September 2, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted electronically via regulations.gov

Re: CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies, etc., CMS-1770-P, RIN 0938-AU81

Dear Administrator Brooks-LaSure,

The American Academy of Dermatology Association (AADA) represents more than 16,500 dermatologists nationwide. We are writing to provide comments on the Centers for Medicare & Medicaid Services (CMS) proposed *CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies*. The AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease. We appreciate the opportunity to provide comments on the proposed rule on the Physician Fee Schedule (PFS) and Quality Payment Program (QPP). The AADA urges CMS to take these recommendations and concerns into consideration when developing the final rule and formulating future policy.

I. Proposals Related to the Medicare Physician Fee Schedule

A. Proposed Conversion Factor

CMS has calculated that the RVU Conversion Factor (CF) will be reduced by 4.42%, from $34.6062 in 2023 to $33.075. The CMS proposed conversion factor includes the budget neutrality adjustment from the 2022 implementation of improved payments to Evaluation and Management (E/M) Office Visits as well as the

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requirement under the Medicare Access and CHIP Reauthorization Act (MACRA), that the statutory physician payment update for CY 2023 is zero percent. However, the CF does not include the Protecting Medicare and American Farmers from Sequester Cuts Act, which provided a 3.00% increase in PFS payment amounts for services between January 1, 2022, and before January 1, 2023. Due to this expiration of the increased payment, the CY 2023 CF will be calculated as though the 3.00% increase for the CY 2022 CF had never been applied.

It is important for CMS to consider that in addition to the CF reduction, physicians will be facing the statutory sequestration cuts mandated by PAYGO – the pay-as-you-go legislation of March 2021. Overall, physicians are facing an almost 8.5% decrease which does not take into consideration the 2% statutorily imposed Medicare sequestration cuts. While these looming payment cuts require Congressional action, they further strain medical practices.

Updates to the physician fee schedule have not only woefully fallen behind payments to hospitals and nursing facilities, but year after year they also have failed to keep up with inflation. In the past twenty years, practice expense, as measured by the Medicare Economic Index, has risen 39% while inflation, as measured by the Consumer Price Index, has risen 51%. According to the Medicare Trustees' Reports, Medicare physician payment reimbursement has risen just 11% while hospital and nursing facilities updates have increased by 60% or more, significantly outpacing physician reimbursement. Adjusted for inflation, as measured by the Medicare Economic Index, physician reimbursement has declined 20% from 2001 to 2021.

While the physician fee schedule has not kept up with inflation, increased costs are significantly impacting physician practices. Practice staff, including administrators, nurses, and medical assistants are demanding higher wages due to inflation. Physician practices must also contend with additional increase in the cost of overall practice expenses and supplies. This lop-sided payment system is not sustainable. Most importantly, it threatens the viability of all medical practices and will impact Medicare beneficiaries' access to care. The current payment structure has contributed to consolidation and increased hospital ownership of physician practices, which are more costly, reduce competition, and are less patient centered.

Furthermore, our country continues to face a Public Health Emergency (PHE) due to COVID-19 coupled with the expanding monkeypox outbreak that further stresses the system. Medical practices continue to face enormous financial challenges and uncertainty, with increased expenses incurred for office redesign and personal protective equipment accompanied with decreased revenue because the number of patient encounters must be reduced for the safety of patients and staff. Inflation rates are increasing exponentially, and the health care field is feeling the impact.

We acknowledge that CMS normally must adhere to the budget neutrality requirement when establishing the CF. However, removing the 3.00% increase to the CF for CY 2023 significantly reduces physician payment because the CY 2022 CF was already reduced by nearly 3.85% from CY 2021. These are not normal times. The decrease in the CF along with rising costs due to inflation need to be considered to fully understand the financial impact for physicians. **CMS must not inflict further economic devastation on the medical community by drastically cutting payments for services.**

CMS should use any of its available authorities to increase physician reimbursement to at least the same rate as inflation. At minimum, CMS should extend the budget neutrality payment adjustment of 4.42% to maintain the value of the CF at the same level in 2023 as it was in 2022 to $34.6062. AADA also calls on CMS to work with the Congress to develop a long-term solution and ensure physician reimbursement is, at a minimum, tied to inflation like other Medicare payment systems.

B. Global Surgical Package Valuation

It has taken over 20 years to establish the relative values of the over 4,200 codes that CMS is proposing to revise. While AADA appreciates the opportunity to provide input once again, AADA questions CMS' rationale to revalue these codes and believes that such a discussion is misconceived. A large part of the decision by CMS to revalue focuses on studies conducted by the RAND Corporation, a CMS contractor, to investigate the actual number of post-operative visits per 10- and 90-day global services.

The AADA has significant concerns with the Rand Study. It is unclear whether the RAND Corporation investigated actual chart notes or only claims data. Moreover, the non-valued postoperative follow up code, 99024 was used by RAND and CMS to evaluate whether such services occur, but this code is routinely underreported. By not reviewing the actual chart notes, Rand and CMS did not conduct a comprehensive, accurate evaluation. Relying on a flawed method to gather data to be used to further adjust physician payment is extremely problematic and may result in adverse consequences for Medicare beneficiaries.

Consider the alternative scenario should CMS move forward with revaluing or eliminating the global surgical services. If patients require medically necessary services beyond the date of the procedure, such as suture removal or incision care management, then the additional costs will be passed on to the patient and thus create an increased burden to Medicare beneficiaries who may not have the means to cover additional co-pays or coinsurance costs. Patients may choose to not return for medically necessary follow-up visits as they might be cost prohibitive, thus resulting in more costly complications that could have been avoided. This would disproportionately affect those patients with limited financial means and further exacerbate health disparities and health outcomes for those beneficiaries. Bundled global services are in line with CMS' goals to streamline care and increase accessibility. Patients feel comfortable with and are well served by the present paradigm in which they can see their surgeon as often as they need to without fear of incurring additional cost for routine or complicated postoperative recovery.

There is no shortcut to collect the number and quality of postoperative visits that are delivered, especially using claims around an unpaid CPT code with non-validated methodology. **We recommend that CMS conduct a definitive study that would involve collection of inpatient and outpatient records for a statistically valid evaluation of postoperative visits for all 10-and-90-day global codes.**

CMS is considering various approaches they could pursue, such as:

(1) revaluing all 10- and 90-day global packages at one time (perhaps with staggered implementation dates);
(2) revaluing only the 10-day global packages (because these appear to have the lowest rate of postoperative visit performance, per RAND's analysis of claims data);

(3) revaluing 10-day global packages and some 90-day global packages (such as those with demonstrated low postoperative visit performance rates as identified in RAND's analysis of these services); or
(4) relying on the Potentially Misvalued Code process to identify and revalue misvalued global packages over the course of many years.

The AADA has overall concerns with each of these proposed scenarios. The complexities of the valuations make it impossible to simply revalue global package code by subtracting the post-procedure visits. CMS must first identify the best methodology with the RUC and other appropriate stakeholders to appropriately re-value these codes including pre-intra and post-service work and assess that methodology through the rulemaking process. Once the methodology is understood, CMS must allow sufficient time to ensure that the codes are valued fairly. While we understand the four different approaches CMS would like to take and are seeking feedback on, without identifying the actual revaluing methodology being proposed for the first three, it would be premature to comment. However, should CMS choose to move forward with any of these proposals, any revaluation must occur through the RUC valuation process over a reasonable and agreed upon timeframe by the RUC. It is unrealistic to expect the RUC or CMS to revalue all the codes at the same time. Many code families are going through the RUC process for other reasons and their respective global periods are being examined and sometimes adjusted. One alternative for looking at this fairly is having this process occur 'naturally' through RUC as the codes come up for review to ensure an adequate and thorough review in the setting of work being performed. Each code family is different and needs adequate time to be reviewed in the setting of these factors. In addition, it will be important to prevent inconsistency with code relativity when determining the implementation timeline.

CMS believes that changes to health care delivery may impact proper valuation of global services and is soliciting comment on whether changes to health care delivery, including changes in coordination of care and use of medical technology over the past three decades, as well as during the recent PHE, have impacted postoperative visits.

Since the public health emergency, many patients and practices have increased the use of electronic means of communication as part of post-operative care and overall care. Many patients may not want to risk further in-person exposure, but still require medical care beyond the date of service resulting in portal communications, emails, or phone calls. This shift, however, does not necessarily support a devaluation of services and CMS should be mindful of this if looking to revalue any global surgical service. In addition, these non-direct services often take place with the typical patients along with face-to-face E/M services that the surgeon performs. Currently, these services are not separately billable and when CMS only relies on claims data, much of this post-operative work is not captured. Lastly, while there may have been a shift in postoperative visits during the public health emergency, the AADA believes that postoperative services are trending back to traditional face-to-face encounters. Evaluating how technology is being incorporated into postoperative care at this time of evolution may result in conclusions inconsistent with long-term trends. **We urge CMS to not consider any further movement on this until the public health emergency is over and patients and physicians settle into a new normal.**

Furthermore, the AADA shares CMS' expressed concern if a surgeon is referring the patient to follow-up with an unrelated group and specialty, such as primary care, yet still accepting the global payment. We would hope that this is an extremely unlikely event as primary care physicians are not equipped to evaluate

post-surgical patients. However, CPT coding allows for appropriate reporting for that type of care coordination and those appropriate modifiers should be used. This allows for proper payment to go to the appropriate physician for pre-surgical, surgical, and post-surgical work. Appropriate enforcement would require coding education, not revaluation of the services. Lastly, it is common for nurse practitioners and physician assistants in the same group practice as the surgeon to follow physician orders and see the patient in post-operative care. This is incident-to billing and does not result in a reduction of payment per CMS' rules on incident-to. The physician is involved as needed in these instances.

Before CMS continues discussion on possible revaluation for these global surgical services, it will be important for CMS to determine if indeed post-service visits are as compromised as the RAND study suggests. We believe the methodology used to capture the information does not reflect real world care. We urge CMS to carefully consider the overall impact of any methods they may wish to utilize in revaluing 10- or 90-day global surgical packages for reasons outlined above.

C. *Payment for Medicare Telehealth Services Under Section 1834(m) of the Social Security Act*

CMS proposes an addition of a telehealth indicator to clinician and group profile pages, as technically feasible. The indicator would distinguish the services provided via telehealth by the physician. **The AADA agrees to adding a telehealth indicator to clinician and group profiles as this will provide patients with up-to-date information on telehealth services provided by the clinician.** Telehealth indicators will empower patients to research if and which telehealth services are offered by a provider and removes the burden and time of medical office staff to provide this information via phone.

Additionally, CMS is proposing to extend the application of certain Medicare telehealth flexibilities for an additional 151 days after the end of the PHE for COVID-19, including allowing Medicare telehealth services to be furnished to patients located anywhere within the U.S. **The AADA agrees with this proposal as it is consistent with the AADA's teledermatology position.** Continuing to not limit geographic area for telehealth services allows patients better access to care.

Additionally, AADA agrees with extending the services offered via telehealth. Extension allows providers to have covered telemedicine services (specific to those codes on the Medicare Telehealth Services list) and allows additional time for the services to be considered for permanent additions to category 1 & 2 of the Medicare Telehealth Services list. AADA is in support of extending these important telehealth flexibilities permanently as there has been such an increase in access to care because of them.

D. Evaluation and Management Services

1. Other Evaluation and Management Services

For CY 2023, CPT updated the remaining E/M services with key elements and/or time in their code descriptors. As with the revision of the office-based E/M services, all services were re-surveyed and revalued. All such codes increased in value resulting in a negative impact on the conversion factor to maintain budget neutrality across the board. **While we recognize that CMS must adhere to the budget**

neutrality rules, the AADA urges CMS to work with Congress to find a legislative fix to increase the conversion factor because a reduction in payments for non-E/M services rendered cannot be supported with rising costs due to inflation.

2. E/M Split (or Shared Visits)

CMS proposes to delay the implementation of new rules for reporting split (or shared) visits to be based on "substantive portion" policy until January 1, 2024, for services furnished in facility settings. CMS believes that delaying implementation of this policy would allow for the changes in the coding and payment policies for "Other E/M" visits to take effect for CY 2023. Furthermore, this allows for a one-year transition for providers to get accustomed to the new changes and adopt their workflow in practice. The delay affords CMS additional time to consider more recent stakeholder feedback and evaluate whether there is a need for additional rulemaking. **AADA supports this delay and appreciates CMS for considering stakeholder comments.**

E. Payment for Skin Substitutes

CMS proposes to treat skin substitutes (including synthetic skin substitutes) as incident to supplies when furnished in non-facility settings and to include the costs of these products as resource inputs in establishing practice expense RVUs for associated physician's services effective January 1, 2024. This proposal would mean skin substitutes are treated in the same manner for purposes of payment when furnished in non-facility settings and would be consistently contractor priced through 2024. Given these significant changes, CMS believes maintaining the current treatment of these products for purposes of payment during 2023 will aid interested parties through the transition. CMS also proposes to discontinue the use of the term skin substitutes beginning January 1, 2024, and to instead refer to this suite of products as "wound care management products."

The AADA appreciates CMS' efforts to improve and clarify policies and procedures as well as assign appropriate and consistent HCPCS codes to skin substitute products. However, the AADA does not support CMS' proposal to use a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal-based material, because the cost of the skin substitute products vary based on how the product is categorized. A single payment methodology will bring undue burden to healthcare providers who will have to obtain these products at different pricing levels to continue to provide excellent patient care. **The AADA also welcomes the proposed phased-in plan specifically for the improvement of policies and procedures and assignment of consistent single Alpha HCPCS code over the next 5 years.**

While the AADA recognizes and understands CMS' point that these products are not technically substituting for the patient's skin, but rather serving as a wound covering to promote healing, **the AADA has concerns that introducing a term that is entirely different from the terms used in CPT or ICD-10-PCS for the application of these products would just create further confusion rather than add clarity.** CPT uses the term "skin substitute" and ICD-10-PCS uses the term "tissue substitute." Also, CMS' proposed terminology could cause confusion with the CPT "active wound care management" codes that describe

non-excisional debridement. The term "wound care management" could in fact do the opposite and cause further confusion for coders, especially if skin substitute is still being documented by physicians.

The AADA does not support CMS' proposal to categorize skin substitute products as incident to supplies. As the cost of skin substitutes continues to increase, bundling payment for these products will pose a financial burden to dermatologists because practice expense does not increase at the same rate as the price increase for these products nor consider any variations in costs. In addition, separate HCPCS codes were created for the different and unique skin substitutes and that methodology requires that each of the skin substitute products are unique enough and have cost variations to warrant their own code. Maintaining separate reimbursement in the office for skin substitute products under the ASP+6% payment methodology helps alleviate the financial burden of acquiring the product for continued excellent patient care. **We also welcome future stakeholder engagement opportunities with CMS to provide additional input consistent with the perspectives and experiences of dermatologists.**

F. Proposals and Request for Information on Medicare Part A and Part B Payment for Dental Services

CMS is proposing to cover and reimburse for additional dental services, such as dental examination and treatment preceding an organ transplant. CMS seeks comments on other medical conditions where Medicare should pay for dental services—i.e., cancer treatment or joint replacement surgeries, as well as comments on when additional dental services may be integral to the clinical success of other medical services. AADA does not have a position on the inclusion of additional dental services covered under Medicare. However, AADA is concerned how additional covered services would impact the conversion factor because of statutorily prescribed budget neutrality rules. **Thus, AADA urges CMS to work with Congress on updating budget neutrality rules so that additional services would not negatively impact reimbursement for current-covered Medicare services.**

G. Rebasing and Revising the Medicare Economic Indicator

CMS proposes to update the MEI weights using 2017 data from the United States Census Bureau's Service Annual Survey (SAS). However, the Agency clarifies that they will not implement these new weights in 2023 as they must first seek additional comments due to significant redistribution. The current MEI weights are based on data obtained from the AMA's Physician Practice Information (PPI) Survey. This survey was last conducted in 2007/2008 and collected 2006 data.

AADA agrees with CMS that the 2006 data that is currently being used is significantly outdated, and we support rebasing and revising the MEI to reflect increases in practice costs due to inflation and other factors. However, AADA has concerns with CMS' proposal to use 2017 data from United States Census Bureau's SAS as this proposal would result in significant redistribution within physician payments and 2017 data does not accurately reflect current practice expenses.

As CMS is aware, AMA is conducting an updated PPI Survey. **We urge CMS to collaborate with the AMA on this new data collection effort to ensure consistency and reliability in physician payment. Updates to MEI weights should be postponed until new AMA survey data are available.** It is anticipated that the new data collection effort would begin in 2023 and be based on 2022 data.

H. Requirement for Electronic Prescribing for Controlled Substances for a Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD

In its 2022 Physician Fee Schedule (PFS) final rule, CMS established several Electronic Prescribing of Controlled Substances (EPCS) compliance policies, including but not limited to requiring prescribers to electronically prescribe annually at least 70 percent of their Medicare Part D controlled substances (i.e., Schedule II, III, IV & V). In the 2023 PFS proposed rule, CMS proposes several updates and revisions to their EPCS policies. Physicians prescribing fewer than 100 Part D prescriptions annually would be exempt from the EPCS compliance requirements. While proposing to implement this compliance program in 2023, CMS also proposes to delay enforcement from 2023 to 2024, which will consist of letters being sent to non-compliant physicians urging them to adopt and use EPCS to the following year (January 1, 2024 through December 31, 2024).

The AADA supports promoting the value and convenience of electronic prescribing of controlled substances and welcomes the delay in the proposed implementation of this program. However, we encourage CMS to approach compliance on a "carrot-vs-stick" approach, considering the ongoing pressures caused by the COVID-19 pandemic and its aftermath. When considering future enforcement action, the AADA cautions that increasing the severity in penalties for non-compliant prescribers may not necessarily produce desired policy objectives but rather results in unintended consequences in the wake of current daunting realities, including but not limited to physician burnout, small private practice recovery from the pandemic and access to patient care.[1]

I. Proposal to Revise HCPCS Level II Coding Procedures for Wound Care Management Products[2]

As CMS is aware, prior to 2021, all wound care management products were assigned a Q code and are paid based on average sales price (ASP) plus a statutorily mandated six percent add-on. As part of the application for HCPCS Level II code, CMS also required proof of how the product was regulated by the FDA as well as verification that the product was medical and legally on the market.

In this proposed rule, CMS is proposing to uniformly assign A codes to all new applications for all wound care management products including those that are not regulated by FDA as drugs or biological products for which HCPCS Level II is requested and would be eligible for separate payment. This will affect HCPCS Level II code requested for the first time as well as for wound care management products that were previously assigned a Q code. **The AADA supports the assignment of all codes with the same alpha characters for ease of identification.**

CMS proposes to discontinue the evaluation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) wound care management product HCPCS Level II coding applications on a quarterly basis beginning January 1, 2024, and to instead evaluate them through the biannual coding cycle for

[1] https://www.jaad.org/article/S0190-9622(21)00895-1/fulltext#relatedArticles Beyond burnout: Talking about physician suicide in dermatology Michelle S. Lee, BA, Vinod E. Nambudiri, MD, MBA Published: April 21, 2021DOI:https://doi.org/10.1016/j.jaad.2021.04.057.

[2] As stated in Section E of this comment letter, AADA opposes changing the term "skin substitute" to "wound care management products."

nondrugs and non-biological products. **The AADA supports the biannual review of the HCT/Ps to align new coding updates with other HCPCS Level II codes.**

CMS is also proposing to change the wound care management products that were previously assigned a Q code to an A code with eventual discontinuation of Q code use. All new wound care management applications will be assigned an A code, not a Q code. **The AADA support the change from Q codes to A codes for consistency of all wound care management codes and ease of identification.**

CMS is also proposing to require a HCPCS Level II re-application of previously approved Q codes that were described as 361 HCT/P within 12 months (effective date of the final rule on January 1, 2024) of code change from Q code to A code. **The AADA does not support the recommendation to re-apply for approval that was previously granted as Q-codes just to maintain the status of the A code change.** Code applications should be grandfathered into the process unless the applicant feels that there are major changes that may affect the wound care management product not previously identified or reviewed by the FDA.

Additionally, CMS is proposing to require a recommendation letter from the FDA's TRG to be submitted as part of the HCPCS Level II application for all wound care management products described by the applicant as a 361 HCT/P, regardless, if it is a first-time application or re-application for a product with an existing Q code. **The AADA does not support obtaining and submitting an FDA TRG recommendation letter for all wound care management products previously approved by the FDA as this will prove to be an additional burden for applicants to go through and may impact access to needed medical supplies for beneficiaries.** Affected products with an existing Q Code must be grandfathered into this new process. Requirement for FDA TRG recommendation letters can be considered as part of the new applications submitted after the Final rule implementation on January 1, 2024.

CMS does not propose resubmission of a HCPCS Level II coding application for HCT/P wound care management products whose applications already included a TRG recommendation letter from the FDA. **The AADA supports this as well.**

CMS proposes to take a similar approach for all new 361 HCT/Ps in which Q codes are issued before January 1, 2024. **The AADA supports a consistent policy approach.**

II. Updates to the Quality Payment Program

A. Traditional Merit-Based Incentive Payment System (MIPS)

1. Quality Performance Category

For 2023, CMS proposes to change the Dermatology Specialty Measure Set by adding three new measures, including two measures developed by the AAD. The measures are:

- Psoriasis – Improvement in Patient-Reported Itch Severity
- Dermatitis – Improvement in Patient-Reported Itch Severity
- Screening for Social Drivers of Health

We thank CMS for including the AAD measures, and we support the inclusion of the two AAD pruritus measures into MIPS and the Dermatology Specialty Measure Set.

CMS also proposes to remove QPP Measure 265: Biopsy Follow-up as a quality measure from MIPS because the measure has reached the end of the topped-out lifecycle. **The AADA does not support the removal of the QPP Measure 265. It is a high priority measure used in multiple specialty sets within the QPP program. QPP 265 should be kept for continued use in traditional MIPS and for future MVPs.**

CMS is proposing to remove the following two previously finalized quality measures from traditional MIPS due to the proposal of adding the Adult Immunization Status measure:

- Q110: Preventive Care and Screening: Influenza Immunization
- Q111: Pneumococcal Vaccination Status for Older Adults

The AADA does not support removing QPP Measure 110 and QPP Measure 111 as they are established measures that are not topped out. While there is value in the new measure, it should be rolled out in parallel with the old measures so that it can establish a benchmark.

More generally, we believe that CMS should not retire measures that are topped out, but more appropriately mandate that reporting clinicians may only report a measure for which their median performance is more than 95% for two consecutive reporting years. This would force MIPS participants with high performance in specific areas to move on to other areas which there is potential for improvement. Saving measures from becoming topped out is important because these measures are expensive to develop and test and are only topped out among the MIPS participants who report them, most probably, a small minority of participating clinicians. Limiting the reporting period for participants with high performance on a specific measure would allow other participants who have not focused on the topped-out measures to report them and improve in these areas and extend the useful life of previously topped-out measures. Because this may be logistically challenging to implement, and certainly should not be the responsibility of the registries, CMS may want to consider the overall rate of reporting the measure by MIPS participants. That is if only a small percentage of MIPS participants are reporting the measure there remains potential for the measure to inspire broader participation and hence improvement in care.

2. Improvement Activities Category

CMS proposes to update **IA_CC_13 Practice Improvements for Bilateral Exchange of Patient Information (Medium Weighted)** to require this use of OpenNotes to reduce clinician burden because OpenNotes focuses on principles that support direct access to medical records rather than utilizing a specific software. While AADA appreciates CMS' concern for physician burnout, we are concerned with this measure that not all dermatology practices use OpenNotes and many others likely have different platforms. **We urge CMS to revise the Improvement Activity to provide an alternative to OpenNotes software.**

As another means to reduce clinician burden, CMS proposes to consolidate several improvement activities related to participation in a QCDR into one single activity, IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements (Medium Weighted). Similarly, CMS proposes to consolidate IA_PSPA_20 into IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes. CMS reasons this consolidation will decrease physician burden. **The AADA once again thanks CMS for working towards alleviating clinician burden, and AADA supports the proposal to consolidate several similar improvement activities.**

3. *Promoting Interoperability Category*

With regards to proposed changes to the Promoting Interoperability (PI) Category, AADA is most concerned with CMS' Prescription Drug Monitoring Program (PDMP) proposals. Most concerning is the modification of the PDMP measure from optional to required. **The AADA opposes PDMP measure requirement for 2023 as it creates undue burden for eligible clinicians to track and report this additional measure.** However, should the measure become a requirement, AADA supports CMS offering the following two exclusions:

- any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; and
- any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

However, again, we urge CMS not to make this a requirement as even claiming the exemption is additional burden for eligible clinicians.

AADA supports CMS proposal to add "Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)" measure optional as an alternative measure in the Health Information Exchange (HIE) objective. **Adding the measure will allow physicians to have more opportunities to earn credit for the HIE objective while promoting health information exchange nationally.**

With respect to scoring of this performance category, the AADA supports the e-prescribing measure, however, we again re-state our opposition to making the PDMP measure a requirement and urge CMS to maintain the PDMP measure as optional. **Finally, the AADA supports maintaining the E-prescribing objective at 20 points for CY 2023. Additionally, AADA supports modification of scoring methodology for PI category and scoring methodology if exclusions are claimed.**

CMS proposes to consolidate the current options from three to two levels for active engagement for the Public Health and Clinical Data Exchange**. The AADA opposes this proposal requiring MIPS eligible clinicians to submit their level of active engagement for each measure reported. Given the public health emergency is still ongoing and that many practices/eligible clinicians have had to re-tool their practices just to function during this challenging time, there may still be a need to maintain the three options of engagement. We request CMS revisit this proposal after the public health**

emergency is over. Furthermore, CMS should not require the reporting of which level an eligible clinician is engaged in as this additional reporting requirement is also burdensome, especially during the PHE.

The AADA opposes CMS' proposal to discontinue the automatic reweighting for NPs, PAs, CRNAs, and CNSs. The AADA is concerned whether such mid-level providers can fulfill and successfully report all required PI objectives. Furthermore, if they cannot match the required objectives there is uncertainty if exclusions would become available, which the AADA would support.

Finally, the AADA supports CMS' future direction to "work with industry and other Federal partners to advance common standards for exchange of information between PDMPs, EHRs, pharmacy information systems, and exchange networks." AADA appreciates CMS seeking stakeholder input, and AADA and board-certified dermatologists welcome the opportunity to participate in such discussions.

4. *MIPS Scoring*

AADA thanks CMS for its proposal not to alter the performance category weights for 2023 and we support maintaining the minimum performance threshold at 75 points. The AADA is disappointed that the exceptional performance threshold has been removed for CY 2023 as required by statute, so physicians and other providers will not be able to receive bonus payments in CY 2025. AADA strongly urges CMS to work with Congress to extend these bonuses as they were incentives for enhanced participation and may have helped practices recoup productivity and administrative costs lost in implementing and reporting MIPS program requirements.

5. *Small Groups and Other Special Accommodations*

AADA appreciates CMS' efforts to support small/solo practices by reducing burdens and offering technical support, and we urge CMS to continue to offer flexibilities for small/solo eligible clinician offices. For example, in the CY 2022 PFS final rule, CMS finalized removing the 3-point floor for each measure that can be reliably scored against the benchmark and score the measure from 1 to 10 points starting with the CY 2023 MIPS payment year. **The AADA supports CMS continuing to offer the 3-point floor for small practices for reporting quality measures.**

For CY 2023 performance period, CMS proposes to give eligible clinicians the option to submit quality performance category data via Medicare Part B claims, direct and log in and upload submission types, and **the AADA supports the continued ability to report through administrative claims for small practices.**

Due to the on-going COVID-19 PHE, CMS has applied certain automatic extreme and uncontrollable circumstances exemptions nationwide which absolve MIPS eligible clinicians from participation in the program without penalty. **We encourage CMS to keep both the automatic and application-based (as appropriate) extreme and uncontrollable circumstances options available for eligible clinicians, especially small practices, and as it relates to COVID-19 as we are not out of the pandemic fully yet**

and even after the pandemic is declared over, there may be residual negative effects that practices may have to address for some time.

Additionally, as established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability, Quality, Cost, and/or Improvement Activities performance categories under specific circumstances.[3] **We support continuing to have automatic re-weighting of the PI category for small dermatology practices.**

6. *Digital Quality Measures (dQMs)*

In this proposed rule, CMS is further revising its potential future definition such that a dQM is a quality measure, organized as self-contained measure specification and code package, that uses one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. **AADA believes that this definition is unclear. More clarification is needed on how non-EHR data sources will be collected, and how will dermatology data standards be determined and added.**

7. *RFI – FHIR Based API Standards*

The RFI towards achieving data standardization and transformation seems good in theory but infrastructure readiness and implementation support are still a concern. Implementation may create a heavy burden for eligible clinicians that are not already technologically prepared and/or savvy. Technology-related shortcomings or glitches must also be carefully considered. It would be best to have a transition period where clinicians who are more ready could report with this framework and those that are not would still have traditional options available – especially since many efforts to modernize practices may have been derailed due to the pandemic.

Additionally, careful consideration should be given to which specific sources will be used to develop dQMs as not all sources may be equally reliable and there may be issues of interoperability, therefore each should be evaluated individually. We encourage CMS to continue to "collaborate with federal agencies to define and prioritize additional data standardization needs and develop consensus with federal partners on recommendations for future versions of the USCD and directly collaborate with ONC to build requirements to support data standardization and alignment with requirements for quality measurement."

We support CMS' plan to develop robust implementation guides to support the education and roll out of these future requirements. We support CMS' notion that "…prior to the implementation of any mandatory FHIR-based eCQM reporting requirements within our quality programs, it would be necessary to undertake voluntary reporting of FHIR-based eCQMs to allow time to learn and enhance systems and processes, both internally and among providers and vendors."

[3] 81 FR 77240 – 43; 82 FR 5368 – 86; 82 FR 53783 – 85.

8. Transforming MIPS: MVP Strategy

a. MVP Overview

As evidenced by the lengthy, detailed comments above on the various MIPS proposals, the program is burdensome, complicated, and not clinically relevant. CMS' response to the criticism of MIPS has been to develop MIPS Value Pathways (MVPs) with the aim of streamlining the accountability for cost, quality and the use of technology around clinical conditions or episodes of care. In the proposed rule, CMS continues to move forward with its plan and will make MVPs available for voluntary reporting beginning with the CY 2023 MIPS performance period and intends for MVPs to become the only method to participate in MIPS in future years. CMS also intends for MVPs to be a pathway to APM participation.

CMS asks several questions, including how to use MVPs to obtain more meaningful performance data, better align clinician experience with MVPs and APMs and ensure MVPs are a bridge to APMs, among others. **To that end, the AADA strongly recommends that the only way to drive "more meaningful" performance from specialties is to allow the specialty societies to create their own MVPs.** MVPs that are prescribed by CMS are not meaningful to the provider or the patient, nor do they drive "meaningful performance." **It is clear that specialty societies themselves must be empowered to produce their own MVPs with substantial latitude in size and scope of MVP focus, and we strongly urge CMS to heed this advice.**

Regarding the transition from MVP to APMs, both require quality measures and cost savings. However, we would need safeguards that the cost aspect of the MVP is fully vetted, tested and has consensus for many years (as an MVP) before it is transitioned into a APM risk model. Also, the penalty / bonus structure of MVPs must mirror the cost sharing of the APM--meaning that that the risk of the APM should not be magnitudes higher than the penalty was for the MVP. Additionally, the cost measures associated with MIPS are claims based, average measures of cost of an episode of care. A successful APM will require a more nuanced risk stratification that ensures that those physicians who treat the sickest and underserved patients are not disadvantaged.

As previously stated, AADA does not support the removal of the QPP Measure 265. It is a high priority measure, used in multiple specialty sets within the QPP program. QPP 265 MIPS should be kept for continued use in traditional MIPS and for future MVPS.

b. MVP Development

CMS is proposing to broaden the opportunities for the public to provide feedback on viable MVP candidates posting draft versions of MVP candidates on the QPP Website to solicit feedback for a 30-day period. CMS also states, if they determine changes should be made to the candidate MVP, CMS will not notify the interested parties who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process.

The AADA has significant concerns with these proposals as comments received during the public comment period and/or changes created to the submitted MVP would not be communicated to the group that submitted the MVP prior to rulemaking. Societies must at a minimum be notified if the

submitted MVP is changed and ideally be involved in the discussion and provided the rationale to change an MVP. No one knows the measures better than the specialty society, and often what may seem like a small change in the reporting criteria or diagnosis codes can lead to a significant change in the intent of the measures or MVP overall.

Additionally, allowing the specialty to develop the MVP will also allow them to facilitate incorporating how team-based care fits into the care plan. The unfortunate consequence of combining multiple clinicians into the same MVP will drive consolidation. Such a paradigm makes it impossible for solo and small private practices to survive. Consolidation in medicine eventually drives down competition and increases cost.

c. MVP Reporting Requirements

CMS expects QCDRs, qualified registries, and Health IT vendors who support MVPs to support all measures and activities across the Quality, Promoting Interoperability, and Improvement Activities performance categories that are included in the MVP. However, the major barrier for QCDRs to support all MVPs activities is lack of interoperability. CMS has had interoperability as a goal for years but has never held EMRs accountable. Most interoperability barriers exist because EMRs are unwilling to map data extraction to QCDRs.

QCDRs have the technical resources. It is the EMR refusal to map, or their lack of responsiveness to QCDR requests that is the barrier. EMRs should not be able to select which measures they will support within an MVP; they must be able to support all quality measures within an MVP that they have rights to use.

d. Subgroups

The AADA has concerns with CMS' subgroup reporting. Specifically, AADA has concerns that it is difficult to separate cost and attribute to a subgroup, which may impact the subgroup score. **CMS should clarify what happens if a subgroup isn't assigned a score, and whether that will harm the group overall. We urge CMS to reevaluate this proposal.**

9. Qualified Clinical Data Registries

CMS has confirmed to AADA that QCDR measures within an MVP cannot be used by other institutions or entities without consent from the stewarding organization. If permission is not authorized, they would have to use the MIPS only measures within an MVP. **The AADA agrees with this statement and urges CMS to be explicit within rulemaking as CMS evolves the program.**

Additionally, the AADA has several concerns with CMS proposal related to QCDR requirements. CMS is proposing adding a new measure for QCDRs on "Screening for Social Drivers of Health." While AADA recognizes the rationale for the measure, **we urge CMS to make measure specifications publicly available for review before such measure could be added to a specialty measure set. Registries need time to review the specifications and map the measure before implementation.**

CMS also proposes to remove the 3-point floor that was previously established for certain types of measures (measures with benchmark, measures without benchmark, measures that don't meet case minimum). However, CMS will not remove the 3-point floor for new measures or small practices. CMS

also proposes removal of measures after being topped out for 2 consecutive years. The AADA believes that these proposed changes provide an unfair impact to physicians and additional burdens. These scoring changes, combined with the reset of benchmarks for measures with substantive changes, make it extremely difficult for practices to meet the performance threshold and be successful in the program. Even if a practice's performance has remained steady or possibly even slightly improved, it is likely that their score would decrease over time. **The AADA recommends CMS to keep the 3-point floor for measures as such scoring changes cause an undue burden on physician practices.**

Finally, with regard to CMS proposal on third-party intermediaries, CMS needs to clarify that registries will not be responsible for reviewing or validating any data submitted via third-party intermediary. We also ask CMS to provide additional information on how it plans to operationalize proposals and whether data can be submitted piecemeal.

III. Conclusion

Thank you for the opportunity to provide comments to this proposed rule. Please contact Chad Appel, JD, AADA Director of Public Policy & Healthcare Economics at cappel@aad.org or 202-712-2614 if there are any questions about the recommendations in this letter. We appreciate the opportunity to work with CMS to improve the Medicare program.

Sincerely,

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