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December 20, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave. SW
Washington, DC 20201

RE: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule (CMS-1715-IFC)

Dear Administrator Verma:

On behalf of the over 80,000 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) 2020 Medicare Physician Fee Schedule interim final rule (CMS-1715-IFC) published in the *Federal Register* on November 15, 2019.

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 and reimbursement is measured and paid for under the provisions contained in this rule, the ACS has a vested interest in CMS' Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP). With our 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 modifications to the PFS and QPP. Our comments below are presented in the order in which they appear in the rule.

PROVISIONS OF THE FINAL RULE FOR THE PFS

Determination of Malpractice (MP) Relative Value Units (RVUs)

Methodology for the Proposed Revision of Resource-based MP RVUs

In the CY 2020 PFS proposed rule, the Agency solicited comment regarding its proposed methodological refinements to the collection of the professional liability insurance (PLI) premium data used to conduct the statutorily required 5-year review and update of MP RVUs. **The ACS commends CMS for the additional work that it has undertaken to respond to our previous comments about insufficient premium data collection.** We are appreciative of the changes made in this final rule regarding major versus minor surgery premiums. For the CY 2020 MP RVU update, the Agency proposed to combine minor surgery and major surgery premiums when both are present in the filings for a specialty to create surgery service risk groups. The Agency indicated that it would consider surgical services with physician work RVUs greater than 5.00 as "major surgeries" for this analysis. In our comments to the proposed rule, we highlighted numerous distortions in work RVU assignments for certain surgical specialties and questioned if the arbitrary 5.00 work RVU threshold used to categorize surgical services, along with the overall combination of minor and major surgery premiums, contributed to such irregularities.

In this final rule, CMS acknowledged the ACS' comments and did not finalize its proposed methodological refinement to combine major surgery and minor surgery premiums, nor did it finalize its proposal to use a physician work RVU greater than 5.00 as a threshold to categorize surgical services as major surgery (or to categorize surgical services under 5.00 as minor surgery). **We thank the Agency for maintaining its existing surgical risk factor calculation process for CY 2020 and encourage CMS to work with the physician community to develop an appropriate work RVU threshold for minor and major surgeries for use in future MP RVU updates.**

However, the ACS remains concerned that some of the changes made as part of the new MP RVU update methodology and related specialty crosswalks finalized by the Agency are inaccurate and flawed. Our specific concerns with the CMS' MP RVU update methodology, along with our recommendations to improve this methodology, are described below.

- Imputation of premiums. The Agency finalized the use of partial and total imputation within its premium data set when CMS specialty names are not distinctly identified in the insurer filings. In instances where insurers report data for some (but not all) specialties that explicitly corresponded to a CMS

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specialty, where those data were missing, the Agency used partial imputation based on available data to establish what the premiums would likely have been had that specialty been delineated in the filing. In instances where there are no data corresponding to a CMS specialty in the filing, the Agency used total imputation to establish premiums.

We recognize that CMS has worked to collect more robust PLI premium information, but we remain concerned with the crosswalk imputations made by the Agency for certain specialties with insufficient data. **The ACS believes that this specialty mapping methodology is particularly flawed when the designated CMS specialty has very different practice patterns and premium costs than the "related" specialty identified by the Agency. This methodology may result in premiums that do not accurately reflect the services and inherent risk associated with a given specialty.** We urge CMS to work with the RUC to translate data from the specialty descriptions in insurers' rate filings to the appropriate specialty codes in order to avoid future inappropriate crosswalks or imputations.

- Premium rates for non-physician practitioner (NPP) specialties. CMS finalized a policy to maintain the current assignment of a risk factor of 1.00 for NPP specialties, which corresponds to the lowest physician specialty risk factor (i.e., Allergy/Immunology), if premium data for such NPP specialties were not robust enough to be used. **The ACS opposed this methodology and urged the Agency in its comments on the proposed rule to crosswalk NPP specialties without sufficient premium data to other NPP specialties with premium data instead of crosswalking to Allergy/Immunology.** In response to the ACS' comments, CMS stated that its proposal was to maintain the crosswalk of NPPs for which it had insufficient or no premium data to the lowest physician specialty, *not* to crosswalk NPP specialties with insufficient or no premium data to the risk factor of another NPP specialty for which it was able to collect data. As such, the Agency asserted that it would be inappropriate to adjust its proposal to crosswalk certain NPP specialty risk factors to those of other NPP specialties, rather than to the lowest physician specialty risk factor.

  We question why the Agency was unwilling to adopt NPP-to-NPP specialty crosswalks simply because these crosswalks were not included in the CMS' original proposal, as crosswalking to a different anchor would not have significantly deviated from such proposal. The ACS sent concrete evidence to the Agency demonstrating that NPP risk factors and premiums are significantly less than physician risk factors and premiums, and that the continued application of these unsubstantiated crosswalks may result in overcompensation for NPPs while negatively impacting the MP RVUs for all

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other specialties due to budget neutrality. **We seek clarification from CMS regarding its rationale to finalize its NPP-to-Allergy/Immunology crosswalk—which the Agency itself describes as "a matter of necessity, not clinical relationship"—despite feedback from multiple specialty societies and the American Medical Association (AMA) Specialty Society Relative Value Scale (RVS) Update Committee (RUC) indicating that this methodology is flawed and would produce inaccurate PLI premium imputations**.

Review and Verification of Medical Record Documentation

CMS finalized a general principle to allow a physician, physician assistant, or advanced practice registered nurse who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students, or other members of the medical team. This policy will apply across the spectrum of all Medicare-covered services paid under the PFS in all settings.

We appreciate the Agency's efforts to reduce documentation burden and replication of effort for clinicians, but we are concerned that this proposal does not include enough safeguards to ensure provider accountability, data accuracy, and patient safety. **The ACS urges CMS to monitor the implementation of this policy and any program integrity issues that arise from its use to ensure that the validity and completeness of patient health information and Medicare claims are not inadvertently compromised.**

Care Management Services

Comment Solicitation on Consent for Communication Technology-Based Services

In the CY 2019 PFS, CMS finalized separate payment for eight services that could be furnished via telecommunications technology. For CY 2020, the Agency finalized a policy that permits a clinician to obtain a single advance beneficiary consent for multiple communication technology-based services or interprofessional consultation services. CMS states that obtaining advance consent includes ensuring that the patient is aware of applicable cost sharing.

The ACS agrees that beneficiaries should be informed of any potential cost sharing, but we question how this would be communicated to—and consent subsequently received from—the patient, particularly for non-face-to-face care management services. We cannot envision a legally binding general consent process during which a patient provides consent for future, yet-to-be determined services that may be furnished without the patient being present, and therefore are

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concerned about a clinician's potential liability in the face of difficulty obtaining patient consent for these services. **We urge CMS to clarify the specific communication technology-based and interprofessional consultation services for which a single advance consent would apply.** The ACS recommends that separate beneficiary consent be obtained for all other non-face-to-face services not included in the Agency's list of communication technology-based and interprofessional consultation services to which this policy applies.

Payment for Evaluation and Management (E/M) Visits

Office/Outpatient E/M Visit Coding and Documentation

- Code 99XXX (*Prolonged office visit*)

Along with other prefatory language, CMS adopted the use of code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services*) when (1) time is used for code selection, and (2) when the time for a level 5 office/outpatient visit is exceeded by 15 or more minutes. CMS demonstrated how the prolonged office/outpatient E/M visit time would be reported in Table 33 of the final rule:

TABLE 33: Total Proposed Practitioner Times for Office/Outpatient E/M Visits When Time Is Used to Select Visit Level

Established Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)	CPT Code
40–54 minutes	99215
55-69 minutes	99215x1 and 99XXXx1
70-84 minutes	99215x1 and 99XXXx2
85 or more minutes	99215x1 and 99XXXx3 or more for each additional 15 minutes
New Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)	**CPT Code**
60-74 minutes	99205
75-89 minutes	99205x1 and 99XXXx1
90-104 minutes	99205x1 and 99XXXx2
105 or more minutes	99205x1 and 99XXXx3 or more for each additional 15 minutes

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We reiterate our comments that the use of code 99XXX as described in Table 33 does not align with the Current Procedural Terminology (CPT) guidelines and CMS' description in the text of this final rule. Per CPT, code 99XXX is used when the maximum time for a level 5 visit (54 minutes for an established patient and 74 minutes for a new patient) is exceeded by an additional 15 minutes, not when the maximum time for a level 5 visit is exceeded by between 1 and 15 minutes, as shown in Table 33. **CMS did not respond to our comment, but we urge the Agency to consider the table below as correct reporting.** For example, although the code range in the descriptor for code 99215 is 40-54 minutes, add-on code 99XXX cannot be reported until an additional 15 minutes of service has been provided after the maximum time for code 99215 (i.e., 54 minutes). This means that code 99215 is reported for service time up to 68 minutes, and then one unit of code 99XXX may be reported for 69-83 minutes.

Established Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)*	CPT Code
40-68 minutes	99215
69-83 minutes	99215x1 and 99XXXx1
84-98 minutes	99215x1 and 99XXXx2
99 or more minutes	99215x1 and 99XXXx3 or more for each additional 15 minutes
New Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)*	**CPT Code**
60-88 minutes	99205
89-103 minutes	99205x1 and 99XXXx1
104-118 minutes	99205x1 and 99XXXx2
119 or more minutes	99205x1 and 99XXXx3 or more for each additional 15 minutes

- Split/Shared E/M Service

In our comments to the proposed rule, we noted that the proposed 2021 CPT office/other outpatient services guidelines are inconsistent with the Medicare guidelines for split/shared E/M services. Per CMS guidelines, "split/shared" office visit E/M services only apply to ***established*** patients, while the new 2021 CPT introductory guidelines for the ***new*** patient office visit codes 99202-99205 specifically describe "incident to" work and time of both the physician and qualified health care professional (QHP) for selecting a level of code. This appears to conflict with the Medicare Claims Processing Manual, and the ACS asked for clarification on the "incident to" policy rules relative to the revised CPT guidelines for new patient office visit codes. CMS responded by stating that the Agency will review and consider the public comments received on this topic in future rulemaking. **We stress the importance of clarifying this issue as soon as**

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possible as clinicians, coders, and practice managers work to understand the new office/other patient coding guidelines and prepare to apply them correctly within their practices in 2021.

Simplification, Consolidation and Revaluation of Healthcare Common Procedure Coding System (HCPCS) Codes GCG0X and GPC1X

CMS finalized the deletion of code GCG0X and revised the code descriptor for code GPC1X 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. **As we stated in our comments to the proposed rule, we oppose the establishment of code GPC1X.** This add-on code is not necessary, given CMS' proposal to adopt the new CPT framework for E/M code level selection, which allows for selecting a higher-level service when more complexity (or more time) is involved. In the CY 2019 MPFS proposed rule, CMS stated the need for codes GPC1X and GCG0X was justified in order to account for additional costs and resources not reflected in the proposed single payment rate for levels 2 through 5 visits.

Under the CY 2020 PFS, however, this add-on code is no longer justified and therefore not warranted because CMS rescinded its proposal for a single payment rate for levels 2 through 5 visits. The Agency's justification for the add-on codes in the CY 2019 PFS was that the blended payment rate would have resulted in decreased reimbursement for certain specialties that typically bill mostly level 4 and 5 visits and would also have decreased payment for primary care clinicians by not accounting for the type and intensity of primary care visits. **That rationale no longer holds true under CMS' new policy of retaining the various visit levels, because physicians may bill a higher-level E/M code for visits that require additional resource costs based on the level of MDM or time.**

- Additional Resource Costs

In this final rule, CMS states that there are "additional resource costs" inherent in furnishing some kinds of office/outpatient E/Ms that are not recognized in the revised E/M code set. To account for additional resource costs described by the revised code GPC1X, CMS finalized 11 minutes of work time and no practice expense inputs. This work time is static and applies to any level of office/outpatient E/M code.

We disagree that every office/outpatient E/M visit for any new or established patient requires a single specific additional amount of physician and/or QHP

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work time that is not captured in the revised office/outpatient E/M coding structure.

The relationship of additional work time to the work time of each office/outpatient E/M code is inversely proportional. For example, 11 minutes related to a range of 15-29 minutes for code 99202 is a much higher percentage than how 11 minutes relates to a range of 60-74 minutes for code 99205. CMS has not provided any literature to show that the additional resource costs of such a service is the same for all E/M codes at all levels.

In addition, the assignment of 11 minutes of physician and/or other QHP time has a specific implication: that no matter what level of medical decision making (MDM) is required for a patient encounter, the physician and/or QHP will require an additional 11 minutes on the date of the encounter for services that are not included in or defined by the MDM guidelines and/or various other care management codes that can be reported concurrently.

Finally, with respect to reporting the office/outpatient E/M codes based on time, an additional 11 minutes of physician and/or QHP time will easily allow reporting of the next level of code regardless of the MDM required. In fact, for codes 99212 and 99213, an additional 11 minutes can actually result in reporting ***two*** levels higher. For example, the time range for code 99213 is 20-29 minutes. The addition of 11 minutes to 29 minutes results in 40 minutes, which can be reported with code 99215 (time range = 40-54 minutes).

- Typical Patient

CMS states in this final rule that the revised office/outpatient E/M visit codeset and RUC-recommended values more accurately reflect the resources associated with a ***typical visit***. However, the Agency believes the typical visit described by the revised code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. As such, CMS believes that there is still a need for code GPC1X because the revised office/outpatient E/M visit code set does not recognize that there are additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits.

We disagree that a code should be created to generically provide additional office/outpatient E/M visit payment for atypical patients for several reasons, as outlined below.

- The Harvard study, the RUC process, and CMS have always used the "typical patient" to develop recommendations for work and time. The assumption was that there is a wide variety of patient presentations,

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including some that require more work and some that require less work and that the typical (or median) work and time would result in overall equity.

- CMS has stated that for purposes of estimating the specialty level impacts, the agency assumed that the following specialties would bill code GPC1X with 100 percent of their office/outpatient E/M visit codes **because these 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**: 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, nephrology, infectious disease, psychiatry, and pulmonary disease.

  However, as shown in the table below, the RUC survey data clearly show that the median (i.e., "typical") responses for work RVU and total time for primary care providers was less than providers of specialty care. Further, the RUC recommendations (accepted by CMS) represent an increase above the median (typical) values for primary care providers.

CPT Code	Descriptor/ Specialty Group*	Survey N	Work RVU	% diff. from REC	Total Time	% diff. from REC
99202	**New Pt, 15-29 min day of visit**		**0.93**		**22**	
	PCP	572	**0.90**	**-3%**	**22**	**0%**
	Surgery	368	**1.00**	**8%**	**22**	**0%**
	Medicine	241	**1.00**	**8%**	**25**	**14%**
99203	**New Pt, 30-44 min day of visit**		**1.60**		**40**	
	PCP	664	**1.50**	**-6%**	**38**	**-5%**
	Surgery	448	**1.92**	**20%**	**38**	**-6%**
	Medicine	382	**1.92**	**20%**	**44**	**10%**
99204	**New Pt, 45-59 min day of visit**		**2.60**		**60**	
	PCP	675	**2.25**	**-13%**	**57**	**-5%**
	Surgery	460	**2.69**	**3%**	**58**	**-3%**
	Medicine	487	**2.75**	**6%**	**66**	**10%**
99205	**New Pt, 60-74 min day of visit**		**3.50**		**85**	
	PCP	595	**3.25**	**-7%**	**80**	**-6%**
	Surgery	388	**3.60**	**3%**	**80**	**-6%**
	Medicine	489	**3.68**	**5%**	**91**	**7%**

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CPT Code	Descriptor/ Specialty Group*	Survey N	Work RVU	% diff. from REC	Total Time	% diff. from REC
99212	**Established Pt, 10-19 min day of visit**		**0.70**		**18**	
	PCP	627	**0.75**	**7%**	**17**	**-6%**
	Surgery	411	**0.75**	**7%**	**19**	**6%**
	Medicine	315	**0.76**	**9%**	**20**	**11%**
99213	**Established Pt, 20-29 min day of visit**		**1.30**		**30**	
	PCP	694	**1.20**	**-8%**	**30**	**0%**
	Surgery	468	**1.39**	**7%**	**30**	**0%**
	Medicine	488	**1.35**	**4%**	**32**	**7%**
99214	**Established Pt, 30-39 min day of visit**		**1.92**		**49**	
	PCP	703	**1.92**	**0%**	**49**	**0%**
	Surgery	469	**2.00**	**4%**	**47**	**-4%**
	Medicine	519	**2.00**	**4%**	**50**	**2%**
99215	**Established Pt, 40-54 min day of visit**		**2.80**		**70**	
	PCP	658	**2.75**	**-2%**	**70**	**0%**
	Surgery	380	**3.00**	**7%**	**70**	**0%**
	Medicine	497	**2.79**	**0%**	**72**	**3%**

*For purposes of grouping the survey data, the involved specialties agreed to the following three groupings and specialty assignment: **PCP Specialties:** Certified Nurse Midwife, Family Practice, General Practice, Geriatric Medicine, Hospice and Palliative Care, Internal Medicine, Nurse Practitioner, Pediatric Medicine, Physicians Assistant, Preventive Medicine. **Surgical Specialties:** Cardiac Surgery, Colorectal Surgery (Proctology), Dermatology, General Surgery, Gynecological Oncology, Hand Surgery, Interventional Cardiology, Interventional Pain Management, Interventional Radiology, Neurosurgery, Obstetrics/Gynecology, Ophthalmology, Orthopedic Surgery, Otolaryngology, Plastic and Reconstructive Surgery, Podiatry, Surgical Oncology, Thoracic Surgery, Urology, Vascular Surgery. **Medicine Specialties:** Addiction Medicine, Cardiac Electrophysiology, Cardiology, Endocrinology, Gastroenterology, Hematology, Hematology/Oncology, Infectious Disease, Medical Oncology, Nephrology, Neurology, Optometry, Osteopathic Manipulative Medicine, Pain Management, Pathology, Physical Medicine and Rehabilitation, Psychiatry, Pulmonary Disease, Rheumatology, Sports Medicine.

- The work and time for all global procedure codes are based on the typical patient. Infrequent outlier operative work requires reporting modifier 22 (*Increased procedural services*) along with documentation that must support the substantial additional work and the reason for the additional work (i.e., increased intensity, time, technical difficulty of procedure, severity of patient's condition, physical and mental effort required). For 2018, there were 142,591 Medicare claims related to 3,429 CPT codes that had modifier 22 appended and approved for additional payment. These claims represent only 0.02 percent of the total claims for these 3,429 codes. The low number of claims with modifier 22 does not indicate that there were few outlier patients requiring substantial additional work that was more than typical, but rather we believe it is

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because Medicare Administrative Contractors adhere to the concept of "typical" patient and median payment. This information strongly invalidates establishment of a code that assigns additional work RVUs and time to pay for "more than the typical" for all E/M services reported by primary care providers and some specialty providers.

- Crosswalk Code

CMS has based the time and work RVU assigned to GPC1X on a crosswalk to code 90785 (*Interactive complexity (List separately in addition to the code for primary procedure)*). Code 90785 was created for CPT 2013 to replace a component of a series of interactive psychiatric diagnostic interview exam and interactive individual psychotherapy services under an old framework of codes using play equipment, physical devices, a language interpreter, or other mechanisms of communication. This add-on code of 11 minutes is ***only*** meant to be reported for time specifically related to the time to manage the anxiety, maladaptive communications, emotional reactivity, and conflict of ***non-patient participants*** (i.e., parents, family, caregivers) present during a session. Further, the work related to the code includes documentation of the nature of the interactive work, and communication with participants and others between sessions to ensure the treatment plan is implemented (as well as to put away play materials when play therapy is provided). Without regard to the time, work value, and/or current reporting of code 90785, we can agree that this code describes very specific work related to specific guidelines and that the work was previously described and reported with deleted codes. In contrast, code GPC1X is to be reported for ***unidentified 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. This information brings into question the validity of using code 90785 as a crosswalk of "similar work and time" for GPC1X.

We also note that code 90785 has only been surveyed once and has recently been identified by the RAW through a screen of high-volume growth, requiring an Action Plan for the upcoming January 2020 RUC meeting. The code was clearly defined in CPT and the work and several typical patients were described through the RUC process. None of the typical patient vignettes were patients who were in a facility, however (for Medicare), more than 60 percent of the claims are for patients in a facility. Further, 40 percent of 2017 Medicare claims for code 90785 came from less than 6 percent of providers reporting this service. This information brings into question the current time and work assigned to code 90785, and therefore also questions the validity of using 90785 as a crosswalk for any code at this time.

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In summary, HCPCS code GPC1X is not warranted because:

- The additional resource costs for any additional work and/or time are inherent to the new CPT coding framework for office/outpatient E/M visits which allows for selecting a higher level of service when more complexity (or more time) is required.

- The RUC and CMS process for code valuation has always been based on the typical patient which incorporates work and time for atypical patient outliers that may require more or less work.

- The RUC survey data for the office/outpatient E/M codes show that the typical patient for primary care providers requires less work and/or time than specialty care providers which refutes the idea that code GPC1X is needed to provide extra payment to primary care providers because the median work RVU for the E/M codes undervalues their work.

CY 2020 UPDATES TO THE QUALITY PAYMENT PROGRAM

MIPS Program Details

Transforming MIPS: MIPS Value Pathways

CMS finalized a new Merit-based Incentive Payments System (MIPS) framework, known as MIPS Value Pathways (MVP), which will start with the 2021 MIPS performance period (2023 MIPS payment year). The MVP framework aims to connect measures and activities across the four MIPS performance categories, incorporate a set of administrative claims-based population health quality measures, provide data and feedback to clinicians, and enhance information to patients. MVP is also intended to streamline MIPS reporting by focusing the number of required measures to best assess the quality and value of care within a particular specialty or condition. We would like to thank CMS for being responsive to the College's feedback and finalizing MVPs, which have the potential to better align QPP objectives and focus on a patient's condition. We also are thankful that CMS has recognized verification programs as an important component of improving quality in surgical care. In our initial comments on the proposed rule, and in our comments below, we strongly encourage CMS to step outside of the current MIPS framework and allow for innovation of a truly patient-centric program.

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In the ACS comments on the MPFS proposed rule, we outlined a list of recommended MVP guiding principles, a framework to score surgical MVPs based on our guiding principles, and a description of the ACS Transforming Health Care Resources to Increase Value and Efficiency, or "THRIVE" demonstration project, which is a partnership with Harvard Business School's (HBS) Institute for Strategy and Competitiveness to define value based on outcomes that matter to patients and the cost of delivering those outcomes.[1] Since our submitted comments, we have continued to engage stakeholders on the development of surgical MVPs and have moved forward in our progress with ACS THRIVE, which will inform the development of MVPs. As part of this continued work, below we provide additional recommendations for how surgical MVPs should be pilot tested. These recommendations focus on the creation of a streamlined program that align incentives to focus on what matters to the patient throughout their care journey.

Verification Programs as the Foundation for Surgical MVPs

ACS strongly recommends that surgical verification programs, such as the Surgical Quality Verification Program (SQVP),[2] provide the foundation for surgical MVPs. Having verification as the center of a value-based quality program will result in a carefully designed program built on evidence-based standards. This framework will allow for program components to be built into a cohesive system, including: condition and procedural systems for human factors/systems engineering, data management for reliably tracking outcomes as part of an improvement cycle, and promoting interoperability. We provide several examples of how verification programs can streamline MIPS requirements. For Promoting Interoperability (PI), the 2015 Certified Electronic Health Records (CEHRT) requirements can be built into the SQVP standards for verification with positive incentives available for PI beyond the use of CEHRT, such as using national standards for data exchange. Full Improvement Activity credit could be recognized for participation in a verification program because quality improvement activities are key to verification. Quality can be scored based on a combination of the level of verification program participation, conformance

[1] American College of Surgeons. American College of Surgeons and Harvard Business School's Institute for Strategy and Competitiveness partner to develop value measurement tool for hospitals. July 2019. Retrieved from: https://www.facs.org/media/press-releases/2019/acsthrive071819

[2] American College of Surgeons. "Optimal Resources for Surgical Quality and Safety." 2017. Retrieved from: https://www.facs.org/quality-programs/about/optimal-resources-manual

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measures, and performance measures. To score the verification level as part of the quality score, a phased implementation approach where performance is initially scored based on meeting a limited number of standards would allow for a transition period. As the program evolves, scores can be increasingly tied to more complete performance on the overall standards met.

Guidelines for Scoring MVPs

As part of our proposed rule comment letter, ACS advocated for value to be thought of as an assessment or judgement that is made by the patient, and therefore must measure health outcomes that matter to the patient. We believe that in order for patients to assess their care, the MVP framework should further emphasize the patient's journey, measuring the overall care for a condition or procedure. As discussed above, scoring for quality should constitute three categories with shared attribution for the majority of the care team level based on: participation in verification programs to ensure the system pursues excellence to provide the highest possible quality care to the patient; conformance measures, which includes clinical standards and monitoring high risk events related to preventable harms (i.e. "do no harm"); and performance measures, which measure the achievement of patient goals that are valid for differentiating outcomes for a condition or procedure. We note that this all must be pilot tested prior to implementation.

Since the submission of our comments, we have continued to think through the implementation of this framework and how incentives can be aligned to motivate clinicians and their hospital/systems to transition from measuring care in the current MIPS program. Below is a list of additional guiding principles that should be considered when pilot testing MVPs:

1. **MVPs must be voluntary, but positive incentives should encourage the transition toward surgical MVPs**. More than half of surgeons are employed, and therefore many decisions on how to participate in the QPP are made by the heath system administration and based on overall enterprise revenue. Therefore, if a multi-specialty group has been performing well in the GPRO Web Interface and can predict how the group will perform based on primary care metrics, taking on a new specialty and patient-specific care model could appear as burdensome and financially risky. Because of this, in the early years of adoption, it will be important to truly reward practices that take on innovative quality

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programs which are better suited to individual team efforts.

2. **Allow for tiered transition toward use of condition-specific patient-reported outcome measures (PROMs).** Due to the lack of PROMs in the current MIPS program and the general lack of condition-specific PROMs nationally, PROM scoring should be tiered for levels of engagement. In the first year, clinicians and practices should be encouraged by participation levels, which refer to the ability to collect and report PROMs. It will take time for clinicians to figure out a mechanism that works well for their patients and practice. In following years, clinicians and practices can work towards incorporating additional PROMs that are included in the MVP as appropriate and validated for a condition. For some practices, PROs may already be collected in their EHR, such as PROMIS Global. The eventual goal will be for MVP participants to collect and report a broader set of condition-specific PROMs, measuring the outcomes that matter to the patient for that condition.

3. **Reward high fidelity data through positive incentives**. As expressed by ACS in many letters and meetings, the QPP is currently not on the right path to define a value expression for surgical care. Measures do not map to the surgical patient or the care model, resulting in measurement data that are not actionable or meaningful to clinicians and difficult for patients to assess value. The MIPS measurement system does not rely on a single source or entity to aggregate data for MVP benchmarking. High fidelity measures are analyzed and aggregated within a given domain or clinical service line by a single source and submitted to CMS for consistency in data interpretation. This includes standardized data definitions, standardized risk adjustment/data analytics, consistency of data ascertainment methods, and common normalization methods. CMS might think of this concept as similar to topped out measures policy, but instead of disincentives for reporting topped out measures, we recommend positive incentives for reporting nationally benchmarked risk-adjusted measures that rely on a single source of truth.

   To do this, CMS must allow for innovation in MVPs, and think beyond Qualified Clinical Data Registries (QCDRs) as the only mechanism to report new specialty-specific measures in the MIPS. For example, if

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surgical teams are already reporting to a clinical data registry such as ACS National Surgical Quality Improvement Program (ACS NSQIP), MVPs should recognize NSQIP so that they are not required to report QCDR measures in addition to NSQIP—especially when most QCDR measures are self-reported and do not have the same level of rigor as validated and audited clinical data registries that are part of a verification program.

Opportunities for the Use of Digital Standards and Interoperability in MVPs

A challenge with the current approach to advancing health information technology (HIT) through the PI category is the focus on measures, rather than on functionality and incentivizing the advanced use of HIT products. Rather than measuring the number of Consolidated-Clinical Document Architecture (CCDA) sent at transitions of care and patient access to portals, the program should instead require the use of CEHRT, and incentivize the following: early use of data exchange standards, such as Application Programming Interfaces (APIs) using Fast Healthcare Interoperability Resources (FHIR); bidirectional data exchange and the use of a centralized patient cloud; and the use of standard workflows and data capture that drives semantic interoperability and consistency in documentation used for quality measurement. **Creating positive incentives for high fidelity data and the use of tools for exchange between systems will drive more consistent and trusted data, allowing for better benchmarking between clinicians and cohorts, and meeting the quality goals of the MVP.**

The ACS is currently working on a pilot project for driving semantic interoperability based on patient conditions. By developing standard workflows and data points for clinical conditions and making these knowledge artifacts widely available, more consistent data will be collected. These data can better inform clinicians and patients of treatment options based on documented data, create an opportunity for the digitization of workflows within EHRs or third-party applications, and bring together data from disparate sources. Long term, this model would be scalable and able to work alongside advanced technology, such as Artificial Intelligence (AI) or Machine Learning (ML).

For a pilot MVP, the ACS' above project on semantic interoperability could become integrated within multiple facets. The use of CEHRT can be included into surgical verification programs, and the use of standardized workflows and data documentation could be incentivized through MVP tiered scoring. There could be

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further incentives for early adoption of national standards for data exchange, including FHIR-based APIs, and bi-directional exchange with a centralized cloud platform. Lastly, from a holistic perspective**, semantic interoperability will lead to more consistent, standard data across systems and clinicians, which will lead to increased data exchange and more complete patient data, and more accurate benchmarking and quality measurement.**

MVP Scoring Example

Figure 1 (below) illustrates an example framework when considering implementation and scoring. ACS provided this figure in our initial comments to the proposed rule. To expand upon this framework, Figure 2 gives examples of measures and activities that could be included in the surgical MVP framework. These examples are for illustrative purposes only.

In Figure 1, surgeon Jane Doe practices in two hospitals and two of the surgical MVPs align with her practice. In this example, she would have to meet the MVP threshold (percent of surgical cases) by totaling the volume of surgical services for each of the MVPs she is eligible for (note: the appropriate methodology for how to determine the appropriate MVP or mix of MVPs must be analyzed). The MVP Score can be established with a total score by volume and weight assigned to: the SQVP Verification (or other relevant verification program), PROs, and the event rates. ACS weights the SQVP and PROs as the dominant elements. To meet the MVP's program needs, the IA and PI categories are represented within the verification program, with positive incentives available for PI beyond the aspects inherent to the verification programs. For an initial pilot year(s), these broadly applied components—verification, performance, and conformance measures—can be a starting place. In future years, more detailed metrics could be refined for each MVP, if needed. Inputs for how to measure and weight the components would require guidance from a multi-stakeholder community. ACS is currently working on how to determine differing levels of verification for the purposes of incentivizing high-valued surgical care, and how to assess performance and conformance measures as part of the Total Weighted Average MVP score.

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Figure 1. Surgical MVP Scoring Example (for illustrative purposes)

Jane Doe: Hosp A N=200		**MVP – Colon Cancer**	**MVP – Breast Cancer**
Verification Program: SQVP	Highest Weight in MVP Score	Score based on verification level	Score based on verification level
Performance: PROMIS, MSKCC Bowel Function Index (for colon), etc.	Medium Weight in MVP Score	Score based on performance	Score based on performance
Conformance: SSI/Readmit/Risk Calculator (Event rates)	Lowest Weight in MVP Score (least important)	Score based on performance	Score based on performance
Hospital A MVP Score (Y+Z)		Y	Z
Jane Doe: Hosp B N=100		**MVP – Colon Cancer**	**MVP – Breast Cancer**
Verification Program: SQVP	Highest Weight in MVP Score	Score based on verification level	Score based on verification level
Performance: PROMIS, MSKCC Bowel Function Index (for colon), etc.	Medium Weight in MVP Score	Score based on performance	Score based on performance
Conformance: SSI/Readmit/Risk Calculator (Event rates)	Lowest Weight in MVP Score (least important)	Score based on performance	Score based on performance
Hospital B MVP Score (A+B)		A	B
Surgeon Total MVP Score=Weighted Average of Hospital A and Hospital B			

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Figure 2 expands upon the Figure 1 and illustrates the translation of key components of the MVP and MIPS program for the condition of colon cancer. As discussed above, the verification program can be thought of as the foundation of the surgical MVP to create the structure to cohesively include a condition and procedural system for human factors/systems engineering, data management for reliably tracking outcomes as part of an improvement cycle, and promoting interoperability beyond the core requirements of the current PI program.

Figure 2. MVP Scoring Example to Meet MIPS Requirements: Colon Cancer (for illustrative purposes)

		MIPS Performance Categories		
		Quality	Improvement Activity	Promoting Interoperability
MVP – Colon Cancer	Verification Programs	Surgical Quality Verification Program (SQVP) **OR** Complex GI Verification	PDSA (Plan-Do-Study-Act) Cycle based on outcome data from conformance and performance measures	Inherent attestation within verification program (use of CEHRT) <u>Opportunity for bonus points:</u> • Data exchange using FHIR-based API; • Use of standard workflows and data points (e.g., demonstratable semantic interoperability); • Bi-directional data exchange; use of a patient cloud platform
	Conformance Measures	Readmission, SSI, Anastomotic Leak	Risk-adjusted outcomes data	
	Performance Measure	MSKCC Bowel Function Index[3] PROMIS Global[4]	Condition-specific PROM data	

[3] Temple, LK; Bacik, J; Savetta, SG: Gottesman, L; Paty, PB; Weiser, MR; Guillem, JG; Minsky, BD; Kalman, M; Thaler, HT; Schrag, D; Wong, WD. The development of a validated instrument to evaluate bowel function after sphincter-preserving surgery for rectal cancer. Dis Colon Rectum. 2005; 48(7):1353-65. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/15868235

[4] Patient Reported Outcomes Measurement Information System. Global Health. 2017. Retrieved from: http://www.healthmeasures.net/images/PROMIS/manuals/PROMIS_Global_Scoring_Manual.pdf

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Population Health Measures

In the final rule, CMS noted their intent to implement a foundational population health core measure set using administrative claims-based quality measures. The Agency notes that these measures can be broadly applied to communities or populations and can result in MVP measure tracks that provide more uniformity in the programs' measures, allow focus on important public health priorities, and increase the value and applicability of MIPS performance data in the context of APMs. As discussed throughout our comments to the proposed rule, surgeons do not find these types of measures actionable or meaningful to caring for surgical patients. It will be burdensome and frustrating for surgeons if MVP performance is impacted by measures that are more actionable and relevant to primary care physicians. Therefore, we did not include population health measures as part of the surgical MVP example. **We ask CMS to provide examples of how population-based claims measures have demonstrated improvements in surgical care, and whether this information has been meaningful to surgical patients. Without this information, we do not believe that these measures will encourage coordination and promote value for surgical patients.**

Promotion of Consistent Verification Standards Across a Condition or Episode

On a larger scale, we believe this framework has the ability to reduce clinician burden and resolve the siloed nature of the MIPS program while promoting verification programs that have demonstrated improvements in quality. We consistently hear from surgeons that they are required to report different quality data from one payer to the next, and that they have to focus on "passing the test" for each payer, rather than being able to hone in on a set of consistent and meaningful metrics. There are also reports of inconsistent performance rates for the same event, based on how one payer defines, analyzes, and aggregates SSI, for example. Also concerning, due to clinical operating budgetary constraints, we have heard that some hospitals and systems sometimes have focused on measures suited for a payment program because of the impact on revenues, and this resulted in fiscal reductions to known successful and vital internal quality programs. Therefore, we strongly encourage CMS to take the opportunity with MVPs to think beyond the QPP, and consider how CMS can influence value-based care with alignment across federal programs and possibly private payers. We believe that if the MVP program is implemented in a truly patient-centric way, this

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framework will promote cross-category credit and work to standardize the definition of a verified center, also known as a Centers of Excellence (COEs), across the country.[5] By standardizing COEs and aligning those standards with national incentive programs such as MIPS, clinicians and systems can follow the same standards which could enable the adoption of standards across systems and adoption by private payers in tiered quality programs. This would greatly reduce administrative burden.

Third Party Intermediaries

Completion of QCDR Measure Testing

CMS finalized its proposal that beginning with the 2021 performance period, all QCDR measures must be fully developed with completed testing results at the clinician level prior to submitting the QCDR measure at the time of self-nomination.

While ACS agrees with the concept of verifying measure validity and reliability before large scale implementation in a payment program, we do not agree with the CMS strategy for measure testing as an additional criterion for QCDR measures without first reframing the entire quality measure enterprise. We do think that QCDR measures and MIPS measures should do a better job of ensuring a higher level of measure integrity in a more strategic way, which fit the quality improvement goals within current clinical care models. In other words, CMS and the clinical community should set specific quality goals for an episode of care and implement measures to track impacts on patient expectations and outcomes. Currently, the entire CMS measure enterprise is ad hoc on a minute-to-minute basis and largely still based on billable services. What we need to do is to define the strategic and operational limitations within the measure framework and come up with a better solution for measuring quality as part of a payment program. This solution must also fit the care model. As advances in clinical care augment the care models, CMS will need to make changes to its quality metrics and then apply these with incentives through their payment programs. Specialty societies lack limitless resources to underwrite the operation of a strategic measure environment

[5] Li, J; Burson, RC; Clapp, JT; Fleisher, LA. Centers of excellence: Are there standards? Healthcare (Amst). 2019 Oct 29:100388. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/31672494.

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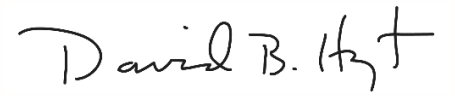
and therefore this needs to be included when accounting for the overall economics of health care.

The ACS appreciates the opportunity to provide feedback on this 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, Regulatory Affairs Manager, at vmujumdar@facs.org, or Jill Sage, Quality Affairs Manager, as jsage@facs.org.

Sincerely,



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