. For now, this measure would be optional, but CMS asks for feedback on whether it should be included in the foundational layer of MVPs in the future. *The Alliance urges CMS to maintain the Screen for Social Drivers of Health as a voluntary measure.* Screening measures like this one are most appropriate for facility-level accountability since facilities have the capacity, including staff resources, to conduct these assessments on all patients. If a clinician or practice has the capacity to screen all patients, then they should have the option to choose this measure. However, clinicians who might find it difficult to conduct these screenings on all patients due to limited time with the patient, lack of resources, and workflow issues should not be required to report this measure.

In the 2023 Inpatient Prospective Payment System (IPPS) final rule, CMS adopted the same measure under the Hospital Inpatient Quality Reporting (IQR) program. In the finalized specifications, the following patients are excluded from the denominator: (1) Patients who opt out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on the patient's behalf during their inpatient stay. However, the specifications of the version of this measure proposed for MIPS do not include any exclusions. *The* 

Alliance urges CMS to include appropriate exclusions in the final version of this measure to account for patients who may opt out of the screening.

In the IPPS rule, CMS also talks about how providers may use a self-selected screening tool and collect these data in multiple ways. While we suspect that CMS intends to offer the same flexibility for the MIPS version of this measure, it does not discuss this in the rule. We urge CMS to allow clinicians reporting this measure to use a self-selected screening tool and collect these data in ways that best accommodate the populations they serve and their individual needs.

Finally, the Hospital IQR Program is a pay-for-reporting program, while payments are tied to performance under MIPS. We request that CMS clarify how it intends to set benchmarks and evaluate performance under this measure, which, as proposed, requires screening of all patients with no exclusions. Will the benchmarks be based simply on the percentage of patients screened, and if so, would perfect performance equate to screening 100 percent of patients or simply 70 percent, which satisfies the data completeness threshold?

#### Third Party Intermediaries General Requirements

# **QCDR Measure Approval Criteria**

CMS proposes to delay the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year. Under this proposal, a QCDR measure approved for the CY 2023 performance year or earlier would not need to be fully developed and tested until the CY 2024 performance year. A new QCDR measure proposed for the CY 2024 performance year would be required to meet face validity, and CMS would require full testing at the clinician level before the QCDR measure can continue in the program beyond the first year.

The Alliance supports this delay and appreciates CMS' recognition of concerns regarding the burden of full measure testing and the continuing impact of the COVID-19 PHE on QCDR participation rates. However, we are frustrated with the timing of this announcement. The 2023 QCDR self-nomination period opened on July 1, 2022, and closes on September 1, 2022, which means that any existing registry that wished to re-apply for 2023 had to proceed under the assumption that the full measure testing requirements are still in effect. CMS' lack of action on this issue has made QCDRs an impractical and unattractive option for many specialty societies, which has led to an increasing number of registries dropping out of the program or seriously considering doing so. This is very disappointing since QCDRs were intended to offer specialists a pathway to introduce more focused, relevant, innovative, and patient-centered measures, thus exacerbating specialist disengagement from the program. This also impacts the availability of QCDR measures to populate MVPs since QCDR measures must be fully tested at the clinician level prior to inclusion in an MVP. We strongly urge CMS to weigh the value of the full testing requirements against the negative impact it has on meaningful specialty engagement, and to reconsider implementing the full testing requirements for purposes of both traditional MIPS and MVPs.

# Publicly Reporting Utilization Data on Profile Pages

CMS proposes publicly reporting Medicare procedural utilization data on the Care Compare clinician and group profile pages to assist patients and caregivers with health care decision-making and allow for more granular clinician searches. CMS would begin publicly reporting procedural utilization data no earlier than CY 2023 and would include a disclaimer on profile pages that the utilization data only represents the care that has been provided to Medicare beneficiaries and does not include those of patients with other forms of insurance. Rather than showing thousands of rows of individual Healthcare Common Procedure Coding System (HCPCS) data — as CMS does for the research community in the Provider Data Catalog (PDC) — CMS proposes to collapse HCPCS codes using the Restructured Berenson-

Eggers Type of Service (BETOS) Codes Classification System into procedural categories. BETOS is a taxonomy that allows for grouping health care services codes for Medicare Part B into clinically meaningful categories and subcategories. For procedures in which no Restructured BETOS categories are available, CMS would utilize procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures.

The Alliance does not support the inclusion of utilization data on the Care compare clinician and group profile pages. We appreciate the need to provide patients and their caregivers with meaningful information to support medical decision-making. However, utilization is not a clear or consistent indicator of quality. Additionally, this proposal would fail to provide patients with a complete or accurate assessment of a practice's performance since it is limited to procedure data and Medicare claims data, potentially misleading and confusing the public.

We are also concerned about CMS' proposal to collapse HCPCS codes using the BETOS Codes Classification System. The BETOS system is outdated and includes no standard or systematic way to group procedures by CPT/HCPCS code beyond very broad categories. In fact, some of our members' specialty codes are not even captured by this system. As a result, we fear that this attempt to collapse and simplify procedure codes will result in inaccuracies and generalizations about specialists that will further mislead patients.

While we oppose this proposal in its entirety, if CMS decides to finalize this policy, we strongly urge the agency to first conduct comprehensive testing with both clinicians and patients to ensure these data are appropriate, useful, and accurately reflective of clinical practice. Clinicians should also be able to review and correct data before it is publicly reported. Finally, we strongly urge CMS to include an additional disclaimer to remind the public that utilization does not necessarily equate to quality and that many factors besides utilization may contribute to a clinician's overall performance.

# Qualifying Participants (QPs) in Advanced APMs

RFI on Quality Payment Program Incentives beginning in Performance Year 2023

As specified under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, starting with the 2023 performance year/2025 payment year, QPs will no longer qualify for a 5 percent APM incentive payment. Instead, those who are QPs in 2023 will receive a zero percent update in 2025. Starting with the 2024 performance period and 2026 payment year, QPs will be eligible for a higher base conversion factor update (0.75 percent vs. 0.25 percent for non-QPs, including those participating in MIPS). Clinicians participating in MIPS will continue to be eligible for up/down payment adjustments, with the max penalty being -9%. MACRA also prescribes specific payment and patient thresholds that clinicians must meet to become a QP. Specifically, for performance years beginning with 2023, the Medicare Option QP Thresholds will increase to 75% (from 50%) for the payment amount method and 50% (from 35%) for the patient count method.

The Alliance is very concerned about the negative impact these shifting policies will have on specialty eligibility for the QP track and the general movement of specialists towards APMs. To date, there have been very limited opportunities for specialists to participate meaningfully in Advanced APMs and to qualify as QPs. Most existing models are primary care or population-focused and provide no material role for specialists. Alliance member organizations have a long history of attempting to work with the CMS Innovation Center and the Physician-Focused Payment Model Technical Advisory Committee to establish specialty-specific APMs. Despite these heavy investments of time and financial resources, few specialty-focused models have been tested by CMS to date.

We urge CMS to work with Congress to make technical updates to MACRA that 1) extend the incentive payments for QPs in Advanced APMs and 2) maintain the current QP threshold levels.

Physicians are already facing staggering Medicare payment reductions compared to other Medicare providers, and the nominal payment updates authorized under MACRA will perpetuate this problem. Even if CMS were to provide opportunities for specialists to participate in more meaningful payment and delivery models, specialists would still need the APM incentive payment to offset the financial risk and additional administrative costs associated with implementing those models. They also should not be excluded from this track of the QPP due to higher participation thresholds when they were never even given the opportunity to qualify at the current threshold.

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We appreciate the opportunity to comment on these important issues and welcome the opportunity to meet with you to discuss them in more detail. Should you have any questions or wish to schedule a meeting, please contact us at info@specialtydocs.org.

Sincerely,

American Association of Neurological Surgeons
American Association of Neurological Surgeons
American Academy of Otolaryngology-Head and Neck Surgery
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society