

September 8, 2023

Chiquita Brooks-LaSure, MPP Administrator Centers for Medicare & Medicaid Services Attention: 1784-P P.O. Box 8016 Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies;

and Basic Health Program (CMS-1784-P)

Dear Administrator Brooks-LaSure:

On behalf of the over 88,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2024 Medicare Physician Fee Schedule (MPFS) proposed rule published in the *Federal Register* on August 7, 2023.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large portion of our members' performance is measured and paid for under the provisions contained in this rule, the ACS has a vested interest in the MPFS and Quality Payment Program (QPP). With our more than 100-year history in developing policy recommendations to optimize the delivery of surgical services, lower costs, improve program integrity, and make the U.S. healthcare system more effective and accessible, we believe that we can offer insight to the Agency's proposed changes to the MPFS and QPP. Our comments below are presented in the order in which they appear in the rule.

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PROVISIONS OF THE PROPOSED RULE FOR THE PFS

Determination of Practice Expense (PE) Relative Value Units (RVUs)

Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)

The MEI, first implemented in 1975, has long served as a measure of practice cost inflation and a mechanism to determine the proportion of payments attributed to physician earnings and practice costs. The MEI measures changes in the prices of resources used in medical practices, such as labor (both physician and non-physician), office space, and supplies. These resources are grouped into cost categories, and each cost category is assigned a weight (indicating the relative importance of that category) and a price proxy (or proxies) that CMS uses to measure changes in the price of the resources over time. The MEI also includes an adjustment to account for improvements in the productivity of practices over time.

From 1975, when payments reflected the usual, customary, and reasonable charge payment methodology, through 1993, the year after implementation of the Resource Based Relative Value Scale (RBRVS), the physician earning component was 60 percent and the PE component, including professional liability insurance (PLI) costs, was 40 percent. These initial weights were derived from data obtained from the American Medical Association (AMA). In 1993, the MEI components were updated using AMA data and then proportioned to 54.2 percent physician work, 41 percent PE, and 4.8 percent PLI. Currently, the allocation is 50.9 percent physician work, 44.8 percent PE, and 4.3 percent PLI. In the CY 2023 PFS final rule, CMS finalized a policy to rebase and revise the MEI to reflect more current market conditions faced by physicians in furnishing services. As part of this policy, CMS sought to dramatically shift payment allocation away from physician earnings (work) to PE—47.3 percent physician work, 51.3 percent PE, and 1.4 percent PLI—using non-AMA data from 2017. The current MEI weights are based on data obtained from the AMA Physician Practice Information (PPI) survey. This survey was last conducted in 2007/2008 and collected 2006 data. Changes in MEI weights over time are shown in the table below.

MEI Components	1975-1992	1993	Pre-MEI Rebase	Post-MEI Rebase
Physician Work	60%	54.2%	50.9%	47.3%
Practice Expense	40%	41.0%	44.8%	51.3%
Professional Liability Insurance	(included w/ PE)	4.8%	4.3%	1.4%

Despite finalizing the rebasing and revising of the MEI last year, CMS delayed implementation of using 2017-based MEI cost weights for CY 2023, both in light of the AMA's new PPI data collection efforts and because the methodological and data source changes to the MEI would have significant impacts on

MPFS payments. Therefore, CMS again delays implementation and does not propose to incorporate the 2017-based MEI in MPFS rate setting for CY 2024.

The ACS acknowledges that the data currently utilized for the MEI are outdated, and we understand the need for consistent and timely updates to practice cost data. However, we are extremely concerned that CMS' proposal to update MEI weights under a budget neutral paradigm will create significant disruptions to physician payment, as such a drastic increase to the MEI PE component will in turn devalue physician work. We support the Agency's proposed delay to MEI updates for CY 2024 and believe such updates should continue to be postponed until data from the AMA's 2023 PPI survey are made available to CMS to inform MEI changes. In the future, all significant data updates (e.g., PPI survey results, supply and equipment pricing, and clinical labor pricing) should occur simultaneously and should be phased in to avoid abrupt impacts to individual services and specialties.

Valuation of Specific Codes

Ultrasonic Guidance, Intraoperative (CPT code 76998)

In 2018, the AMA RVS Update Committee (RUC) Relativity Assessment Workgroup (RAW) created a screen for CMS/other codes with Medicare utilization of 20,000 or more, and Current Procedural Terminology (CPT®) code 76998 was subsequently identified as part of that screen. During the RUC's review, CPT code 76998 was found to be billed by multiple specialties for procedures in which ultrasound use varied significantly. Intraoperative ultrasonic guidance may (1) be required for a portion of a procedure or the entire procedure, and (2) be performed by the operating physician or by a physician other than the operating physician. No dominant specialty was identified for CPT code 76998.

The work related to CPT code 76998 has been bundled over time into codes for certain procedures (e.g., varicose vein ablation, hemorrhoidectomy, catheter injection) because it was a typical or required service for the provision of such procedures. The RUC referred this issue to the CPT Editorial Panel to clarify correct coding and accurately differentiate physician work given that multiple specialties currently report CPT code 76998. After utilization was removed for vein ablation procedures, most urological procedures, cardiac procedures, and intra-abdominal procedures through instructions and/or new or revised codes, the Editorial Panel determined that the dominant use of CPT code 76998 would be related to breast surgery, allowing for to it be surveyed in 2022.

CMS disagrees with the RUC-recommended work RVUs of 1.20 for CPT code 76998 and instead proposes the total time ratio work RVU (wRVU) of 0.91, as shown in the following table.

CPT Code	Descriptor	Current wRVU	RUC- Recommended wRVU	CMS Proposed wRVU
76998	Ultrasonic guidance, intraoperative	1.20	1.20	0.91

CMS states that a work RVU of 0.91 for CPT code 76998 adequately values the surgeon's 5 minutes of preservice time, 12 minutes of intraservice time, and 5 minutes of postservice time when compared with the key reference CPT code 76641 (*Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete*), which has a work RVU of 0.73. We disagree with this comparison, as CPT code 76641 describes an ultrasound study that is typically performed by a technician in an office through intact skin and where the saved images are then reviewed and an interpretation report is generated by a radiologist at a later time—this is not urgent, high-intensity work.

For CPT code 76998, a surgeon uses an ultrasound probe directly in an open wound intraoperatively to scan for cancer at the margins of tumor resection and interprets the images in real time to help direct the limits of surgical excision of the mass. Images are saved and a postoperative report is generated by the surgeon for future reference to frozen section pathology information. Furthermore, CPT code 76641 represents a single ultrasound session, whereas CPT code 76998 includes multiple, separate ultrasound maneuvers that require a more intense, repeated, and immediate interpretation to identify tissue that may need to be excised during the same procedure with the intent of both (1) preventing a subsequent operation to remove additional tissue, and (2) limiting the amount of breast tissue removed during the initial operation. The associated urgency and high level of intraoperative interpretation is much greater than the type of imaging described by reference CPT code 76641.

The Agency proposes a lower work RVU to account for the 7-minute decrease in total time. However, the current time associated with CPT code 76998 was assigned by CMS and not reviewed during the Harvard study or by the RUC. The Agency has failed to provide information about how it assigned time to this code—if such time was based on relativity to other imaging services, we wish to highlight that CPT code 76998 is not a service performed by radiologists but instead has consistently been reported almost exclusively by surgeons, and therefore any relativity that was set in some fashion for "CMS Other" radiologist time-assigned codes is not appropriate. Finally, the RUC recommendation was not to maintain the current value, but to recommend a work RVU of 1.20 based on the survey data using magnitude estimation. Given this information, we request that CMS accept the RUC-recommended work RVU of 1.20 for CPT code 76998.

Services Addressing Health-Related Social Needs

In an effort to "identify gaps in appropriate coding and payment for care management/coordination and primary care services under the MPFS," CMS proposes to establish separate coding and payment for

community health integration (CHI) services, social determinants of health (SDOH) risk assessments, and principal illness navigation (PIN) services.

While the ACS recognizes the importance of addressing health-related social barriers to patient care, we believe that the G-codes proposed by CMS for CHI, SDOH, and PIN services may be duplicative of both work and PE already accounted for in existing CPT codes. CMS itself notes that payment for these activities is currently included in payment for other services such as evaluation and management (E/M) visits and care management services. Furthermore, the CPT Editorial Panel included, as an example of moderate level medical decision making (MDM) for E/M visit coding and level selection, a clinical scenario where diagnosis or treatment is significantly limited by SDOH. The CPT E/M Guidelines defined SDOH as "economic and social conditions that influence the health of people and communities. Examples may include food or housing insecurity"—CMS adopted these guidelines for MDM in E/M visits. As such, we do not believe that the Agency has made a clear justification for the necessity of a separate coding and payment paradigm for CHI, SDOH, and PIN services.

If CMS proceeds with implementation of these G-codes, we wish to highlight the following issues for consideration:

- CHI Services. CMS states that there is currently no separately enumerated statutory Medicare benefit category that provides direct payment to community health workers (CHWs) for their services. Additionally, the Agency believes current Healthcare Common Procedure Coding System (HCPCS) coding does not specifically identify services provided by CHWs, even though CHWs may facilitate access to care through community-based services. CMS thereby proposes to create two new G-codes describing CHI services performed by certified or trained auxiliary personnel, which may include a CHW, incident to professional services and under the general supervision of a billing practitioner. We disagree with this proposal for the following reasons:
 - CMS does not have the statutory authority to implement separate payment for CHW services as a new benefit category.
 - Each year, the federal government allocates funds to states to support social services for vulnerable children, adults, and families through the Social Services Block Grant (SSBG). In fiscal year 2022, SSBG allocations to states totaled more than \$1.7 billion. We believe that the proposed separate payment for CHI services will be duplicative of certain services already paid for by the SSBG. As such, if CHI services are implemented, a portion of the annual SSBG funding should be allocated to Medicare Part B to cover the costs of these services under the MPFS.
 - o There is extensive overlap of activities included in existing CPT codes for care management

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¹ P.L. 97-35

services and the proposed CHI activities—for example, both include managing care transitions; coordinating practitioner, home- and community-based care; and helping the patient access healthcare providers for clinical care. If the proposed G-codes codes are implemented, a new and duplicative layer of provider will be established: a physician/qualified healthcare professional (QHP) will communicate a CHI plan to clinical staff, who will communicate that plan to a CHW, followed by activities of the CHW communicated back to clinical staff and then back to the physician/QHP—this process creates an extremely inefficient feedback loop. The G-code descriptors that CMS proposes will allow a supervising physician/QHP to report both care management services and CHI services furnished by a CHW for the same services over a calendar month. This further highlights CMS' ill-advised creation of G-codes that do not have well-defined, exclusionary reporting guidelines and that further break up primary care patient care services into component coding minutiae that will not be auditable.

Communication about patients' health-related social needs primarily remains an issue not because of reimbursement but because of the many silos within the healthcare system. CMS' proposal would pay to develop another group of Medicare providers (i.e., CHWs) without a clear demonstration that these efforts will improve such communication or, ultimately, the care that patients receive. We recommend that the Agency first complete a more thorough assessment of how existing care management services may already incorporate work associated with community health integration. If CMS continues to believe that separate coding and payment for CHI services is necessary, we urge the Agency to seek authority and funding from Congress before establishing a new Medicare social services benefit category.

- SDOH Risk Assessments. CMS proposes that an SDOH risk assessment may occur every six months. While we believe that CMS has already accounted for SDOH risk assessment in the guidelines for MDM in E/M visits and therefore separate payments for such assessments is not necessary, if CMS were to move forward with policymaking for this service, it should instead be provided once per year as part of an annual Medicare wellness visit. Yearly SDOH risk assessments should be considered best practice but should not warrant additional coding and separate payment.
- PIN Services. CMS proposes that PIN services could be billed separately when certified or trained auxiliary personnel—under the direction of a billing practitioner—are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least three months. We acknowledge the great benefit that care navigators, peer specialists, and other personnel provide to critically ill patients, but we believe that CMS has failed to demonstrate that such services are not already included in the work or PE of existing care management codes.

Evaluation And Management (E/M) Visits

Office & Outpatient E/M Visit "Complexity" Add-on Code

The ACS has long expressed opposition to HCPCS code G2211 and its predecessor codes because this code will harm surgical practices and, in turn, surgical patients. G2211 was intended to make certain specialties whole when first proposed in 2018, but the policy basis for this code no longer exists because CMS did not move forward with the single payment rate for office/outpatient E/M levels 2 through 5. It is also no longer necessary given the many other codes that have been revised and/or newly established that provide additional validated resource-based reimbursement for ongoing patient care. **Therefore**, we strongly urge CMS not to implement G2211. If CMS does move forward with implementing G2211, we urge the Agency to make a lower utilization assumption for the first year to mitigate the budget neutrality impact and allow additional time for assessing the true utilization of G2211.

A summary of our views is as follows:

- There is no longer a valid justification for G2211 because under the new office or outpatient E/M coding structure, physicians and QHPs have the flexibility to bill a higher-level E/M code to account for increased MDM *or* total time of the encounter.
- Numerous reportable and resource-based validated codes are available for documenting work and time across various complexity levels and continuing care, making G2211 duplicative of work already represented by existing codes.
- If implemented, this code will inappropriately result in overpayments to those using it while at the same time penalizing all physicians due to a reduction in the Medicare conversion factor that will be required to maintain budget neutrality under the MPFS.
- Implementing G2211 is expected to introduce disruptions to the resource-based RVUs of E/M services under the MPFS.

RULEMAKING AND PUBLIC LAW HISTORY OF G2211

CY 2019 MPFS Proposed Rule

In 2018, CMS proposed to change the documentation requirements for office/outpatient E/M codes such that practitioners would have the choice to use either the 1995 E/M documentation guidelines, the 1997 E/M documentation guidelines, time, or MDM as described by the 2019 CPT code set to determine the E/M code level to report. In addition, providers would only need to meet documentation requirements associated with a level 2 visit for history, exam, and/or MDM (except when using time to document the service).

CMS Proposes a Single Payment for Office Visits

In alignment with these proposed documentation changes, CMS also proposed to develop a single

payment rate for office/outpatient E/M visit levels 2 through 5 for new patients (CPT codes 99202-99205) and a single payment rate for office/outpatient E/M visit levels 2 through 5 for established patients (CPT codes 99212-99215). Instead of creating a new HCPCS G-code related to the two new single payments, CMS proposed to maintain the 2019 CPT office/outpatient E/M code set and assign the same payment rate for each of the codes that were being collapsed into a single payment—specifically, a single payment for all codes 99202-99205 and a single payment for all codes 99212-99215, no matter what code was reported or how the code was documented. CMS stated that these single payment rates would eliminate the increasingly outdated distinction between the kinds of visits reflected in the 2019 CPT E/M code levels in both the coding and the associated documentation rules.

To set the single payment for each family of office/outpatient E/M codes, CMS used a weighted Medicare frequency calculation for both RVUs and time. This resulted in work RVUs that were slightly higher than the CY 2019 level 3 office/outpatient E/M visit for each family of codes, as shown in the following tables.

Preliminary Comparison of Work RVUs for Office Visits: New Patients		
CPT Code	CY 2019 Non-Facility Work RVUs	CY 2021 Proposed Non-Facility Work RVUs
99201	0.48	0.48
99202	0.93	
99203	1.43	1.90
99204	2.43	1.90
99205	3.17	

Preliminary Comparison of Work RVUs for Office Visits: Established Patients		
CPT Code	CY 2019 Non-Facility Work RVUs	CY 2021 Proposed Non-Facility Work RVUs
99211	0.18	0.18
99212	0.48	
99213	0.97	1.22
99214	1.50	1.22
99215	2.11	

In addition to these proposals, CMS stated that the typical office/outpatient E/M visits, as described in the 2019 CPT code set, did not appropriately reflect different resource costs associated with primary care E/M visits for continuous patient care, nor did they reflect the resource costs associated with certain types of specialist E/M visits, including those with inherent visit complexity. CMS indicated that rather

than maintaining distinctions in services and payments based on the 2019 E/M visit code descriptors, the Agency could better capture differential resource costs and minimize reporting and documentation burden with single payment rates and several corollary payment policies and rate-setting adjustments.

Two Add-on Codes Proposed to Ensure All Specialties Held Harmless from Cuts

In proposing a single payment rate for all levels 2 through 5 of office/outpatient E/M codes, CMS noted that the distribution of reported levels was not uniform across all providers and would result in payment cuts to a subset of providers—an unintended consequence of this proposal. To remedy this payment differential, CMS proposed two HCPCS add-on codes for certain providers in order to recognize the additional relative resources and inherent visit complexity typical of higher-level visits. These visits require additional work beyond that which is accounted for in the proposed single payment rates, which were only slightly greater than a level 3 visit. Most importantly, CMS stated that it believed that primary care and some specialist services frequently involve substantial non-face-to-face work. The Agency also believed no codes were available in the 2019 CPT E/M code set or the single payment rate to account for the extra non-face-to-face time.

CMS proposed HCPCS code GPC1X² to be billed with the office/outpatient E/M codes for the purposes of adjusting payment to account for additional costs incurred in the provision of E/M services beyond the typical resources involved, including non-face-to-face work and to account for additional resource costs above the proposed single payment rate for the levels 2 through 5 visits. In tandem with establishing GPC1X, CMS also proposed HCPCS code GCG0X³ to be reported by specialty providers for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches the Agency believed were generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding. CMS thought these two proposed add-on codes would help mitigate potential payment instability resulting from a single payment rate for office/outpatient E/M code levels 2 through 5 for providers who typically report level 4 and 5 E/M visit codes based on Medicare billing patterns. As shown in the table below, the proposed work RVUs for each new code were based on budget neutrality considerations in concert with the single payment rate for levels 2 through 5 office/outpatient E/M codes.

Preliminary Comparison of Work RVUs for Office Visit Add-On Codes		
CPT Code	CY 2019 Non-Facility Work RVUs	CY 2021 Non-Facility Work RVUs
GPC1X	0.00	0.07
GCG0X	0.00	0.25

² **GPC1X** Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)

³ GCG0X Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)

CY 2019 MPFS Final Rule

After consideration of the comments received on the proposed payment changes, CMS finalized for CY 2021 a revised single payment rate for office/outpatient E/M visits from one payment for levels 2 through 5 to one payment for levels 2 through 4. CMS also finalized for CY 2021 the two slightly revised add-on HCPCS codes GPC1X and GCG0X, along with a revised policy that these add-on codes may only be reported with levels 2 through 4 office/outpatient E/M visit codes. CMS repeated statements that the 2019 office/outpatient E/M codes did not allow for the additional resource complexities for providers who would typically report higher level codes and that the add-on codes would mitigate the consequences of a single payment rate. A comparison of the 2019 work RVUs and the finalized 2021 work RVUs is shown below.

Comparison of 2019 and 2021 Work RVUs for Office Visits: New Patients			
CPT Code	CY 2019 Non-Facility Work RVUs	CY 2021 Non-Facility Work RVUs	
99201	0.48	0.48	
99202	0.93		
99203	1.42	1.76	
99204	2.43		
99205	3.17	3.17	
GPC1X	0.00	0.25	
GCG0X	0.00	0.25	

Comparison of 2019 and 2021 Work RVUs for Office Visits: Established Patients			
CPT Code	CY 2019 Non-Facility Work RVUs	CY 2021 Non-Facility Work RVUs	
99211	0.18	0.18	
99212	0.48		
99213	0.97	1.18	
99214	1.50		
99215	2.11	2.11	
GPC1X	0.00	0.25	
GCG0X	0.00	0.25	

We remind the Agency that the data provided to CMS in May 2019 with the RUC-recommended work RVUs for office/outpatient E/M codes clearly showed that the median primary care survey estimated

work RVUs for 7 out of 9 CPT codes were less than the final RUC recommendations for the code set. Therefore, primary care providers (PCPs) are currently being paid more for office/outpatient E/M services than they estimated their work was worth, thereby negating the belief that the office/outpatient E/M code set does not account for additional PCP work.

CY 2020 MPFS Final Rule

In response to extensive changes to the office/outpatient E/M CPT code descriptors and reporting guidelines, CMS **rescinded** its policy to establish a single blended payment rate for levels 2 through 4 office/outpatient E/M visits in CY 2021 and instead **retained** the 5 levels of office/outpatient E/M codes (albeit 4 levels for new patients). CMS also finalized a new coding structure that: (1) requires a physical exam and history only when medically necessary and (2) allows code level selection using either MDM or total face-to-face and non-face-to-face time of both the physician and/or other QHP on the day of the encounter. In addition, the value of the revised CPT codes would include work performed three days prior to and seven days after the date of the encounter to allow for different practice patterns related to non-face-to-face work. The time period for this novel structure is difficult to audit given that it includes overlapping services with both physicians and QHPs.

CMS Doubles Down on Unnecessary Add-on Codes

Although the revised office/outpatient E/M codes retained multiple code levels (with separate values) and could be reported using MDM that reflected different levels of patient complexity or total face-to-face and non-face-to-face time by both physicians and QHPs, CMS still asserted that the code set did not appropriately reflect differences in resource costs between certain types of office visits and therefore maintained that an add-on code was needed to describe work associated with visits that are part of ongoing comprehensive primary care and/or visits that are part of ongoing care related to a patient's single serious or complex chronic condition. CMS finalized for CY 2021 deletion of code GCG0X and a revised code descriptor for code GPC1X.⁴ While the revised descriptor removed references to specialty type that had existed in prior iterations of the code, as part of the CY 2020 MPFS final rule's regulatory impact discussion, CMS communicated that it continued to base utilization assumptions for GPC1X on the specialties that it had previously listed as part of the code descriptor when the code was designed to address the payment cuts that would have resulted from collapsing the code levels. CMS stated:

[W]e assumed that the following specialties would bill HCPCS code GPC1X with 100 percent of their office/outpatient E/M visit codes: family practice, general practice, internal medicine, pediatrics, geriatrics, nurse practitioner, physician assistant, endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology,

⁴ **GPC1X** Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)

nephrology, infectious disease, psychiatry, and pulmonary disease. We want to underscore that this was an assumption regarding which specialties are likely to furnish the types of medical care services that serve as the continuing focal point for all needed health care services or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition and is not meant to be prescriptive as to which specialties may bill for this service. As stated earlier, there are no specialty restrictions for billing HCPCS code GPC1X.⁵

Overview of Policies Finalized in CY 2020 for CY 2021 for Office/Outpatient Visits

CMS finalized the new office/outpatient E/M codes 99202-99215 and RUC-recommended work RVUs, along with adopting (generally) the new CPT prefatory language and interpretive guidance framework. CMS disagreed with the new add-on CPT code 99417⁶ for prolonged office/outpatient E/M visits and instead finalized HCPCS add-on code G2212⁷, which differed from 99417 by defining the *minimum* time that must be met before reporting additional time for a prolonged visit rather than the *maximum* time. HCPCS add-on code G2212 allows reporting additional time only above the highest-level office/outpatient E/M codes (when code selection is based on time instead of MDM).

CMS finalized separate payment for HCPCS add-on code G2211 (previously referred to as GPC1X) for visit complexity inherent to an office/outpatient E/M associated with care management services that serve as the continuing focal point for all needed services and/or with services that are part of ongoing care related to a patient's single, serious condition, or a complex condition.

Medical Groups Oppose Add-on Code as Unnecessary

Despite much opposition to G2211 by multiple specialty societies and the AMA, CMS continued to assert that G2211 was needed because the typical office/outpatient visit described by (1) the revised and revalued office/outpatient E/M code set, (2) the new prolonged services add-on code G2212, and (3) the family of principle care/chronic care/complex care management services still did not adequately describe or reflect the resources associated with primary care and certain types of other specialty visits. At this point, in the regulatory text included in the *Federal Register*, CMS removed references to the specialties that had been listed in previous iterations of the add-on code. However, the Agency provided a Public Use File (PUF) with its utilization assumptions for G2211, listing the specialties that were

⁵ 84 Fed. Reg. 63157 (November 15, 2019).

⁶ **99417** Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time (List separately in addition to the code of the outpatient Evaluation and Management service)

⁷ **G2212** Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99205, 99215, 99483 for office or other outpatient evaluation and management services) (Do not report G2212 on the same date of service as 99358, 99359, 99416). (Do not report G2212 for any time unit less than 15 minutes)

impacted due to the *original* code level collapse proposal, which continued to serve as the basis of CMS' utilization assumptions.⁸

Public Law Moratorium on Payment of G2211

Following the publication of the CY 2020 MPFS final rule, Congress took note of the significant payment cuts resulting from this new coding scheme for many medical specialties. For surgical specialties, this cut was approximately 3 percent. Concerned about the problematic impact of this policy, Congress included the following language in Section 113 of the *Consolidated Appropriations Act* (CAA), 2021:

The Secretary of Health and Human Services may not, prior to January 1, 2024, make payment under the fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for services described by Healthcare Common Procedure Coding System (HCPCS) code G2211 (or any successor or substantially similar code), as described in section II.F. of the final rule filed by the Secretary with the Office of the Federal Register for public inspection on December 2, 2020...⁹

CY 2023 MPFS Final Rule

CMS noted that HCPCS add-on code G2211 was finalized in the CY 2021 MPFS as a corollary to payment for the revised office/outpatient E/M code set. However, Section 113 of the *CAA*, 2021 delayed Medicare payment for G2211 until "at least" January 1, 2024. CMS adopted the RUC-recommended values for other non-office/outpatient E/M visits effective for CY 2023. However, the Agency still did not believe that the current visit payment structure among and between care settings fully accounts for the complexity of certain kinds of visits, especially for those in the office setting, nor do they fully reflect appropriate relative values since separate payment is not yet made for G2211. No other references to G2211 were made in this final rule.

CY 2024 MPFS Proposed Rule

CMS proposes implementing HCPCS add-on code G2211 for separate payment for office/outpatient E/M visits starting January 1, 2024. CMS reiterated that, to the extent that the Agency adopted the RUC-recommended relative values for E/M visits beginning in CY 2023, CMS does not believe that the RUC-recommended relative values for E/M visits fully reflected appropriate relative values given that separate payment was not yet made for G2211. CMS refined the G2211 policy in two ways: (1) CMS proposes that G2211 will not be payable when the office/outpatient E/M visit is reported with payment modifier -25 (Significant, separately identifiable evaluation and management service by the same

⁹ Consolidated Appropriations Act, 1 U.S.C. § 113 (2021).

⁸ Centers for Medicare & Medicaid Services. CY 2020 PFS Final Rule Utilization Estimates for EM Add-on Code. 2020. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-EM-Add-on-Code.zip.

physician or other qualified health care professional on the same day of the procedure or other service); and (2) CMS revised its utilization assumption of G2211 to be billed with 38 percent of all office/outpatient E/M visits initially and billed with 54 percent of all office/outpatient E/M visits when fully adopted after several years.

We analyzed the impact of implementing G2211 on general surgery. Based on our calculations, if CMS' utilization assumption for CY 2024 of 38 percent utilization of G2211 is correct, general surgery will experience a 1.4 percent cut in CY 2024 due to G2211 alone. If CMS' utilization assumption for CY 2025 of 54 percent is correct, general surgery will experience a 2.1 percent cut due to G2211 alone. These cuts are in addition to the 1.25 percent cut due to the reduction of the initial 2.5 percent increase provided in the CY 2023 PFS by the *CAA*, 2023. CMS states that approximately 90 percent of the budget neutrality adjustment in the CY 2024 MPFS proposed rule is attributable to the implementation of G2211, with all other proposed valuation changes making up the other 10 percent. If CMS does not implement G2211, general surgery will experience a 0.2 percent cut in addition to the 1.25 percent cut due to the reduction of the initial 2.5 percent increase provided in the CY 2023 PFS by the *CAA*, 2023. Therefore, a significant amount of the cuts to general surgery for this year and next could be avoided by CMS not implementing G2211.

We urge CMS to provide information about how the Agency calculated the revised utilization assumptions of 38 and 54 percent of all office/outpatient E/M visits. Our analysis indicates CMS assumed 50 percent utilization of G2211 with all office visit claims that do not include a modifier. This 50 percent assumption results in a 38 percent overall utilization of all office/outpatient E/M claims, with and without modifiers, that was stated in this proposed rule for CY 2024. Similarly, using a 70 percent G2211 utilization assumption for all E/M claims without a modifier results in the 54 percent utilization for all office/outpatient E/Ms that was indicated in this proposed rule for CY 2025. We request that CMS confirm this calculation or, if this was not the approach used, provide information on the calculation of the revised utilization assumptions.

No matter the approach used, CMS' utilization assumption PUF clearly attributes utilization to certain specialties to which CMS previously attributed no utilization at all. CMS has done this without explanation and seemingly without regard for the fact that the use of the code is now more restrictive because of the proposed policy that G2211 cannot be used when an office/outpatient E/M is billed with modifier -25. We are extremely concerned that these dramatic shifts in utilization assumptions call into question the accuracy and fairness of the information provided. We question whether the true utilization of G2211 will be markedly lower than CMS' assumptions and therefore inappropriately cut the conversation factor for all specialties.

In addition, in the proposed rule, CMS stated that while the Agency adopted the RUC recommendations for the revised office/outpatient E/M visit codes, those values did not fully account for the resource costs associated with primary care and other longitudinal care of complex patients. CMS made this statement

as a justification for G2211. We request clarification on why the Agency adopted the RUC recommendations for the office/outpatient E/M visit codes if it did not believe they were accurate.

CMS SHOULD NOT IMPLEMENT G2211 BECAUSE IT IS UNJUSTIFIED, DUPLICATIVE, AND NOT RESOURCE-BASED

G2211 is No Longer Justified

We maintain our opposition to the implementation of G2211 and emphasize that there is no longer a valid justification for its existence. The original rationale for the add-on code was based on CMS' policy for a single payment rate for office/outpatient E/M visit levels 2 through 5, which has since been rescinded. CMS argued that primary care and certain specialty services often involve significant non-face-to-face work, and there were no coding options in the 2019 CPT E/M code set or the single payment rate to account for this additional non-face-to-face time and work—this is no longer true. Additionally, CMS believed that the proposed G2211 add-on code would address potential payment instability resulting from the adoption of a single payment rate for office/outpatient E/M code levels 2 through 5—particularly for providers who typically billed level 4 or level 5 E/M visit codes based on Medicare billing patterns. This is also no longer true because there is no payment instability within the new E/M visit code set.

The current code set no longer supports the justification for G2211, as CMS has retained the various office/outpatient E/M levels and accepted the revised coding structure that incorporates both face-to-face and non-face-to-face work and time of physicians and/or QHPs. This revised structure now includes work and time for three days prior to and seven days after the encounter date. Consequently, payment for HCPCS code G2211 is not justified because, under the new coding structure, physicians and QHPs have the flexibility to bill a higher-level E/M code to account for increased patient complexity or a higher-level code based on total time, which includes non-face-to-face time, even if the encounter itself was not complex.

G2211 is Duplicative of Separately Reportable Work and Results in "Double-Dipping"

CMS maintains that the payment for add-on code G2211 is necessary because the Agency believes the revised office/outpatient E/M visit code set fails to adequately describe or encompass the resources involved in primary care and certain specialty visits for ongoing care management of patients with chronic conditions. However, CMS has not provided details regarding the specific resources required. For instance, it remains unclear what additional resources beyond the 10 days of time and work already accounted for are typically involved and not covered by the revised office/outpatient E/M codes, other non-face-to-face care management codes, and/or other digital medicine codes. Any additional resources, if required, are already reportable using other newly developed codes for ongoing care as an added payment to a single office visit, making payment for G2211 duplicative. Examples of such codes are described below.

- Principal Care Management (PCM) (99424–99427). In the CY 2022 MPFS, CMS adopted new CPT codes for PCM services, which describe ongoing care management services for one single chronic condition. CMS stated that—especially for specialties that use office/outpatient E/Ms to report most of their services—there could be significant resources involved in ongoing care management for a single high-risk disease or complex condition that was otherwise not well accounted for in existing codes.
- Chronic Care Management (CCM) (99490, 99491, 99437, and 99439). In the CY 2022 MPFS, CMS also adopted new CPT codes for CCM, which describe ongoing care management services for two or more chronic conditions. CMS stated that physicians and nonphysician practitioners who furnish ongoing care to patients with multiple chronic conditions require greater resources than those needed to support patient care in a typical E/M service.
- Complex Care Management (Complex CCM) (99487–99489). The Complex CCM CPT codes were adopted in the CY 2017 MPFS and are similar to the CCM codes but are also separately reportable for ongoing non-face-to-face patient care.
- Transitional Care Management (TCM) (99495–99496). The TCM CPT codes were adopted in the CY 2012 MPFS and provide additional reimbursement for care management and care coordination services beginning when a physician discharges a Medicare beneficiary from an inpatient stay and continuing for the following 29 days.
- Prolonged Services Code (99417). In the CY 2020 MPFS, CMS adopted a new CPT add-on code for 15 minutes of prolonged office/outpatient E/M services that require additional time beyond the maximum time for the highest-level codes. The AMA's CPT/RUC Workgroup on E/M specifically included this add-on code to account for more time and resources in response to the earlier CMS proposals.
- *Remote Physiologic Monitoring (99457–99458).* CMS adopted new CPT codes in the CYs 2019 and 2020 MPFS to account and pay for additional non-face-to-face time and PE resources related to ongoing patient care management of a chronic condition.
- *Remote Therapeutic Monitoring (RTM) (98975, 98976, 98977).* In the CY 2022 MPFS, CMS adopted RTM CPT codes for managing patients who use medical devices to collect non-physiological data such as medication adherence, medication response, and pain levels.

It is important to reemphasize that numerous reportable and resource-based validated component codes are available for documenting work and time across various complexity levels and continuing care, making the arbitrary, poorly defined add-on code G2211 duplicative of work already represented by existing codes. If implemented, this code will inappropriately result in overpayment to those using it while at the same time penalizing all physicians with the reduced conversion factor required to maintain budget neutrality.

G2211 is Not Resource-Based

CMS has faced challenges in providing a clear and validated description of the additional resources associated with G2211. The assignment of work RVUs and time to the code was confusing and primarily driven by considerations of budget neutrality and the mitigation of potential payment instability for particular physicians resulting from adopting a single payment rate for office/outpatient E/M visit levels 2 through 5. In other words, the resources allocated to G2211 were primarily based on redistributing available work RVUs due to changes in documentation and payment policies rather than being firmly grounded in resource-based criteria. Given that the proposal to collapse E/M visit levels 2 through 5 into a single payment was rescinded and the new office/outpatient E/M structure based on MDM (complexity) or time was accepted, it can no longer be asserted that code G2211 describes any additional and unaccounted for resources.

If the resources that CMS may be contemplating were for extraordinary circumstances, the chronic/complex care management codes for longitudinal patient-centered care would be appropriate instead of G2211. At the other extreme, it is difficult to justify adding G2211 to a level 2 E/M visit involving a patient with a self-limited or minor problem, minimal or no need for data to be reviewed, and/or minimal risk of morbidity because this visit would <u>not</u> require additional resources to integrate the treatment/management of the illness or injury or to coordinate specialty care in a longitudinal care model. The other visits in between the complex and minor cases would be covered by the current office/outpatient E/M coding structure or other newly available codes and not require add-on code G2211. This argument is even more compelling when code level selection is based on time because if additional time is needed, a higher-level code could be reported even if the visit was not complex. Furthermore, there is no limit when reporting E/M visits using time because the prolonged services add-on code G2212 (or CPT code 99417) may be billed for each additional 15 minutes required. **Therefore, time can never be considered a resource cost for G2211.**

CONSEQUENCES OF IMPLEMENTING G2211

There are significant consequences for physician practices if G2211 is implemented. For example:

• Implementing G2211 is expected to result in payment reductions for many physicians due to its expected impact on the Medicare conversion factor. In the CY 2024 MPFS proposed rule, CMS somewhat mitigated the cut's impact on the conversion factor by estimating lower utilization assumptions for implementing G2211 for CY 2024. However, CMS also states in the rule that approximately 90 percent of the budget neutrality adjustment for CY 2024 is attributable to G2211, with all other proposed valuation changes making up the other 10 percent. ¹⁰ This reduction would still create concerning implications for physician practices and their ability to provide patient care services, especially in today's high inflationary period. This could particularly affect physicians, including primary care physicians, practicing in rural and underserved areas who perform minor

^{10 88} Fed. Reg. 52262 (August 7, 2023).

procedures and other services, such as imaging, that will see reductions in reimbursement to pay for G2211.

• G2211 will increase beneficiary out-of-pocket spending. To calculate the budget neutrality adjustment, CMS estimates that G2211 will be billed with 38 percent of all office and outpatient E/M visits in CY 2024. According to the PUF provided by CMS, this would result in G2211 being billed 83,353,045 times. If CMS utilization assumptions are correct, in CY 2024, patients will spend approximately \$270 million in coinsurance for G2211, but net beneficiary out-of-pocket spending relative to G2211 will likely remain unchanged because of budget neutrality adjustment to the conversion factor. That is, for every extra beneficiary coinsurance dollar spent that is attributable to G2211, the cost will be offset by reduced liability for every other service billed in the MPFS because of the budget neutrality adjustment.

However, CMS states that utilization of G2211 will increase to be billed with 54 percent of all office and outpatient E/M visits in CY 2025. That represents an at least 42.1 percent increase, not accounting for general utilization growth in the number of office and outpatient E/Ms billed. Assuming all other factors are held equal, this results in total beneficiary coinsurance payments for G2211 in CY 2025 of over \$380 million, but there will be no offset for that increased patient liability. As a result, the Agency will increase beneficiary copays by over \$100 million in CY 2025 as a result of G2211.

- **G2211 will be confusing to beneficiaries.** When a beneficiary receives their explanation of benefits (EOBs) for services, they will see an extra co-pay if G2211 were billed. A provider could be asked to explain to a patient that they are billing an E/M service simply for ongoing care. But because this code does not have restrictions for reporting, a provider can add the code at will, even if the provider only sees a patient once per year. Therefore, explaining the need for G2211 could be confusing to a beneficiary given that G2211 does not reflect additional work.
- Implementing G2211 is also expected to introduce disruptions to the resource-based RVUs of E/M services. Implementing G2211 would lead to varying payments for E/M services based on the specialty of the provider delivering the service, as CMS has made assumptions regarding which providers will likely report this non-resource-based code at the expected billing rate. Consequently, CMS would establish a payment policy that rewards certain providers with higher compensation for the same level of work, creating an unfunded bonus without a specific validated resource that can be clearly defined or audited. In contrast, all other codes within the MPFS have a well-defined and validated work definition, allowing for audit. Unfortunately, code G2211 fails to meet these criteria, and approving payment for this code would disrupt the relative resource-based RVUs of E/M services and the integrity of the entire MPFS. Per Medicare statute, CMS is prohibited from paying

^{11 88} Fed. Reg. 52353 (August 7, 2023).

¹² Centers for Medicare & Medicaid Services. CY 2024 PFS Proposed Rule 2022 Utilization Data Crosswalked to 2024. 2023.

https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-p.

¹³ 88 Fed. Reg. 52354 (August 7, 2023).

physicians differently for the same work, and the "Secretary may not vary the . . . number of relative value units for a physician's service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."¹⁴

Given these serious concerns, we strongly urge CMS not to implement G2211. The policy basis for this code no longer exists. It is disingenuous for CMS to continue to put forth unconvincing rationales in its rulemaking over the years to account for why G2211—a code that is not resource-based, is not validated, and is duplicative of other services—should be implemented. G2211 was a stop-gap measure to make certain specialties whole when first proposed in 2018. It is no longer justified given the many other codes that have been revised and/or newly established that provide additional validated resource-based reimbursement for ongoing patient care. The consequences of implementing this code are grim—many physician practices would be harmed, thereby serving as a potential detriment to their ability to deliver timely, affordable, high-quality care to their patients. If CMS does move forward with implementing G2211, we urge the Agency to make a lower utilization assumption for the first year to mitigate the budget neutrality impact and allow additional time for assessing the true utilization of G2211. We are concerned that CMS' utilization assumptions are too high and therefore inappropriately cut the conversation factor for all specialties.

Evaluating E/M Services "More Regularly and Comprehensively"

CMS asks the below series of questions about the process used to define and value physician services.

1. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?

The current E/M codes accurately define the full range of E/M services as they exist today. The recent extensive revisions of the E/M services specifically addressed appropriate gradations by allowing for reporting by MDM (straightforward, low, moderate, and high) or total time on the date of the encounter.

However, we are concerned that CMS continues to add new codes that in turn create an unbundled component coding system due to the significant overlap of codes billable for the evaluation and management of Medicare beneficiaries. For example, we believe that the annual Medicare wellness visit (HCPCS code G0439) should have been a "comprehensive" yearly preventative service—however, many other E/M services (e.g., CPT 99497 (advanced care planning); CPT 99213-99215 (office visit); HCPCS G0444 (depression screening); CPT 93000 (electrocardiogram)) are routinely reported on the same date by the same provider. 2021 Medicare utilization data show that code G0439 is reported alone only 33 percent of the time and is reported

¹⁴ Medicare Physician Fee Schedule, 42 U.S. Code §1395w-4(c)(6) (2022).

with an office visit code 50 percent of the time, underscoring the fact that the appropriate services are not bundled into the annual Medicare wellness visit.

The "Evaluation and Management" section of the 2023 CPT codebook includes 156 codes in the range of 99202 through 99499. Prolonged services codes, non-face-to-face services codes, clinical staff services codes, screening codes, care management codes, and HCPCS Category II codes are all reported for the evaluation and management of a patient. This vast number of codes allows for reporting of many nuanced interactions with a patient both on the day of encounter and between encounters but also results in overlap of codes for E/M services. We believe that E/M and care management services have sufficient gradation of intensity of work but do not comprehensively define typical work. This results in duplicative payment for the same work that remains unaudited by CMS.

2. Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?

The methods used by the RUC are appropriate to develop relative value recommendations for E/M and other HCPCS codes. The RUC has developed numerous policies to improve relativity and ensure consistency—for example, standard packages for preservice time, postservice time, direct PE input benchmarks, and preservice clinical staff time packages have been implemented, allowing for enhanced relativity and comparison across all services.

More than 100 national medical specialty societies participate in the RUC process. These groups devote significant resources to administer provider surveys for codes under review. The recent RUC office/outpatient E/M survey, which was a concerted effort of 51 specialty societies representing 95 percent of Medicare claims for E/M office visits, received 1,700 complete responses from providers. The RUC has conducted a comprehensive review of E/M codes several times since its inception and has proven its ability to refine the values of these and other HCPCS services over time. However, in contrast to the RUC—which bases its process on statistics—we believe that the methods used by CMS to assign values to E/M and other HCPCS codes, especially G-codes, are opaque and not scientifically sound. The Agency's failure to utilize transparent, well-defined mechanisms to determine such values undermines the relative nature of the MPFS and is the antithesis of the clearly defined RUC review process.

One methodological improvement that CMS should consider is to restore the Refinement Panel process that was first implemented in 1994. This multispecialty panel of physicians served to assist CMS in reviewing comments from stakeholders who disagreed with work RVUs proposed by the Agency for a given code. The intent of the panel process was to capture each participant's independent judgment based on their clinical experience and the evidence presented. Following each discussion, panel participants rated the work for the procedure or service in question. Ratings were individual and confidential, and there was no attempt to achieve consensus among the panel

members. The Agency's decision to convene multispecialty panels of physicians and to apply statistical tests to their ratings reflected the need to balance the interests of those who commented on proposed work RVUs against the redistributive effects that would occur in other specialties, particularly the potential adverse effect on primary care services. ¹⁵ In 2011, CMS modified this process and began to independently review every Refinement Panel decision, resulting in the rejection of over 60 percent of the panel's recommendations. In the CY 2016 MPFS, the Agency permanently eliminated the Refinement Panel process. The AMA, ACS, and over 90 other specialty societies opposed CMS' decision and requested the restoration of the Refinement Panel. We again urge CMS to reinstate the Refinement Panel, which would provide an opportunity for stakeholders to present all available data on services under review during rulemaking to a formal panel of objective experts as a form of appeal to CMS' proposed values.

3. Are the current Non-E/M HCPCS codes accurately defined?

Descriptors for HCPCS I CPT procedure codes are defined to reflect how a given procedure is currently furnished—if and when the provision of the procedure changes, the related CPT codes are reviewed for revision or deletion by the CPT Editorial Panel. Through the CPT process, not only are HCPCS I CPT codes generated and accurately defined, but reporting guidelines and instructional parentheticals are also established to ensure proper usage and reporting of such codes.

Descriptors for HCPCS II codes, which are generally used to report services and supplies not included in the CPT code set, are developed by CMS through an application process twice per year or by fiat (e.g., C-codes and G-codes) for a perceived immediate need. **HCPCS II codes are often ill-defined because the Agency does not differentiate them from existing HCPCS I CPT codes.** For example, although new CPT codes were created for 2015 to report high resolution anoscopy, the Agency established similar HCPCS II codes for one year as a result of the ongoing review of the gastrointestinal endoscopy codes set. However, CMS did not use the CPT code descriptor for these temporary G-codes, which caused reporting confusion.

4. Are the methods used by the RUC and CMS appropriate to accurately value the non-E/M codes?

The RUC and CMS do not use the same methods to value non-E/M codes. The RUC's process is based on the original process developed by Harvard for implementation of a resource-based relative value scale. The process used by CMS is typically a calculation made by a non-practitioner using math without physician validation. One glaring example of CMS inaccurately valuing non-E/M codes is its failure to incorporate the RUC-recommended work and time incremental increases for the revised office/outpatient visit E/M codes into global codes. While CMS did finalize adjustments for other bundled services, such as maternity codes, in the CY 2021 MPFS, the house of medicine has been united in its recommendations that CMS incorporate the incremental revised

¹⁵ Medicare Program; Physician Fee Schedule for Calendar Year 1995; Payment Policies and Relative Value Unit Adjustments; Final Rule. BPD-789-FC

office/outpatient E/M values into all of the 10- and 90-day global surgical package codes, as evidenced by the numerous comment letters and meetings the ACS and many other specialty societies have had with CMS over the past several years. As we have consistently held, it has been the Agency's policy to make these changes to the globals. We implore CMS to follow its own precedent and correct this issue.

In addition, we believe the Agency has wasted tens of millions of dollars on contracts with companies to develop new ways to assign values for physician work using unvalidated data and algorithms to then extend such assumptions to all codes. In each instance, the resulting recommendations lacked face validity.

5. What are the consequences if services described by HCPCS codes are not accurately defined?

CPT codes were initially created to facilitate communication among healthcare providers regarding procedures and services. Over the years, the CPT coding process has evolved to incorporate numerous guidelines and explanatory notes to enhance the precision of each code's definition. In contrast to HCPCS II codes, including G-codes introduced by CMS, that lack consistent guidelines, the CPT codebook serves as a comprehensive and all-encompassing reference. For instance, efforts to make annual subjective changes to codes like G2211, along with endeavors to define/redefine related services, have proven to be extremely difficult to understand since such codes were not based on any level of evidence and do not accurately represent relative physician work. In many instances, G-codes developed by CMS are not urgently needed and could have instead been proposed via a recommendation or application for CPT codes. If the need is indeed urgent, the CPT process has shown that it can meet the challenge to rapidly create a CPT code (e.g., COVID-19 vaccine and administration codes).

It is imperative that physicians have one set of clearly defined codes and guidelines to accurately report the services they furnish. If separate HCPCS level II codes are created that are not accurately defined and do not align with the CPT code set, improper reporting of such services to Medicare and other payers could occur. For these reasons, code descriptors should be properly vetted via an established, consistent process to ensure accurate reporting. It is critical to ensure consistency and the validity of expertly defined codes by aligning CMS coding requirements with CPT coding requirements.

6. What are the consequences if services described by HCPCS codes are not accurately valued?

The intent of the RBRVS is to ensure that the payment rate for one service is relative to the payment rate of another when accounting for the resources consumed in the provision of that service. The RUC, in coordination with specialty societies, recommends values for codes based on a relative value scale. However, in some areas, there may be services described by multiple overlapping codes to the extent that the ability to delineate the actual service is blurred. This enables providers to bill

two different codes for a single service, which in turn would provide overpayments if not properly audited. We urge the Agency to research and audit utilization of the over 150 CPT codes and G-codes for reporting unbundled, finite pieces of E/M services. By not accurately valuing a complete E/M service (i.e., eliminating unbundled, finite services), there is a potential for overpayment that may result in fraud, waste, and abuse under the Medicare program.

7. Should CMS consider valuation changes to other codes like the approach in section II.J.5. (Advancing Access to Behavioral Health) of this rule?

CMS should not consider valuation changes like the approach in section II.J.5. of this proposed rule. The calculation proposed for the increase in the behavioral health services is not resource-based and has the potential to distort the RBRVS. The statute that created the RBRVS requires that relative values are based on resource costs. ¹⁶ It is understandable that policymakers wish to improve access to behavioral healthcare—however, distorting relativity within the RBRVS to do so is not appropriate. CMS should not use arbitrary calculations to adjust specific services performed by one specialty to tackle issues outside of the scope of the RBRVS payment system. Access and shortage issues should be addressed through legislative solutions and funded by Congress.

8. We are particularly interested in ways that CMS could potentially improve processes and methodologies, and we request that commenters provide specific recommendations on ways that we can improve data collection and to make better evidence-based and more accurate payments for E/M and other services.

We believe that payments for E/M and other services are inaccurate in part due to a lack of inflation adjustments to RVUs since the inception of the MPFS in 1992. The RUC is capable of recommending relative work RVUs and direct PE details, but because adjustments for inflation have not been applied to such services via statute, CMS cannot pay providers at the appropriate rate for the work and PE measured. One example of current inaccurate payments can be seen in the methodology for calculating PE RVUs where a direct scaling adjustment is applied to ensure that the aggregate pool of direct PE costs derived in Step 3 of the calculation does not vary from the aggregate pool of direct PE costs for the current year. The current scaling factor is 0.4639, which translates to paying 46 percent of actual direct PE for every service. No other areas in government, including payments to hospitals and payments to Medicare Advantage Organizations (MAOs), have been held hostage to an annual change cap for more than 30 years. To make more accurate, evidence-based payment for E/M and other services, Congress must take action to adjust the factors that impact reimbursement rates under the MPFS, and we urge the Agency to recognize the need for and support such actions.

¹⁶ Omnibus Budget Reconciliation Act of 1989, Public-Law 101-239, section 6102

To improve data collection, we encourage CMS to consider examining electronic health record (EHR) data as a credible source for provider work, not only for global codes, but also for services provided by PCPs over a 30-to-90-day period to ensure there is no overlap in work. Services reported over the 10-day global period for E/M office visits should also be reviewed for duplicative work. In addition, because many services can be reported using time, a time modifier could enhance the ability for EHR and other program integrity audits to identify overlapping services provided in person or via telehealth.

- 9. We are particularly interested in recommendations on ways that we can make more timely improvements to our methodologies to reflect changes in the Medicare population, treatment guidelines and new technologies that represent standards of care.
 - Changes to treatment guidelines and technologies typically lead to the deletion or revision of existing CPT codes and/or the creation of new CPT codes. This has been very evident in recent years, as a significant percentage of new CPT codes have been related to new technology, and annual review of low utilization codes results in the deletion of codes in circumstances where standards of care have changed. The CPT process is rigorous in its adherence to level of evidence requirements and is nimble when necessary to create urgently-needed coding solutions (e.g., COVID-19 vaccine codes). However, due to lack of transparency, we do not know what methodologies CMS employs for us to be able to provide recommendations on more timely improvements for HCPCS G-codes. From our perspective, the Agency often reacts to stakeholder requests by creating G-codes—sometimes for services that don't need to be urgently reportable—and often bases them on new technology that has not reached a sufficient level of evidence for support.
- 10. We are also interested in recommendations that would ensure that data collection from, and documentation requirements for, physician practices are as least burdensome as possible while also maintaining strong program integrity requirements.
 - The ACS supports efforts to address the significant administrative burden that affects physicians and their practices. Physicians and other healthcare professionals have limited time and other resources to participate in data collection efforts—as such, engagement of national specialty societies is imperative to obtain adequate data on the resources required in the provision of clinical services. Many of CMS' proposed payment policies for E/Ms (e.g., G-codes, split/shared visits) further increase administrative burden, as the Agency has failed to establish clear guidelines for how such services should be reported, thereby leaving physicians confused about what changes are occurring and how they must adjust their coding and billing processes to accurately report these services.

We also note that many of the new services adopted by CMS and furnished by PCPs and nonphysician practitioners (NPPs) do not have guardrails for appropriate reporting over a short

period of time or within a calendar year. We believe that modifiers (e.g., a modifier when an E/M service is reported using time) would be very useful to assist with program integrity audits. In addition, we reiterate that CMS should collect data (e.g., service times, the number and types of services reported on any one day by a given provider) from EHR vendors to better evaluate billing patterns. Without this important information from EHRs regarding times and visits, in some scenarios, patients may not be receiving the care that they expect and deserve.

11. Finally, we are also interested in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide recommendations to CMS on resource inputs for work and PE valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations.

The RUC is an independent entity, comprised of volunteer physicians and other healthcare professionals from national medical specialty societies, that works to make recommendations to CMS regarding resource inputs and values for physician services—the RUC offers an extremely important level of expert review that otherwise is non-existent. The clinical background and expertise of these volunteers are imperative to ensure a fair, consistent, and resource-based payment system. The RUC's recommendations to CMS are based on extensive granular data to describe physician time, work relativity, and PE resources associated with the provision of procedures and other services. CMS is not required to accept RUC recommendations and, at one time, attempted to retain consultants to determine PE direct inputs for each service described by CPT codes. However, that effort was riddled with methodological inconsistencies and produced data that was not resource-based and was later abandoned. The ACS, as an active participant in the RUC, will continue to support and advocate for the RUC process that allows the united house of medicine a voice in maintaining Medicare relative values.

Split (or Shared) E/M Visits

In the CY 2022 MPFS, CMS finalized a policy for "split" or "shared" services, which are E/Ms furnished in the facility setting and performed by both a physician and an NPP who are in the same group. The policy when fully implemented requires that only the provider who performs the "substantive portion" of the visit (i.e., more than half of the total time spent by the physician and NPP performing the visit) may bill for the visit. However, the practitioner providing the substantive portion of the visit can select the level for the split or shared visit based on MDM. For CY 2022, CMS finalized a phased-in definition of substantive portion to include history, exam, MDM, or time. The Agency delayed the full implementation of the definition of substantive portion as more than half the total time until January 1, 2024. CMS now proposes to delay the implementation of the definition of the "substantive portion" as more than half the total time through at least December 31, 2024.

We support this delay and also reiterate our comments to the CY 2022 MPFS proposed rule related to MDM. Defining the "substantive portion" of the visit using time is not always appropriate, especially when the code level selection is based on MDM and not time. In certain clinical scenarios, the determination of the "substantive portion" of the visit should not be based purely on time, and MDM should instead be the deciding factor of "substantial" rather than length of documentation or time.

We do not believe that the MDM performed by an NPP and a physician are the same, especially in the case of a critical patient. The MDM provided by a physician is more nuanced and involves more expertise than the MDM of an NPP. For example, an NPP could spend considerable time gathering information for the supervising physician to review or undertaking other similar activities, while a surgeon might take on care for a critically ill patient, make several risky decisions, mobilize a whole operative team, decide on which incision or approach to use, and then prepare the patient for rapid exploration. The MDM activities of the surgeon could all take place in a short time span, but these are the critical decisions that make or break patient survival. In addition, some NPPs tend to document more compared to physicians, which could inappropriately justify the NPP as providing the substantive portion of the visit. We acknowledge that CMS does not believe that MDM can be attributed to only one provider, but we also do not believe that that time alone should be the deciding factor for determining the substantive portion for reasons described above.

Payment For Medicare Telehealth Services

Telehealth Originating Site Facility Fee Payment Amount Update

CMS proposes that, beginning in CY 2024, claims billed with place of service (POS) 10 (*Telehealth Provided in Patient's Home*) be paid at the non-facility MPFS rate. Claims billed with POS 02 (*Telehealth Provided Other than in Patient's Home*) would continue to be paid at the MPFS facility rate. We oppose CMS' proposal to pay claims billed with POS 10 at the non-facility rate and urge the Agency to pay all telehealth services at the facility rate no matter the originating site, as we believe the facility rate more accurately reflects the resource-based costs of telehealth services.

Frequency Limitations on Medicare Telehealth Subsequent Care Services

In prior rulemaking, CMS established frequency limitations for certain telehealth services, including once every 3 days for subsequent inpatient visits, once every 14 days for subsequent nursing facility visits, and once per day for critical care consultation services. ¹⁷ Due to the public health emergency (PHE), these limitations were waived through December 31, 2023. The Agency now proposes to remove these limitations for such services for the duration of CY 2024. We are concerned that continuing to waive these limitations without any guardrails will compromise patient safety, as we do not believe that it is best practice for patients in acute care settings—unless such settings are in rural or

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¹⁷ 42 USC § 1395(m)(4)(F)(i)

underserved areas—to be treated on a daily basis via non-face-to-face telehealth visits/consultations in lieu of in-person visits. We recommend that CMS reinstate telehealth frequency limitations for subsequent inpatient, nursing facility, and critical care consultation telehealth services.

Payment For Skin Substitutes

CMS seeks comment on the various cost-gathering approaches that could inform how it establishes direct PE inputs for skin substitute products and develops payment rates for physician services that involve furnishing skin substitute products.

As noted by the Agency in the CY 2023 MPFS, there are approximately 150 HCPCS Q-codes identifying skin substitute products, the cost of which would be added into the direct PE inputs of the CPT codes used to report the application of such products. In many cases, the cost of these products is not trivial. For example, in 2018, total Medicare allowed charges for the skin substitute product reported with HCPCS code Q4131 (*Epifix or epicord, per square centimeter*) was \$96 million. Given that PE RVUs are subject to budget neutrality requirements, suddenly including these products into practice expense would exert significant downward pressure on all other PE RVUs unless the Agency plans to commit additional equivalent funding to the conversion factor to offset these cuts. If incorporating the cost of skin substitute products in direct PE inputs results in budget neutrality reductions, this would penalize all Part B providers whether or not they use skin substitutes in their clinical practice.

We are concerned that the impact of this policy would, over time, drastically scale down wound care management in the office setting, which would thereby limit patient access to these services and unnecessarily prolong wound healing. If the Agency is concerned about proliferation of questionable products and/or excessive Medicare spending on skin substitutes, there are solutions for CMS to explore with providers who use these products, such as application limits for certain wounds, coordination with the CPT Editorial Panel and the RUC to review associated direct PE inputs, or mechanisms to tie Medicare reimbursement more closely to the U.S. Food and Drug Administration's regulation of skin substitutes. The ACS is eager to work with CMS to further discuss solutions and could easily identify surgeons who often use these products to contribute to such a discussion. However, due to the concerns outlined above and the potentially drastic budget neutrality implications, we urge CMS to abandon its efforts to treat skin substitutes as "incident to" supplies and to instead maintain these products as separately billable.

OTHER PROVISIONS OF THE PROPOSED RULE

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging

CMS proposes to pause implementation of the AUC program for reevaluation and rescind current AUC program regulations. The Agency states that this will be a hard pause to facilitate thorough program

reevaluation and, as such, does not propose a time frame within which implementation efforts may recommence. Given the substantial burden and practice expense that AUC requirements imposed on providers—concurrent with CMS' inability to fully operationalize real-time claims-based reporting to collect meaningful and accurate information on AUC consultation and imaging patterns for advanced diagnostic imaging services—we support the Agency's proposed pause to program implementation.

MEDICARE SHARED SAVINGS PROGRAM

Request For Information (RFI) on MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs

CMS previously finalized that the Medicare Shared Savings Program (SSP) Accountable Care Organizations (ACOs) would be assessed using the Advanced Payment Model (APM) Performance Pathway (APP) measure set. The Agency explains that they selected the measures in the APP because they are broadly applicable for the primary care population and the population health goals of the SSP. However, since this policy was finalized, the Agency has heard concerns about the applicability of the APP measures to specialists who are part of ACOs. In response to these concerns, in the CY 2022 MPFS final rule, Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) were finalized to be available for reporting beginning with the CY 2023 performance period of MIPS, with the notion that MVPs will offer clinically relevant quality reporting for specialists and more granular specialty data (through subgroup reporting) for patients to make informed decisions about the care they receive. Considering the public comments described above and the finalization and continued development of the MVPs, CMS is considering incentives for specialists in SSP ACOs to report clinically relevant quality measures.

In this RFI, CMS solicits feedback on scoring incentives that would be applied to an ACO's health equity adjusted quality performance score (beginning in performance year 2025) when specialists who participate in the ACO report MVPs. One consideration is that ACOs may receive up to a maximum of 10 points added to their ACO's health equity adjusted quality performance score if they meet the data completeness requirement and receive a MIPS Quality performance category score. In addition to specialists that participate in the ACO reporting quality via MVPs, an ACO would be required to report all measures in the APP measure set to be eligible for bonus points. CMS also asks for feedback on their overall approach to align quality measures in the Adult Universal Foundation with measures used for evaluation in the SSP.

While we support the use of measure frameworks across programs, we do not support repurposing measures from a failed system (i.e., MIPS/MVPs). Instead, we need to refocus care on the patient. It appears difficult for the Agency and payers in general to see quality and cost from a patient's perspective. For the patient, what matters most is to what extent their overall goals of care are met and how well they can afford that care. Imagine a patient whose health deteriorates despite the best

of primary care and must seek a specialist: most patients rely on their primary care provider for a referral and may simultaneously wonder if the referral they receive is the best fit for them. When suffering from a specific condition, patients cannot turn to MIPS or MVPS to find information that will give them comfort. The information is vague and too general. It does not fit the episode of care which the patient will experience.

From this perspective, it becomes clear that what patients need is a well-defined, standard episode of care. The episode of care should be as inclusive as possible of the services, resources, and personnel necessary to achieve the patient's desired outcome for their defined condition or diagnosis. An inclusive yet targeted episode definition also helps to build shared incentives and coordination across the delivery system in cases such as surgery where numerous providers may participate in care.

MVPs were built based on a fee-for-service (FFS) model where each clinical specialty (including primary care) individually receives payment for the services they provide and are incentivized from a business perspective to provide services in order to earn payment. This system built on FFS has led to physician-centered competition rather than patient-centered care. Furthermore, the budget-neutral MPFS has contributed to a divide between primary and specialty care, putting physicians of all specialties in competition with each other not for improved quality or outcomes, but for scarce financial resources. Among the most unintended consequences of FFS has been this tension between primary care and specialty medicine.

Payers have also underinvested in measures that support patients seeking care. The focus has been on ease of measurement and reducing measure burden, such as using MVPs in the SSP, rather than investing in measures that drive care—in short, CMS and other payers are spending money on metrics that do not measure high-quality and efficient care. The result is that the clinical value extended to a patient by a surgeon and their care team has become less important. Insurers and societal programs have assumed good and safe care, but patients know very little about how to find optimal outcomes, and surgeons along with their teams are undervalued for the social good they deliver. With the current approach to measurement, ACOs will be displeased when they do not experience changes in total spending when using a failed framework for quality. In short, if ACOs want to create savings, they need to deliver and reward high-quality care. It is hard to incentivize based on savings when the program they are promoting (i.e., MVPs) does not support the type of quality that creates savings. Even more, having a quality numerator that does not map to the episode's denominator can result in a race to the bottom.

Specialty medicine will consider alternative business models that value specialty contributions to the care of a patient when business models are seen as fair and with little burden. Most ACO/MSSP business models still consider FFS business model contracts as the primary means for engaging specialty care. The challenge is less about the care models and co-management of care and more about the business models that recognize the specialty services.

Solution: Programmatic Quality Framework for a Condition that Drills Down to the Episode

We must rethink quality from a quality program perspective by centering incentives on meeting patient goals. Measures that follow a quality program, referred to as "programmatic measures," identify clinical frameworks based on evidence-based best practices to provide goal-centered, clinically effective care for patients.

To do this, we first must define the service line and the episodes within that service line. For example, a cancer service line may include a specific cancer and its procedural episodes including surgical oncologic services for biopsy and excision, medical oncology, and/or radiation oncology. These services include ancillary services in imaging and pathology. It is only through acting in concert that patients can discover the care they seek and the systems that can drive them to improve.

Some of the key questions include: who are the role players within the episodes? How do they define outcomes that are meaningful to patients? How do they generate knowledge to drive improvement cycles and continuously iterate on improvement? We must go back to the six Institute of Medicine (IOM) domains (safe, effective, patient-centered, timely, efficient, and equitable), look at the service line, and build a quality program that equips the clinical team to deliver on patient goals, then consider how this might fit the requirements of the law. One way CMS should consider doing this is by acknowledging a programmatic approach to measurement that maps to the goals within the episode of care. It is possible to consider programmatic facility measures as a way of giving credit for the array of specialties contributing to the care episode or service line.

Programmatic Measures for Specialty Care

Programmatic measures have appeal because they focus on team-based care of patients, help guide patients seeking safe and good care, and reduce measurement burden since they are tied to optimal care delivery and improvement. The concept behind the programmatic measure is based on several decades of history implementing programs that demonstrably improve patient care provided by both the clinical team and the facility. Examples include ACS Trauma programs, Geriatric Surgery Verification, Bariatric Surgery Accreditation, ACS Cancer program, and more.

Programmatic quality measures 1) align multiple structure, process, and outcome measures; 2) target condition- or population-specific care; 3) apply to multiple quality domains; 4) address the continuum of care; and 5) are informative to and actionable for care teams and patients. The integration of structures, processes, and outcomes for common clinical purposes is fundamental to programmatic measures and follows the Donabedian framework.¹⁸

¹⁸ Donabedian A. Evaluating the Quality of Medical Care. *Milbank Q.* 1966;44(3):166-203.

Our experience with programmatic measures demonstrates applicability to diverse care settings, limited burden on care providers, and demonstrably better results. Applied correctly, programmatic measures will address the quality gaps created by the current measures such as MIPS/MVPs, increase patient transparency, maximize care integration, and improve outcomes. Programmatic measures have benefits across stakeholders:

- Widespread implementation of these measures would benefit patients and caregivers by increasing transparency and empowering them to make effective decisions about where to receive care.
- Providers would benefit from integration into a commonly shared goal by defining and operationalizing a clinical unit-based system.
- Healthcare systems would benefit from resource and protocol standardization, evidence-based and data-driven processes, and pragmatically functional strategies to achieve improved care and outcomes.
- Payers would benefit by taking a programmatic quality approach because they can be confident that their beneficiaries will receive high-quality care with the most efficient cost savings. Programmatic quality defines the general service lines that brand care in a community setting. A programmatic approach is the clinical subset of care which parallels the business view often referred to as service lines. Within these programs or service lines are their assigned episodes. Episodes are suited for different payment models, such as ACOs or within MAOs. Within a population of an ACO or MAO, it is possible to define patient service lines that best suit the market.

Figure 1 illustrates this programmatic approach and depicts examples of service lines, their associated episodes, and the framework for service line/episode-based quality metrics. As shown in the figure below, a musculoskeletal service line may have a total joint replacement program, a women's health service line may include female organ-specific oncologic services or a maternity care program, and a geriatric service line can include care in multiple settings. For public transparency and business intelligence, each clinical domain should portray the safety (preventable harms), affordability, overall patient goals (patient reported outcomes (PROs)/outcomes), and equitability standards.

Figure 1: ACS Clinical Programmatic Approach

Programmatic Approach

Cardiac Care

Coronary Care Valvular Care Arrythmia Heart Failure

Geriatric Care

Hospital Surgery Emergency Medicine

Complex Gastrointestinal (GI)

Care General GI Hepatic Care

Hepatic Care
Hepatopancreatic Biliary Care
Irritable Bowel Disease

Genitourinary (GU) Care

Renal Care Ureter/Bladder care Urologic Cancer

Transparency Map and Clinical Programs

Generate a core set of transparency metrics.

Within each of the clinical domains, establish the business intelligence for public transparency. These should portray **Safety** (preventable harms), **Affordability**, overall **Patient Goals** (PROs/Outcomes) and **Equitability** standards.

Musculoskeletal Care

loint replacement

Women's Health

Gynecology

Prevention, screening

Spine

Osteoarthritis Rheumatology

Primary Care

Prevention, screening Chronic care Coaching and co-management

Pulmonary Care

Chronic Obstructive Pulmonary Disease (COPD) Asthma care Sleep Apnea

Oncology Prevention

Prevention, Screening Treatment to End-of-Life Stage-based Survival Coaching and Co-management

Maternity Care

Vaginal C-Section Rates Maternal-Fetal Medicine/ High Risk Avoidable Harms

Neurology/Psychology Care

Stroke Care Mental Health

Vascular Care

Carotid Stroke Aorta Peripheral Artery/Venous

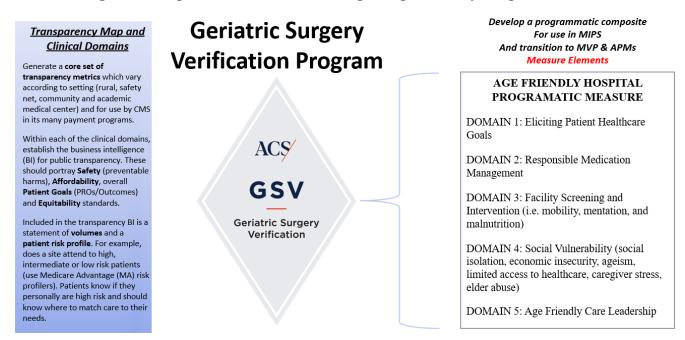
The programmatic approach can define a standardized definition of an episode where quality (numerator) maps to the denominator (price/cost), where cost directly maps to quality and is agnostic across payers and payment programs. The ACS uses its verification programs to assess episode readiness of a surgical delivery system to meet the test of operational soundness. We think of verification as the foundation necessary to give the care team what is needed to deliver optimal care. As displayed in Figure 1, programmatic measures can be developed for a multitude of services lines; we envision approximately 12 to 15 major condition-based programmatic measures to supplement the primary-care focused Universal Foundation. They can even evolve to include existing CMS measures that measure a process or outcome for the same condition, similar to the Universal Foundation.

Programmatic Measure Example: Age-Friendly Hospital Measure

In early 2023, the ACS submitted a programmatic measure, the *Age-Friendly Hospital Measure*, to the CMS Measures Under Consideration (MUC) list to demonstrate how programmatic measures could be implemented in CMS programs. This measure considers the full program of care needed to care for geriatric patients. It incentivizes hospitals to take a holistic approach to the care of older adults by implementing multiple data-driven modifications to the entire clinical care pathway from the emergency department to the operating room to the inpatient units and beyond. The measure puts an emphasis on the importance of defining patient (and caregiver) goals not only from the immediate treatment decision, but also for long-term health and aligning care with what the patient values. It includes five domains with attestations that acknowledge certain processes, outcomes, and structures that are necessary for providing high-quality, holistic care for older adults.

Figure 2 below illustrates how the domains of the *Age-Friendly Hospital Measure* we designed to encompass essential elements of the ACS Geriatric Surgery Verification Program. The measure 1) aligns multiple structure, process, and outcome measures; 2) targets condition or population specific care; 3) applies to multiple quality domains; 4) addresses the continuum of care; and 5) is informative to and actionable for care teams and patients. The Geriatric Surgery Verification Program verifies overall facility readiness for surgical care in older adults. Once a facility completes the steps of verification successfully, they can display the diamond emblem to signal to the public that the facility has completed the requirements of verification and is dedicated to delivering high-quality care to this population.

Figure 2: Programmatic Measure Example: Age-Friendly Hospital Measure



Through this example, it is possible to envision that each service line and its episodes should fit within a verifiable framework as a foundation for episode-based care. These standards seek to assure patients of essential components needed to make the transition from silos of FFS to team-based care. Are the suppliers aligned? Do risk-bearing entities have value-based compensation systems? Does the risk-bearing entity meet the care delivery standards that care coordinate with PCPs? Do participants provide a transparent care tracking system, have data driven improvement cycles, and publicly report on episode-based outcomes metrics and price transparency? These standards are needed to ensure the integrity of a quality program for a given condition. When applying this framework to the SSP, ACOs should engage specialists in a programmatic quality approach for transparency, similar to the Age-Friendly Hospital Measure. Patients seeking care or their ACO PCP acting as their agent should have choices, which are optimally informed with actionable metrics.

Although it is beyond the scope of this RFI to discuss the denominator, the key to what we have explained above is ensuring that CMS is thinking about developing a numerator that

appropriately maps to the denominator and considers price variation for high-risk patients versus low-risk patients. If ACOs (or any type of payment model) do not appreciate the episode's high-risk cost, specialists may migrate to low-risk patients and high-risk patients will have further reduction in access. The episode needs to identify more than mean or median cost and enable detection of the variation in price based on the risk of patients. When patients are more complex and the care is more involved and complicated, the episode is triggered with a starting point. The pre-trigger and post-trigger events require a breakdown of patients into risk categories and into post-triggering sequelae that appreciate when a patient consumes more services. A high-risk patient with 3-5 unstable chronic conditions who undergoes a specialty care event will naturally consume more resources than a low-risk patient with no co-morbidities. It is also important to note that patients often have more than one condition being treated in the same window of time. Business rules must apply to assign the right services to the right episodes to determine an appropriate risk-adjusted price. Without these business model safeguards, bundled pricing is subject to gaming and could result in unintended consequences for patients.

UPDATES TO THE QUALITY PAYMENT PROGRAM

Transforming the Quality Payment Programs

CMS states how the proposals in this rule advance their National Quality Strategy goals. They highlight their work focused on increasing alignment across value-based programs, advancing health equity, and accelerating interoperability. The Agency outlines current work, such as the implementation of the Universal Foundation, updates to the CMS Equity Plan in the CMS Framework for Health Equity, and efforts to support the transition to a digital and data driven health care system.

Quality Payment Program Vision and Goals

For many years, the ACS has worked with CMS to reshape and meet the vision and goals for the QPP set forth by the Agency. We have decades of experience in running quality programs by setting the highest quality standards for surgeons and hospitals, helping them meet and exceed those standards. Our programs are in more than 4,000 hospitals and measurably improve quality of care, prevent complications, and reduce costs. All our programs instill a culture of quality using a programmatic approach inclusive of the right structure, sound, evidence-based processes, outcomes tracking, transparency, and owning improvement as a system. Making these cultural changes can be a major undertaking. The programmatic approach encompasses the nine domains listed below in Table 1. These nine domains are consistent across all ACS quality programs.

Amongst the most recognized of the ACS programs are the Trauma Center Verification Program, the Commission on Cancer, and the Metabolic and Bariatric Surgery Verification Program. Evidence in peer-reviewed literature demonstrates that mortality in verified trauma centers is statistically lower than in non-verified centers; bariatric surgical care in verified bariatric centers has lower mortality, lower

costs, lower complications, and lower failure-to-rescue; and breast cancer care is statistically superior in verified breast cancer centers. ^{19,20,21,22,23,24,25} The College currently has 13 different quality programs overall. ²⁶

Our expertise and experience running ACS quality programs provide a wealth of knowledge on what works and what does not work in driving improvements in care. For years we have made the argument that single metrics focused on clinicians/specialties and services will only perpetuate the silos created by FFS and continue to fragment care, while wasting resources on chasing meaningless metrics. These concerns are nothing new and are consistently heard across stakeholder feedback. How to resolve this concern is the challenge. From our experience, the fix must start with the QPP refocusing on the patient,

Table 1: ACS Quality Program Domains

ACS <u>Quality</u> Programs aim to be comprehensive and contain the following <u>9 Domains</u>
1. Institutional Administrative Commitment
2. Program Scope & Governance
3. Facilities & Equipment Resources
4. Personnel & Services Resources
5. Patient Care Expectations & Protocols
6. Data Collection & Surveillance
7. Data-driven Quality Improvement
8. Professional & Community Outreach & Education Programs
9. Basic & Clinical Discovery/Sharing (Optional)

which can be done using a programmatic measurement approach, similar to the ACS quality framework. Programs can be built for the most common 12 to 15 service lines or clinical programs to align specialty care with the Universal Foundation. A detailed discussion of this point is included in the SSP RFI above.

To refocus on the patient, we need to (1) rethink how to build a program around a patient, (2) create incentives for the team to organize around the patient, and (3) deliver on patient goals. ACS programs take different approaches for various health system needs and can be adapted across settings and incentive programs. One approach is to begin very small and focus on a service line that has a clinical champion and buy-in from the different role players or stakeholders. Once the health system overcomes the challenges of a small startup in programmatic quality it becomes easier to scale by adding on another program, then another, and so on. Another approach is to begin more broadly by creating the overarching framework for a Quality Verification Program (QVP). The QVP approach stretches across multiple surgical disciplines and has the greatest impact for all service lines. Then, a more focused approach can be applied in the high-risk, high-volume areas of care. Decisions about the approach that comes first—a small, focused approach or a large, broader approach—are often influenced by payer

¹⁹ MacKenzie EJ, Rivara FP, Jurkovich GJ, et al. A National Evaluation of the Effect of Trauma-Center Care on Mortality. N Engl J Med. 2006;354(4):366-378.

²⁰ Nguyen NT, Nguyen B, Nguyen VQ, Ziogas A, Hohmann S, Stamos MJ. Outcomes of Bariatric Surgery Performed at Accredited vs Nonaccredited Centers. *J Am Coll Surg*. 2012;215(4):467-474.

²¹ Morton JM, Garg T, Nguyen N. Does Hospital Accreditation Impact Bariatric Surgery Safety? Ann Surg. 2014;260(3):540-548.

²² Baidwin NK, Bachiashvili V, Mehta, T. A meta-analysis of bariatric surgery-related outcomes in accredited versus unaccredited hospitals in the United States. *Clin Obes*. 2020;10e12348.

²³ Berger ER, Wang CE, Kaufman CS, et al. National Accreditation Program for Breast Centers Demonstrates Improved Compliance with Post-Mastectomy Radiation Therapy Quality Measure. *J Am Coll Surg*. 2017;224(3):236-244.

²⁴ Miller ME, Bleicher RJ, Kaufman, CS, et al. Impact of Breast Center Accreditation on Compliance with Breast Quality Performance Measures at Commission on Cancer-Accredited Centers. *Ann Surg Oncol*. 2019;26(5), 1202-1211.

²⁵ Winchester DP. The National Accreditation Program for Breast Centers: Quality Improvement Through Standard Setting. Surg Oncol. 2011;20(3):581-586.

²⁶ The Power of Quality. American College of Surgeons. Accessed September 5, 2023. https://www.facs.org/quality-programs/the-power-of-quality/.

incentives and local facility readiness for change. All programs have mechanisms to help systems identify problems and tools/training to drive quality improvement (QI) projects (we describe our detailed approach to QI in the Promoting Continuous Improvement in MIPS RFI below).

This approach only works if the team is incentivized to identify and come together to deliver on what matters to the patient (i.e., refocusing on the patient). MVPs are not organized this way—they are built by largely recycling the siloed MIPS measures, focusing on services delivered by a specialist, such as neurology, rheumatology, anesthesiology, etc. The ACS began working with CMS on a Geriatric Surgery MVP, where a quality verification program was recognized as an Improvement Activity. At the end of our work, the MVP looked similar to general surgery MIPS measurement groups with siloed measures and did little to incentivize teams to build out a geriatric surgery program. Instead, we hope for success in the Age-Friendly Hospital Measure that was put forth last year for use in the Inpatient Quality Reporting (IQR) program. This measure looks at a program of care for elderly care in the hospital. The measures were reviewed by the National Quality Forum Measure Application Partnership (MAP) during the 2022 measure development cycle. Once there is buy-in and implementation at the facility level, then clinician-level programs (MVPs) can align. Without buy-in from the facility, implementing a quality program on the backs of individual physicians will not be successful. Key to this is alignment across payment programs. The programmatic approach can define a standardized definition of an episode where quality (numerator) maps to the denominator (price/cost) and is agnostic across payers and payment programs.

We suggest CMS build their measure evaluation process around the following criteria:

- What impact does the measure have on the patient? Does the measure guide a patient seeking care to a provider or healthcare facility that best meets their needs?
- Does the measure support care teams to form around patients and provide them with the information they need to identify gaps and drive improvement?
- Does the measure provide a payer with the information they need to inform the customers they serve?

This information can be transparently displayed, focusing on prevalent conditions patients are seeking care for—showing that a provider or the care team can be trusted to deliver high-quality and affordable care for these conditions, and ultimately deliver on patient goals. We envision the following information reported publicly:

- 1. Whether the clinician is part of a high performing care team.
- 2. Whether the care team collects data on condition-specific quality measures to track safe and high-quality care delivery and inform improvement cycles.

3. If the facility, care team, or practice has <u>verified</u> standardized structures and processes in place to effectively care for the condition, similar to what we discuss in the *Request For Information (RFI) on MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs* (page 28) about programmatic measurement.

Figures 3 and 4 below illustrate two phases for transparently displaying information on a quality program, and how this information in the numerator (quality) should map to the denominator (price/cost). The phases illustrate additional information that will be made available as the healthcare industry develops the ability to report out PROs, equitable care, and other elements. Note that these figures are conceptual and for illustrative purposes only. **Key to this is how the price of care for patients of similar characteristics or level of risk varies and how this compares to clinical teams/physicians with similar quality scores for this cohort.**

Figure 3: Transparency Framework Phase 1 (draft concept for illustrative purposes only)

PHASE 1: Delivery System Measurement		
Example: Oncology Services		
Oncology Service Line	Our team provides prevention, screening, early diagnosis, treatment, and end-of-life oncologic care for adult and pediatric patients. These services include solid organ malignancies and hematologic malignancies.	
Oncologic Specialists	(4) Medical Oncology, (5) Surgeons, (2) Radiation Therapy	
Verification *	Quality Verification Program (QVP) & Commission on Cancer (CoC) Verified	
Volume **	>2500 Procedures, Local Market Share = 60% for the top 5 solid organs	
Safety	Readmission Rate = < 5% Surgical Site Infections (SSI) Rate = < 5% (Low rates are preferred)	
Affordability	Based on elective cases - \$\$\$\$ (five-point scale, moderate-high cost)	
* Verification programs must be reviewed and accepted by CMS for inclusion ** Volumes less than 20 lose statistical reliability and validity for detailed measurement like safety, quality, or affordability		
(https://www.facs.org/quality-programs/?page=1)		

Figure 4: Transparency Framework Phase 2 (draft concept for illustrative purposes only)

PHASE 2: Delivery System Measurement (expanded)		
Example: Oncology Services		
Oncology Service Line	Our team provides prevention, screening, early diagnosis, treatment, and end-of-life oncologic care for adult and pediatric patients. These services include solid organ malignancies and hematologic malignancies.	
Oncologic Specialists	(4) Medical Oncology, (5) Surgeons, (2) Radiation Therapy	
Verification *	Quality Verification Program (QVP) & Commission on Cancer (CoC) Verified	
Volume **	>2500 Procedures, Local Market Share = 60% for the top 5 solid organs • 3000 Clinic visits • Average time to schedule an appointment – 72 hours	
Safety	Readmission Rate = < 5% Surgical Site Infections (SSI) Rate = < 5% (Low rates are preferred)	
Affordability	Based on Elective Cases - \$\$\$\$ (five-point scale, moderate-high cost)	
Equity Score	Meets market targets for equitable care	
Outcomes	Functional Patient-Reported Outcomes (PRO) and Patient Satisfaction PRO scores are publicly reported • Risk-Adjusted Survival Rates (by condition) and Stage Information (with benchmarks to national results) are available on-demand	
* Verification programs must be reviewed and accepted by CMS for inclusion ** Volumes less than 20 lose statistical reliability and validity for detailed measurement like safety, quality, or affordability		
(https://www.facs.org/quality-programs/?page=1)		

Lastly, in order to operationalize the quality program, having the ability to aggregate episode-specific, condition-specific data is also an important function of delivering patient-centric care. The ACS has developed an open-source platform that is Fast Healthcare Interoperability Resources (FHIR)-based and can safely extract key data from multiple data sources, including a health information exchange. The platform can build out care pathways that align with quality programs to individually track patients involved in complex care as they move through their care journey. We believe a dashboard with this information benefits all involved in the care, including the PCP and specialist who will have all the information about the care the patient receives, regardless of who provided the care or where it was provided, and the patient who benefits from increased transparency.

Promoting Continuous Improvement in MIPS

CMS seeks comments on how they can modify policies under the Quality Payment Program to foster clinicians' continuous performance improvement and positively impact care outcomes for Medicare beneficiaries. Such modifications for MIPS may include requiring more rigorous performance standards, emphasizing year-to-year improvement in the performance categories, or requiring that MIPS eligible clinicians report on different measures or activities once they have demonstrated consistently high performance on certain measures and activities.

In our previous comments to CMS, we emphasize that if CMS truly wants to transform healthcare, the incentives must make it worth the effort. In order to do this, we believe the mindset needs to be changed from one of penalty avoidance to one that: (1) rewards care teams for implementing and maintaining the elements of quality programs that are built around care for specific conditions; (2) aligns with the team-based nature of care delivery; (3) applies improvement cycles; and (4) can provide useful information that supports patients when they must determine where to seek medical care.

The ACS has decades of experience in implementing continuous QI. In order to operationalize a program that can meet these objectives, improving quality improvement, or "improving improvement," is central to the goal and part of all ACS verification and accreditation programs (e.g., ACS Trauma Verification, Commission on Cancer, Children's Surgery Verification, Geriatric Surgery Verification, and the National Accreditation Program for Breast Centers). To support "improving improvement" efforts, the ACS recently developed the ACS Basics Quality Improvement Course designed to ensure the surgical workforce and other quality improvement staff are well-educated on the basic principles of surgical quality and safety.²⁷

To drive improvement, first there must be a cultural commitment across the care team, as well as with leadership, to ensure the appropriate resources are made available and quality improvement is a priority. Then, we must ask ourselves: how have we re-engineered care teams to emerge and measure care to deliver high-quality surgical care? This is inclusive of the appropriate evidence, experience, and alignment with a clinical pathway, which is all included in the ACS verification programs. This leads us to the question: does the care team have the data to evaluate care and find problems with the care plan as delivered? To do this, clinical teams rely on dashboards, clinical data registries, key metrics, case review, and revelation of processes. Finally, do clinical teams have the resources to implement a quality improvement framework, such as a Plan, Do, Study, Act (PDSA) cycle? Did they fix the problem, and how is success evaluated? From here, the cycle repeats. For example, during ACS verification site visits, we survey whether hospital-level, surgery-specific QI initiatives are data-driven, using a formal, standardized QI methodology or tool (i.e., Lean Six Sigma, DMAIC, PDSA, etc.). What are the examples of QI initiatives in the past 12 months? As part of the hospital's case review process, we

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²⁷ ACS Quality Improvement Course: The Basics. American College of Surgeons. Accessed September 5, 2023. https://www.facs.org/quality-programs/quality-improvement-education/qi-basics-course/.

investigate whether there is a surgery-wide, multi-disciplinary/multi-specialty case review conference, primarily for the purpose of identifying cross-cutting process or quality improvement opportunities. Does M&M have a feeder to quality improvement, or is the goal just for educational purposes, and the long list of standards related to QI continues?

At a high level, Figure 5 below illustrates how the ACS implements "improving improvement" across our quality programs, including the various components of the ACS quality programs. The necessary resources, structures, and educational needs are embedded into the ACS quality programs to fully support a continuous quality improvement cycle as illustrated. Key to all of these moving parts is the patient-centricity of the program—what are the patient's goals and what resources does the team have to meet those goals while providing safe, affordable, good, and equitable care?

We would be happy to invite CMS leadership to a verification visit or share our review materials for an in-depth understanding of our process.

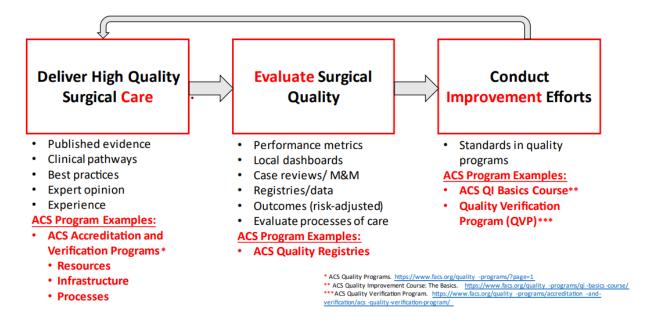


Figure 5: Improving Quality Improvement

As part of this RFI, CMS asks a series of questions about the processes used to improve performance and quality. Our answers to select questions are as follows:

• What changes to policies should CMS consider to assess continuous performance improvement and clinicians interested in transitioning from MIPS to APMs?

CMS programs have previously not incentivized continuous quality improvement, so in that regard the focus of this RFI is a step in the right direction. **However, the fundamental challenge that CMS must**

face when considering how to foster a commitment to continuous improvement is that the "individual physician" is the wrong unit of analysis. Continuous quality improvement is a team sport; focusing on an individual clinician's improvement inherently puts focus on the clinician "passing the test" for MIPS/MVPs and puts the team caring for the patient out of focus for QI efforts. Continuous improvement happens at the program level for the patient's condition. Within the program are episodes and within the episodes are individual services. The focus should be on the patient who is receiving multiple services within an episode. As part of improvement, we must track events; meet patient expectations; meet team member expectations; and identify mishaps, problems, or opportunities for better outcomes. These then become the emphasis for improvement exercises.

• What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?

When quality is tied to a payment system, and that payment system exists as one among many factors that determine care, the impact of the measure is diluted by the focus brought to bear via the fiscal component. Said differently, regardless of the means of payment—FFS, Per Member Per Month, or a bundled episode—the quality of care should stand on its own merit, that the care is safe and the outcome meets the patient's expectations. Quality as a stand-alone, patient-centric measure becomes of singular importance, and payment has its own placeholder, relative to covering the costs needed to deliver the services in a safe manner. In expressing value, the judgment applied by patients and purchasers of the service should see the bright line that separates quality and cost. Today, patients often believe more spending means better care when, in fact, the opposite may be true.

• While we are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement, we are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

A theme throughout our comments for many years is that CMS must look across its various (payment) programs and align value-based care efforts, focusing on the program of care that is needed for a patient's condition. Since the MIPS program was developed in an FFS mindset, with siloed incentives focused on the individual clinician's ability to meet metrics, there must be fundamental changes to the "MIPS-think." The ACS supports efforts that align measures, such as the Universal Foundation, but it is critical that CMS does not use MVPs that simply measure a specialty (e.g., anesthesiology, neurology, nephrology, orthopedic surgery) versus the team of clinicians that are needed to come together to care for a patient with a certain condition. Within these efforts to align measures across programs, CMS must also determine how cross-program credit can be applied for the activities that care teams are already taking part in.

As discussed, the ACS has been advocating for a programmatic approach to quality improvement and value-based care. CMS asked us to create a Geriatric Surgery MVP based on the standards in our Geriatric Surgery Verification (GSV) program, which is a facility-level program. Continuous quality improvement is included in the standards, but is also interrelated to other standards, and the program overall, including the orchestration and commitment of the clinical team, facility, C-suite, and other stakeholders. It is not a separate activity to consider in a silo. In our conversations with CMS, our advocacy efforts focus on the idea that programs cannot be implemented at the clinician level; the lift is too big for an individual clinician at their hospital or outpatient center to get the resources, infrastructure, committee support for QI initiatives, and cultural commitment to implement a program of care. Likewise, QI initiatives cannot be done simply on the clinician level.

In our experience, the most difficult hurdle to a successful quality program is the cultural commitment of all stakeholders (e.g., C-suite/hospital leadership, the department, the clinical team). The program must first gain buy-in from the leadership. For this reason and more, instead of moving forward with a MIPS clinician-level measure, we submitted a "programmatic measure" to the Hospital IQR program, which take key standards from ACS GSV, along with standards from Institute for Healthcare Improvement (IHI) and Geriatric Emergency Department Accreditation (GEDA) Program for a hospital-wide approach to care for older adults. This new type of measure, a "programmatic composite" measure, considers the full program of care needed for geriatric patients. The domains of the measure include:

- Domain 1: Eliciting Patient Healthcare Goals;
- Domain 2: Responsible Medication Management;
- Domain 3: Frailty Screening and Intervention (i.e., Mobility, Mentation, and Malnutrition);
- Domain 4: Social Vulnerability (social isolation, economic insecurity, ageism, limited access to healthcare, caregiver stress, elder abuse); and
- Domain 5: Age-Friendly Care Leadership. 28

The goal is to have this programmatic measure implemented at the hospital-level, then work toward alignment in the QPP—whether that is receiving credit through facility participation or developing an MVP that aligns with the *Age-Friendly Hospital Measure* so there is a standard of care used across programs for older adults. The CMS Center for Clinical Standards and Quality team proved to be an essential driving force to bring all the care teams together to form a unified age-friendly care initiative. For years, entities developed measures independently, and creating interactive groups came from persistence by the Agency that a true programmatic measure would come from all clinical groups working jointly. We also have been working to educate other payers about this approach. Once we have applied quality frameworks, as described above, the focus can turn to measuring the complexity of care and the complexity of the patient (e.g., their goals and expectations). This re-engineering must be recognized structurally and process-wise as an essential step if we are to achieve patient-centered accountability. The ACS believes these measures will help build a better, safer, more age-friendly

²⁸ The measure was reviewed by the MAP with conditional support for rulemaking and will be reviewed again this year after measure revisions.

environment for geriatric patients and will help patients and caregivers know where to get good care that is in line with their values. The *Age-Friendly Hospital Measure* is just one example, but the quality program framework can apply to nearly any condition.

• CMS acknowledges the potential increase in burden associated with increasing measure reporting or performance standards. How should it balance consideration of reporting burden with creating continuous opportunities for performance improvement?

The quality framework outlined in the SSP RFI section, page 28, could greatly reduce burden by aligning the reporting requirements of all key role players in the episode with a single, service line-specific programmatic measure. Such a measure could apply within the model to all participants, with the added benefit of increasing the incentive of care coordination by having everyone working toward the same goals. Adapting this framework is less burdensome because the structures, processes, resources, and activities outlined in the programmatic measure are elements that are necessary, and many times already being done by high-functioning health systems.

MIPS Value Pathways Development, Maintenance, and Scoring

Subgroup Scoring Policies

Facility-Based Score for Subgroups

CMS established policies for facility-based measurement and scoring for MIPS-eligible individual clinicians and groups. If a MIPS-eligible clinician or group meets the threshold for facility-based scoring, CMS will use its performance in the Hospital Value Based Purchasing Program to calculate the clinician's score for the MIPS quality and cost performance categories. In past MPFS final rules, CMS stated that an MVP Participant that is not an APM Entity but is eligible for facility-based scoring will also receive a facility-based score that counts towards their individual score within traditional MIPS. In this proposed rule, CMS recognizes that it overlooked addressing facility-based scoring for MVP Participants that are part of subgroups. The Agency indicates that it does not intend to calculate a facility-based score at the subgroup level and proposes to modify its existing policy to state that, "if an MVP Participant, which is not an APM Entity or a subgroup, is eligible for facility-based scoring a facility-based score will also be calculated." We have expressed our support for the facility-based scoring policy and continue to support CMS' policy of applying the higher of the scores for individual clinicians based on traditional MIPS or MVPs. CMS should similarly apply the group's facility-based score to the subgroup score, if applicable. This would be consistent with other policies for subgroups, including cost scoring.

We also ask CMS to continue to consider ways to map their quality programs to align with the teambased, integrated nature of modern patient care. It is essential that CMS work to align physician and facility quality programs, especially as the trend continues to shift towards employment for many specialties. In our current system, partnerships between the facilities and the care teams are crucial to the delivery of high-quality care. Quality can be greatly impacted by a care team's dedication to implementing programs that are built on evidence-based standards and processes, but this cannot be done successfully without the proper resources and infrastructure that must be provided by the facility. As stated in our response to the RFI on MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs, we envision that the elements of approximately 12-15 major conditionbased programs could be integrated into condition-based programmatic measures for CMS incentive program participation (including MVPs) to supplement the primary-care-focused Universal Foundation and be designed to align with episodes of care. Programmatic measures can evolve to include existing CMS measures which measure a process or outcome for the same condition. We believe these types of measures acknowledge both the hospital that has created a culture and infrastructure to form care teams around the patient and the care teams who work to implement standards and drive improvements in care. When this work is already being done by physicians and facilities, it is important that CMS finds a path forward that can acknowledge and give them credit for their existing systems and programs, instead of placing more burden on physicians and facilities.

MIPS Performance Category Measures and Activities

Quality Performance Category

Data Completeness Criteria

CMS has incrementally increased the amount of data that MIPS-eligible clinicians report to meet the requirements of MIPS quality measures. CMS states that they believe that it is important to incrementally increase the data completeness threshold as MIPS-eligible clinicians, groups, virtual groups, subgroups, and APM Entities gain experience with MIPS to ensure a more accurate assessment of a MIPS-eligible clinician's performance on quality measures and prevent selection bias. For the CY 2024 and CY 2025 performance periods, CMS increased the data completeness criteria threshold from at least 70 percent to at least 75 percent. CMS proposes to maintain the data completeness threshold of at least 75 percent for the CY 2026 performance period/2028 payment year. The Agency also proposes to increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

The ACS appreciates that CMS is maintaining its gradual increase to the data completeness criteria requirements. However, it is important that when there is an increase in reporting requirements, practices are not overly burdened, especially those who are not reporting through electronic clinical quality measures (eCQMs) or other electronic sources. We ask if CMS has considered potential negative impacts on practices that do not have access to electronic reporting

mechanisms, such as increased reporting burden, which might be associated with increasing the data completeness threshold.

MIPS Final Score Methodology

Performance Threshold for the CY 2024 Performance Period/2026 MIPS Payment Year

CMS proposes to revise its policy for identifying the "prior period" by which it will establish the performance threshold beginning with the CY 2024 performance period/2026 MIPS payment year as three performance periods, instead of a single prior performance period. To determine the performance threshold for the CY 2024 performance period/2026 MIPS payment year, CMS proposes to use the CY 2017/2019 MIPS payment year through CY 2019 performance period/2021 MIPS payment year as the prior period. Given this proposed change to the definition of "prior period," CMS proposes to use the CY 2017 through CY 2019 performance periods as the prior period for the purpose of establishing the performance threshold for the CY 2024 performance period, which produces a mean of 82 points. This proposed performance threshold value would be a seven-point increase from the CY 2023 performance period, which is currently 75 points.

The ACS does not support the proposed increase in the performance threshold. While the PHE has ended, practices are still affected by a huge strain on resources including staffing shortages, lack of beds, etc. For many practices, meeting the requirements of these programs is burdensome. The measure scoring policies, such as the benchmarking and the topped-out measure policies, make it extremely difficult to meet the threshold for many specialists. There has also been a general lack of transparency including scoring details available for the cost performance category, making points available for cost an unknown factor. We question why CMS continues to move the goalpost. The goalpost for MIPS should be set to ensure that patients are informed about the care they receive and have the ability to know where to access safe, affordable, good, and equitable care. Chasing siloed metrics with the sole goal of meeting a point threshold becomes meaningless to patients and **extremely burdensome for practices.** There is little incentive to improve and very little information that supports patients based on the current MIPS criteria. We are concerned that as the performance threshold increases and more resources are required to avoid a payment penalty, clinicians may feel that participating in the program is not worth the effort and might even become a disincentive to participate in Medicare—in other words, for many "the juice is not worth the squeeze." We ask: how does this change further goals to drive high quality for clinicians? From the ACS' perspective, tinkering with the scoring does nothing to improve the program. MIPS is not patient-centric; it does not incentivize the care team to organize around the patient to meet patient goals. It does not follow an episode of care; instead, it ensures that an individual specialist can report metrics to compete against their own team members and ultimately game the system with the goal to "pass the test" and ensure payment. We worry that this policy will further push physicians away from MIPS participation and by default lead to even further access issues for Medicare beneficiaries.

Public Reporting on Compare Tools

Incorporating Medicare Advantage (MA) Data into Public Reporting

Since 2015, CMS has been expanding the data about physicians and the items and services furnished to Medicare beneficiaries that must be made publicly available on an annual basis. In the CY 2019 MPFS final rule, CMS established a policy for publicly reporting procedure information on Care Compare clinician profile pages to provide patients with more information in their clinician searches in an understandable format, beginning no earlier than CY 2023. Under this policy, if case counts (N) are below 11 it is categorized as low-volume and CMS prohibits the use of specific procedures or patient counts. Between the time of the CY 2023 MPFS proposed and final rules, Medicare FFS claims data analyses showed that for the initial 13 priority procedures identified, approximately 50 percent of clinician-procedure combinations fall into the low-volume category, which meant that CMS could only publish an indicator that a clinician has "experience" with the procedure rather than specific volume counts. CMS believes the high number of clinicians with a low-volume indicator is partly due to not including data for patients with other coverage, such as MA plans or other payers, for whom a given clinician has also performed such procedures. Based on public comments and consumer testing, including other payer data would help prevent this issue.

Thus, CMS proposes to publicly report aggregated counts of procedures performed by providers based on MA encounter data in addition to Medicare FFS utilization data if CMS determines it is appropriate and technically feasible. While we agree that adding the MA encounter data would offer a more accurate representation of utilization, our bigger concern is posting utilization without appropriate quality information. In the past, the ACS has voiced concern that reporting volume without context could create an unintentional misdirection for patients and other end users.

Contextualizing information in a value expression requires more than a factual report of volume. It requires understanding the clinical appropriateness of the procedure for each specific patient, the risk profile for the volume of patients, their observed to expected safety report for preventable harms, and the overall outcomes that meet patient expectations. For example, a physician who provides complex care to high-risk patients with great success may not administer a high volume of services each year, yet this could be interpreted by a patient as the physician not being experienced. It is well documented that some surgeons performing a relatively low volume of these procedures also achieve excellent outcomes. There is also risk of the opposite scenario in which a patient might mistake high volume with high quality in all patient types; however, a physician may administer a high volume of services but lack experience in patients with higher risk profiles, or the care they delivered was not appropriate for certain patients. This is also documented in the *ACS Statement on Credentialing and Privileging and Volume Performance Issues*, which states for some complex procedures, high case volume could be associated with improvement in surgical outcomes. However, these outcomes may reflect not only the knowledge,

²⁹ Statement on Credentialing and Privileging and Volume Performance Issues. American College of Surgeons. April 1, 2018. Accessed September 7, 2023. https://www.facs.org/about-acs/statements/credentialing-and-privileging-and-volume-performance-issues/

experience, and skill of the individual surgeon, but also the aggregate ability of the institution and hospital staff to provide high-quality care for specific groups. In other words, there are many other factors that tell the story of a patient's outcomes or surgeon's care. Reporting on the individual surgeon's volume without consideration for overall program of care for a condition, including the clinical team, the facility's resources, and many other factors, is an incomplete and even inaccurate proxy for quality. As such, without a proper framework, sharing volume without clarifying details may lead to information that could impact patient trust, especially to the most vulnerable in high-risk public hospitals or rural areas where access and choice are the first order of quality to be addressed.

RFI: Publicly Reporting Cost Measures

Currently, data from the CY 2021 performance period/2023 MIPS payment year regarding MIPS-eligible clinicians' performance in the quality, improvement activities, and Promoting Interoperability performance categories that meet public reporting standards are publicly available on the Physician Compare tool profile pages and in the Provider Data Catalog (PDC). At this time, cost measure information from the cost performance category is not publicly reported. However, given the number of cost measures CMS has adopted in MIPS for at least two years and the end of the PHE, the Agency is evaluating ways to publicly report performance on cost measures on clinician and group profile pages. CMS intends to propose in future rulemaking to publicly report MIPS cost measures beginning with data from the CY 2024 performance period/2026 MIPS payment year in CY 2026 on the Compare Tool clinician and group profile pages and in the PDC in 2026.

The ACS feels that this initiative is premature. We find it misleading to display a list of the mean or median costs for certain services. Adding to the confusion is the term "cost." Cost to a patient is the price of goods and services. The cost to a physician is the cost to produce those same goods and services. We believe CMS cost refers to the patient costs or price for the goods and services delivered. Further, if price refers to a single service, it does not represent the total price for the sum of common services used in treating a patient. Imagine how patients feel when trying to interpret their EOBs, especially when trying to recover from a major ailment. The price should come from the patient's perspective and serve their needs to understand the cost for the services they needed for their condition. To achieve this, price must be defined for the common sum of services within a service line or episode of care. It is also important that the definitions of cost and price are understood. Cost and price are two sides of the same coin, but they are not the same. Price can be described as how much is ultimately paid for something and cost refers to the resources used and personnel required to deliver the goods and services. Based on these definitions, we believe that price is extremely important to the consumer.

Reporting the mean or median of price is also not patient-centric. With modern price analytics, it is possible to report risk-adjusted price. Patients with comorbidities and other confounding aspects to their

³⁰ Coffron MR, Opelka F. Price and cost: Both are important to achieve value-based care. *Bulletin of the American College of Surgeons*. February 3, 2021. https://bulletin.facs.org/2021/02/price-and-cost-both-are-important-to-achieve-value-based-care/. Accessed September 5, 2023.

underlying condition require personalized care that may prove more or less costly in price. In general, low- to intermediate-risk patients tend to be consistent with the mean or median. High-risk patients have much more variance in services needed and these additions add significantly to care. For price transparency to become a trusted and effective aspect of healthcare, it must be tailored to the patient to some degree. General price reports would only be helpful to those who least need it.

Price is an essential piece of the value equation and must be accounted for when publicly reporting for value-based programs. Price may be construed as the denominator in the Value=Quality/Cost or price equation. This represents a non-numeric expression of the relationship of the quality-of-care relative to the price for the sum of all services to deliver the care. Recent efforts to increase transparency have focused on price, which is important but insufficient if not coupled with actionable quality data. Quality and price (cost) must be inextricably linked at the service line or episode level if we are to inform patients, their PCP, and other stakeholders trying to contract for services. This means that, to the extent possible, they should be measured for the same cohort of patients using the same standard episode definitions as the unit of measurement.

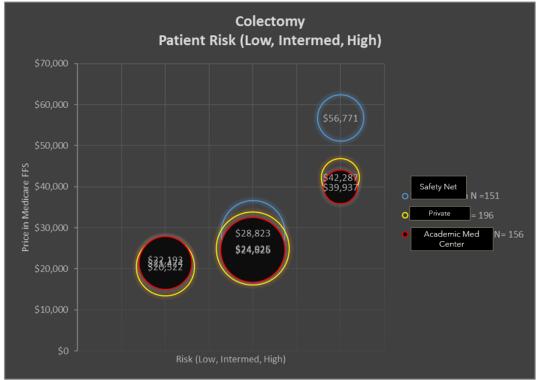
When faced with complex care packaged into an episode, it can be challenging to make both the quality and price of that care transparent in a way that is easily understandable. If the measures specified for the episode displayed the value expression of quality and price (cost) as an easily understandable relationship of these two factors, it would help patients and their PCPs choose care that is safest and has the best outcomes for what they are willing to pay or can afford. Short of providing episode-specific information together, there is risk of patients choosing solely on price, either selecting the least expensive option and assuming it is safe (potentially based on misleading or unrepresentative measures) or even choosing the more expensive option in a misguided belief that higher price equals better quality. Quality in episodic payment models should include reporting using the IOM approach with the numerator (STEEEP metrics: Safe, Timely, Effective, Efficient, Equitable, and Patient-centered) and a standard, open-source grouper to define the denominator for that episode (for example the grouper maintained by the not-for-profit Patient-Centered Episodes of Care System (PACES) Center for Value in Healthcare³¹).

One way to promote the availability of such specific value expressions to inform patient choice would be to incentivize delivery systems that report them. The greater incentives should go to systems which are the most transparent and have the best results. CMS could also consider patient incentives, rewarding those who seek higher-value care through reduced copays or other means.

³¹ A Common Standard for a Common Use. Patient Centered Episode System. www.pacescenter.org. Accessed September 5, 2023.

Figure 6. Example of Risk-Stratified Episode Price

Procedure Specific Patient Risk and Competitors



Please note that this figure is for illustrative purposes only.

For price measurement to be helpful for patients, factors such as an expected versus observed price ratio should be developed and the display should include insights into the price of care based on a patient's level of risk. This requires a breakdown of patients into risk categories with appropriate adjustments to price. A high-risk patient with 3 to 5 unstable chronic conditions who undergoes a specialty care event will naturally consume more resources than a low-risk patient with no comorbidities. Applying risk adjustments that define categories of patients will help to protect against adverse selection. Figure 6 above is an example of risk-stratified episode cost by setting derived from Medicare FFS data. The image illustrates the price of an episode in three different settings and the price of episode in a patient with a low-risk profile (left cluster), intermediate risk profile (middle cluster), and high-risk profile (right cluster). Certain care teams may be more adept in managing patients from safety net environments; other teams face challenging patients with complicated social determinants, unmanaged chronic conditions, or other factors that affect the outcome and cost of care. Other teams are more adept at managing high-risk, frail, elderly patients. Sharing this information with patients in a way that is understandable for them will support them in making more informed decisions when seeking care.

In summary, the goal of all public reporting efforts should be to meaningfully display where patients can find safe, affordable, high-quality, and equitable care. The Agency has prioritized health equity, and a large part of equity is giving the patient information about whether they can *afford* the care they seek. The information available on Care Compare should focus on prevalent conditions or domains of care and show that a provider or care team can be trusted to deliver high-quality and affordable care for these conditions. Including the following points on a physician's profile pages will be the first step in making Care Compare a resource that empowers patients to make decisions that are best for them:

- 1. Whether the clinician is part of a high performing care team.
- 2. Whether the care team collects data on condition-specific quality measures to track safe and high-quality care delivery and inform improvement cycles.
- 3. If the facility, care team, or practice has <u>verified</u> standardized structures and processes in place to effectively care for the condition, similar to what we discuss in the *Request For Information* (RFI) on MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs (page 28) about programmatic measurement.
- 4. The price of care for patients of similar characteristics or level of risk and how this compares to physicians with similar quality scores for this cohort.

This information should be made easily available to the patient as well as to PCPs, ACOs, MAOs, and other stakeholders. Information available to patients should be clearly defined, including what elements of their care journey are encompassed in the price information. Patients should be educated on where to look and how to interpret the data made available to them when seeking a service line within a given episode. Then comparative information about system A versus system B or others in their local markets should be available. For example, a patient seeking care after a cancer diagnosis may find that System A has a public-facing dashboard that includes the minimum required reported elements for its cancer service line, along with any additional aspects of care it seeks to provide the local market to inform it such as certifications, participation in verification programs, quality improvement efforts, or other distinctions.

Ideally, to avoid unnecessary confusion, prices used for physician scoring or public reporting should be comparable to prices provided to patients as part of efforts to help them shop for services and to avoid surprises from unanticipated charges related to their care. Recent federal price transparency efforts in the forms of new laws and executive orders require surgeons and health plans to provide patients with an up-front estimate of how much their care is likely to cost in the form of both good faith estimates (GFEs) and advanced EOBs for the summary of all services a patient would expect to receive. Different federal requirements currently use different methodologies for producing these estimates.

These efforts are currently completely unrelated to the 30 percent of the final MIPS score for physicians in FFS Medicare representing the cost (or price) of care. This assessment currently relies heavily on broad measures with few exclusions (Medicare Spending Per Beneficiary and Total Per Capita Cost of Care) or a small number of overly narrow episode-based cost measures applicable to only a small (but growing) percentage of physicians. Furthermore, like with quality, these measures are frequently reported at the large group level and the episodes and measures in question may not even capture the price of care provided by the physician being measured. It is therefore conceivable that the pricing information received by patients to inform their assessment of value and care decisions will differ substantially from the pricing information used for payment purposes, resulting in confusion and mixed incentives.

The Role of Standard Episode Definitions and Grouping Logic

Pricing information in all programs and transparency efforts should be streamlined to provide a single, reliable source of price assessment and information for surgical patients and for use in value-based payment analysis. This can be achieved through use of a single price based on an episode grouper standard that reflects all services likely related to an episode of care. Such episodes should be defined in a way that is comprehensive of charges likely to occur and exclusive of charges unrelated to the care in question. An episode grouper is essentially a piece of software that combs through charges and assigns them to episodes of care based on a collection of clinical data files and a set of specified rules or logic. After scanning the groupers currently used, we found most hold black box clinical logic and lack accuracy for assigning the right service to the right episode. Many narrow the inclusive services only to allow those services that reach a common threshold. This does little to identify the high service needs of a high-risk population or the excessive costs of a low-frequency event. Only clinical oversight of the episode definitions in an open-source manner with trusted engagement of payers and patients allows for an episode definition to reach reasonable utility for price transparency. Using open source, standard episode definitions and grouping business logic for managing co-occurring episode events will define the episode for assessment across programs, which would provide the medical community with a common standard for assessing price. This approach for price reporting would readily translate into a comparable value framework for price transparency across payers and meet or exceed the accuracy of GFEs produced to meet current requirements for price transparency efforts and compliance with the No Surprises Act. It would also offer the opportunity to improve MIPS cost information with a more accurate, real price expression that lines up conveniently with improved quality measures.

Overview of QP Determinations and the APM Incentive

CMS discusses the Secretary's goal of having all people with Traditional Medicare in an accountable care relationship with their healthcare provider by 2030. To achieve this, the Agency seeks to develop, propose, and implement policies that encourage broad participation in Advanced APMs. In the CY 2017 QPP final rule, CMS finalized the policy for Qualifying APM Participant (QP) determinations. CMS states that under current policy, most eligible clinicians participating in Advanced APMs receive their

QP determinations at the APM Entity-level. However, the Agency received feedback in a RFI in the CY 2023 MPFS proposed rule that this policy may have inadvertently discouraged some APM Entities, such as ACOs, from including certain types of eligible clinicians leading those clinicians to be excluded from participation in Advanced APMs. To work towards their goals of promoting patient-centered care integrated across the care continuum, CMS proposes to amend their policy for QP determination so that beginning with the QP Performance Period for CY 2024, it would make all QP determinations at the individual-level rather than at the APM Entity-level. They also propose to change the definition of "attribution-eligible beneficiary" so that a single definition using covered professional services will be applied, regardless of the Advanced APMs a clinician participates in. This would modify the sixth criterion of the definition of "attribution-eligible beneficiary" to include any beneficiary who has received a covered professional service furnished by the eligible clinician (represented by their National Provider Identifier [NPI]) for whom CMS is making the QP determination.

The ACS supports efforts to increase specialty participation in APMs; however, from our perspective, these proposals do not solve the foundational issue with specialty APM participation. As we have stated in past comments, the expiration of incentives, shortfalls of the APM development process, lack of updates for a multi-year window are counter to the goals of the Medicare Access and CHIP Reauthorization Act (MACRA) and CMS. MACRA included a number of provisions aimed at facilitating and incentivizing the transition to value-based healthcare. This included both a framework for the creation of advanced APMs, and short- and long-term incentives for physicians to adopt these models. The gap between the expiration of the early APM Incentive Payments and the higher updates for QPs is only one factor limiting the success of the transition to value.

Another major factor is the discontinuation of incentive payments for participation in APMs before the pathway to participation is clear for many specialists. This is due largely to the failure of APM proposals submitted by stakeholders to be implemented or even demonstrated by CMS or its Innovation Center. This has led to a lack of buy-in from the physician community and a complete reliance on the part of CMS on the use of the financial incentives in the law, which, as noted, are flawed and in many cases not substantial enough to merit taking on additional burdens or risk associated with the currently available models. The ACS strongly believes that physicians are much more likely to participate in models which provide actionable information on how to continuously improve quality of care and lower cost for their specific patients. Models that fail to provide actionable information, or otherwise benefit their patients through improved quality, are more likely to be seen as burdensome, and therefore struggle to attract and keep participants. It is also important for CMS to consider the change management and behavioral economics at play as the business model continuously shifts from surgical private practice (self-determination) to system-level employment.

The ACS supports efforts in Congress to extend the APM incentive until additional models can be implemented to increase opportunities for surgeons and other specialists to participate meaningfully in APMs. We also support relaxing participation thresholds as long as participation in the models is substantial and increases value to patients.

However, these steps alone will not be enough, and additional steps will be necessary to provide the opportunities needed for meaningful participation by specialists as envisioned by MACRA. A library of Physician-Focused Payment Model Technical Advisory Committee (PTAC) recommended models exists that could help to meet the promise of MACRA, but CMS partnership with stakeholders is necessary to advance such models. Some of these models have now been public for more than six years. While measurement science and policy priorities have shifted and may be in need of updating, the underlying proposals still hold great promise. One meaningful step that CMS could take would be to provide grants to demonstrate the merits and measure the effects of PTAC-recommended models on a modest scale, with CMS technical assistance provided to ensure that successful models could be easily expanded and incorporated into the CMS library of models.

The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Mujumdar, Chief of Regulatory Affairs, at vmujumdar@facs.org, or Jill Sage, Chief of Quality Affairs, at jsage@facs.org.

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