



September 6, 2022

Chiquita Brooks-LaSure, MPP  
Administrator  
Centers for Medicare & Medicaid Services  
Attention: CMS-1770-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts (CMS-1770-P)

Dear Administrator Books-LaSure:

On behalf of the over 84,000 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) 2023 Medicare Physician Fee Schedule (MPFS) proposed rule published in the *Federal Register* on July 29, 2022.

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 College 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

### Valuation of Specific Codes

#### *Anterior Abdominal Hernia Repair (CPT codes 157X1, 49X01, 49X02, 49X03, 49X04, 49X05, 49X06, 49X07, 49X08, 49X09, 49X10, 49X11, 49X12, 49X13, 49X14, and 49X15)*

CPT code 49565 (*Repair recurrent incisional or ventral hernia; reducible*) was identified by the Resource-based Relative Value Scale (RVS) Update Committee (RUC) as potentially misvalued with a site of service anomaly: less than 50 percent inpatient status; includes inpatient visit codes; and greater than 5,000 utilization. The stakeholder societies reviewed the site of service data for CPT code 49565 and found an almost even split of 48 percent between the inpatient and outpatient settings, with a small percent performed in ambulatory surgical centers.

Noting the bimodal distribution of services, the societies requested referral of CPT code 49565 to the American Medical Association (AMA) CPT Editorial Panel to update anterior abdominal hernia repair coding to reflect the current standard of practice. The Panel approved the following changes for CPT 2023:

- Delete all current open and laparoscopic codes for repair of anterior abdominal hernias;
- Delete add-on code 49568 for mesh for open ventral/incisional hernias and large defects as a result of necrotizing soft tissue infection;
- Create 12 new codes (49X01-49X12) for anterior abdominal hernia repair by any approach (i.e., open laparoscopic, robotic); by initial or recurrent; by total defect size; and by reducible or incarcerated/strangulated;
- Create two new codes (49X13-49X14) for parastomal hernia repair by reducible or incarcerated/strangulated;
- Create one new add-on code (+49X15) for removal of mesh/prosthesis to be reported only with the new hernia repair codes;
- Create one new code (157X1) for mesh/prosthesis for delayed closure of external genitalia, perineum and/or abdominal wall defect(s) due to soft tissue infection or trauma; and
- Assign a 000-day global period in response to the bimodal site of service for this family of hernia repair codes.

The RUC recommendations for these new codes considered the variability of the postoperative work by whether the typical patient is: (1) discharged the same day; (2) stays overnight as an outpatient with a separate evaluation and management (E/M) visit on the same date; or (3) is admitted to the hospital with a separate E/M visit on the same

date.

CMS disagrees with many of the RUC-recommended work relative value units (RVUs) for the codes within this family that it believes to have a postoperative overnight stay built into their valuation. **We wish to highlight that the Agency’s interpretation is incorrect, as none of the work RVU recommendations made by the RUC include any work beyond midnight on the day of the procedure.** We urge CMS to review the RUC minutes and recordings of the discussion at the meeting to confirm that none of the work RVU valuations included any E/M work beyond midnight on the day of the procedure.

### **23-Hour Policy**

CMS states that it disagrees with the RUC-recommended work RVUs for these codes because the RUC did not completely apply the 23-hour policy calculation (finalized in the CY 2011 PFS final rule) in formulating its recommendations.<sup>1</sup> Additionally, CMS disagrees with the RUC-recommended work RVUs for the CPT codes in this family for which the RUC considered the patient to be admitted during the postoperative period because the RUC did not apply the 23-hour policy when formulating its recommendations. **We believe that the CMS discussion of this issue includes four major inconsistencies, as described below.**

- CMS states the following in this proposed rule: “...in the CY 2011 PFS final rule (75 FR 73226), the work RVUs for services that are typically performed in the outpatient setting and require a hospital stay of less than 24 hours may in some cases involve multiple overnight stays while the patient is still considered to be an outpatient for purposes of Medicare payment.”

CMS indicates several times that patients are still considered to be an outpatient for purposes of Medicare payment if they stay less than 24 hours, “even if their stay may involve multiple nights.” We believe this statement is nonsensical—two midnights cannot be passed for a time period of less than 24 hours. **We ask CMS to clarify this statement and to provide examples of instances where this might occur. Further, we seek confirmation that the Agency is not proposing changes to the Two-Midnight rule regarding inpatient versus outpatient status.**

- CMS states the following in this proposed rule: “Because such services are typically furnished in the outpatient setting, they should not be valued to include inpatient postoperative E/M visits.”

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<sup>1</sup> 75 FR 73226

In this same rule, CMS proposes to adopt the revised E/M CPT codes 99221-99223 and 99231-99233, which allow these codes to be reported for hospital inpatient or observation care services. CPT codes 99218-99220 and 99224-99226 (observation care) will be deleted. Observation care is considered outpatient by CMS; therefore, the merging of inpatient and observation care facility E/M services recognizes that the physician work is not different based on the patient's facility status, while still acknowledging that the facility status impacts facility resource use and facility payment (e.g., diagnosis-related groups [DRG] or ambulatory payment classification groups [APC]). **If this is correct, then the 23-hour policy—which assumes that physician E/M work is different based on a patient's facility status (inpatient versus observation/outpatient)—is no longer valid.**

- CMS states the following in this proposed rule: *“The level of discharge day management services included in the valuation of such services should similarly not reflect an inpatient discharge and should therefore be reduced.”*

CMS proposes to adopt the revised CPT codes 99238-99239, which allow these codes to be reported for hospital inpatient or observation care discharge services. Similar to our argument above regarding initial and subsequent inpatient and observation care E/M services and the fact that observation care is considered outpatient by CMS, the revision of CPT codes 99238-99239 recognizes that the physician work is not different based on the patient's facility status, while still acknowledging that the facility status impacts facility resource use and facility payment (e.g., DRG or APC). **If this is correct, then the 23-hour policy—which assumes physician E/M work is different based on a patient's facility status (inpatient versus observation/outpatient)—is no longer valid.**

- CMS states the following in this proposed rule: *“As discussed in CY 2011 rulemaking, the intraservice time from the inpatient level E/M postoperative visit should be reallocated to the immediate postservice time of the service.”*

**The ACS has numerous concerns with this statement, described below.**

- Immediate postservice time is defined as *“Immediate postoperative care on day of the procedure, including non-skin-to-skin work in the OR, patient stabilization in the recovery room or special unit and communicating with the patient and other professionals (including written and telephone reports and orders).”* **Immediate postoperative work includes such work furnished through discharge from recovery.** A postoperative E/M service on the day of the operative procedure, if performed, is a separate and unique stand-alone service. Thus, an E/M service when performed during the period after discharge from recovery until midnight of the same day are separate and distinct. There is also no difference in work to provide a separate

E/M service furnished to a postoperative patient by the operative surgeon compared with any other provider. **The level and work value for care of the patient should be the same regardless of the specialty of the provider and determined by the degree and complexity of medical decision making (MDM).**

- CMS has not provided a rationale for including only intraservice time from the RUC database for an E/M service instead of the total time for the service. **We question if CMS has evidence that postoperative visits furnished later on the day of surgery do not involve pre- or post-time related to a separate E/M service for activities, such as evaluation of the patient for new problems, calls from family or clinical staff on the floor, reviewing new tests/imaging, or discussing the patient with other physicians or clinical staff (e.g., therapists, dieticians) on the care team.**
- CMS has never provided a rationale for why the Agency believes the intraservice time for an E/M service provided at the patient’s bedside and on the floor or unit should have a work intensity of 0.0224 instead of the intensity of a discrete E/M service. For example, the current intensity of CPT code 99231 is 0.054, which is more than twice the intensity that CMS places on the surgeon’s postoperative work by relegating intraservice time to the immediate postoperative time category. **We wish to remind CMS that, per statute, specialties should not be paid differently for the same service. This policy is discriminatory and the ACS urges CMS to compensate physicians who perform the same service(s) equally.**
- CMS accepts the work RVUs and times for the revised CPT codes 99231-99233 in this same proposed rule. These revised codes no longer have pre-, intra-, and post-service time categories. For example, CMS accepts a single time of 25 minutes for CPT code 99231. **This will further exacerbate the discriminatory and inequitable treatment of global code valuation.**
- When the Agency first established its 23-hour outpatient policy, the ACS provided written feedback to CMS that addressed the decision-making process for valuing procedure codes that have Medicare outpatient status, the use of refinement panels, and the arbitrary discount in physician work for the same work performed by any provider of a non-global service. Included in our feedback was the following statement:

*CMS has now implemented a policy by which it is creating differential payments for the same work performed by different physicians as a backdoor mechanism for reducing the work RVUs for surgical procedures. They have valued the worth of a surgeon for postoperative evaluation and management work at about 30 percent of a non-surgeon. Non-surgeons are allowed to provide the same work to the same patient at 100 percent*

*reimbursement...we believe that this policy leads to a loss of validity and integrity of the current system.<sup>2</sup>*

**We continue to believe there is no valid justification for discounting a postoperative E/M service visit later on the same day of surgery to equal only the intraservice time of the visit multiplied by an intensity of 0.0224.** Surgeons do not round on a postoperative patient the same day without: (1) reviewing interval chart notes prior to the face-to-face visit with the patient; (2) charting the visit and confirming or modifying the current orders; and (3) discussing the patient with unit clinical staff and consulting physicians (when appropriate).

CMS implemented its 23-hour policy for discounting surgical postoperative work based on the argument that the Agency could not include inpatient work in their time/work file. However, CMS has also erroneously rejected past RUC recommendations for outpatient/observation codes, indicating that “these inpatient codes” could not be included for procedures that are typically outpatient. **Despite this statement, CMS went on to concur with the CPT Editorial Panel that there is no difference in physician work for an inpatient E/M service and an observation (i.e., outpatient) E/M service.**

For these reasons, we firmly believe that the 23-hour policy calculation is flawed given the CPT changes to facility E/M CPT codes 99231-99233 and 99238-99239, which CMS proposes to accept in this rule. **We urge the Agency to abandon this policy as no longer valid and to accept the RUC recommendations for physician work for the anterior abdominal hernia codes, along with the implantation of mesh code, that are based on magnitude estimation and not a building block approach.**

**CPT Code 49X01**

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
49X01	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	NEW	6.27	5.96

CMS disagrees with the RUC-recommended work RVU of 6.27 for CPT code 49X01 and instead proposes a work RVU of 5.96, as shown in the table above.

CPT code 49X01 will typically (more than 50 percent of the time) involve same-day discharge of the patient. CMS disagrees with the RUC-recommended work RVU of 6.27

<sup>2</sup> American College of Surgeons. (2011, November 29). *CY 2012 Medicare Physician Fee Schedule Final Rule and CMS Refinement Panels* [comment letter].

for CPT code 49X01 because the Agency believes it falls above the median value range for codes with similar times. CMS bases its proposed work RVU of 5.96 on the intraservice time ratio of 90 minutes of intraservice time of a current hernia repair code—CPT code 49560 (*Repair initial incisional or ventral hernia; reducible*)—compared to the 45 minutes of intraservice time for CPT code 49X01. CMS also supports its proposed work RVU of 5.96 using CPT code 93453 (*Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed*), which has a work RVU of 5.99, the same intraservice time (45 minutes) as CPT code 49X01, and a slightly higher total time of 113 minutes.

CMS proposes a calculated value that is below the survey 25<sup>th</sup> percentile work RVU because it falls above the median value for codes with similar times, but fails to state which CPT codes were reviewed to determine that the RUC recommendation was above the median. **Without such information, we cannot provide a cogent discussion about why the value for 49X01 should be above the median of a group of unknown comparator codes.** CMS used a 90-day global code and intraservice time ratio to calculate a proposed value for this 0-day global code, rather than rely upon the process of magnitude estimation used by the RUC and accepted by CMS for innumerable other CPT codes. Finally, the Agency uses a percutaneous catheterization code that includes time and work for low intensity imaging and radiological supervision and interpretation as support for the proposed work value.

CMS’ calculations and mismatched code comparisons are incorrect on numerous levels. **We urge CMS to accept the RUC-recommended work RVU of 6.27 for code 49X01 based on magnitude estimation in comparison to reference codes and to others in the family of codes that were surveyed.**

**CPT Code 49X07**

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
49X07	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	NEW	7.75	7.42

CMS disagrees with the RUC-recommended work RVU of 7.75 for CPT code 49X07 and instead proposes a work RVU of 7.42, as shown in the table above.

CPT code 49X07 will typically (more than 50 percent of the time) involve same-day discharge of the patient. CMS disagrees with the RUC-recommended work RVU of 7.75 for code 49X07 because the Agency believes it falls above the median value range for

compared to codes with similar times. CMS bases its proposed calculated work RVU of 7.42 on the intraservice time ratio of 100 minutes of intraservice time for a current hernia repair code—CPT code 49565 (*Repair recurrent incisional or ventral hernia; reducible*)—compared to the 60 minutes of intraservice time for CPT code 49X07. CMS also supports its proposed calculated work RVU of 7.42 using CPT code 52353 (*Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)*), which has a work RVU of 7.50, the same intraservice time (60 minutes) as CPT code 49X07, and a very similar total time of 133 minutes.

CMS proposes a calculated value that is below the survey 25<sup>th</sup> percentile work RVU because it falls above the median value for codes with similar times, but fails to state which codes were reviewed to determine that the RUC recommendation was above the median. **Without such information, we cannot provide a cogent discussion about why the value for 49X07 should be above the median of a group of unknown comparator codes.** CMS uses a 90-day global code and intraservice time ratio to calculate a proposed value for this 0-day global code. Finally, the Agency uses a CPT code describing an endoscopy through a natural orifice as support for its proposed calculated work value. However, CPT code 52353 is not as intense or complex as 49X07 and therefore is not an appropriate comparison code.

CMS’ calculations and mismatched code comparisons are incorrect on numerous levels. **We urge CMS to accept the RUC-recommended work RVU of 7.75 for code 49X07 based on magnitude estimation in comparison to reference codes and to others in the family of codes that were surveyed.**

**CPT Codes 49X02, 49X03, 49X04, 49X05, 49X08, and 49X09**

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
<b>49X02</b>	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	NEW	9.00	8.46
<b>49X03</b>	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	NEW	10.80	10.26
<b>49X04</b>	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of	NEW	14.00	13.46



CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
	defect(s); 3 cm to 10 cm, incarcerated or strangulated			
49X05	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	NEW	14.88	13.94
49X08	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	NEW	10.79	10.25
49X09	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	NEW	12.00	11.46

CPT codes 49X02, 49X03, 49X04, 49X05, 49X08, and 49X09 will typically (more than 50 percent of the time) require an overnight stay for the patient. For these codes, the RUC survey indicated that an E/M service would be performed later on the same after surgery when the patient is in the postsurgical unit/floor. CMS disagrees with the RUC-recommended work RVUs for CPT codes 49X02-49X05 and 49X08-49X09, stating that the RUC did not fully apply its 23-hour policy calculation when determining the work RVU recommendations for these codes.

Although the RUC removed the E/M visit and moved intraservice E/M time into the immediate posttime category for these codes, CMS insists that the RUC did not also subtract and add work RVUs per the 23-hour policy. CMS further notes that it does not believe that postoperative hospital visits for outpatient services should be valued at the inpatient level since the typical case is a patient who would be ready to be discharged from the hospital in 23 hours or less.<sup>3</sup> Instead, CMS believes that step 2 of the 23-hour hour policy calculation, which involves deducting the RVUs of the inpatient hospital visits from the starting work RVU value and subsequently reallocating the time associated with the intraservice portion of the inpatient hospital visits to the immediate postservice time of the 23-hour stay code, should be fully applied.

**We believe that CMS’ discussion of this issue is fraught with inconsistencies.** First, CMS dismisses the fact that the RUC recommendation of the survey 25<sup>th</sup> percentile already includes a reduction in work RVUs, as the RUC-recommended values are significantly below the survey median work RVUs. In addition, the Agency’s argument

<sup>3</sup> 75 FR 73226

that inpatient visits should not be allowed for procedures that typically have a facility outpatient status is no longer valid as, in this same proposed rule, CMS accepts that the physician work values and times are the same for both inpatient and observation (i.e., outpatient) E/M services.

By continuing to rely on its flawed 23-hour policy, which has been invalidated by the Agency’s own acceptance of the revised facility E/M codes, the inequitable payment to surgeons who furnish the same hospital E/M services that nonsurgeon physicians provide will be further exacerbated. We remind CMS that, per statute, specialties should not be paid differently for the same service and, as evident with the Agency’s acceptance and merging of inpatient and observation care E/M codes, continuing the 23-hour policy is unlawful. **We urge CMS to accept the RUC recommendations for CPT codes 49X02, 49X03, 49X04, 49X05, 49X08, and 49X09 based on magnitude estimation in comparison to reference codes and to others in the family of codes that were surveyed. We also urge CMS to compensate surgeons fairly and equally and to rescind its erroneous and unlawful 23-hour policy.**

**CPT Codes 49X06, 49X10, 49X11, 49X12, 49X13, and 49X14**

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
<b>49X06</b>	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	NEW	20.00	18.67
<b>49X10</b>	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	NEW	16.50	15.55
<b>49X11</b>	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	NEW	16.97	16.03
<b>49X12</b>	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	NEW	24.00	22.67
<b>49X13</b>	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or	NEW	14.24	13.70

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
	recurrent, including placement of mesh or other prosthesis, when performed; reducible			
<b>49X14</b>	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated	NEW	18.00	17.06

CPT codes 49X06, 49X10, 49X11, 49X12, 49X13, and 49X14 will typically (more than 50 percent of the time) require the patient to be admitted for 2 or more nights. CMS states that, for purposes of calculating the recommended work RVUs, the RUC considered these CPT codes to describe an admitted inpatient service, while the Agency considers such CPT codes to describe outpatient services for purposes of billing. Therefore, CMS believes that inpatient work in the postoperative period should not be included in the valuation. Instead, the Agency believes the 23-hour policy should be applied to these codes.

**We believe that CMS’ discussion of this issue is fraught with inconsistencies.**

- The 23-hour policy was implemented for outpatient services, and CPT codes 49X06, 49X10, 49X11, 49X12, 49X13, and 49X14 clearly describe inpatient services. **In the CY 2023 OPPS proposed rule, CMS proposes to add these six codes to the Inpatient Only List based on clinical review that such procedures require a hospital inpatient admission or stay. Therefore, we do not understand the statement that the Agency still considers these codes to describe outpatient services for purposes of billing, and we question how CMS arrived at the conclusion that inpatient services on the Inpatient Only List should be considered outpatient services for purposes of billing.** Even if these codes were typically outpatient—which is not the case—and the 23-hour policy applied, the Agency did not correctly adjust immediate post-service times.
- The RUC-recommended values for these six codes were based on a rank order of the entire family of codes with acknowledgement that these six codes describe procedures that are not commonly performed. The calculated reductions that CMS proposes devalues highly complex and intense procedures for sick patients, essentially compressing the codes at the higher end of the relative scale. The adjustments that CMS made to this set of codes results in intensities that are lower and out of rank order when compared with other intense and complex procedures.

**We urge CMS to accept the RUC recommendations for CPT codes 49X06, 49X10, 49X11, 49X12, 49X13, and 49X14 based on magnitude estimation in comparison to reference codes and to others in the family of codes that were surveyed. We also urge CMS to compensate surgeons fairly and equally and to rescind its erroneous**

and unlawful 23-hour policy.

**CPT Code 49X15**

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
<b>+49X15</b>	Removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic)	NEW	5.00	2.61

CPT code 49X15 describes mesh removal that is not always required and is not typical. Technology and research have developed types of mesh that are now being implanted which are incorporated into the abdominal wall, reducing the risk of infection, complications, and recurrence. When mesh removal is indicated, it is typically due to hardening and fracturing of aged mesh (e.g., years after a colectomy), or when gross contamination and infection has occurred (e.g., enterocutaneous fistula involving the mesh). The work to remove mesh is typically significant, in that the mesh is often integrated with the abdominal wall or adhered to intestine, and involves removal of all of the mesh, not just a small portion. An add-on code to report mesh removal prior to hernia repair, when required, allows for accurate reporting of this work only when performed.

CMS disagrees with the RUC-recommended work RVU of 5.00 for add-on CPT code 49X15 and instead proposes a calculated work RVU of 2.61, as shown in the table above. The Agency states that the RUC recommendation for CPT code 49X15 is higher than the work RVUs for many other CPT add-on codes with similar times, and bases its proposed work RVU of 2.61 on the reverse building block methodology (BBM). CMS does not state how it arrived at a calculated value of 2.61 using a reverse BBM. However, since this is a new code not previously described and is currently reported with an unlisted code, we do not understand how a reverse BBM could be applied in general.

CMS supports its proposed work RVU of 2.61 using CPT code 15774 (*Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)*), which has a work RVU of 2.50 and the same total time of 45 minutes. **We strongly disagree with the selection of CPT code 15774 as supporting appropriate physician work for 49X15.** CPT code 15774 describes use of small cannulas to subcutaneously inject fat in additional small aliquots to fill a soft-tissue defect, typically on the head or face. The intensity and complexity of this procedure in no way compares with open dissection of scarred in mesh from the abdominal wall fascia without damaging the abdominal wall and intraabdominal contents prior to repairing the abdominal hernia.

**We believe there are two CPT codes that are more comparable to CPT code 49X15 in terms of intensity and complexity:**

- CPT code 67340 (*Strabismus surgery involving exploration and/or repair of detached extraocular muscle(s) (List separately in addition to code for primary procedure)*)—assigned a work RVU of 5.00 and total time of 45 minutes—was reviewed in October 2020. CPT code 67340 describes sharp and blunt dissection to open the inferonasal and superonasal quadrants to visualize scarring and to dissect and elevate the conjunctiva over the muscle insertion followed by muscle dissection and cleaning the scar tissue prior to completing the primary or index procedure. **CPT code 49X15 similarly uses sharp dissection to remove the previously placed and scarred mesh from the abdominal wall fascia while preventing damage to intraabdominal contents and removing the mesh in total or near total entirety prior to completing the primary hernia repair procedure.**
  
- CPT add-on code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)*)—assigned a work RVU of 4.88 and intra-time of 45 minutes. CPT code 57267 describes placement of virgin mesh via a vaginal approach to repair a defect requiring less intense and complex work than CPT code 49X15, which involves dissection of scarred-in mesh from the abdominal wall fascia without damaging the abdominal wall and intraabdominal contents prior to repairing the abdominal hernia.

**We request that CMS consult with surgical Medical Officers regarding these more appropriate comparison add-on codes, as we are certain that they would not agree that CPT code 15774 and the proposed value accurately reflect a relative comparison of work to CPT code 49X15. Upon rereview with Medical Officers, we urge CMS to accept the RUC recommendation of 5.00 work RVUs for CPT code 49X15.**

**CPT Code 157X1**

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
<b>157X1</b>	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma	NEW	8.00	7.05

Implantation of mesh with both open and laparoscopic hernia repair is now typical (more than 50 percent of the time) and therefore was bundled into the new anterior abdominal hernia repair codes. When CPT code 49568 was created in 1993, mesh implantation with

hernia repairs was not typical. This is supported by the typical patient described in 1993 requiring mesh as having a 10-centimeter midline incisional hernia (i.e., a very large hernia). With emerging research on the causes of hernia recurrence, changes in technology, and development of new types of mesh or other prosthesis, implantation of mesh is now typical for all types and sizes of hernias to reduce the incidence of recurrence. This was supported by the literature submitted with the code change application for the new hernia repair codes.

Included in the application for the new hernia repair codes that bundled mesh insertion, CPT code 49658 (*Implantation of mesh or other prosthesis for open incisional or ventral hernia repair or mesh for closure of debridement for necrotizing soft tissue infection (List separately in addition to code for the incisional or ventral hernia repair)*) was deleted. This resulted in rare “left over” work for implantation of mesh related to closure for a large open wound after debridement for necrotizing fasciitis. As described in the vignette for CPT code 157X1, necrotizing soft tissue infections typically result in a large open wound that cannot be closed primarily. When the infection has resolved, absorbable mesh or other prosthesis is placed to allow healing by secondary intent until such time that a skin graft or skin closure can be accomplished.

CMS states that for purposes of calculating the recommended work RVU of 8.00, the RUC considered CPT code 157X1 to describe an inpatient service, while the Agency considers CPT code 157X1 to describe an outpatient service for purposes of Medicare billing. Further, CMS does not believe that work typically associated with an inpatient service should be included in the work RVUs for the outpatient services to which the 23-hour policy applies. Therefore, the Agency asserts the valuation for this code should not include inpatient work in the postoperative period and the 23-hour policy should be fully applied to CPT code 157X1.

**We believe that the CMS discussion of this issue is fraught with inconsistencies, as described below.**

- The flawed and invalid 23-hour policy was implemented for outpatient services and CPT code 157X1 clearly describes an inpatient service. **In the CY 2023 OPPS proposed rule, CMS proposes to add CPT code 157X1 to the Inpatient Only List based on clinical review that this procedure requires a hospital inpatient admission or stay. Therefore, we do not understand the statement that the Agency still considers this code to describe outpatient services for purposes of billing, and we question how CMS arrived at the conclusion that inpatient services on the Inpatient Only List should be considered outpatient services for purposes of billing.** Even if CPT code 157X1 (in addition to CPT codes 49X06, 49X10, 49X11, 49X12, 49X13, and 49X14, as noted above) was typically outpatient—which is not the case—and the 23-hour policy applied, the Agency did

not correctly adjust immediate post-service time.

- The resulting intensity for CMS-proposed value is only 0.05, which is less than the intensity of simple, intermediate, and complex repair of wounds. Specifically, CPT codes 12001-12018 (simple repair of wounds, 000-day global) all have intraoperative intensities greater than 0.05.

**We request that CMS consult with surgical Medical Officers to determine if the proposed value for CPT code 157X1 is appropriate when the resulting operative intensity is less than every code for simple repair of a superficial wound. Upon rereview with Medical Officers, we urge CMS to accept the RUC recommendation of 8.00 work RVUs for code 157X1.**

**49X01-49X14 Direct Practice Expense Inputs – CA002**

CPT Code	Labor Code	Nonfacility (NF) / Facility (F)	Labor Activity Code	Labor Activity Description	RUC Recommendation	CMS Refinement
49X01	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X02	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X03	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X04	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X05	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X06	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X07	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X08	L037D	F	CA002	Coordinate pre-surgery services	20	10

				(including test results)		
49X09	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X10	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X11	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X12	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X13	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10
49X14	L037D	F	CA002	Coordinate pre-surgery services (including test results)	20	10

Patients with an abdominal hernia typically have comorbidities, such as obesity, that contribute to the development of the defect. Furthermore, clinical evidence indicates that obese patients often have additional comorbidities (e.g., diabetes, hypertension).

Undergoing a major surgical hernia repair procedure requires significant preoperative clinical staff work. **For clinical staff activity CA002 (*Coordinate pre-surgery services (including test results)*), the clinical staff will coordinate collection and documentation of preoperative imaging/lab results and patient-specific information for the surgical procedure, including the coordination of requisite preoperative assessment with the anesthesiologist. Clinical staff will also enter and record all clinical updates in the electronic health record (EHR).** When the RUC PE Advisory Committee reviewed the practice expense for almost 7,000 CPT codes in 2001-2004, they considered the typical time needed for this clinical staff activity when performed prior to a major surgical facility-only procedure, and determined that 20 minutes would typically be required. During review of the anterior abdominal hernia repair codes, the RUC acknowledged this work and agreed that the time required was consistent with a clinical staff time of 20 minutes for a typical major surgical procedure that typically would have a 90-day global period.

In addition, it is important to note that CMS attended the RUC PE Subcommittee meetings, during which the Subcommittee submitted a recommendation to the RUC to



create a new 0-day global package to account for major surgical procedures that have had a global period assignment of 0-days or have changed from 90-days to 0-days. These final RUC recommendations were based on prior rules that relied on RUC standard packages—not CMS standard packages—when assigning clinical staff time to such major surgical procedures even though they may have a 0-day global assignment. It is egregious and counterproductive for the Agency to ignore the new facility 0-day global package for major surgery when it has firsthand knowledge of such a package through meeting attendance and receipt of a RUC recommendation prior to publishing this proposed rule.

A global period of 0-days no longer applies only to minor procedures or endoscopies through a natural orifice. We are disappointed that CMS refuses to consider expert medical opinion from the RUC and the house of medicine and instead relies on outdated information and internal programmatic policies. **We urge the Agency to accept the RUC recommendation of 20 minutes for clinical activity CA002 for CPT codes 49X01-49X14, which appropriately reflects relative clinical staff work for these major surgical procedures.**

**49X01-49X14 Direct Practice Expense Inputs – CA003**

CPT Code	Labor Code	Nonfacility (NF) / Facility (F)	Labor Activity Code	Labor Activity Description	RUC Recommendation	CMS Refinement
49X01	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X02	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X03	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X04	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X05	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X06	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X07	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X08	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X09	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X10	L037D	F	CA003	Schedule space and equipment in facility	8	5

49X11	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X12	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X13	L037D	F	CA003	Schedule space and equipment in facility	8	5
49X14	L037D	F	CA003	Schedule space and equipment in facility	8	5

Undergoing a major surgical hernia repair procedure requires significant preoperative clinical staff work. **For clinical staff activity CA003 (*Schedule space and equipment in facility*), the clinical staff will interact with the facility staff to schedule the operating room time and coordinate needed supplies and equipment. Checklists will be reviewed. There are no standard hernia repair supply/equipment kits (e.g., “hernia repair supply kit 1 or kit 2”). Each repair is unique to the patient and their comorbidities and the supplies and equipment that need to be available will be communicated to the facility by the surgeon's clinical staff.** When the RUC PE Advisory Committee reviewed the practice expense for almost 7,000 CPT codes in 2001-2004, they considered the typical time needed for this clinical staff activity when performed prior to a major surgical procedure, and determined that 8 minutes would typically be required for this back and forth coordination between the surgeon, the anesthesiologist, and the facility. During review of the anterior abdominal hernia repair codes, the RUC acknowledged this work and agreed that the time required was consistent with a clinical staff time of 8 minutes for a typical major surgical procedure that typically would have a 90-day global period.

In addition, it is important to note that CMS attended the RUC PE Subcommittee meetings, during which the Subcommittee submitted a recommendation to the RUC to create a new 0-day global package to account for major surgical procedures that have had a global period assignment of 0-days or have changed from 90-days to 0-days. These final RUC recommendations were based on prior rules that relied on RUC standard packages—not CMS standard packages—when assigning clinical staff time to such major surgical procedures with a 0-day global assignment. It is egregious and counterproductive for the Agency to ignore the new facility 0-day global package for major surgery when it has first-hand knowledge of such a package through meeting attendance and receipt of a RUC recommendation prior to publishing this proposed rule.

A global period of 0-days no longer applies only to minor procedures or endoscopies through a natural orifice. We are disappointed that CMS refuses to consider expert medical opinion from the RUC and the house of medicine and instead relies on outdated information and internal programmatic policies. **We urge the Agency to accept the RUC recommendation of 8 minutes for clinical activity CA003 for codes 49X01-**

**49X14, which appropriately reflects relative clinical staff work for these major surgical procedures.**

**49X01-49X14 Direct Practice Expense Inputs – CA004**

CPT Code	Labor Code	Nonfacility (NF) / Facility (F)	Labor Activity Code	Labor Activity Description	RUC Recommendation	CMS Refinement
49X01	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X02	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X03	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X04	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X05	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X06	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X07	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X08	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X09	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X10	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X11	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X12	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
49X13	L037D	F	CA004	Provide pre-service education/obtain consent	20	7

49X14	L037D	F	CA004	Provide pre-service education/obtain consent	20	7
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Patients with an abdominal hernia typically have comorbidities, such as obesity, that contribute to the development of the defect. Furthermore, clinical evidence indicates that obese patients often have additional comorbidities (e.g., diabetes, hypertension). Undergoing a major surgical hernia repair procedure requires significant preoperative clinical staff work. **For clinical staff activity CA004 (*Provide pre-service education/obtain consent*), the clinical staff will contact the patient/family to review the procedure, complication risks, process of recovery (including how pain and possible ileus will be managed), and answer patient/family questions.** When the RUC PE Advisory Committee reviewed the practice expense for almost 7,000 CPT codes in 2001-2004, they considered the typical time needed for this clinical staff activity when performed prior to a major surgical procedure, and determined that 20 minutes would typically be required. During review of the anterior abdominal hernia repair codes, the RUC acknowledged this work and agreed that the time required was consistent with a clinical staff time of 20 minutes for a typical major surgical procedure that typically would have a 90-day global period.

In addition, it is important to note that CMS attended the RUC PE Subcommittee meetings, during which the Subcommittee submitted a recommendation to the RUC to create a new 0-day global package to account for major surgical procedures that have had a global period assignment of 0-days or have changed from 90-days to 0-days. These final RUC recommendations were based on prior rules that relied on RUC standard packages—not CMS standard packages—when assigning clinical staff time to such major surgical procedures with a 0-day global assignment. It is egregious and counterproductive for the Agency to ignore the new facility 0-day global package for major surgery when it has first-hand knowledge of such a package through meeting attendance and receipt of a RUC recommendation prior to publishing this proposed rule.

A global period of 0-days no longer applies only to minor procedures or endoscopies through a natural orifice. We are disappointed that CMS refuses to consider expert medical opinion from the RUC and the house of medicine and instead relies on outdated information and internal programmatic policies. **We urge the Agency to accept the RUC recommendation of 20 minutes for clinical activity CA004 for codes 49X01-49X14, which appropriately reflects relative clinical staff work for these major surgical procedures.**

### 49X01-49X14 Direct Practice Expense Inputs – CA005

CPT Code	Labor Code	Nonfacility (NF) / Facility (F)	Labor Activity Code	Labor Activity Description	RUC Recommendation	CMS Refinement
49X01	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X02	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X03	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X04	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X05	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X06	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X07	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X08	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X09	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X10	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X11	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X12	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X13	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3
49X14	L037D	F	CA005	Complete pre-procedure phone calls and prescription	7	3

Patients with an abdominal hernia typically have comorbidities, such as obesity, that contribute to the development of the defect. Furthermore, clinical evidence indicates that obese patients often have additional comorbidities (e.g., diabetes, hypertension). Undergoing a major surgical hernia repair procedure requires significant preoperative clinical staff work. **For clinical staff activity CA005 (*Complete pre-procedure phone calls and prescription*), the clinical staff will contact the patient/family to review preoperative medication changes, review the patient’s medical status, and answer final pre-admission questions. This requires clinical staff to review the patient’s chart, interact with the surgeon and any other consulting physicians regarding preoperative medication changes, and then call the patient/family. There are typically several phone calls and time spent on non-face-to-face records review and coordination.** 3 minutes is not sufficient for this clinical staff work. The RUC acknowledged such required work and agreed that clinical staff time of 7 minutes was appropriate for these major surgical procedures.

In addition, it is important to note that CMS attended the RUC PE Subcommittee meetings, during which the Subcommittee submitted a recommendation to the RUC to create a new 0-day global package to account for major surgical procedures that have had a global period assignment of 0-days or have changed from 90-days to 0-days. These final RUC recommendations were based on prior rules that relied on RUC standard packages—not CMS standard packages—when assigning clinical staff time to such major surgical procedures with a 0-day global assignment. It is egregious and counterproductive for the Agency to ignore the new facility 0-day global package for major surgery when it has first-hand knowledge of such a package through meeting attendance and receipt of a RUC recommendation prior to publishing this proposed rule.

A global period of 0-days no longer applies only to minor procedures or endoscopies through a natural orifice. We are disappointed that CMS refuses to consider expert medical opinion from the RUC and the house of medicine and instead relies on outdated information and internal programmatic policies. **We urge the Agency to accept the RUC recommendation of 7 minutes for clinical activity CA005 for CPT codes 49X01-49X14, which appropriately reflects relative clinical staff work for these major surgical procedures.**

**49X01, 49X07 Direct Practice Expense Inputs – CA037**

CPT Code	Labor Code	Nonfacility (NF) / Facility (F)	Labor Activity Code	Labor Activity Description	RUC Recommendation	CMS Refinement
49X01	L037D	F	CA037	Conduct patient communications	6	3
49X07	L037D	F	CA037	Conduct patient communications	6	3

Patients with an abdominal hernia typically have comorbidities, such as obesity, that contribute to the development of the defect. Furthermore, clinical evidence indicates that obese patients often have additional comorbidities (e.g., diabetes, hypertension). The typical patient with a smaller hernia defect will be discharged on the same day of the procedure, although some patients will remain in the hospital overnight or longer. When patients are discharged on the same day, the clinical staff will assist with necessary post-discharge care via phone or electronically, such as: responding to patient/family questions about home activity restrictions; confirmation of discharge antibiotics if needed, as well as pain medication and pain control methods; coordination with other physicians involved in the care of the patient for transfer of records; and transitioning discharge information to the surgeon’s office EHR, including medication lists, correspondence and imaging or lab results pending at discharge. This work includes more than the one phone call that might be more common for other 0-day global minor procedures such as a simple laceration repair or colonoscopy. The RUC acknowledged this work and agreed that the time required was consistent with the clinical staff time of 6 minutes assigned for the same day discharge of patients undergoing a major surgical procedure.

A global period of 0-days no longer applies only to minor procedures or endoscopies through a natural orifice. We are disappointed that CMS refuses to consider expert medical opinion from the RUC and the house of medicine and instead relies on outdated information and internal programmatic policies. **We urge the Agency to accept the RUC recommendation of 6 minutes reflective of at least two phone calls for clinical activity CA037 for codes 49X01 and 49X07, which appropriately reflects relative clinical staff work for these major surgical procedures.**

**157X1 Direct Practice Expense Inputs – CA001-CA005**

CPT Code	Labor Code	Nonfacility (NF) / Facility (F)	Labor Activity Code	Labor Activity Description	RUC Recommendation	CMS Refinement
157X1	L037D	F	CA001	Complete pre-service diagnostic and referral forms	5	3
157X1	L037D	F	CA002	Coordinate pre-surgery services (including test results)	7	3
157X1	L037D	F	CA003	Schedule space and equipment in facility	4	3
157X1	L037D	F	CA004	Provide pre-service education/obtain consent	0	0
157X1	L037D	F	CA005	Complete pre-procedure phone calls and prescription	4	3

CMS states the following in this proposed rule: “For CPT code 157X1, the RUC recommendation is 20 minutes of clinical staff activities, which is standard for an emergent procedure package. We do not agree that the service described by CPT code 157X1 should be considered an emergent procedure. Therefore, we are proposing the minimal clinical staff package minus pre-service education for CPT code 157X1, for a total of 12 clinical staff time minutes.”

The Agency has disregarded that the RUC discussion and recommendation was to use the times that relate to emergent procedures as a “proxy/crosswalk” for CPT code 157X1— not as a specific package. CMS and the RUC often use crosswalks for unusual or rare procedures or services when they do not fit an existing standard. It is egregious that CMS chooses to adhere to a formulaic mold of a “standard package” purely to ease programming of their database by non-medical staff.

The typical patient undergoing the procedure described by CPT code 157X1 will have been in the hospital for many days to weeks. After resolution of the necrotizing infection and multiple debridements, mesh may be an option for closure. The preoperative clinical staff work will be limited to activities to coordinate the surgeon’s schedule, timing of the procedure, arranging for supplies/equipment with the hospital and confirming approval with the patient’s insurer. For these reasons, the RUC’s recommendation for CPT code 157X1 was to crosswalk to the times assigned for emergent procedures, as described below.

- **CA001:** Five minutes or more is required for clinical staff to ensure all diagnostic testing has been ordered and is available in the office medical record for the surgeon’s review and that the procedure using the mesh has been approved by the payor.
- **CA002:** Seven minutes or more is required for clinical staff to ensure collection and documentation of imaging/lab results, patient-specific information and other relevant patient information, including the requisite preoperative assessment with the anesthesiologist, is available in the office medical record for the surgeon’s review.
- **CA003:** Four minutes or more is required for clinical staff to interact between the surgeon’s office and the facility to schedule space, supplies, equipment, and review checklists.
- **CA005:** Five minutes or more is required for clinical staff to confirm the surgeon’s preoperative patient medication changes and new medication orders are documented in the facility and office medical records. Clinical staff will also likely field calls to the office from the patient’s family about the upcoming surgery.



**Based on this information, we urge CMS to accept the RUC recommendations for time that use the emergent procedure clinical staff times as a proxy for preoperative clinical staff activities related to CPT code 157X1.**

***Removal of Sutures or Staples (CPT codes 15851, 158X1, and 158X2)***

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
15851	Removal of sutures or staples requiring anesthesia (ie, general anesthesia, moderate sedation)	0.86	1.10	1.10
158X1	Removal of sutures or staples not requiring anesthesia (List separately in addition to E/M code)	NEW	0.00	0.00
158X2	Removal of sutures and staples not requiring anesthesia (List separately in addition to E/M code)	NEW	0.00	0.00

In October 2021, the CPT Editorial Panel approved the deletion of CPT code 15850, revision of CPT code 15851, and addition of two new related CPT add-on codes, 158X1 and 158X2.

CMS proposes to accept the RUC-recommended work RVU of 1.10 for CPT code 15851. **We agree with CMS’ decision to accept the RUC work RVU recommendation for this code.** Add-on CPT codes 158X1 and 158X2 are considered PE-only codes. CMS proposes the RUC-recommended direct PE inputs for CPT codes 15851, 158X1, and 158X2 without refinement. **We agree with CMS’ decision to accept the RUC PE recommendations for these three codes.**

***Delayed Creation Exit Site from Embedded Catheter (CPT code 49436)***

CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*) was finalized as potentially misvalued in the CY 2022 and was found to be appropriate to value for the non-facility/office setting.

CMS disagrees with the RUC-recommended time of 5 minutes for clinical activity code CA013 (*Prepare room, equipment and supplies*) and instead proposes the standard time of 2 minutes, stating that an adequate rationale was not provided for the additional time in the global space. This proposed reduction of 3 minutes to the CA013 clinical labor activity also carries over to the equipment times, which the Agency proposes to reduce by the same 3 minutes. For CA013, we note that the PE Summary of Recommendation (SoR) form did indeed include a rationale for the additional time—specifically, the rationale stated: ***“In addition to the standard 2 minutes related to setting up a room for an E/M service, all the additional sterile supplies, catheters, and instruments will need to be set up in the room.”***

The procedure described by CPT code 49436 is not an E/M service that only requires placement of table paper, a pillow, a tongue depressor, and otoscope tips (i.e., 2 minutes of standard activity). The PE spreadsheet that accompanied the PE SoR lists 36 (mostly sterile) supply items (including packs) that must be collected and set up in the procedure room. These details alone should be sufficient information for the Agency to acknowledge that setting up the supplies for this procedure will take at least 3 more minutes than the standard 2 minutes allocated for an E/M service. **We urge CMS to accept the RUC recommendation of 5 minutes for CA013 as minimal time to collect and set up a large number of mostly sterile supplies in the office procedure room for CPT code 49436.**

### **Evaluation and Management (E/M) Visits**

#### ***Hospital Inpatient or Observation Care (CPT Codes 99218-99236) / Discharge Day Management (CPT Codes 99238-99239)***

The CPT Editorial Panel deleted observation care codes and revised CPT codes 99218-99239 to create a single set of codes for inpatient and observation care. The CPT Editorial Panel also changed the code descriptors for CPT codes 99218-99236 to allow level of service to be based on total time or MDM, as well as updating documentation requirements. CMS proposes to adopt the revised code descriptors, guidelines, and work RVUs for this set of codes. **We appreciate CMS’ review and acceptance of these revised codes; however, we suggest that the Agency create a place of service code for “observation” to allow for clear reporting and tracking of E/M services for patients admitted under observation status versus patients seen in the emergency department and reported with place of service “outpatient.”**

We also wish to highlight that the Agency's proposal to accept the CPT changes for this set of codes acknowledges what the ACS has been advocating for many years—**there is no difference in the physician E/M work related to a patient visit in a facility other than the level of MDM or total time that is used for code selection.** CMS’ continued insistence that the acuity of the patient that is admitted versus placed in observation is the discerning factor in physician payment is incorrect—the Agency has confused the resource cost of the facility with payment for physician work. **Likewise, the 23-hour policy that is based on such a non-existent difference should be rescinded. We strongly urge CMS to correct the misguided statements to the contrary and acknowledge the fact that physician work is not the same as facility resource use, and that a physician visit in a facility at the same MDM level is the same whether the patient is admitted as inpatient or admitted for observation care.**

### ***Proposed “8 to 24 Hour Rule” for Hospital Inpatient or Observation Care***

CMS proposes to retain the “8 to 24-hour rule” regarding payment of discharge management services as follows:

- For less than 8 hours of inpatient or observation services, the practitioner would report only initial inpatient or observation care codes 99221-99231.
- For a minimum of 8 hours, but less than 24 hours, the practitioner would report same day admission and discharge codes 99234-99236.
- For a patient that is admitted to inpatient or observation care and then discharged after more than 24 hours, the practitioner would report 99221-99223 for services on the date of admission and 99238-99239 for discharge day management services on the date of discharge.

**We agree with retaining this 8 to 24-hour rule. In addition, we urge CMS to develop the same reporting of E/M services for codes with a global period when the patient is placed under observation status or is admitted as inpatient, instead of deleting CPT visit codes for global services and moving time from one postoperative category to another.**

### ***Proposed Definition of Initial and Subsequent Hospital Inpatient or Observation Visit***

The revised CPT codes 99231 through 99233 describe subsequent hospital inpatient or observation care services similarly. For CPT 2023, a “subsequent” service is reported when the patient has received any professional services from the physician or other qualified health care professional or another physician/other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice during the stay.

CMS does not recognize subspecialties and proposes slightly amended definitions of “initial” and “subsequent” services:

- An initial service would be defined as one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.
- A subsequent service would be defined as one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.

CMS also proposes that, for both initial and subsequent visits, when advanced practice nurses and physician assistants are working with physicians, they are always classified in a different specialty than the physician. Specifically, CMS highlights that in the Medicare Claims Processing Manual, the Agency’s longstanding taxonomy for MPFS services will continue to apply, where, for payment purposes, physicians and nonphysician providers (NPPs) are not classified as having the same specialty, and the MPFS does not recognize subspecialties.<sup>4</sup> However, CMS is continuing to consider whether the Agency could better align this payment taxonomy with clinical practice, where we might consider NPPs as working in the same specialty as the physicians with whom they work, and/or recognize subspecialties.

The Agency’s discussion of this issue is confusing. On the one hand, CMS cites the Medicare Claims Processing Manual, which indicates that physicians and NPPs are not classified as the same specialty—but, on the other hand, the Agency proposes a definition that talks about physicians and NPPs of the same specialty. **We question if CMS is proposing to make a change to the taxonomy of the MPFS.**

We understand that specialty designation is important to the definition and reporting of initial versus subsequent visits. We also agree that there should be some mechanism for NPPs to report their specialty area and find this issue no different that surgeons having to “claim” a specialty when signing up to participate in Medicare. For example, general surgeons can indicate their specialty as general surgery, colorectal surgery, surgical oncology, or vascular surgery independent of board certification. However, general surgeons cannot designate their specialty as breast surgery, endocrine surgery, transplant surgery, or bariatric surgery because these are not Medicare-approved specialties. Surgeons working in these specialty areas typically default to identify as general surgeons. Similarly, NPPs should be able to identify as practicing within a particular specialty area, and if instead they practice with many specialties in a group, then they identify as a generalist (e.g., general surgery, internal medicine, family practice). The outstanding question is how NPPs can designate a Medicare-approved specialty and still indicate they are an NPP and not the physician specialty.

**We suggest that CMS consider expanding the Medicare specialty code designations for NPPs by establishing new two character specialty codes for nurse practitioner specialties (e.g., NA, NB, NC) and physician assistant specialties (e.g., PA, PB, PC).** This would be followed by requesting that all NPPs with NPIs register their specialty over a given time period, transitioning away from the current specialty codes of 50 and 97—or allowing these two codes to remain as a “generalist” designation. Although this would not be a finite solution, it would help to simplify reporting based on same or different specialty.

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<sup>4</sup> Pub 100-04, chapter 26, section 10

### ***Transitions Between Settings of Care and Multiple Same-Day Visits for Hospital Patients Furnished by a Single Practitioner***

CMS proposes to retain its current policy that for the purposes of reporting an initial hospital inpatient or observation care service, a transition from observation status to inpatient status does not constitute a new stay. In addition, the Agency proposes to retain its policy that, if a patient is seen in a physician’s office on one date and receives care at a hospital (for inpatient or observation care) on the next date from the same physician, both visits are payable to that physician, even if less than 24 hours has elapsed between the visit and the hospital inpatient or observation care. CMS also proposes to retain its current billing policy in the Medicare Claims Processing Manual that a physician may bill only for an initial hospital or observation care service if the physician sees a patient in the ED and decides to either place the patient in observation status or admit the patient as a hospital inpatient.<sup>5</sup> **We support CMS’ proposal to retain these policies.**

### ***Prolonged Services for Hospital Inpatient or Observation Care***

To replace deleted CPT codes 99356 and 99357, the CPT Editorial Panel created CPT code 993X0 (*Prolonged inpatient or observation 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 inpatient and observation Evaluation and Management services*). Additional CPT guidance for 2023 states, “Code 993X0 is used to report prolonged total time (that is, combined time with and without direct patient contact) provided by the physician or other qualified health care professional on the date of an inpatient service (that is, 99223, 99233, 99236, 99255, 99306, 99310). Prolonged total time is time that is 15 minutes beyond the time required to report the highest-level primary service.”

CMS proposes to not adopt CPT code 993X0, as the Agency believes that the billing instructions for CPT code 993X0 will lead to administrative complexity, potentially duplicative payments, and limit the ability to determine how much time was spent with the patient using claims data. CMS instead proposes to create a single G-code that describes a prolonged service and applies only to CPT codes 99223, 99233, and 99236 only when time is used to select the level of E/M service.

*GXXX1: Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using 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*

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<sup>5</sup> IOM 100-04, Chapter 12, 30.6.1.A

99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (Do not report GXXX1 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0, 99415, 99416). (Do not report GXXX1 for any time unit less than 15 minutes).

This is consistent with Medicare policy to report prolonged services HCPCS code G2212 instead of CPT code 99417 for each additional 15 minutes of prolonged office or other outpatient E/M services.

In the ACS’ CY 2021 MPFS proposed rule comment letter, we strongly agreed with CMS that reporting CPT code 99417 after the minimum time of CPT code 99205 or 99215 is met would be double counting of time.<sup>6</sup> We noted that, given the work RVU and time associated with CPT code 99417, it is inconceivable that code 99417 should be reported for only 1 minute above the time range of codes 99205 or 99215.

Similar to our comments about CPT code 99417, we agree with CMS that reporting CPT code 993X0 after the minimum time of codes 99223, 99233, and 99236 is met would be double counting of time. We note that, given the work RVU and time associated with CPT code 993X0, it is inconceivable that code 993X0 should be reported for only 1 minute above the time range of CPT codes 99223, 99233, and 99236. **Therefore, we agree with the Agency’s proposed new HCPCS code GXXX1 for reporting 15 minutes of prolonged services in conjunction with facility E/M CPT codes 99223, 99233, and 99236.**

***Emergency Department (ED) Visits (CPT Codes 99281-99285)***

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
99281	Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional	0.48	0.25	0.25
99282	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making	0.93	0.93	0.93
99283	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making	1.60	1.60	1.60
99284	Emergency department visit for the evaluation and management of a	2.74	2.60	2.74

<sup>6</sup> American College of Surgeons. (2020, September 22). *Medicare Program; CY 2021 payment policies under the Physician Fee Schedule and other changes to Part B payment policies (CMS1734-P)* [comment letter]. <https://www.facs.org/media/bgnip2f3/cy-2021-mpfs-proposed-rule-payment-comments.pdf>

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
	patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making			
99285	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making	4.00	4.00	4.00

CMS received a public comment indicating that relativity between the ED visits and office/outpatient E/M visits should be maintained. This commenter submitted a specific recommendation for CPT codes 99283-99285 that was higher than the RUC-recommended values, stating that the Agency should preserve the relationship that was established in prior years and that they believe would have likely been maintained had the office/outpatient E/M visits been reviewed prior to the ED visits. In order to avoid the rank order anomaly—whereby an ED visit would be valued lower than the analogous office/outpatient E/M visit—CMS proposed and eventually finalized the values recommended by this single commenter in the CY 2021 MPFS.

Following the implementation of the revisions to the office/outpatient E/M visits for the CPT 2021 code set, the CPT/RUC Workgroup on E/Ms standardized the rest of the E/M sections in the CPT code set. In February 2021, the CPT Editorial Panel revised the five ED visit codes to align with the principles included in the E/M office visit services by documenting and selecting level of service based on MDM, effective January 1, 2023. The descriptor for CPT code 99281 was revised such that the code may not require the presence of a physician or other qualified health care professional (QHP). The CPT Editorial Panel also revised the MDM level in the descriptor for CPT code 99282 from “low” to “straightforward” complexity, and from “moderate” to “low” complexity for CPT code 99283. These five codes were resurveyed and reviewed at the April 2021 RUC meeting with recommendations submitted to CMS for the CY 2023 MPFS rulemaking cycle.

CMS accepted the RUC recommendations for four of the five ED visit codes. CMS disagrees with the RUC-recommended work RVU of 2.60 for CPT code 99284 and instead proposes to maintain the current work RVU of 2.74. CMS notes that the survey conducted for CPT code 99284 maintained a work time of 40 minutes, and the level of medical decision making in the code’s descriptor also remained unchanged at “moderate” complexity. Therefore, CMS continues to believe that the levels 4 and 5 ED visits are more accurately valued higher than the levels 4 and 5 new patient office/outpatient E/M visits to reflect their higher typical intensity. CMS states that given there has been no change in the surveyed work time or level of MDM for this service, and that the work RVU of 2.74 that was finalized in the CY 2021 MPFS remains the most accurate

valuation for CPT code 99284.

**We disagree with the assumptions that CMS makes regarding CPT code 99284.** The RUC had considerable discussion about the entire family of codes and its relationship to the new patient office/outpatient family of codes. For CPT codes 99281-99284, the RUC agreed that the values should be equivalent to the office/outpatient visit codes based on level of MDM. Given that the surveyed times for CPT codes 99281-99284 were lower than the times for office/outpatient visit codes, the “intensity” component of the work RVU is then higher than MDM comparable to office/outpatient visits. **The total time of 40 minutes for CPT code 99284 at the RUC-recommended work RVU of 2.60 results in a work per unit time of 0.065, which is significantly greater than the comparable office/outpatient E/M CPT code 99204, which has a total time of 60 minutes, work RVU of 2.60, and a work per unit time of 0.043.**

**The Agency’s argument that CPT code 99284 should have a greater work RVU than CPT code 99204 because of the place of service disregards the fact that work includes both time and intensity.** In the case of CPT code 99284, a value that is the same as CPT code 99204 results in a significantly greater intensity. In addition, by increasing the value of CPT code 99284 to 2.74, the Agency creates a rank order anomaly within the family of ED codes—the intensity of CPT code 99284 becomes greater than the intensity of CPT code 99285. All of these variables of work, time, and intensity were considered by the RUC when reviewing and valuing CPT codes 99281-99285. **We urge CMS to accept the RUC recommendations for all five ED codes, including the work RVU of 2.60 for code 99284.**

***Prolonged Services on a Different Date than an E/M Service (CPT Codes 99358-99359)***

CMS notes that the RUC resurveyed and provided recommendations to revalue CPT codes 99358 and 99359. For CPT 2023, these codes are to be reported in relation to other physician or other QHP services, including E/M services at any level, on a date other than the face-to-face service to which it is related. However, the Agency proposes to assign an inactive status to these codes for purposes of MPFS payment.

We agree with CMS’ concern about program integrity, duplicative time, counting time that was not included in the surveyed timeframe, the administrative complexity of having multiple prolonged service codes, and the Agency's ability to determine how much time was spent with the patient using claims data if CPT codes 99358 and 99359 were given an active status and allowed to be reported with codes. We also agree with CMS’ discussion about the different surveyed timespans for different groups of E/M codes, which make it impossible to determine if there is overlap in time and work between an E/M services and prolonged service CPT codes 99358-99359. If the code descriptors



were clear about the timespan that the work RVU relates to—for example, the office visit codes include time from 3 days before and 7 days after the date of encounter—then it would be clear on which dates time could be counted for prolonged services. However, the E/M code descriptors do not have this information, and more importantly, different families of E/M services have different timespans. **We support the proposed policy to assign an inactive status to CPT codes 99358-99359 for Medicare payment until such time that CPT guidelines and code descriptors provide transparent information about the timespan included in the work RVU for each code.**

***Consultations (CPT Codes 99241-99255)***

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
99242	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	N/A	1.08	N/A
99243	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	N/A	1.80	N/A
99244	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	N/A	2.69	N/A
99245	Office or other outpatient consultation for a new or established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.	N/A	3.75	N/A
99252	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.	N/A	1.50	N/A
99253	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	N/A	2.00	N/A

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
99254	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded	N/A	2.72	N/A
99255	Inpatient or observation consultation for a new or established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 80 minutes must be met or exceeded.	N/A	3.86	N/A

The RUC revised code descriptors, deleted two codes, and revalued the work RVUs of the consultation codes during its October 2021 and January 2022 RUC meetings. The Agency did not review the RUC recommendations for the eight revised consultation codes and noted that CMS stopped paying for the consultation codes beginning in CY 2010.

Office consultation services are more work than the analogous office visit (non-consultation) E/M service due to the additional work to generate and send a written report to the requesting physician/QHP that identifies additional labs, imaging and/or tests ordered and reviewed, test findings and expert opinion for management of the patient’s problem(s). In addition, consultations carry more liability due to the expert opinion provided. Since the inception of the MPFS, the work RVUs for the office consultation codes have always been higher than the office visit E/M codes. The Harvard study acknowledged this difference in work. The RUC and CMS confirmed this difference in work in the 2006 review.

When CMS finalized its policy to no longer recognize office consultation codes for payment, the Agency noted that, “Conventional medical practice is that physicians making a referral and physicians accepting a referral would document the request to provide an evaluation for the patient. In order to promote proper coordination of care, these physicians should continue to follow appropriate medical documentation standards and communicate the results of an evaluation to the requesting physician. This is not to be confused with the specific documentation requirements that previously applied to the use of the consultation codes.”

The AMA responded to the Agency’s change in policy, noting that the CPT Editorial Panel was revising coding guidelines for consultation codes to reflect instructions in the CMS Carrier Policy Manual. CPT 2010 specifically added the following text: “The written or verbal request for consult may be made by a physician or other appropriate

source and documented in the patient's medical record by either the consulting or requesting physician or appropriate source. The consultant's opinion and any services that were ordered or performed must also be documented in the patient's medical record and communicated by written report to the requesting physician or other appropriate source.”

We are disappointed that CMS did not take the time to review the RUC recommendations and supporting evidence that the time and value of a consultation is different than an office or facility E/M service. The RUC and stakeholder societies that furnish consultation services recognize the difference in physician work and liability related to documentation and expert opinion and continue to advocate for payment for these services. **We urge CMS to review the RUC recommendations and reconsider its policy regarding these services.**

### **Payment for Skin Substitutes**

CMS proposes an overhaul of the nomenclature, coding, and payment of skin substitute products, effective January 1, 2024. Such changes would include:

- **Terminology.** CMS proposes to change the terminology applicable to these products from “skin substitutes” to “wound care management products.”
- **Bundling.** CMS proposes to end separate payment for these products and instead plans to treat them as “incident to” supplies starting in 2024, which means that CMS will bundle payment for them into payment for the service to apply them. More specifically, CMS plans to incorporate the cost of skin substitutes into the direct practice expense RVUs.
- **Coding.** CMS plans to discontinue all existing Q-codes for skin substitutes. Beginning in 2024, all skin substitutes—including those new to market as well as those that currently have Q-codes—would receive A-codes.
- **FDA TRG Letters.** Finally, as part of the move towards A-codes, all skin substitutes regulated as 361 Human Cells, Tissues, and Cellular and Tissue-Based Products (361 HCT/Ps), including those already marketed and billed pursuant to Q-codes, must obtain a letter from the Food and Drug Administration’s (FDA) Tissue Reference Group (TRG) containing a recommendation as to their regulatory status.

We address each of these proposals below.

- **Terminology.** CMS proposes the terminology change because, in the Agency’s view, the term *skin substitutes* is so broad as to constitute a “misnomer.” However, the proposed terms *wound care management* and *wound care management products* fail to provide any additional specificity. First, the term *wound care management* does not describe a supply, but instead describes a service or procedure. Second, the term

*wound care management product* suggests that skin substitutes are the same as bandages, as these are also used in and commonly associated with wound care management. As CMS notes, skin substitutes are not themselves technically a substitute for skin, but they can stimulate the host to generate lost tissue through a variety of mechanisms of action—something a bandage or dressing cannot do. Although CMS expressly acknowledges that skin substitutes are not bandages or wound dressings and believes that *wound care management* would not sweep in standard dressings, we are concerned that the proposed term would do exactly that: the sweeping term *wound care management products* functionally places these currently distinct families of products in the same definitional category. **The ACS urges CMS to maintain use of the term “skin substitutes” until such time that clear and uniform coding changes can be made by the CPT Editorial Panel both in coding guidelines and code descriptors.**

- **Bundling.** CMS proposes to add the cost of the approximately 150 existing skin substitute supply items that are currently separately billable as HCPCS codes into the direct PE inputs of the CPT codes for reporting application of the products. **The ACS is extremely concerned by the lack of detail as to how the process to accomplish this by January 1, 2024 will unfold.** It is unclear whether the AMA CPT Editorial Panel will be involved and, if so, how that process would align with CMS’ proposed implementation date of January 1, 2024. CMS could circumvent the CPT process and simply add a line item, but adding payment for approximately 150 products into the direct PE for all wound care codes would be a significant undertaking that will require the Agency to determine what is the “typical” or average product to be bundled into a given code. This will likely require more than a year since the Agency will first need to propose all the changes in rulemaking, but cannot do this until all the products receive FDA TRG letters. The proposed 2024 implementation date for such an endeavor without code-by-code input from stakeholders is overly ambitious and likely to fail.

Additionally, given that PE RVUs are subject to budget neutrality requirements, suddenly including these products into practice expense will exert significant downward pressure on all other PE RVUs, unless the Agency plans to commit additional equivalent funding to the conversion factor funding offset these reductions. In many cases, the cost of these products is not trivial. For example, in 2018, the Medicare allowed charges was \$96 million for the skin substitute product reported with HCPCS code Q4131 (*Epifix or epicord, per square centimeter*). As CMS notes, there are approximately 150 HCPCS Q-codes identifying skin substitute products and the costs that must be incorporated into the PE RVU pool as a result of this proposal are likely to be significant and may destabilize the PE RVUs for all other codes without a commiserate addition of funding. If incorporating the cost of these products in the direct PE inputs results in budget neutrality reductions, this proposal amounts

to a penalty on all Part B providers, whether or not they use skin substitutes in their clinical practice.

We are concerned that this proposal would, over time, drastically reduce or even end wound care management in the office setting, which will leave patients with reduced access to these services and result in prolonged wound healing. If the Agency is concerned about proliferation of questionable products and/or excessive Medicare spending growth on skin substitutes, there are solutions for CMS to explore with practicing clinicians who use these products, such as application limits for certain wounds, or solutions that more closely tie Medicare reimbursement to FDA regulation of skin substitutes, as we discuss in more detail below. 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 procedural concerns outlined above and the potentially drastic budget neutrality implications, we urge CMS to abandon its proposal to treat skin substitutes as “incident to” supplies and to instead maintain these products as separately billable.**

- **Coding.** If these products remain separately billable when used in the physician’s office, maintaining them in Q codes would be the least disruptive, as it would not require a change in billing or coding practices. However, we understand that Q-codes are not intended to be permanent and that CMS wishes to establish a permanent “home” for these products in terms of coding. Creating permanent HCPCS A-codes as medical/surgical supplies is an option. **Therefore, if the continued use of Q codes is not possible, we urge the Agency to consider the use of A-codes for separately billable skin substitutes.**
- **FDA TRG Letters.** As part of its transition to HCPCS A-codes, CMS plans to request a TRG letter from each product claiming to be regulated as a 361 HCT/P for which the Agency does not yet have a TRG letter. CMS specifies that twelve skin substitute products currently reimbursable via HCPCS Q-codes already have a TRG letter, but does not specify which of the approximately 140 remaining products will need to provide a TRG letter to verify 361 HCT/P status, versus how many are regulated by the FDA as devices and would thus not need a TRG letter. As a result, it is difficult for affected stakeholders to quantify the burden this proposal will present for the FDA TRG. If the proposal will create delays obtaining the required TRG letters, we would be concerned about the potential impact on access to these products for patient care. We urge CMS to work with affected manufacturers who in good faith promptly request a TRG letter but are unable to obtain it in the timeframe CMS proposes.

Aside from our concerns about potential delays at the FDA, we appreciate CMS' attempt to ensure that products reimbursed by Medicare are appropriately regulated. There are risks to patient safety when a product claiming to be a 361 HCT/P should actually be regulated as a medical device subject to premarket review or clearance by the FDA. We understand that CMS is seeking a way to verify that the products it covers as 361 HCT/Ps are in fact 361 HCT/Ps, and we agree that the FDA TRG letter can serve that purpose. However, obtaining TRG letters with regulatory status recommendations can be accomplished without simultaneously overhauling coding and reimbursement processes and triggering potentially significant budget neutrality reductions in the process. **As noted above, we urge CMS to maintain the separately billable status for skin substitute products in the physician office setting and to provide manufacturers with a reasonable timeframe (accounting for potential delays at the TRG resulting from this proposal) in which to obtain TRG letters for skin substitute products regulated as 361 HCT/Ps.** If a manufacturer does not comply or if a particular skin substitute product receives a letter indicating that it is not appropriately regulated as a 361 HCT/P, then CMS can end coverage for those products until the Agency receives proof of the appropriate FDA regulatory status.

### **Rebasing and Revising 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 practices costs. The MEI measures changes in the prices of resources used in medical practices including, for example, labor (both physician and non-physician), office space and medical 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% and the practice expense component, including professional liability insurance (PLI) costs, was 40%. These initial weights were derived from data obtained from the AMA. In 1993, the MEI components were updated, using AMA data and then proportioned to 54.2% Physician Work, 41% Practice Expense and 4.8% PLI. Currently, the allocation is 50.9% Physician Work, 44.8% Practice Expense and 4.3% PLI. The CMS proposal is to dramatically shift payment allocation away from physician earnings (work) to practice expense: 47.3% Physician Work, 51.3% Practice Expense and 1.4% PLI using non-AMA data.

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 History

	1975-1992	1993	Current	Proposed
<b>Physician Work</b>	60%	54.2%	50.9%	47.3%
<b>Practice Expense</b>	40%	41.0%	44.8%	51.3%
<b>Professional Liability Insurance</b>	(included with PE)	4.8%	4.3%	1.4%

CMS proposes to update the MEI weights using 2017 data from the United States Census Bureau’s Service Annual Survey (SAS). The proposed shift in payment weights from physician work to practice expense principally favors Diagnostic Testing Facility (+13%), Portable X-Ray Supplier (+13%), Independent Laboratory (+10%), and Radiation Therapy Centers (+6%) to the detriment of Cardiothoracic Surgery (-8%), Neurosurgery (-8%), Emergency Medicine (-8%) and Anesthesiology (-5%), among other specialties.

In addition to significant specialty redistribution, geographic redistribution would also occur, as CMS proposes to modify weights of the expense categories (employee compensation, office rent, purchased services and equipment/supplies/other) within the practice expense Geographic Practice Cost Index (GPCI). A significant reduction in the weight of office rent from 10.2% to 5.9% would lead to reductions in the payment to urban localities and increases to payment in rural areas and states with a single GPCI. CMS’ impact analysis should also be expanded to consider how significant decreases in PLI payment may negatively impact geographical areas with relatively high PLI premiums.

The changes in the MEI that CMS is proposing are almost entirely related to the category weights. A change in the price proxy is recommended for just one of the cost categories, which accounts for only 2% of the index. CMS is not proposing a change to the productivity adjustment. The proposed changes in the category weights are primarily derived from the Census Bureau’s 2017 SAS for the “Offices of Physicians” industry, which was not designed with the purpose of updating the MEI. As a result, there are key areas (physician work, nonphysician compensation and medical supplies) where CMS must use data from other sources to work around this important gap.

**We wish to highlight that there are a number of flaws in utilizing the SAS data for this purpose.** For example, CMS used BLS data to split out the US Census SAS data using the NAICS 6211 “Offices of Physicians” category. However, only 64% of employed physicians are in this category in both the US Census SAS and BLS OEWS datasets. This analysis excludes 36% of physicians who are employed in other health care

settings, such as hospitals. For example, the NAICS 6221 “General Medical and Surgical Hospitals” category was not included in CMS’ analysis and this category includes 158,880 employed physicians according to the 2017 BLS OEWS data. Hospital-based physicians have a higher proportion of physician earnings and PLI cost relative to other practice costs, as many of these other costs are the responsibility of the hospital or other facility. **CMS’ proposal greatly underrepresents the cost share of physician work and PLI relative to practice expense due to this inappropriate exclusion.**

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 practice expense component will in turn devalue physician work. Updates to MEI weights should be postponed until CMS identifies more appropriate mechanisms to update these data on a more frequent basis, including collaboration with Congress and medical specialty societies to ensure consistency and reliability in physician payment data collection efforts.** In the future, all significant data updates (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.

## **OTHER PROVISIONS OF THE PROPOSED RULE**

### **Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers**

CMS proposes to expand Medicare coverage of and payment for certain colorectal cancer (CRC) screening tests by lowering the minimum age from 50 to 45 years of age. **The ACS recognizes that age is one of the most important risk factors for colorectal cancer, with incidence rates increasing with age and nearly 94 percent of new cases of colorectal cancer occurring in adults 45 years or older.<sup>7</sup> As such, we thank CMS for its efforts to expand CRC screening testing and to align Medicare policy with U.S. Preventive Services Task Force guidelines, which recently recommended that CRC screening begin for adults aged 45 years.**

The Agency also proposes to expand the regulatory definition of “colorectal cancer screening test” to include follow-up screening colonoscopies after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Such non-invasive stool-based CRC screening tests include guaiac-based fecal-occult blood tests, immunoassay-based fecal-occult blood tests, and Cologuard™ Multitarget Stool DNA tests. Under this proposal, beneficiary cost-sharing (i.e., coinsurance and deductible)

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<sup>7</sup> U.S. Preventive Services Task Force. (2021, May 18). *Colorectal cancer: Screening*. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening>



would not be applicable for the stool-based test nor the follow-up colonoscopy screening tests.

The College believes that the overall goal of programmatic cancer screening using any CRC screening test is to prevent cancer, allow for early detection and treatment, and reduce cancer mortality. As such, follow-up colonoscopies are integral to non-invasive stool-based CRC screening, since improvements in CRC health outcomes would not be possible without the follow-up. **We appreciate CMS’ acknowledgement that, per feedback provided by the ACS and other medical professional organizations, stool-based CRC screening tests have evolved and become more frequently utilized relative to flexible sigmoidoscopies and screening colonoscopies due to low follow-up colonoscopy rates and patient access barriers, among other factors.** We thank CMS for addressing cost-sharing related to CRC screening services, and support the elimination of coinsurance and deductibles for such services to reduce out-of-pocket costs for Medicare beneficiaries.

### **Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation**

#### ***Overarching Comments***

- We have responded to CMS questions about improving the global surgical package valuation through comments, letters, and meetings since 2012.
- We strongly encourage CMS to disregard the RAND recommendations for revaluation of the global codes given that the RAND methodology is not only flawed but is based on numerous assumptions about data that are not transparent to the public. We encourage CMS to release the underlying data and assumptions used by RAND.
- We encourage CMS to reach out to EHR vendors and Medicare Administrative Contractors (MACs) to obtain actual data on the number of postoperative visits provided.
- We suggest that CMS consider eliminating the 10-day global period and review codes with that global period to determine if a 0-day or 90-day global period is most appropriate, but this must only be done by engaging stakeholders and reviewing the codes for relative valuation, not by using a formulaic building block valuation approach.
- We encourage CMS to continue to work with specialty societies as it moves forward so we can weigh in on the Agency’s policy considerations related to revaluation of

global surgical packages.

We provide comments below on the areas where CMS solicits feedback in this rule.

### ***Changes to Health Care Delivery and Payment for E/M Services***

CMS solicits comment on whether changes to health care delivery, including changes in coordination of care and use of medical technology over the past three decades, as well as during the recent public health emergency, have impacted: the number and level of postoperative E/M visits needed to provide effective follow-up care to patients; the timing of when postoperative care is being provided; and who is providing the follow-up care.

**Health care delivery has changed dramatically over the past three decades.** Notably, health care delivery has become increasingly complex due to the rise in availability of clinical data, medical technology, and team-based care. The many available data points and additional requirements for coordination of care across teams has increased the number of decisions that physicians must make regarding diagnosis, treatment, and care plans. This increased work applies to surgeons as well as other medical specialties, such as primary care.

In addition, the shift of care from the inpatient to the outpatient setting, as well as pressure to send patients home sooner after inpatient surgery, has not decreased total work, but instead has moved work from the facility to the office/outpatient setting. For example, surgeons must now coordinate medication dosing changes required postoperatively (e.g., blood thinners, antibiotics, multi-modal pain management regimens) with chronic disease medications. Surgeons must also coordinate at-home postoperative therapy, educate patients/caregivers and respond to their questions about dressing changes, feeding tube management, safe ambulation, and more. As patients are discharged earlier to their homes, diet and activity that used to be regulated in the hospital now must be closely monitored by the surgeon in the office/outpatient setting. **This evolution in the complexity of health care delivery has led to the undervaluation—rather than overvaluation—of many global surgical codes.**

### **Factors Affecting Postoperative E/M Care**

CMS also seeks feedback on the following factors that could affect ways that postoperative E/M care is provided.

- CMS believes that some beneficiaries are not receiving the number of postoperative visits that were contemplated when valuing the global surgical

packages.

There are two major problems with this theory:

- (1) It is a longstanding CMS/RUC agreement that codes are valued to represent care delivered to “the typical patient,” and not care delivered to “every patient.” CMS has offered no evidence that the number of postoperative visits included in global codes are not representative of care delivered to the “typical patient;” and
- (2) To the extent that the number of postoperative visits are associated with procedure changes over time, there is an ongoing process for revaluing that procedure. Further, CMS oversees the Potentially Misvalued Services initiative. If the Agency believes a code is misvalued, CMS can place it on the list of Potentially Misvalued Services.

It is also not possible to know with certainty whether some beneficiaries are not receiving the number of postoperative visits that are included in the values of global surgical codes because CMS has not studied reliable data sources on this question. **The RAND publication offers no information that warrants an across-the-board, one-size-fits-all revaluation of global codes.**

**We believe that RAND’s findings regarding the global codes data collection effort, which began in 2017, are invalid due to the false assumptions that: (1) all provider visits were correctly submitted; (2) all the claims were transmitted to the contractor; and (3) the contractor submitted all claims to CMS.** We have received feedback from multiple surgeons involved with this survey that call into question the validity of such data collection efforts and interpretation of those data by RAND.

Additionally, MACs should have access to electronic health records (EHRs) for audit purposes. Many physician office EHRs require reporting of CPT code 99024 for every postoperative visit in the office setting to close out a patient record, so this would be a much more reliable way to count the number of postoperative office visits, as even though a physician typically reports CPT code 99024 to close out a visit encounter (whether face-to-face or via telehealth), that record might not be transmitted to an insurer. In other words, patient office records may include CPT code 99024 encounters even though payor records may not capture this encounter. **We urge CMS to consider working with its intermediaries to obtain EHR data on the number of postoperative office visits provided within a global period.**

We also reiterate from our CY 2015 MPFS proposed rule comments the position that global surgical payments are based on typical work but allow for variations in the actual

postoperative services that may result in more or less work than typical.<sup>8</sup> **According to the surgical package definition in the CPT surgery guidelines, global surgical services provided by a physician to any patient by their very nature are variable.** As such, in some cases, patients might not receive the number of postoperative visits included in the value of a global surgical code because their postoperative recovery was more straightforward than the typical case. However, in other cases, patients might require more postoperative care because their recovery was more complicated.

This dynamic works in *both* directions—surgeons are likewise not paid more when the number of postoperative visits exceed that which is “typical” for a given procedure. For example, seromas, wound dehiscence, or need for resuturing wounds might not be typical for some abdominal surgeries. However, when they do occur, additional time and/or postoperative visits beyond the typical number are required. In these instances, the level or number of postoperative visits in the global payment cannot be changed, and no additional procedure codes can be reported unless the patient is returned to the operating room. Thus, the surgeon would be paid for fewer visits than what were actually provided.

We also note that when modifier 22 (*Increased procedural services*) is used, it only refers to increased work for the procedure itself and does not apply to postoperative hospital or office work. There is no modifier to account for increased services during the postoperative or preservice period.

This is distinctly different from how E/M visits are reported for medical patients where an unusual encounter can be reported and paid simply by using a higher level of code. Unlike E/M visits, there are no higher level procedure codes when work is greater than typical. Theoretically, every operation should be classified as straightforward or complex. **The typical patient is straightforward for most procedures, but many procedures can be complex, meaning that surgeons who provide care to the range of patients (i.e., not only the straightforward cases) will never be fully compensated for the amount of work they perform.**

- CMS also states that beneficiaries might not be receiving any follow-up E/M visits at all during the global periods either because the physician who performed the surgical procedure had determined they are unnecessary or as the result of more comprehensive discharge planning.

**It is highly unlikely that global surgery codes that have been recently reviewed and surveyed would include postoperative visits that do not occur.** In fact, several global codes do not include a postoperative visit at all based on RUC review, such as CPT codes

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<sup>8</sup> American College of Surgeons. (2014, September 2). *Medicare Program; Revisions to payment policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & other revisions to Part B for CY 2015* [comment letter].

64615-61617 (*Chemodenervation of muscle*). As mentioned above, we urge CMS to investigate obtaining records from Medicare contractors that can show definitively whether postoperative visits are being provided, or whether fewer than the contemplated number of postoperative visits are being provided.

- CMS asserts that physicians might be performing postoperative visits, but the visits are outside the global period.

**In the case of codes with a 10-day global periods, it is possible that some visits could be provided outside the global period.** For example, a biopsy that is negative and requires no stitches might not require a postoperative visit, or communication of the pathology result could occur via an electronic portal to the patient instead of requiring the patient to come into the office for a visit. Surgeons' schedules for operating room time, postoperative visit time, and clinic time typically do not vary from week to week. For some operations where the patient is discharged from a facility on the same day as the procedure (e.g., incision and drainage of an abscess), the standard of care may be to see the patient within one or two days because the first 24 to 48 hours following the procedure are critical. In other instances (e.g., wound repair), the patient may be seen anytime between 7 and 21 days based on the size and location of the repair and the day the surgeon is in clinic. Furthermore, a follow-up visit with the same provider may occur outside of the 10-day global for clinical reasons. For example, removal of sutures on a knee or elbow are likely to take place more than 10 days post-operation given the high failure rate when sutures are removed too soon from high flexion areas. In addition, there could be circumstances where the patient themselves are not able to return within the 10-day global period.

- CMS asserts that physicians might be instructing patients to follow up with another physician or NPP, without formally transferring follow-up care.

**We urge CMS to determine whether physicians are instructing patients to follow up with another physician or NPP by looking at patient-level claims throughout the global period to identify whether E/M claims were submitted by other providers with the same diagnosis.** This information can and should be audited to confirm which postoperative visits were provided by the surgeon and which were provided by another physician or NPP. While this may occur in some isolated circumstances, we do not have any information or belief that this is a common practice.

### **Recent Coding Changes and the Impact on Global Packages**

CMS also solicits comments on whether or how recent changes in the coding and valuation of separately billable E/M services may have impacted global packages. These changes could include expansion of payment for non-face-to-face care management

services, such as transitional care management (TCM), chronic care management (CCM), complex chronic care management (CCCM), and principal care management (PCM).

**The coding changes to non-face-to-face care management services (e.g., TCM, CCM, CCCM, PCM) would not affect the valuation of global surgical payment.**

Most of these codes are not billed by surgeons as part of postoperative care and are instead billed by primary care physicians for their ongoing work for a patient's chronic condition, not an operation.

- Transitional Care Management: TCM services occur during a 30-day period that begins when a physician discharges a patient from an inpatient medical stay and continues for the next 29 days. Only one physician or NPP may bill for the TCM services, which involve helping transition a patient back to the community setting after a stay in certain facility types. **Medicare does not allow physicians to bill TCM services within a postoperative global surgery period.** TCM services reporting was developed to incentivize primary care physicians to take on the care of medical patients without a medical home. Primary care physicians indicated that there was non-face-to-face work that was not covered in an E/M service for new patients between discharge and the first office visit. TCM codes do not relate to surgeons discharging a patient and seeing the same patient in the office, as there is clinical staff time included for discharge management in codes with a global period.
- Chronic Care Management: CCM services are generally non-face-to-face services provided to Medicare beneficiaries who have multiple chronic conditions expected to last at least 12 months or until the death of the patient. The service period for CCM services is one month. Only one physician or other QHP who assumes the care management role for a beneficiary can bill for providing CCM services to that patient in each calendar month. **The types of services covered by the CCM codes are ongoing chronic care services and do not include postoperative care, and therefore these codes do not affect the valuation of global surgical packages.**
- Complex Chronic Care Management: CCCM codes are similar to CCM codes, but with more cumulative minutes over a 30-day period of non-face-to-face consultation time spent establishing or monitoring a care plan. **Similarly, the types of services covered by the CCCM codes are ongoing chronic care services and do not include postoperative care, and therefore these codes do not affect the valuation of global surgical payment.**
- Principal Care Management: **PCM codes are intended to cover services for patients with only one complex chronic condition that requires management**

**by a specialist.** Postoperative office visits, on the other hand, address the underlying surgery and the follow-up from that surgery—not to manage a chronic condition that might have been a precipitating event for the surgery. The PCM codes are not for use in following up with a surgical patient, nor are postoperative visits used to manage an ongoing chronic condition. These codes and services are unrelated to postoperative work.

CMS solicits comments on whether global packages, especially those with 10- and 90-day global periods, continue to serve a purpose when physicians could otherwise bill separately, not only for the postoperative E/M visits they furnish, but also for aspects of postoperative care management they furnish for some patients. As discussed above, the non-face-to-face care management services, such as TCM, CCM, CCCM or PCM, would not affect the valuation of global surgical packages. **We generally support the concept of bundled payment, and global codes are one of the earliest forms of a value-based payment model.** Bundled payment is a way to focus clinicians on the appropriate management of patients; support cost containment; and encourage alignment between surgeons, facilities, and payors.

In addition, disassembling the global codes into the procedure and separately billable postoperative office visits would require patients to pay separate copays for each follow-up visit. If patients had to pay for individual follow-up visit copays, even if the total copay for the procedure and the follow-up visits was the same as the copay for a global code, CMS will have introduced a disincentive for the patient to obtain medically necessary follow-up care. This could have serious patient safety implications and could adversely affect patient outcomes after surgery. The global surgical package model averts such a disincentive for patients. Despite our general support of bundled payment, we note that there could be some instances in which it would be more appropriate for certain families of CPT codes to move from 10- and 90-day global surgical packages to a 0-day global. **Ultimately, we encourage CMS to take a nuanced approach depending on the specific codes.**

### **Components of Preoperative or Postoperative Care Only Compensated as Part of Global Package**

**To reiterate our statements from our CY 2015 MPFS comments, there is a different mix of postoperative direct PE inputs for global E/Ms and separately reported E/Ms.<sup>9</sup> The E/Ms performed in a surgical global period often include additional—and justifiably more expensive—supplies (e.g., specialized bandages and dressings, different postoperative incision care packs) and equipment (e.g., specialized**

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<sup>9</sup> American College of Surgeons. (2014, September 2). *Medicare Program; Revisions to payment policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & other revisions to Part B for CY 2015* [comment letter].

**examination tables, cast cutters, surgical and exam lights, ultrasound units, endoscopy equipment) relative to standard, separately reported E/M services.**

Certain surgical E/M services also include additional clinical staff time relative to the clinical staff time for separately reported E/M visits, such as the additional clinical labor time required to care for stomas or for the setup and cleaning of scope equipment required at a postoperative visit. The postoperative clinical staff type and time are both carefully considered by the RUC and are directly related to the typical patient condition and type of service performed for the specific CPT code that has been valued.

Lastly, malpractice insurance for surgeons is not captured adequately in separately reported E/M services due to dilution by other providers with very low premiums who report these services.

### **Misalignment Between E/M Visits Included in Global Codes and Separately Billable E/M Service**

The ACS and other stakeholders have expressed grave concerns that recent changes to the coding and valuation of standalone office and outpatient E/M visits finalized in the CY 2021 MPFS have skewed the relativity between these visits and the value of E/M visits included in the current global package valuations. CMS did not modify the values of the E/Ms in global surgical packages. The Agency notes that it was unclear whether it would be appropriate to treat the E/M visits reflected in the global surgical packages as discrete components of the package (i.e., using a building block approach versus magnitude estimation).

**The E/M visits reflected in the global packages are indeed discrete components but are valued using magnitude estimation, not as discrete components.** Physician work is comprised of both time and intensity. Since 1997, each time the payments for office/outpatient visits were increased, the Agency also adjusted the 10- and 90-day global payments to reflect the increased values of the E/M portion of these codes. **The incremental increases to the E/M codes were based on magnitude estimation (not building block) and therefore it was and remains appropriate for the same incremental increases based on magnitude estimation to be applied to global code E/M components.**

We stress that the changes to the E/M codes were not made via a building block methodology, but rather via magnitude estimation, a methodology that the Health Care Finance Administration (HCFA) and CMS have accepted since the inception of the resource-based relative value scale (RBRVS). For example, if the standalone E/M visit increase was 20 percent based on magnitude estimation, there is no reason why the same E/M visit for global codes should not receive the same treatment and the same incremental change in work. **Therefore, the incremental magnitude estimation**



**increase should be applied to global codes (as it was in previous years) for the changes to separately billable E/Ms that went into effect in 2021.**

CMS also states that if the number and level of E/M services for global packages is not appropriate, adopting increases in the value of E/M services in global surgery codes would exacerbate rather than ameliorate any potential relativity issue. **We do not agree with this rationale because we do not believe reliable data have been collected to indicate that the number and level of E/M services in global surgery codes are not appropriate. We urge CMS to adjust the values of the global surgical packages for which the Agency has accepted the RUC-recommended values since the passage of the Medicare Access and Children’s Health Insurance Program (MACRA). The RUC has reviewed 245 10- and 90-day global codes since the passage of MACRA, and CMS has accepted the RUC recommendations for the number and level of postoperative visits as accurate for all these codes.**

For example, high volume CPT code 52601 (*Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*) was reviewed in 2016 and total time file visits were reduced to 2.5. Similarly, high volume CPT codes 27130 (*Total hip arthroplasty*) and 27447 (*Total knee arthroplasty*) were reviewed in 2019 with a reduction in time file visits and work RVUs. During this review, data from EHRs for three large institutions representing over 20,000 arthroplasties were provided to support the RUC survey data.

**In addition, CMS also accepted the number and level of postoperative visits for an overwhelming majority of codes revised prior to the passage of MACRA. This is evidence that the Agency has considered the RUC review an effective process for evaluating potentially misvalued codes.** To maintain relativity, CMS should proportionately adjust the global codes to reflect the increased office and outpatient E/M values.

Further, with the acceptance of the inpatient/observation E/M codes in this proposed rule, CMS should also incrementally adjust the global codes to reflect those values as well as the office and outpatient E/M values. This will allow the RUC to continue updating these codes as necessary with guidance and input from CMS and medical specialty societies to address potentially misvalued services. Without an adjustment to the global codes, the bedrock of relativity within the fee schedule is degraded. This promotes an unfair and inaccurate valuation of physician work for some, but not all, specialties. Unless this error is corrected, future work by the RUC and CMS will progressively deviate from the established relative value of different physician services across the fee schedule in ways that are certain to compound imbalances to the RBRVS.

**In many of our prior comment letters, we have stated that applying the RUC-recommended E/M incremental changes to standalone E/Ms, but not to the E/Ms that are included in the global surgical package since the inception of the fee schedule, will disrupt the relativity between codes in the MPFS.** Changing the values for some E/M services but not for others disrupts this relativity, which was mandated by Congress, established in 1992, and refined over the past 30 years. Since the inception of the fee schedule, E/M codes have been revalued three times: in 1997 (after the first five-year review), in 2007 (after the third five-year review) and in 2011. When the payments for office visit codes were increased in these instances, CMS also appropriately adjusted the global code values to reflect such changes in recognition of the fact that the Harvard study set relativity of all procedures and services when the first MPFS was implemented.

### **Strategies to Address Global Package Valuation**

#### ***RAND Methodology***

CMS believes that RAND has provided a comprehensive roadmap for a possible revaluation strategy and solicits input on the RAND methodology, including advantages and drawbacks of applying the RAND methodology to revaluation. The ACS has commented extensively on the RAND methodology for evaluating the data it collected, along with RAND’s model for how valuation of global packages would change. We expand on our prior comments below.

#### **Issue #1: No Visits Reported for Some Procedures**

In our CY 2020 MPFS comments, we stated that, in a briefing with RAND organized by the AMA on August 13, 2019, the authors of the report indicated that when calculating the ratio of observed-to-expected postoperative visits for both 10- and 90-day global procedures, physicians who could have reported, but did not report, were considered to have reported no visits.<sup>10</sup> **To assume that those who did not have their postoperative visits received by the Medicare intermediary as affirmatively stating that they did not provide any visits related to the global procedures is not a valid conclusion, as no audit was conducted of these providers to confirm this assumption.**

In fact, a U.S. Government Accountability Office (GAO) December 2019 document entitled “Assessing Data Reliability” addresses the need for computer-processed data audit and validation.<sup>11</sup> This guide is informative, given that RAND was hired to assess (i.e., audit) the collected data for CPT code 99024 reporting and to make

<sup>10</sup> American College of Surgeons. (2019, September 10). *Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1715-P)* [comment letter].

[https://www.facs.org/media/5pbc0vjd/combined\\_cy\\_2020\\_mpf\\_s\\_proposed\\_rule\\_payment\\_and\\_quality.pdf](https://www.facs.org/media/5pbc0vjd/combined_cy_2020_mpf_s_proposed_rule_payment_and_quality.pdf)

<sup>11</sup> U.S. Government Accountability Office. (2019). *Assessing data reliability* (supersedes GAU-09-680G). GAO-20-283G.

<https://www.gao.gov/products/gao-20-283g>

recommendations about the data validity, outcomes, and remedies, if needed. RAND neglected to assess the data validity by going back to the data source (i.e., the providers) to confirm that accurate and complete data were submitted. If RAND had confirmed the accuracy of its work, instead of making baseless conclusions, it likely would have discovered that there was significant data missing from its review.

In addition, section 523 of MACRA states: “*The Inspector General of the Department of Health and Human Services shall audit a sample of the information reported under clause (i) to verify the accuracy of the information so reported.*”<sup>12</sup> Further, a work plan summary on the Office of Inspector General (OIG) website indicates that the OIG will review a sample of global surgeries to determine the number of postoperative services documented in medical records and compare that to the number of postoperative services reported in the data collected by CMS. This report has not been published to date, but the OIG website indicates that it is expected to be released in 2022. **We urge CMS to consider this OIG audit report and allow stakeholder comments before proceeding with a global code valuation strategy based on RAND’s false assumptions.**

The RAND conclusions about postoperative work without an audit to confirm that complete data were collected is concerning given that only 46 percent of providers expected to participate submitted CPT code 99024 for the one-year period on which the report was based. **This means that more than 50 percent of providers expected to report were erroneously assumed to never perform a postoperative visit.** Additionally, only 17 percent of physicians were classified as “robust reporters,” meaning the majority of those who reported did not submit one claim for a postoperative visit for at least half of the procedures performed in the collection period.

**Despite repeated requests from stakeholders, CMS did not establish a process by which practitioners could confirm that CMS received submitted claims reporting CPT code 99024.** This need for confirmation is critical due to the numerous hurdles for reporting, including required updates to practice management software and updates to code scrubbing protocols in the claims clearinghouses to allow transmission of claims for CPT code 99024 to CMS, but not to other private payors or to self-pay patients. Without some form of feedback, it is impossible for physicians to know whether the CPT 99024 codes that they attempted to report were transmitted and received.

**It is highly probable that the collected data are not accurate—in fact, much of the data summary defies face validity.** For example, CPT code 61312 (*Craniectomy or craniotomy for evacuation of hematoma, supratentorial; extradural or subdural*) is indicated in the RAND report to incur an average of 2.81 postoperative visits. This emergent procedure involves drilling burr holes and cutting a craniotomy flap, making

<sup>12</sup> Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. 114-10, 129 Stat. 87, 114<sup>th</sup> Cong. (2015).

<https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf>

dural incisions and creating a dural flap, removal of clots and gross blood, identifying contused areas of the brain and treating appropriately, placing a subdural catheter through a burr hole for postoperative drainage, placing an intracranial pressure monitor, further inspections, and treatments before replacing the bone flap and closure. It is inconceivable that an average of 2.81 visits (for both hospital and office encounters) is accurate for a patient undergoing such a complex procedure. It is also impossible that between 25 and 50 percent of the respondents performed no visits for such a patient as indicated in the RAND tables. Similarly, CPT code 61510 (*Craniectomy, trephination, bone flap craniotomy; for excision of brain tumor, supratentorial, except meningioma*) is indicated in the RAND report to incur an average of 2.14 postoperative visits. It is implausible that an average of 2.14 visits (for both hospital and office encounters) is accurate for such a patient and procedure. It is also impossible that between 25 and 50 percent of the respondents performed no visits.

### **Issue #2: Use of Outdated Time File**

The RAND report uses an old CMS time file to extrapolate conclusions and recommendations. The RUC continues to identify potentially misvalued codes and when these codes are reviewed, the number and level of visits are often revised along with a revision to the work RVUs. For example, high volume CPT code 52601 (*Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)*) was reviewed in 2016 and total time file visits were reduced to 2.5. However, the 2019 RAND report indicates that 7 expected visits are in the CMS time file and this information influenced its recommendation about misvaluation of codes.

Similarly, high volume CPT codes 27130 (*Total hip arthroplasty*) and 27447 (*Total knee arthroplasty*) were reviewed in 2019 with a reduction in time file visits and work RVUs. During this review, data from EHRs for three large institutions representing over 20,000 arthroplasties were provided to support the survey data. This would suggest that: (1) the RAND analysis is outdated, and (2) the collected data for CPT code 99024 are not complete or accurate.

### **Issue #3: Facility versus Office 99024 Reporting**

**The data tables in the RAND reports do not show reporting of CPT code 99024 for facility versus office settings.** There is also no mention of an analysis of whether the postoperative visits reported with CPT code 99024 were performed in the facility or the office. Having more information about the site of the postoperative visits would have been useful to confirm that clinicians knew that they were required to report both facility and office postoperative visits. This could also expose issues with claims submission for

a hospital visit through the hospital records system versus through an office where physicians may have more control over claims submissions. This highlights another aspect of where a reporting flaw might have occurred and RAND's sensitivity analysis was not sufficient to confirm that all the visits that were provided were counted. Again, simply because clinicians reported some visits does not mean that they were reporting all visits for both hospital and office encounters and that both hospital and office claims management systems were processing and submitting the CPT code 99024 claims reported by surgeons.

We remain extremely concerned with CMS developing a global codes revaluation strategy based on the results of the RAND analysis of data collected (or not collected) from multiple claims processing sources. As noted above, MACRA requires the OIG to audit a sample of the global codes data collected to verify the accuracy of such data. **We would anticipate that the OIG audit report would include information about any disparities in reporting, such as some providers showing CPT code 99024 claims only from office encounters, some physicians only reporting one CPT code 99024 claim even though multiple encounters are found in the medical records, and/or no claims for CPT code 99024 were collected even though medical records show multiple patient encounters.**

#### **Issue #4: Average RVW**

The RAND approach to revaluing global codes uses a reverse building block methodology, notwithstanding that the value for the codes were not established using BBM. When subtracting the full value of a postoperative visit, RAND used the mean work RVU of a mixture of current global visits to subtract work RVUs that the results of the RAND report indicate did not occur. RAND provided an example of this method, stating that if the database indicates one CPT code 99213 and one CPT code 99212, the mean of these two work RVUs was used to determine the work RVUs to subtract. However, when looking at how visits are described on RUC SoR forms and considering actual practice, we find that the first and most significant visit supports the higher level CPT code 99213 to assess wounds, remove drains, remove sutures/staples, discuss therapy, among others. If a second visit is not needed within 90-days (which we still do not agree is a correct assumption), then it would be the lower-level visit (CPT code 99212). By using the mean value of these visits, this approach incorrectly assumes the missed visit could be either level. **This approach is not clinically sound, as if a visit truly did not occur, it would not be appropriate to subtract an average value of two visits rather than subtracting the value of the lower visit based on clinical assessment.**

### **Issue #5: CMS Data Collection Education**

Data collection occurred from July 1, 2017, to June 30, 2018. None of the RAND reports provide information about how CMS educated providers to report services. An eight-page “Guidance Document” on this issue can be found on the U.S. Department of Health and Human Services (HHS) website, dated July 1, 2017 (the metafile data source date is June 17, 2017).<sup>13</sup> However, we do not know how or when this information or any other CMS educational information were sent to physicians in the states where data were being collected. We also note that the HHS document states, “Although not required, practitioners are encouraged to begin reporting prior to July 1, 2017, to ensure that their practices have sufficient time to update software, test systems, and train staff to accurately report postoperative visit data.”<sup>14</sup> This implies that CMS recognized the enormous burden placed on physicians to determine how to submit data and still—without confirmation that all claims processing software were updated and coding staff were trained—the Agency began collecting data.

Many specialty societies, including the ACS, worked diligently to inform their members of this new reporting requirement, but based on feedback from surgeons, we strongly believe that a large percentage of physicians who were required to submit data were not adequately informed of the importance of reporting CPT 99024 for every postoperative visit. We are aware of only a few members receiving a single, and somewhat ambiguous, letter from CMS on this issue and the need to report *after* the reporting period had already begun. The ACS offers coding courses several times a year to both surgeons and certified coders, and no attendees were aware of such requirements during the data collection period when asked at such courses. In “Responses to Comments on RAND Global Services Reports,” however, RAND indicated that procedure-based specialties had high rates of reporting and provided the data in Table 3.2 below:

**Table 3.2. Claims-Based Reporting Rates for Select Procedure-Based Specialties**

<b>Specialty</b>	<b>Reporting Rate (%)</b>
Orthopedic surgery	95
Vascular surgery	92
Ophthalmology	91
Neurosurgery	91
Urology	90
Plastic and reconstructive surgery	89
Dermatology	87

SOURCE: CMS Integrated Data Repository (December 13, 2018) (CMS, 2018).

<sup>13</sup> U.S. Department of Health & Human Services. (2017). New claims-based reporting requirements for postoperative visits guide for practitioners. <https://www.hhs.gov/guidance/document/new-claims-based-reporting-requirements-post-operative-visits-guide-practitioners>

<sup>14</sup> Centers for Medicare & Medicaid Services. (2017). New claims-based reporting requirements for postoperative visits: Guide for practitioners. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CMS-claims-based-data-reporting-provider-education.pdf>

The report indicates these data suggest that, despite the barriers that commenters have described, a large percentage of practitioners in procedure-focused specialties knew about the reporting requirement and successfully submitted claims for postoperative visits. The report also states that, among more complicated surgeries represented by 90-day global procedures, the issue was not that no postoperative visits were furnished, but rather that fewer visits were reported than expected. The report concludes that together, this pattern of postoperative visit reporting is inconsistent with a scenario in which physicians were unaware or unable to report the visits.

We do not understand how the reporting rate percentage data in Table 3.2 can be accurate given that so many high-volume 90-day global codes had a reporting statistic of zero at the 25th percentile and most of the 10-day global codes had a reporting rate of zero at the 25th percentile and median. Table 3.2 confirms that RAND assumed every provider reported correctly and that no claims for CPT code 99024 meant no postoperative encounters occurred. **We contend that this assumption (without audit) has resulted in invalid statistics—including the reporting rate percentage published in Table 3.2.** Without a way to confirm that RAND’s assumptions are valid, anything short of perfect reporting would incorrectly result in fewer than expected postoperative visits reported.

### **Alternatives to RAND's Proposed Methodology**

CMS also requests input on specific alternatives to RAND’s proposed methodology (which uses assumptions about collected data and reverse building block), such as requesting the RUC to make recommendations on new values. We reiterate our statements from our prior comment letters that we believe RUC-reviewed postoperative work has been appropriately surveyed, vetted, and valued using magnitude estimation of total work. **We support the RUC’s deliberative process for evaluating codes, which utilizes standard physician magnitude estimation surveys based on the Harvard study to establish work RVUs.** As a peer review group, all medical and surgical specialties participate and judge the data as presented. Those data are subjected to much inspection, review, and deliberation before the RUC makes recommendations for valuation.

We continue to believe that this process remains the best approach to valuation of resource consumption. Isolated cases and anecdotal information are not accepted as typical. While we do not believe that more accurate data sources or valuation approaches currently exist for all aspects of the global period, we again encourage CMS to consider examining EHR data on the number of CPT code 99024 visits reported as a credible data source than the self-reported data collected as required by MACRA and incorrectly analyzed by RAND.

### ***Potential Revaluation Strategies***

CMS believes that the RAND reports indicate that there is a mismatch between the value of the global package and the work being performed, and that for some services, the number of postoperative visits typically furnished by the billing physician is much lower than what was reflected in the global package—thus, it may be necessary to revalue those services. CMS seeks comments on the following strategies:

- Revaluing all 10- and 90-day global packages at one time (perhaps with staggered implementation dates): This would be an enormous undertaking and create significant burden for specialty societies. **We do not support this approach because we do not see a way to properly and fairly revalue all 10- and 90-day global codes accurately in a such a short timeframe.** Currently, the RUC uses a survey methodology to determine the relative value of codes. Revaluing all 10- and 90-day codes at once would overtax the RUC’s and specialty societies’ ability to survey codes. We note that it took five years to review the practice expense for all codes and that implementation was delayed until all codes were reviewed, and even then, implementation was staggered over four years. We also do not believe that revaluation of all codes based on the methodology set forth by RAND is appropriate given that we are not confident about the data collection and analysis, and that the OIG audit has not yet occurred. In addition, any audit should be transparent and open for public comment.
- Revaluing only the 10-day global packages: **This could be a potential first step for CMS to consider in addressing the concerns with global surgical package valuation.** We suggest that if the 10-day global period were to be eliminated, it should first be determined whether a 0-day or 90-day global period is most appropriate for a given code(s) by engaging the relevant stakeholders and then reviewing the code(s) for valuation relative to other 0-day and 90-day global period codes. We do not support an approach that would simply subtract the value of a certain number of postoperative visits.
- Revaluing 10-day and some 90-day global codes (such as those with demonstrated low postoperative visit performance rates as identified in RAND’s analysis of these services): Again, we do not agree with the RAND analysis as to which codes have low postoperative visit performance rates. There is a process already in place, used for decades, and has properly adjusted the values as new data was evaluated. For example, there have already been many high-volume and high-value codes that CMS and the RUC have identified that have been reviewed where postoperative visits and work RVUs were lowered, including CPT codes 22633 (*Lumbar arthrodesis*), 27130 (*Total hip arthroplasty*), 27447 (*Total knee arthroplasty*), 52601 (*Transurethral electrosurgical resection of prostate*), 63030 (*Lumbar laminotomy*), and 66984



*(Extracapsular cataract removal with insertion of intraocular lens prosthesis)*. If CMS would like to examine additional 90-day global codes, the Agency can create a list of codes that are potentially misvalued for the RUC to consider, keeping in mind the resources and time necessary to fairly determine a proper valuation.

- Relying on the Potentially Misvalued Code process to identify and revalue misvalued global code packages over the course of many years: As mentioned above, this is another possible approach that has been used for many years to manage the examination of the values of global codes.

If CMS were to move forward with a revaluation strategy, we stress that the Agency should only utilize a clear, consistent, and proven methodology. **The Agency should not use one method, such as magnitude estimation for E/M codes—including arbitrarily applying E/M incremental increases to 30-day global E/M services codes (e.g., care management)—and then use reverse building block to reduce surgical services. CMS should not move forward without developing an implementation methodology with stakeholder input that carefully considers the concerns above.** We urge the Agency to utilize any available means to obtain comments, including Open Door Forums and town hall meetings with the public, among other avenues, and also urge CMS to allow stakeholders to provide additional written comments on policies that CMS is developing for collecting data, either in the form of a response to a request for information (RFI), written comments following a town hall, or by some other mechanism.

## **ACS COMMENTS TO CY 2023 QUALITY PAYMENT PROGRAM PROPOSED RULE**

### **Introduction**

To achieve value-based care, the ACS asserts that the concept of “value” in health care must be defined in terms of results that matter to the patient for the condition they have, with the goal for all stakeholders to deliver care based on what the patient values. Patients on a care journey need patient-centric measures across their clinical pathway that appreciate the achievement of their care goals. These measures should inform patients about where to get safe (preventable harms), affordable, good (outcomes), equitable care. Delivering on patient goals and gaining the trust of the patient requires the orchestration of the clinical team working together. Measuring quality efforts at the patient-level and rewards for quality attainment or improvement should celebrate all members of the care team jointly coming together to co-manage the patient for their condition, including the facility. To do this, the ACS advocates for a “comprehensive quality program,” which we define as a quality framework focusing overarchingly on the care of the patient, including the goals and outcomes important to the patient, while also valuing the infrastructure,

resources, and processes needed to deliver optimal care and continuously drive improvement.

To achieve this in the Quality Payment Program (QPP), there are several objectives that could guide CMS towards patient-centric value-based care. We encourage CMS to evaluate the success of their programs based on these objectives.

**1. *Programs should inform patients about where to get care for their condition.***

Twenty years of the National Quality Forum (NQF) and CMS actions in quality have not produced reliable public knowledge for patients. If a patient is diagnosed with a condition such as a cancer, there is no reliable information available on the Care Compare website showing where to seek care for the type of cancer they have; even referring clinicians often do not have transparent and reliable information to use for directing referrals. Currently, for the majority of surgeons, Care Compare only shows performance on primary care focused CMS Web Interface measures and if they use Certified Electronic Health Record Technology (CEHRT). Where possible, for highly prevalent conditions, quality programs should: build teams, leverage condition-specified measures to drive improvement, use these attributes to inform patients about where to find the care they expect, and incentivize and reward quality. In instances where conditions are not as prevalent, quality programs should assure the proper structure, processes, and outcomes are framed by the care team to fit the domains of care (such as excellence in trauma, cancer, and geriatric surgical care). This type of information is what should be prioritized for public reporting.

**2. *Quality programs should incentivize shared accountability with co-managed elements of care across the team and the facility.***

In complicated care models, it takes a well-orchestrated team to deliver outcomes safely, affordably, adequately, and equitably. That is to say that care models are complicated, and patients are complex when factoring in their goals and expectations of care. Appreciating the distinction of applied medical science alongside meeting a patient's needs across a care team in co-managing the care plan is key to achieving true quality in healthcare. Comprehensive quality programs take the complicated care model and translate it into a customized care plan, which reflects the complexity of care for each individual patient.

Yet, the current CMS quality programs (including MIPS Value Pathways [MVPs]) continue to individually measure clinicians in silos where specialists are forced to think, "I don't have enough measures for the care I deliver in MIPS! What measures will I be held accountable for in MIPS/MVPs?" In response, professional society organizations scramble to develop measures that fit into this flawed framework and help to ensure that specialists can avoid penalties under the

QPP. In reality, this framework ends up disaggregating the care team’s efforts, is contrary to the ongoing transition to patient-centered value-based care that relies on the co-management of patients, and moves us farther away from our goals of truly raising the bar on patient care. MVPs and sub-group reporting are efforts to align care teams around a patient for a condition, which we support, but they are largely measuring the wrong things—they continue to focus on siloed actions, individual processes, and avoidable harms.

For shared accountability, the clinical team should be measured on the joint effort of a comprehensive quality program, where they must come together to achieve outcomes that matter to the patient. Integrating structure, process, and outcome elements, originally introduced by Donabedian, are critical to the comprehensive quality program, as well as how these elements come together as an interconnected and interrelated set of measures for a condition.<sup>15</sup> By using standards, facilities and providers are aligned for continuous, reliable, and standardized care. In addition to adequate outcomes, adhering to clinical protocols, having the correct personnel and equipment, and an aligned organization are essential attributes for achieving high quality.

**3. *Programs should include price transparency for an episode of care.***

Information on the comprehensiveness of a quality program, along with comparable information on the price of that care, are prerequisites for a valid depiction of the value of care. Just as in quality, the dashboard should be meaningful and actionable to the end user. Quality and affordability are primary elements of assessing value.

The ACS believes that shared accountability for both quality and price should align around the episode of care and appreciate shared accountability for the team of providers. This generates the best opportunity for examining the care plan for the value of the services needed to deliver the desired outcomes. Without shared price accountability, a single team member may seek more testing, labs, and images, while the other team members feel this is excessive, wasteful, or unnecessary. Without shared accountability, the excessive care attributed to one clinician will persist. We understand the constraints under the current law, and we encourage CMS and other stakeholders to work with Congress to reconfigure the payment incentive structure. We discuss incentives in #4 as well.

Additionally, the price transparency model helps patients understand the total cost of care when the attributes are episode-based. The episode-based price should ideally come from a national standard. Patients cannot price shop if every payer or hospital defines episodes with differing inclusions and exclusions. Instead,

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<sup>15</sup> Donabedian, A. (1980). *Explorations in quality assessment and monitoring* (Vol 1), Health Administration Press.

patients should be provided with the “plausible list of services” included for a typical patient for the care team under consideration. The price dashboard should include the average price and risk-adjusted variable prices for high-risk, intermediate-risk, and low-risk patients since patients’ risk modifies the services needed to care for a patient appropriately.

The price for an episode should also inform patients about the breakdown of the number of providers, and the number and types of services (e.g., E/M, procedures, labs, imaging) included in an episode at a site of care. Price reports can appreciate the overlapping nature of multiple episodes and can report episode price by splitting the cost for related services among the overlapping episodes or all the costs may be assigned to each individual episode.

There are more attributes of price transparency to consider that are beyond the scope of this comment letter since this area is still evolving. Ideally, price transparency should define what is actionable and meaningful to the end users, beginning with the patient. Ultimately price transparency should complement the quality expression since these are the “two sides of the coin” for expressing value. These efforts serve to promote MIPS to MVP to value-based care by layering on price transparency alongside quality of care for an episode of care specific to the patient’s condition.

**4. *CMS and other payers must use the appropriate levers for payment incentives to achieve value-based care outlined in objectives 1-3.***

To date, there have been many hurdles to incentivize comprehensive quality programs that deliver on what matters to the patient and transparently informs the public on how to find care for their condition. The ACS has put forth efforts across CMS programs that aim to appreciate what is needed to transition toward patient-centered value-based care. However, these efforts have largely failed because of the lack of incentives for hospitals and clinicians to change the way they participate in programs. This, coupled with the unknown impact of these changes on their revenue is simply not worth the risk.

Change is hard. If a hospital-owned physician practice has employed its quality staff for CMS quality programs and built resources to aggregate the traditional measures for the surgical team, the primary care and medical specialists similarly have a cadre of staff combing through records to meet hospital or ambulatory surgical center (ASC) measures. These efforts meet a payment incentive objective. They are not likely to change to a more patient focused quality improvement (QI) program if payment is more easily secured in their current measurement workflows. Our experience informs us that without a health plan or CMS incentives, most prefer to remain in their current set of measures when

given a choice between continuing current measures or moving to an improved quality program. The return on investment by plans and federal efforts through quality programs must exceed the initial incentives in order to create the change movement needed for value-based care. Without implementing quality as a program, the cost to patients and the overall cost of care are negatively impacted.

**If CMS truly wants to transform healthcare, the incentives must make it worth the effort. From the ACS’ perspective, 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 quality framework used must appreciate that healthcare is complicated (measurable of team functionality relative to the science of medicine that comes from guidelines down to care plans) and complex (less easily measured and deals with the variation in care—when customizing care to the patient, their goals/expectations, the resources available, and so forth). This is an important distinction because it determines what and where you measure and how you drive improvement. In surgical care, simple ‘lumps and bumps’ are not overly complicated or complex. However, with multi-morbid patients, multiple organ injury in trauma, cancer or vascular reconstruction, and so on, care can get very complicated, and the patients are complex. Care plans with multiple inputs with joint or shared accountability can result in care coordination and better-informed patients, leading to optimal outcomes.

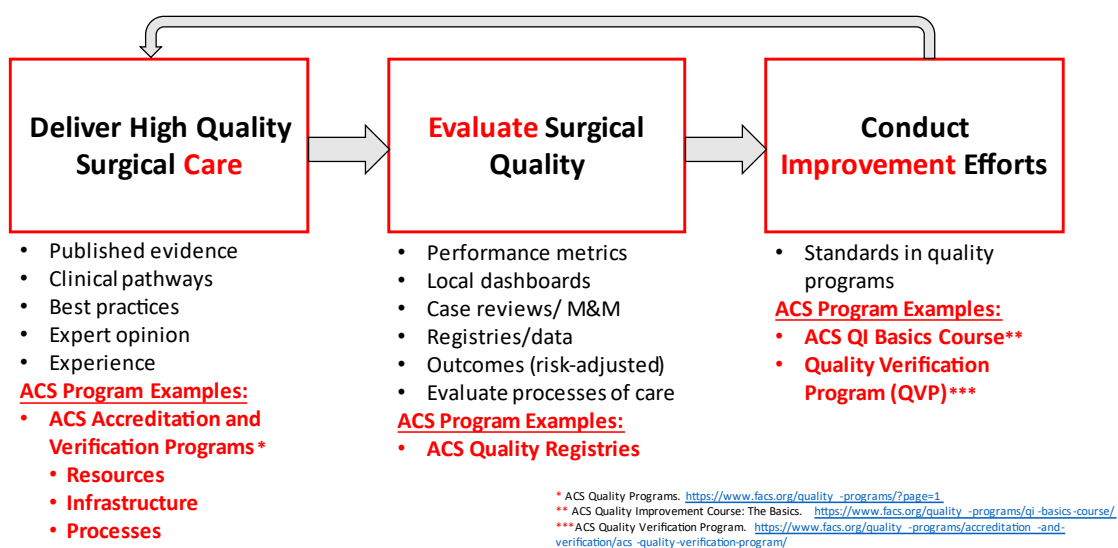
In order to operationalize a program that can meet these objectives, improving quality improvement, or “improving improvement” is central to the goal and part of all ACS verification and accreditation programs (Trauma Verification, Commission on Cancer, Children’s Surgery Verification, Geriatric Surgery Verification, National Accreditation Program for Breast Centers, and others). 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.<sup>16</sup> To drive improvement, we must first have a cultural commitment across the care team, as well as with leadership, to ensure the appropriate resources are made available and quality 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. Does the care team have the data to evaluate care and find problems with the

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<sup>16</sup> The American College of Surgeons. (n.d.). *The ACS quality improvement course: The basics*. <https://www.facs.org/quality-programs/qi-basics-course/>

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? And the cycle repeats. The figure below illustrates how the ACS implements “improving improvement” across the ACS 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 in Figure 1.

**Figure 1. Improving Quality Improvement**



Another example of a quality program with a similar framework is the Collaborative Quality Initiatives (CQIs) partnership with Blue Cross Blue Shield of Michigan (BCBSM), described in a recent publication by Howard et al.<sup>17</sup> There are currently 23 CQIs which are organized around a condition. The CQI framework is “data driven, clinician led, and collaborative.” CQIs also rely on a continuous QI framework that includes five key components: collection of clinical data, analysis of data, feedback on performance, development of QI initiatives, and implementation of QI initiatives; with a secondary component of the dissemination of knowledge with publications and national presentations. Centers have dedicated clinician leadership and directed their own QI initiatives similar to those across the ACS quality programs, such as PDSA. CQIs have regular collaborative-wide meetings to share knowledge. With clinical dashboards, the performance of individual hospitals is shared internally—results are not used or shared beyond QI efforts to enable a learning health system across participating hospitals where

<sup>17</sup> Howard, R., Grant, J., Leyden, T., & Englesbe, M. (2022). Improving the quality of health care through 25 years of statewide collaboration in Michigan. *NEJM Catalyst Innovations in Care Delivery*. 3(9), 1-29. <https://doi.org/10.1056/CAT.22.0153>

both high performing and low performing hospitals are engaged for shared learning.

Once we have applied quality frameworks, as described above, the focus can turn to measuring the complicated care and the complexity of a patient (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. Our experience with the ACS verification programs has informed our thinking. For the payer community to assume that care teams are already properly organized into continuous improvement in clinical operations is a bridge-too-far. **If we are to, someday, arrive at tracking patient reported outcomes (PROs) for specific conditions, we must first reconsider how to optimally frame a team in a patient-centered, condition-specific manner.** Rethinking how we get there means pulling back from the silos of measures in the NQF-style and think about what a measure framework looks like. A way to validate this framework that might serve as a bridge from how NQF reviews measures, is considering whether a set of measures can come together to inform a broader construct, such as the “quality of community-based maternity care,” described as **content validity** by Schang et al. (2021). Content validity looks at the “valid set” of indicators instead of “valid indicators” in a silo.<sup>18</sup> Schang et al. (2021) explains that because of the multidimensional nature of care, conclusions about measure constructs depend on the indicator set as a whole, and not just single indicators. For example, patients might be interested in the construct of “quality of community-based maternity care” instead of simply focusing on timely support during labor.<sup>18</sup>

## MEDICARE SHARED SAVINGS PROGRAM

The Medicare Shared Savings Program (MSSP), also known as the Shared Savings Program, is a voluntary CMS program that encourages groups of doctors, hospitals, and other health care providers to come together as an Accountable Care Organization (ACO) to give coordinated, high-quality care to Medicare beneficiaries. The Shared Savings Program plays a large role in the transition toward value-based care. According to a recent MedPAC report, the MSSP accounts for most of the beneficiaries assigned to ACO or ACO-like payment models, and 19 percent of Medicare beneficiaries are in the MSSP.<sup>19</sup>

To support the MSSP and other alternative payment model (APM)-type models in the transition toward value-based care, the Center for Medicare and Medicaid Innovation (CMMI) launched a strategic refresh in 2021 with a focus on expanded coverage, advancing health equity, and improving outcomes. As part of the refresh, CMMI set the goal to move 100 percent of beneficiaries in Traditional Medicare and the majority of

<sup>18</sup> Schang, L., Blotenberg, I., & Boywitt, D. (2021). What makes a good quality indicator set? A systematic review of criteria. *International Journal for Quality in Health Care*, 33(3), 1-10. <https://doi.org/10.1093/intqhc/mzab107>

<sup>19</sup> Medicare Payment Advisory Commission. (2022). *July 2022 data book: Health care spending and the Medicare Program*. MedPAC.

Medicaid beneficiaries into accountable care relationships by 2030. To do this, CMMI notes the need for the integration of specialists into ACOs, along with effective collaboration with primary and specialty care.<sup>20</sup> There has been a steep incline in the volume of specialty care visits among Medicare beneficiaries with an 83 percent increase in the number of physicians that the primary care physician (PCP) needs to coordinate with (from an average of 52 in 2000 to 59 in 2019).<sup>21</sup> However, to date, the Shared Savings Program has had little engagement of specialty medicine and has been largely focused on primary care.

The ACS strongly supports CMS' interest in refining the MSSP, along with the focus on improving health equity. We fully support the concept of “whole person care” which will require the appreciation of the value of specialty care in the MSSP. In doing this, APMs must remove silos of care, reduce waste, and build teams that are focused on safe, affordable, good, and equitable care. The comprehensive quality framework outlined in the introduction is payer agnostic and we strongly encourage further exploration as to how it can best fit into the ACO model, as opposed to the current reliance on a one-size-fits-all, primary care-focused measure set. **The ACS is eager to work with ACOs to identify quality demonstration projects to define the numerator for specialty care in the value equation.**

In addition, the ACS supports CMS' efforts to strengthen financial incentives outlined in the MSSP proposals, including additional incentives for low revenue ACOs. **However, as part of these efforts, CMS must also consider incentives that will entice specialties to participate in new models—this includes financial incentives, but also more meaningful metrics that reflect specialty care and promote team-based co-management guided by the patient's needs and expectations.** In thinking through the incentives, the behavioral economics of risk-bearing must also realize the need for more upside than downside risk—this is supported by the universally recognized Kahneman principles espoused in his wisdom of how individuals react in the world of behavioral economics.<sup>22</sup> We can define the appropriate quality numerator for surgical care but without the appropriate incentives, we expect specialty medicine to continue in a siloed fee for service (FFS)-style business model. Again, the reason specialty medicine persists in FFS business models is an expression of the challenges in change management. 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

<sup>20</sup> Fogler, S., O'Connell, M., Quinton, J., Ritter, C., Waldersen, B., & Rawal, P. (2022, June 17) Pathways for specialty care coordination and integration in population-based models. *Centers for Medicare & Medicaid Services*. <https://www.cms.gov/blog/pathways-specialty-care-coordination-and-integration-population-based-models>

<sup>21</sup> Barnett, M. L., Bitton, A., Souza, J., & Landon, B. E. (2021). Trends in outpatient care for Medicare beneficiaries and implications for primary care, 2000 to 2019. *Annals of Internal Medicine*. 174(12), 1658-1665. <https://doi.org/10.7326/M21-1523>

<sup>22</sup> Kahneman, D., Sibony, O., & Sunstein, C. R. (2021). *Noise: a flaw in human judgment* (First edition). Little Brown Spark.



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.

## UPDATES TO THE QUALITY PAYMENT PROGRAM

### **Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs – Request for Information**

In the CY 2022 PFS final rule, CMS stated their aim to move fully to digital quality measurement in CMS quality programs and value-based purchasing programs. In this RFI, CMS continues to build on their goals and strategies to achieve the move toward digital quality measurement. They specifically focus on data standardization activities related to leveraging and advancing standards for digital data and approaches to transition to Fast Healthcare Interoperability Resources (FHIR) electronic clinical quality measure (eCQM) reporting in the future. In following sections of this RFI, CMS states that they envision quality measurement as only one use case for digital data in a learning health system where standardized digital data can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. The Agency also clarified that they plan to transition to digital quality measures (dQMs) incrementally, by beginning with the uptake of FHIR Application Programming Interface (API) technology and shifting to eCQM reporting using FHIR standards.

To reiterate our past comments in response to the RFI in the CY 2022 PFS proposed rule, the ACS is supportive of using digital tools to capture the full scope of patient data. Leveraging digital tools to support the generation and management of knowledge can inform patient care and quality improvement efforts. Over the past two years, as CMS has presented this and similar RFIs in various proposed rules, the ACS has been critical of the value of dQMs if they are only focused on automating and decreasing reporting burden for single, disaggregated metrics. Single metrics offer little value to patients when they are seeking high-quality care and little value to physicians for driving quality improvement cycles. Creating a digital framework to aggregate data for single metrics will make it easier and less burdensome to collect data, but if the measurements do not drive meaningful quality improvement cycles or appreciate the comprehensive patient journey and patient goals, we are left with the same disaggregated measure problem we have now and are trying to fix.

**From the ACS' perspective, the goals of this effort should be centered on reducing burden through the aggregation of data that helps the patient, care team (not just an individual clinician), and the payer community identify who can deliver safe,**

**affordable, good, and equitable care for any condition. The ACS suggests that CMS consider developing objectives and creating a digital strategy to achieve this objective.** If these objectives can be achieved, the ACS envisions benefits could be experienced by the entire healthcare system and could also provide efficiencies that would lead to overall cost savings.

It would be extremely beneficial to develop ways to digitally aggregate data for a care team working together to deliver care for a certain condition, such as total joint replacements, cardiac surgical care, cancer care, etc. Digitally aggregating data can validate that the care teams have necessary structural elements in place, that they are following evidence-based care processes, are participating in ongoing quality improvement efforts, and are incorporating PRO and patient experience measures. Using aggregated digital data to validate these elements of a quality improvement program will reflect how the care team is meeting patient goals for care that better aligns with the modern care model. From the ACS' perspective, we cannot assume that the critical structural and process elements of care delivery are happening on their own, therefore we believe that these elements of quality measurement are just as important to track as outcomes.

Consider a complicated, multi-morbid geriatric patient in the Medicare program about to undergo a significant surgical procedure. The care team involves pre-facility care, in-facility expertise, a surgical team, and a post-discharge rehabilitation team. Should each team member track a series of unrelated digitally acquired measures that have little to do with optimizing this patient's care, or should the care team outline the integrated care services to maximize success and minimize the impact of the co-morbidities? While it is possible to implement the enhanced recovery after surgery (ERAS) protocols for optimal cardiac, renal, pulmonary care, etc., and perioperatively focus on opioid avoidance and healthy brain function, taking a patient centric approach to digital knowledge sharing is very different from digital measures for each physician.

In addition, digital services should be leveraged by building knowledge around a patient's care pathway through aggregation of clinically relevant data on open standards-based platforms that can ingest data from numerous sources. These digital services, such as Clinical Decision Support (CDS)—tools that can track conditional or procedural cohort data to assess a team's conformance with the care plan, real-time data aggregation, and analytics for improvement events and research, patient-centered quality metrics, etc.—are nascent and hold great promise to enhance knowledge sharing around care.

As we have stated in the past, open architecture platforms are essential to expand medical knowledge management and optimize care. By using open standards-based platforms, data can be leveraged from a variety of data sources, such as health information exchanges (HIEs), clinical data, public health registries, EHRs, personal devices,

commercial payer databases, and other sources to allow for a more complete picture of the patient and their healthcare needs. Having access to the full scope of patient information opens the door for shared and co-managed care across providers and facilities, along with increased ability to track patients' outcomes and recovery long term. This architecture can meet and exceed payor needs for quality metrics, as well as enrich clinical knowledge. However, retooling the healthcare industry for digitally supported knowledge enhancements takes considerable capital investment. If Medicare continues to distract the health informatics development and operations (DevOps) by focusing merely on metrics tied to payment activities, these capital needs to support better outcomes will be delayed. **We continue to encourage CMS to think more broadly about the underpinnings of digital healthcare so that the four aspects of care outlined above—CDS, cohort analytics, clinical research, and payor quality metrics—are similarly recognized when making capital investments in quality of care.**

### *Potential Future Definition of Digital Quality Measures (dQMs)*

CMS clarifies that dQMs are quality measures organized as self-contained measure specifications and code packages that use one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (e.g., medical devices and wearable devices), patient portals or applications (e.g., for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), HIEs, registries, and other sources. CMS seeks comment on the refined dQM definition and on potential considerations or challenges related to non-EHR data sources. **The ACS thanks CMS for acknowledging that dQMs should be designed to incorporate multiple sources of patients' health information.** Important patient data that can support clinical decision making and quality improvement efforts can be found in various sources beyond a local EHR instance, and the ability to aggregate data from all sources of patient data allows for more accurate and detailed tracking to inform patient interventions and improve outcomes. **However, we suggest that CMS change its emphasis from aggregating data with dQMs that focus on single metrics to developing a definition for digital services that can be applied to support a "quality program" framework. For a description of the "quality program" framework refer to page 57.**

### *Data Standardization Activities to Leverage and Advance Standards to Digital Data*

In the Fiscal Year (FY) 2022 PFS final rule, CMS stated that they are considering implementing eCQM quality reporting via FHIR-based APIs using standardized interoperable data. As mentioned above, CMS states that they envision quality measurement as only one use case for digital data in a learning health system. On the

other hand, standardized digital data can support multiple use cases, including quality measurement, quality improvement efforts, CDS, research, and supporting larger public health efforts. **The ACS agrees that standardization will be crucial to the success of the transition to digital quality measurement, and we thank CMS for acknowledging that digital services and standardized data have use cases across many aspects of healthcare delivery.** As CMS develops their strategy for leveraging standardized data in the transition to dQMs, it is important that CMS considers how they will take available standards and align them around a patient's condition to reach the goal of bringing a team together to deliver better care.

CMS also discusses the need for standardization across implementation guides (IGs)—value sets that organize the specific terminologies—and codes that define clinical concepts. Based on previous feedback, CMS states that they will continue to focus on leveraging the interoperability requirements for standardized APIs in certified health IT, set by the Office of the National Coordinator for Health Information Technology (ONC) 21st Century Cures Act final rule, including data elements for quality measurement that are consistent with the United States Core Data for Interoperability (USCDI) standard. The Agency seeks comment on the following IGs, additional IGs they should consider, and other data and reporting components where standardization should be considered to advance the learning health system:

- U.S. Core Implementation Guide
- Quality Improvement Core (QI) Implementation Guide
- Data Exchange for Quality Measures (DEQM) Implementation Guide
- Quality Measure (QM) Implementation Guide
- Clinical Guidelines (CPG) Implementation Guide

As we stated in our comments to the FY 2023 Inpatient Prospective Payment Systems (IPPS)/Long Term Care Hospital (LTCH) proposed rule, standardizing IGs will be important in the transition to dQMs, but the IG will only be effective if the measure or guideline it is implementing is effective. The IG provides standards for the measure structure, metadata, logic, and other clarifying definitions and details necessary for implementation. In other words, **the standards, structures, logic, etc. within the IG that supports the measure may be right for the measure, but if the measure itself does not inform patients and the clinical team, the overall goal of better quality and value of care will not be achieved.** When we engage technical experts who are responsible for writing implementation guides and eQMs, they are tied to the current state of measurement. **It is important that developing dQMs and implementing IGs for digital measures is a collaborative effort between the technical experts, clinical experts, and QI experts.** As we have stated, we see multiple shortfalls in our current quality measurement systems and without input from clinical and QI experts, those tasked with designing the technical elements of the measures will not be appreciative of

these shortfalls. A collaborative effort is necessary to continue to learn from the shortfalls of our current system and develop measures that not only reduce burden through automated data collection and aggregation, but also provide information to patients about where to seek the best care and support clinicians' efforts to deliver high value care.

In addition, it is critical that CMS evaluate the overall impact of the quality measure inventory before fully transitioning to dQMs. Digital quality measures should be designed to aggregate data across multiple digital sources to enhance accountability across the entire clinical team and drive improvements in care, not to merely meet the objectives of a payment incentive program. As we have stated in the past, there are other sources of patient data in standardized formats aside from FHIR that will also be useful to quality measurement, such as operative and pathology reports using structured data capture (SDC) and enhanced recovery protocols. CMS should consider ways to incorporate these data in digital quality measurement in the future.

### ***Approach to Achieve FHIR eCQM Reporting***

CMS considers the transition to FHIR-based eCQM reporting as the first step to dQM reporting and outlines the activities that they believe will be necessary to achieve this. The Agency asks for feedback on near term and future plans needed to report FHIR-based eCQMs and future dQMs. From the ACS' perspective, a phased-in approach is necessary to make this transition, thus we urge CMS to take the necessary time to ensure that the transition to dQMs is done in a way that is safe and effective. They must allow opportunities to test the efficacy and impact of the measures, gather stakeholder feedback, and implement processes to iterate the measures until they achieve the desired goal of informing improved patient care. There should be a formal evaluation process to determine whether there is evidence that measures improved patient care.

We also agree that CMS must eventually acknowledge dQMs that expand beyond the current inventory and structure of traditional CMS eCQMs. Currently, most eCQMs focus on using claims and payer data to evaluate singular processes and outcomes. As we have discussed throughout our comments, measures that only evaluate isolated or rare event rates and disconnected processes will not push our system towards higher quality care and improved value in the modern healthcare delivery system. Singular measures will not incentivize a team to organize care around a patient for the patient's condition. While we acknowledge that digitizing measures could lead to reduced burden, that should not be the goal in itself; thus making it easier to report an ineffective measure offers little value for stakeholders and detracts from patient care.

If CMS only focuses on eCQMs in their first phase of dQM implementation, CMS will be limited and will not realize the many opportunities that other dQMs offer. First, CMS

should evaluate the eCQMs to determine their impact and effectiveness to determine the value of the measures prior to taking steps to digitize them.

In addition, eCQMs should only be one piece of a larger digital strategy. The ACS recommends CMS pursue the eCQM transition while simultaneously beginning to accumulate the functionalities and processes for gathering the data needed to support quality programs. We should explore how eCQMs can be supplemental to other types of digital quality measurements that will offer more meaningful information for care teams, patients, payers, etc.

### **Advancing the Trusted Exchange Framework and Common Agreement (TEFCA) – Request for Information**

Section 4003(b) of the 21st Century Cures Act, enacted in 2016, required HHS to take steps to advance interoperability for the purposes of ensuring full network-to-network exchange of patient health information. Specifically, Congress directed the ONC to “develop or support a trusted exchange framework, including a common agreement among health information networks nationally.” Since then, HHS has pursued development of the Trusted Exchange Framework and Common Agreement (TEFCA) with goals of: establishing a universal policy and technical floor for nationwide interoperability; simplifying connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value; and enabling individuals to gather their health care information.

In 2022, ONC released the Trusted Exchange Framework—a set of non-binding principles for health information exchange—and Common Agreement Version 1—a contract that advances those principles. CMS states that they are considering other ways to advance information exchange under TEFCA. They are interested in opportunities to encourage exchange under TEFCA through CMS regulations for certain health care payers, including Medicare Advantage, Medicaid Managed Care, and Children’s Health Insurance Program (CHIP) issuers. CMS is also considering future opportunities to encourage information exchange under TEFCA for payment and operations activities, such as submission of clinical documentation to support claims adjudication and prior authorization processes.

**The ACS strongly supports the importance of TEFCA and the implementation and widespread adoption of these exchange networks because they present countless opportunities for clinicians and other stakeholders to enhance patient care and augment healthcare knowledge.** The ACS has emphasized the need for a shift from storing data in standalone EHRs to shared knowledge assembled in platforms that feed to data lakes and leverage the available web services through channels enhanced by TEFCA. This is the future of healthcare delivery.

By implementing data lakes to store the full depth of clinical knowledge, and through opportunities to develop logic to better organize and present those data to physicians (instead of only utilizing the information held by a single EHR), quality of care and access to high-quality care will be improved for patients. The ability to reach across care teams and coordinate care, inform and engage patients, track social determinants, etc. are all enhanced by fully realizing the functionalities that can be built at the HIE and TEFCA level. For example, data lakes can hold hubs of information about individual patients, conditions, and about individual clinicians that treat patients with specific conditions. Additionally, by incorporating certain capabilities and logic within the data lake, physicians can have real-time access to data that can give them better insight into their success rates for surgical treatments on their patients with chronic conditions or dual-eligible patients. They might also be able to pull down data that helps them understand their practice profiles for pain management in geriatric surgical patients and any associations to postoperative delirium, confusion, or falls, for example. These, and many more aspects of care, cannot be tracked in a single EHR system and require the ability to aggregate and utilize data on a larger scale.

This presents many opportunities for the engagement of specialty societies and other stakeholders. Organizations with clinical expertise can enhance the applied sciences because more content and context will be available when long-term knowledge is broadly available and exchanged. This can better support the development of many services, such as standards for care, care pathways, and guidelines supported by widespread data about real-time patient care. This also can create opportunities for research and development in many important clinical areas. By leveraging HIEs, widespread exchange under TEFCA, and integrating connection with data lakes hosted by specialty societies, these activities can take place closer to real time while being supported with expansive knowledge, as compared to current practices that access data in single EHRs or registries. **Given the many use cases, we urge CMS to explore opportunities to offer federal support for HIEs that leverage data lakes to fully recognize their potential.**

At this time, most digital healthcare has been focused on EHRs, interoperability exchanges, and performance measurement. These are foundational elements that have allowed us to realize greater potential for what can be possible for medical knowledge, machine learning, and other elements of artificial intelligence in health care. CMS might wish to consider exploring knowledge management beyond the limits of mere data exchange by sponsoring symposia focused on shared knowledge in a learning health system. This would help inform where there are opportunities in CDS, informing patients, research, improvement, and education. The complicated nature of care and complexities of individual patients call for highly customized care beyond the limits of a single clinician. Building the knowledge assets required to extend a learning health system will take time and investments from government agencies.

In addition, we ask CMS to explore the concept that other non-clinical documents can be exchanged between Qualified Health Information Networks (QHINs) and their participants. We envision that QHINs could create a library of documents that would fulfill specific request types. Currently, exchanges do not take a query, construct data elements into a document, and make these documents available to exchange participants. The ability to organize and share information about non-clinical variables, such as the inventory of medical supplies, medications, etc. could be helpful for resource planning, understanding capacity, and population health at the local level.

CMS asks specific questions about ways that they can help to advance the goals of TEFCA through policy, measurement, or other mechanisms in their programs. **While the ACS strongly supports a framework, such as TEFCA, that encourages more data sharing and interoperability across the healthcare system, TEFCA is not mature enough to measure at this time.** For example, currently the regional coordinating entity (RCE) has not released any standard operating procedures (SOPs), which provide the operational “nuts and bolts” of TEFCA; thus, it is difficult for entities to fully assess whether they should participate. Stakeholders have also stated that many potential health information networks (HINs) that may wish to become QHINs to support TEFCA are only structured to allow Health Insurance Portability and Accountability Act (HIPAA)-permitted treatment, payment, and limited health care operations, as well as some limited public health use cases. However, TEFCA envisions supporting HIPAA-authorization based use cases (such as Benefits Determinations) and Individual Access Services (IAS), which are not yet as tested in this space. **As we have stated, as TEFCA matures, it will provide an environment for optimal exchange. When this is achieved, CMS should consider a measure that will also lead to incentives for participation in exchange networks.**

Finally, CMS also asks stakeholders to share their concerns about enabling exchange under TEFCA. They ask about potential increases in burden, or other financial or technical barriers, and ways CMS can reduce these barriers. As the availability of clinical data and knowledge increases, the depth of information about individual patients will exceed individual human capacity and can overwhelm the clinical team. Managing this much information—true big data—requires teams with highly specified roles, oversight, shared accountability, and a redesign of the practice of medicine. When care is limited, simple, and only requires a few visits, these data are not as critical, and care can be easily managed. However, when a multi-morbid patient with a complex illness, such as a malignancy, enters the picture, the shared co-management environment will outperform the traditional transactional, one-stop-at-a-time medicine. It is the coordinated efforts of each role player doing their part and supporting each other that leads to optimal care. Leveraging data across time and settings will allow for care team redesign and business models that have more alignment with the modern care model.



## **Transforming MIPS: MVP Strategy**

### ***MVPs and APM Participant Reporting Request for Information***

CMS acknowledges the challenges regarding meaningful specialty clinician participation within the MVP framework and APMs. CMS also cites stakeholder feedback to previous RFIs that have requested closer alignment between MVPs and APMs. As CMS moves forward with MVP implementation, it seeks feedback on ways to better align clinician experience between MVPs and APMs to ensure that MVP reporting serves as a bridge to APM participation. CMS is also looking for feedback on the benefits and disadvantages of various approaches that might achieve this alignment, while keeping in mind its goals of enhancing specialty-specific performance measurement, information available for patients, and reducing complexity where possible.

The ACS appreciates that CMS is exploring ways to align the clinician experience in MVPs to better align with APMs. When thinking about how to transition clinicians into APMs, it is important that these frameworks first define quality of care for a condition to incentivize clinical teams to focus care around the needs of the patient. If the quality of care for a condition is defined first, the model will be more patient-centric and payment (program) agnostic, then could be used in any quality incentive program (e.g., MIPS, APMs, ACOs, FFS).

Aligning these frameworks should be a progression that continually is working to better identify the current care pathway and patient goals. Most patient conditions, whether acute or chronic, require some level of co-management. For example, modern care is complicated, patients are complex, and they are typically managed by a team of clinicians that co-manage the patient's multiple conditions. In the team-based model, it is important that we consider the role of each clinician and how they work with the other members of the team to deliver comprehensive care, as opposed to thinking about each clinician and separating their work out into silos.

This begs the question: how do you define the chronic care set and acknowledge co-management of the chronic conditions between PCPs and specialties? Most physician services can be accounted for in APMs. Chronic disease management might be better suited to the per member per month model (PMPM), while acute and surgical care could be placed into episodes of care. However, both chronic care and acute care services will likely be managed in part by both the PCP and the surgeon. There also could be a small number of services and procedures that would remain most efficient in the FFS business model. Services such as caring for a sore throat, or cataracts procedures encompass a small number of fees and there would be little value in bundling these services.

In conclusion, **the ACS suggests CMS conduct an assessment that reviews all elements of the modern care model, the roles of each clinician, and who leads the management of chronic versus acute care so that healthcare business models seamlessly align to the care model.** Care models are customized to individual patients in a care plan and implemented by role players in their suite of overlapping workflows. These are workflows that can be digitally mapped using case management or business process mapping tools. These tools are clinically-readable as well as machine-readable. In the current state, the business model and care model are not integrated, which has resulted in an exceedingly complicated and disaggregated system.

### ***MVP Development and Reporting Requirements***

#### Development of New MVPs

CMS proposes to modify the MVP development process such that when the Agency receives a new candidate MVP, evaluates it through the MVP development process, and determines it “ready” for feedback, CMS would post a draft version of the MVP on the QPP website and solicit feedback from interested parties, as well as the general public, for a 30-day period. CMS states that they would review the feedback and determine if any changes should be made to the candidate MVP prior to potential inclusion of the MVP in a notice of proposed rulemaking. CMS also clarifies that if it determines changes should be made, it will not notify the interested parties who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process.

**The ACS appreciates CMS efforts to improve transparency in the development of MVPs by encouraging stakeholders to review and provide feedback on MVPs. However, we are concerned CMS is not planning to notify the submitters of the candidate MVP following the receipt of the stakeholder feedback prior to including the MVP in the rulemaking process.** The ACS is concerned because MVP developers are likely the leading experts in the MVP topic or condition. When developing an MVP, specialty societies will likely convene groups of experts to engage in MVP development and these experts should be given an opportunity to review and understand the public feedback. The public feedback could bring up issues that the expert groups have already considered and chosen not to include for certain reasons that only those with extensive experience may realize. In a different scenario, where the public feedback raises an issue or question that the expert group had not considered, it is important for them to also review this and determine the best way to integrate in the current MVP design.

For example, the Geriatric Surgery MVP, which the ACS is currently developing in collaboration with CMS, is based on the ACS Geriatric Surgery Verification (GSV) program. The GSV program standards were developed using the Modified Delphi method, receiving input from more than 50 multistakeholder organizations. The

multistakeholder group identified clinical frameworks based on evidence and best practices that provide goal-centered, clinically effective care for older patients. Based on the methodology used to develop the standards used in the MVP for Geriatric Surgical Care, we would expect that any updates to the measure as a result of public comment should also be reviewed with the same level of rigor to ensure that the intent of the measure or MVP is not altered. These standards were also recently adapted and submitted as a new measure for the Inpatient Quality Reporting (IQR) program, which is intended to align facilities with the MVP.

**The ACS also asks CMS to clarify the MVP submitter’s role. Is it similar to a measure steward relationship where there is ownership of the MVP with responsibilities for updating and maintaining the MVP?**

**Finally, MVPs should be evaluated for their ability to inform care and help patients identify where they will receive the best care for their condition.** When MVPs are submitted, it is important that CMS and all stakeholders understand the goals, and how the MVP will be evaluated to determine if goals were met. They should also be evaluated from the perspective of each stakeholder who will be using the MVP data. For example, a survey or similar assessment instrument could be administered to patients, payers, and providers. The survey instrument for patients could provide feedback on the usefulness of the information that was publicly reported. Payers could offer information regarding MVP participation and associated decreases in complications, improved safety, and/or improvements in the overall cost of care. Finally, providers could share feedback on whether they were able to apply the MVP information in a meaningful way for improvement exercises. CMS could consider an example from the Michigan CQIs in partnership with BCBSM, who are creating a process of improving improvement where a group of peers review improvement activities for their merits and utility for actual improvement.<sup>23</sup> **Engaging users to gain real-world demonstrations of how they used the MVP data, what they gained from it, and if they were able to set targets for improvement would be helpful in evaluating the value of the MVP.**

#### Proposed New MVPs

CMS proposes five additional MVPs that would be available for reporting starting with the CY 2023 performance period: Advancing Cancer Care; Optimal Care for Kidney Health; Optimal Care for Neurological Conditions; Supportive Care for Cognitive-Based Neurological Conditions; and Promoting Wellness. Our comments pertain to the Advancing Cancer Care MVP. For CY 2023, CMS proposes the Advancing Cancer Care MVP support of the Administration’s Cancer Moonshot Mission, and the importance of

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<sup>23</sup> Howard, R., Grant, J., Leyden, T., & Englesbe, M. (2022). Improving the quality of health care through 25 years of statewide collaboration in Michigan. *NEJM Catalyst Innovations in Care Delivery*. 3(9), 1-29. <https://doi.org/10.1056/CAT.22.0153>

cancer care more generally. The MVP is most relevant to oncologists and hematologists who provide fundamental treatment and management of cancer care.

**The ACS supports the Administration’s prioritization of cancer care and believes the Advancing Cancer Care MVP is a good first step in looking across the condition of cancer and beginning to align the various multidisciplinary clinical pathways. However, to take this a step further with the goal of value-based care, we strongly encourage CMS and other stakeholders to move beyond “MIPS-think” which is when CMS considers a condition then populates the condition-specific MVP or measure set with singular MIPS measures that are often attributed to individual providers.**

The ACS has extensive experience running cancer care quality programs. The Commission on Cancer (CoC), which is led by the ACS, was established in 1922 and is a multistakeholder effort that establishes standards to ensure quality, multidisciplinary, and comprehensive cancer care delivery in health care settings; conducts surveys in health care settings to assess compliance with those standards; collects standardized data from CoC-accredited health care settings to measure cancer care quality; uses data to monitor treatment patterns and outcomes, and enhance cancer control and clinical surveillance activities; and develops effective educational interventions to improve cancer prevention, early detection, cancer care delivery, and outcomes in health care settings.

Based on our experience, we support MVP development where CMS, in collaboration with stakeholders who contribute to the patient’s cancer care, lay out the structure, process, and outcome for the clinical pathway. It is important to define the care pathways, clinical roles, and expectations for all team members’ contribution to care—instead of plugging in specialty measures separately. One misconception that has resulted in the failure of the current measurement system is that the measure enterprise has separated structure/process/outcome measures from each other. This separation of measures is not what was envisioned by Donabedian’s framework; the various measures must be interrelated. The importance of alignment cannot be overstated—if there is something wrong with the structure or the process, you will see it in the outcome; it is in the structure and process where you find the problems, and they should be thought of as interconnected. As a result of this misconception, the enterprise is working backward to "align." We emphasize this based on observations that decades of specialization have parsed care and resulted in care pathways that are not always woven together in a manner that optimizes care. This becomes more apparent with conflicting business practices and misalignment of quality improvement efforts. We believe Donabedian had it right when he envisioned a framework that pulls the care team together. To overcome the impact of this misalignment, we created the many ACS verification programs and have observed meaningful improvement in care outcomes and experience.

By applying this to cancer, to truly drive improvements, as part of MVPs, CMS should also incentivize the adoption of a cancer accreditation or verification program such as the CoC or participation in the Oncology Medical Home which aligns with the facility. The CoC and other ACS quality programs have demonstrated that by using standards, facility and providers are aligned for continuous, reliable, and standardized care. To this point, there must be collaboration in thinking through the elements of a cancer clinical pathway. Without limiting an MVP to what is in MIPS or a registry, what elements of safety should be tracked, and what are the key structures and resources needed? How will value that matters to cancer patients be tracked, evaluated, and improved upon? Tools to initially consider that are used for measuring patient outcomes are Shared Decision Making (SDM) 9, European Organization for the Research and Treatment of Cancer (EORTC) Quality of Life Questionnaires, or BREAST-Q, to name a few.<sup>24</sup> Patient reported outcomes (PROs) that address health equity in cancer care, such as measures of inclusion, are also an area of much needed further development. Because racial disparities in access to cancer care in the U.S. are well established, there should be an effort to assess access to cancer care on a local level across racial disparities as part of the MPV.<sup>25, 26</sup>

Also critical for determining value to the patient are cost measures that are transparent about the price, and help patients understand the total cost of care when the attributes are episode-based. Cost measures should be based on a national standard for consistent comparisons. The CMS Total Per Capita Cost (TPCC) measure does not inform patients or clinical teams—it just lumps all costs together based on Tax Identification Numbers (TINs)—but how does total cost across a TIN help to inform clinicians or patients about the specific cost of cancer? Instead, patients should be provided with the “plausible list of services” included for a typical patient with their condition or procedure for the care team they expect to provide their care. This episode of care represents the sum of all services related to their care. In contrast, individual prices for individual services leave a patient with no real way of understanding the anticipated list of services they will need and the price it will cost.

The price for an episode should inform patients about the breakdown of the number of providers, and the number and types of services (e.g., E/M, procedures, labs, imaging) included in an episode at a site-of-care. It is important for price transparency to recognize that patients may have overlapping conditions. For example, a patient with chronic or

<sup>24</sup> Cohen, W. A., Mundy, L. R., Ballard, T. N., Klassen, A., Cano, S. J., Browne, J., Pusic, A. L. (2015). The BREAST-Q in surgical research: A review of the literature 2009-2015. *Journal of Plastic, Reconstructive, & Aesthetic Surgery*. 69(2), 149-62. <https://doi.org/10.1016/j.bjps.2015.11.013>

<sup>25</sup> Reeder-Hayes, K. E., Mayer, S. E., Olshan, A. F., Wheeler, S. B., Carey, L. A., Tse, C. K., Bell, M. E., Troester, M. A. (2019). Race and delays in breast cancer treatment across the care continuum in the Carolina Breast Cancer Study. *Cancer*, 125(22), 3985-3992. <https://doi.org/10.1002/encr.32378>

<sup>26</sup> Jatoi, I., Sung, H., Jemal, A. (2022). The emergence of the racial disparity in U.S. breast-cancer mortality. *New England Journal of Medicine*, 386(25), 2349-2352. <https://doi.org/10.1056/NEJMp2200244>

concurrent acute conditions (diabetes, or pneumonia) may undergo care for an unrelated medical condition or a surgical procedure. Episode business logic allows for ways to define and attribute multiple concurrent services so that patients understand the total cost of care and understand the costs attributed to different conditions or procedures. It is also important to highlight the need for a standardized price report. If one commercial insurer defines the services included in a price differently from another insurer or Medicare, a single delivery system may have five to ten different prices due to variances in the list of services included or excluded by the non-standardized price reports. This is illustrated in Figure 2 and Figure 3 below. We strongly encourage CMS to explore beyond the current MIPS cost measure methodology to better align with price transparency efforts.

**Figure 2: Example of Non-standardized Episode Definitions for Price Transparency**  
**Episode Definitions and Price**

Hospital	Inpatient		Hypothetical - Non-standardized Episode Definitions for Price Transparency	
Procedure	Colectomy for Cancer or AAA repair			
Episodes		Episode Price	Episode Definition inclusions	Episode exclusions (separately billed)
	United Health	\$15,000	Surgeon + Anesthesia + Facility for 30 days	Pathology, Imaging, outpatient labs, Hospitalists, SNF, Rehab, ED, readmissions
	BCBS	\$45,000	Surgeon + Anesthesia + Facility + Preop + Post discharge + Labs + Imaging + Hospitalists + Med Consultants	Only exclude other conditions but assign all labs and imaging to the surgical bundle
	Cigna	\$32,000	Surgeon + Anesthesia + Facility + Labs + Imaging	Post discharge rehab, SNF, Hospitalists and Med Consultants
	Aetna	\$12,000	Surgeon + Anesthesia + Facility	Pathology, outpatient labs, Hospitalists, SNF, Rehab, ED, readmissions
	CMS	\$15,000	Surgeon + Anesthesia+ Facility + Labs + Imaging + Readmissions	Pathology, Hospitalists, SNF, Rehab, ED, readmissions

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**Figure 3: Example of Standardized Episode Definitions for Price Transparency**  
**Episode Definitions and Price**

Hospital	Inpatient		Hypothetical - Standardized Episode Definitions for Price Transparency	
Procedure	Colectomy for Cancer or AAA repair			
Episodes		Episode Price	Episode Definition inclusions	Episode exclusions (separately billed)
	United Health	\$42,000	Surgeon + Anesthesia + Facility + Preop + Post discharge + Labs + Imaging + Hospitalists + Med Consultants	Only exclude other conditions but assign all labs and imaging to the surgical bundle
	BCBS	\$45,000	" "	" "
	Cigna	\$38,000	" "	" "
	Aetna	\$47,000	" "	" "
	CMS	\$25,000	" "	" "

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And, finally, to reiterate our introductory comments starting on page 57, we encourage CMS to overarchingly evaluate the success of the MVP program based on the following objectives:

1. *Programs should inform patients about where to get care for their condition.*
2. *Quality programs should incentivize shared accountability with co-managed elements of care across the team and the facility.*
3. *Programs should include price transparency for an episode of care*
4. *CMS and other payers must use the appropriate levers for payment incentives to achieve value-based care outlined in objectives 1-3.*

### ***Subgroup Reporting***

#### Reporting MVPs and Team-Based Care

In the CY 2022 PFS final rule, CMS discussed that MVPs may be constructed to reflect the team-based health care model. It also finalized that beginning with the CY 2026 performance period, multispecialty groups will be required to form subgroups to report MVPs. In this proposed rule, CMS encourages multispecialty groups to choose an MVP that includes measures that are attributable to all clinician types that participate in the group. The ACS continues to advocate for the acknowledgement of the team-based care model in CMS programs and appreciates that CMS is encouraging this through subgroup reporting with multispecialty groups. From the ACS' perspective, the path to team-based integrated care is organized around the patient (not the services in a payment system) by determining what matters to the patient alongside what the clinical team must track to deliver on patient goals and ensure patient safety. To achieve patient-centric value, individual clinicians participate in the care for a patient in the context of an episode. For example, a surgical patient may receive care from a PCP, surgeon, anesthesiologist, medical specialist, radiologist, and a pathologist. These clinicians have their distinct roles in the context of team-based care, and together share accountability for the cost and quality of that episode for that patient. To this end, we support the development of subgroups within clinical domains, such as joint replacement, spine teams, cancer, trauma, etc. Organizing subgroups around clinical domains would acknowledge all clinicians who regularly participate together in episodes of a given type, medical or surgical, and thus form the normative standards of care for those episodes. **To this point, we urge CMS not to limit participation in subgroups (i.e., only allowing one subgroup to be reported for each TIN-NPI [National Provider Identifier] combination), particularly at the outset of the MVP track.** This is contrary to the intent of MVPs—which should provide physicians from a group practice the flexibility to partner with a variety of colleagues depending on the episode and needs of the patient—and will disincentivize participation in MVPs.

**The ACS also opposes both making MVP reporting mandatory as well as mandatory subgroup reporting. Physicians need as much time as possible to re-engineer how they report quality, determine the necessary structures and processes, incorporate safety and outcome measures, and make the business case for participating in MVPs, and how to participate as a subgroup.** This is a major shift from current practice, and groups will need additional time to overcome the challenges and costs that come with these changes. Instead of using a heavy-handed, punitive mandatory approach, CMS should consider how to tier the rewards and provide incentives that encourage change. CMS should try to use existing performance data to model the potential results of MVP reporting and subgroup reporting, which will better inform CMS on the limitations of the current approach/help to improve current flaws. It will also allow group practices to understand what information and scoring is produced by an MVP and enable them to identify how to best form subgroups to successfully engage in this process.

Finally, while we understand the limitations budget neutrality poses on real financial incentives in the current law (positive incentive payments have stayed too low for return on investment in MIPS), CMS could explore additional incentives that may include bonus points, being held harmless from a penalty, alignment of scoring for MVPs with APMs and across payment systems (similar to the facility-based scoring methodology, highlighting efforts publicly, and so on). CMS might also consider creating a pathway that makes it easier for physicians to form a MSSP ACO. This could be done by providing up-front investments to qualifying physicians who participate in MVPs and allowing for up to seven years of upside-only financial risk, which would serve as a starting place for using MVPs as a glide path to APMs. This would be a similar approach to what CMS is proposing in the MSSP.

#### Subgroup Scores for Administrative Claims Measures and Cost Measures

When subgroup reporting was established in the CY 2022 PFS Final Rule, CMS finalized that subgroups' performance would be assessed at the subgroup level across all the MIPS performance categories. Subgroups must also be scored on each selected population health measure that does not have a benchmark or meet the case minimum requirement based on their affiliated group score. Scores for cost measures, population health measures, and outcomes-based administrative claims measures are calculated by CMS using administrative claims. CMS states that because subgroups are formed for QPP participation, it is unable to identify subgroups using existing or future claims data. Because of this, CMS explains it may not be possible to test these measures for validity and reliability for subgroups using claims data. Because of these and other issues with calculating administrative claims-based measures at the subgroup level, CMS proposes to assess subgroups on measures in the cost performance category, population health



measures, and outcomes-based administrative claims measures in the quality performance category, based on their affiliated group. Therefore, it is our understanding that subgroups would only be scored as a subgroup on Promoting Interoperability (PI), Improvement Activities (IAs), and quality measures that are not claims-based measures.

There are multiple ways to calculate cost using claims. The current methodology uses relative cost and attributes various services within the claims to different individual clinicians, which results in overlap, or double counting services, across the care team. For example, if multiple physicians are working together to care for a patient who requires a CT scan to confirm a diagnosis, the CT would be attributed separately to multiple providers on the clinical team which results in overcounting the cost. A surgeon treating an oncology patient requires the CT for planning and staging the care. The oncologist uses the same CT to determine stage and develop a treatment plan. The PCP uses the same CT to consider how to advise their patient and co-manage their patient. Attributing the CT to each clinician creates double counting and confusion. It lends itself to splitting the team accountability rather than building a team optimization of care. It fits a payment accountability plan more so than a care accountability plan. Parsing shared services across physicians who are co-managing care is counterintuitive to building co-managed, shared accountability for quality and overall care expenditures. This approach serves payer perspectives in assigned price attribution with less regard for building on overall team efforts to influence the price of care. Does the current approach lead to the sort of waste reduction that focuses on team-based, efficient use of care with shared accountability? It still seems to distract from a patient-centric approach to understanding the total cost of care and where the opportunities are for improvement.

**A standardized approach that helps patients understand the affordability of their care could be applied at the subgroup level. Cost can also be calculated using total cost of care across the care team instead of at the individual clinician level—the cost of care for the team should be the guiding principle.** If each payer has their own way of expressing cost or price attribution, this creates noise that leads to a loss of focus on the true intent around price transparency and shoppable services. This would also align payer's interest in cost accountability with the patient's total cost of care and price transparency efforts. When measuring total cost of care at the subgroup level, all clinicians are accountable to the patient. From the ACS' perspective, the subgroup should be sharing accountability for the cost of care; this way they can demonstrate their efficiencies or areas for improvement as a group, with exception of those who do not work in acute episodes.

Defining the cost or price for an episode of care begins with a standard definition of an episode, including the inclusive and exclusive services, as defined by clinical subject matter experts. The episode center demonstrates the total cost of care for the sum of plausible services assigned to an episode from the patient's perspective. Business logic is

required to assign services and sort through the confounding issues when overlapping episodes of care are considered. For example, a cancer patient undergoes episodes of care from a surgeon, from a medical oncologist, and from a radiation therapist. Those three episodes of care use shared services, such as labs and imaging (i.e., a CT scan). These labs and imaging services can be assigned to each of the three episodes as a means of double and triple counting them, or they may be split and shared services with partial assignment to each. **As CMS explores how to calculate cost for subgroups, they should first conduct a study that compares their current methodology of scoring relative cost comparisons against total cost of care for the group. No matter what methodology is used, it is crucial that all three teams understand the attribution methods that were used so they may react and take meaningful action to reduce the waste in resources.**

Additionally, the price of care delivered varies appropriately by patient risk categories. The business logic applied must use recognized risk adjusters, so the high costs associated with high-risk patients do not create disincentives to care for these patients or lead to misdirecting clinical needs in order to avoid misinformation about price transparency. **Finally, the ACS urges CMS to adopt a scoring hierarchy that gives subgroups the higher of their subgroup or group score on administrative claims quality measures and cost measures. Physicians who participate in MVPs should be held harmless from any downside risk for at least the first two years of participation while they gain familiarity with it and while CMS collects and shares data about whether MVPs are meeting their goal to improve quality and reduce unnecessary costs for the Medicare program and beneficiaries**

To make strides in driving improvement, payers, clinicians, and other stakeholders could work toward the development of a library of QI initiatives across all major diseases. In the Michigan QI improvement referenced above, the authors noted that a peer review activity sorted through the improvement activities for their utility and anticipated effectiveness. For subgroups to make functional improvements, perhaps a library of QI initiatives would serve as the toolkit to help guide working groups toward meaningful improvements. Subgroups could be built based on common high-cost care pathways where QI initiatives are aligned with cost to drive improvements—we imagine there might be approximately 200 QI initiatives across diseases that populate the library. This would be a collaborative national effort with inputs from across specialty medicine and surgery. CMS would serve as the final approval for adoption of the improvement activities accepted in the library.

## **Quality Performance Category**

### ***Quality Data Submission Criteria***

#### **Submission Criteria for Quality Measures, Excluding the CAHPS for MIPS Survey Measure**

In the CY 2019 performance year, CMS defined high priority measures as an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. CMS proposes to amend the definition of “high priority” measure to include health equity measures, beginning with the CY 2023 performance period.

**The ACS supports the addition of health equity measures to the types of measures that fall under the high-priority definition.** It is well established that social determinants of health (SDOH) factors can impact the quality of care. Patients with certain social risk factors may experience lack of access to health care services, limits on resources, lack of preventative care, poor early detection, and limited chronic care maintenance, which can contribute to care inequities and ultimately result in worse overall outcomes in surgical care. Therefore, it is important to continue to prioritize measures that take steps to advancing health equity. **However, we seek clarity on which measures would fall under this definition. We anticipate that the Screening for Social Drivers of Health proposed measure would be included in this definition and encourage CMS to determine additional measures that can address and drive improvements in health equity.**

### ***Selection of MIPS Quality Measures***

#### **Screening for Social Drivers of Health Proposed Measure**

CMS proposes the adoption of an evidence-based drivers of health (DOH) measure that would support identification of specific DOH associated with inadequate healthcare access and adverse health outcomes among patients. The “Screening for Social Drivers of Health” measure assesses the percent of patients who are 18 years or older screened for food insecurity, housing instability, transportation problems, utility difficulties, and interpersonal safety.

**The ACS supports CMS’ efforts to increase screening for DOH, and agrees that screening and identifying social drivers is critical to understanding how to meet the unique needs of patients, including efforts to ensure a trusting relationship between the patient and care team. Once DOH can be identified, then processes and certain actions must be in place to support patients who screen positive. If no further action**

**is taken, then we see this as a missed opportunity.** While we believe CMS is headed in the direction toward a more robust set of equity measures, we want to emphasize that it is not enough to simply evaluate who conducts screenings but whether the clinician takes steps to address the risk factors identified in the screening practice, whether it be through a referral to community resources or other actions. When patients screen positive for one of the domains, processes should be in place to share that information with an interdisciplinary care team that organizes around the patient and coordinates to optimize care, communication, follow-up, and tracking of the patient following treatments. We also seek clarity on whether there are exclusions for this MIPS measure. **The inpatient version of this measure, finalized in the 2023 IPPS, excludes the following patients from the denominator: patients who opt out of screening, and patients who are unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on the patient’s behalf during the inpatient stay. We believe that these are important exclusions and should be included in the MIPS version of this measure.**

The ACS is currently working to develop a quality framework for health equity that will inform the development and implementation of equity standards in the ACS Quality Verification and Accreditation Programs. These standards will be developed in phases, first focusing on equity standards at the leadership level of a healthcare institution, then progressing to the environment, workforce, and equity standards in patient care. We envision that these standards could be used as a programmatic measure (a measure that incentivizes a comprehensive quality program such as an accreditation or verification program) across CMS programs. This type of measure could ensure a practice’s or facility’s commitment to closing the health equity gap across the various domains of a quality program. This effort is discussed in further detail in our response to the RFI on MIPS Quality Measure Performance Category Health Equity beginning on page 85.

The effect of social drivers is experienced at the local level, and many factors—such as, geographic location, available resources, and population characteristics—can play a role in the prevalence of social drivers and their impact on healthcare outcomes and delivery. **There is also much to learn in this space—especially how to screen those with limited access to care. Therefore, the ACS supports flexibility in the selection of screening tools. Flexibility should be allowed until we can better understand DOH and their impact before standardizing screening tools across care settings, geographic locations, and patient populations. Moving forward, CMS should evaluate the impact of DOH on health outcomes that they continue to evaluate and adjust the domains for social drivers.**

## **RFI on MIPS Quality Performance Category Health Equity**

To facilitate efforts to reduce health inequities, CMS is considering the development of broadly applicable health equity measures for potential use within traditional MIPS and MVPs. They ask for public comment on various questions about the type and structure of health equity measures that would be appropriate for implementation in MIPS.

Health equity is the sixth domain of quality of the Institute of Medicine (IOM) domains of quality care. We believe that quality and health equity are synonymous—high-quality care cannot be fully achieved without appreciating health equity, and health equity cannot be achieved without recognizing quality and safety. It is well established that SDOH factors impact quality of care. Patients with certain social risk factors may experience lack of access to health care services, limits on resources, lack of preventative care, poor early detection, and limited chronic care maintenance which can contribute to care inequities, and ultimately result in worse overall outcomes in surgical care. **While there are multiple areas that have already been identified as ways to advance health equity—such as the need for improved data collection—creating measures around activities that will ultimately advance health equity is an area where there is a great need for further research and consideration.**

CMS asks for feedback on how a measure would best capture health equity needs under MIPS in the future. As we have stated in our past comments, the first step should be defining the goals of this effort. Then a strategy should be developed around how the goals will be achieved and improved upon. **When setting goals for advancing equity and addressing disparities, it will be important to take a phased approach:**

- **Conduct a review and shine a light on the problem.** CMS and other stakeholders should continue to focus on ways to reliably define and identify the multifactorial challenges that impact Medicare beneficiaries. This should be done through reviewing evidence-based literature and available data, collecting and analyzing new data, etc. CMS should not implement measures until they are able to reliably and validly identify the gaps in care and the metrics are tested to ensure they are providing actionable information that drives quality improvement. Improved collection of data is foundational to this effort. We cannot begin to determine what we will need to measure until we can understand the population and their needs.
- **Reward innovation.** CMS should take steps to reward those who have defined and identified factors that present greater challenges for at-risk patient groups and are using their resources in innovative ways to address health equity gaps. Their methods should be shared to help inform efforts collectively. So that CMS can test health equity measures, the Agency could consider incentives through pay-for-reporting or confidential reporting where clinicians get credit for simply reporting data, but

performance is not tied to payment or publicly reported.

- **Research and development.** Research and development will drive the advancement of these efforts. This is the stage where the problems and solutions can be tested to ensure that desired outcomes to advance equity can be achieved.
- **Socializing solutions.** To continue to drive change, it is critical that the health care community socializes their experiences. Sharing solutions that have worked, along with methods that have not worked, will help the broader healthcare community as it continues to discover how to best address health care disparities. CMS could help to create a platform to facilitate these efforts.

**As CMS continues to develop its strategy for measuring healthcare disparities, we ask the Agency to take a comprehensive look at how its policies can enrich practices that care for the most complex patients.** Physicians that care for complex patients with various social risk factors are faced with many challenges to achieve good patient outcomes. These challenges may be exacerbated by perverse incentives that reduce their already strained resources. There is a critical need to better measure inherent disparities to bring attention and investment to under-resourced areas and populations, and then change the payment system so that it is accountable for the results of every individual.

The ACS witnesses the many dimensions of inequities in surgical care and seeks to use our resources to help the nation overcome the barriers of inequities. The ACS is currently working to develop a quality framework for health equity that will inform the development and implementation of equity standards in the ACS Quality Verification and Accreditation Programs. The ACS is taking an incremental approach to developing these standards, first focusing on equity standards at the leadership level of a healthcare institution, surgical department, and more. Standards at this level will first be focused on who is accountable for the policy, workforce culture, etc. They will identify what metrics are being implemented, the tools that are being used to measure success, and the plans for improvement when the metrics are not met successfully. The next iteration of standards will focus on the environment: is it safe, comfortable, inclusive, etc.? The final two iterations will be focused on the workforce and equity standards in patient care. Diversity in workforce will incorporate standards that assess factors such as, whether institutions are employing physicians and healthcare workers across racial and ethnic backgrounds, so workforce is representative of the patient population.

**Our strategy is to first focus on developing health equity standards for surgical practices, but in the future, the standards could be expanded beyond surgery into additional areas of health care. We envision the health equity standards could be used as a programmatic measure (a measure that incentivizes a comprehensive quality program such as an accreditation or verification program) across CMS**

**programs. This type of measure could ensure a practice’s or facility’s commitment to closing the health equity gap across the various domains of a quality program, including culture, resources and staffing to support the effort; patient care expectations and protocols; data collection and surveillance data-driven quality improvement; and community outreach and education programs.**

### **Linking Health Equity Measures to Improvement**

CMS also asks how a health equity measure should be designed to provide actionable information and link to improvements in the quality of care delivered to at-risk populations. Resources should be allotted to facilitate the sharing of information with healthcare providers and determine what metrics provide information that spurs action and improvements in care. **As we have stated previously, an important standard to apply in evaluating payment quality incentives is their effectiveness in providing patients with knowledge of where to find high quality care in their community. When considering meaningful performance differences, this should be key—what information do patients value and how will that information reliably help them seek equitable care?**

Once high-quality equitable standards are developed, quality measures and improvement activities should be viewed as a cycle that continuously improves by first delivering high quality equitable care, and evaluating and conducting improvement efforts—all as part of a cycle that continually iterates. We call this “improving improvement.” When healthcare institutions commit to advancing health equity, this is done in multiple steps that continuously inform and build off each other. This effort cannot be done in silos, but instead relies on commitment and coordination across the hospital, care team, families, and community.

### ***Assessing the Collection and Use of Self-Reported Patient Characteristics***

CMS recognizes that collection of standardized, complete, and accurate patient data is a prerequisite for measuring and reporting quality for patients with social risk factors (i.e., stratifying quality measures by patient characteristics). These data include patient demographics and social drivers of health (referred to as “patient characteristics”), which are not routinely or systematically collected across the health care system. CMS is considering ways to encourage clinicians to collect social risk information, including through the development of a measure that tracks the completeness of self-reported patient characteristics such as race, ethnicity, preferred language, gender identity, sexual orientation, disability status, income, education, employment, food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. CMS asks for stakeholder input on various questions to better understand the feasibility and usefulness of a measure that promotes the collection of self-reported patient characteristics data.

Data sources that are currently in use, such as billing and administrative data, can serve as proxies, but will not be able to provide the proper level of detail and context that gets to the heart of the issues that patients face. These broad approaches will be helpful in giving us a general sense of the needs within a population. **As the ACS has stated in the past, the lack of standardization in demographic and SDOH data presents a major challenge in addressing needs. We agree that to achieve more widespread collection, aggregation, and tracking of SDOH data, improvements in collection methodologies and standardization are necessary across the entire healthcare system. In the same way that emphasis has been put on standardization of clinical information data in the medical record, SDOH information should also be consistently collected and maintained as part of the patient’s medical record.** The ability to collect accurate and real-time SDOH data and put these variables in the hands of the clinician at the bedside could drastically change care delivery across the phases of care. Having these data would allow clinicians to tailor care based on SDOH from how they conduct screening, prevention, and early intervention to preoperative planning, postoperative recovery, and post-discharge management.

CMS asks about the importance of using a standardized tool with coded questions and data elements to collect self-reported patient characteristics across clinicians and practices. They also seek input on how the use of a consistent screening tool to collect SDOH information might improve CMS’ ability to meaningfully compare performance across clinicians. **While we ultimately support the goals of standardized screening tools, at this time, the ACS believes that practices should be given flexibility in selecting tools that best align with their local needs.** Key to collecting these data is also the clinical team’s ability to establish a trusting relationship with the patient so that the patient is comfortable sharing personal information. Since we are still in the early stages of collecting and understanding these data, it is important that we first achieve widespread screening before mandating the types of tools that physicians must use. Given this, we feel that flexibility should be allowed until we can better understand SDOH and their impact before standardizing screening tools across care settings, geographic locations, and patient populations. Even while providing flexibility, CMS should engage with patients and other stakeholders to explore how to develop screening tools that incorporate variables that can be assessed across all populations and additional elements that can be customized and included to fit the specific needs of each practice. This is an area that will require large investments in research by CMS and other stakeholders.

### ***Assessing Patient-Clinician Communication***

Effective patient-clinician communication is essential to achieving understanding of patient goals, empowering patients, and providing high-quality care across all patient care settings and clinician types. When patients must rely on unqualified individuals to



interpret medical information, there is the risk of misunderstandings that can lead to harm. CMS is considering the development of a patient reported outcome measure (PROM) that assesses the receipt of appropriate language services and/or the extent of clinician-patient communication.

Expanding the use of PROMs in CMS programs will reflect a transition to a more patient-centric program by assessing outcomes that matter most to patients. We encourage CMS to promote research that furthers the use of PROMs to better drive us towards recognizing health equity gaps and moving the system towards incorporating the patient voice into care. This should include identifying ways to increase patient activation in the PROM process to enhance response rates and more meaningfully inform the entire care team. **PROMs that measure patient-clinician communication should assess whether patients felt they were treated respectfully, whether they felt their voice was heard and personal goals understood, and if they experienced a trusting relationship with the care team.** Inclusion is a much-needed area of development in health care and could encompass a patient's feeling of receiving care that is sensitive to their culture, beliefs, language, race, ethnicity, sexual orientation and gender identification, personal circumstances, and so on.

### **Promoting Interoperability Performance Category**

#### ***Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure under the Electronic Prescribing Objective***

In the CY 2022 PFS final rule, CMS maintained the *Query of PDMP* as an optional measure for the CY 2022 performance period in light of efforts to: improve the technical foundation for EHR-PDMP integration, to support the continued implementation of the SUPPORT for Patients and Communities Act, to continue CMS' review of alternative measure approaches, and address concerns from interested parties about the current readiness across states for implementation of the existing measure. However, CMS believes MIPS eligible clinicians have now had adequate time to grow familiar with this measure and that significant progress has been made in availability of PDMPs and solutions which support accessibility of PDMPs to health care providers in all 50 states. Therefore, beginning with the CY 2023 performance period, CMS proposes to require MIPS eligible clinicians to report the *Query of PDMP* measure (which requires reporting a "yes/no" response) for the PI performance category. CMS also proposes to expand the *Query of PDMP* measure to include Schedule III and IV drugs in addition to Schedule II opioids.

As discussed in this proposed rule, CMS maintained the measure as optional for multiple years due to PDMP availability and integration into EHR systems. If this measure is made mandatory, **the ACS suggests that CMS create a mechanism that can track**

**PDMP functionalities and identify where the failure points with the current PDMP structure exist.** Barriers to regular PDMP utilization could be failures in the technical systems, resistance from clinicians, etc., and tracking these failure points will be helpful in determining how to best overcome the barriers to effective PDMP integration.

***Health Information Exchange (HIE) Objective: Proposed Addition of an Alternative Measure***

CMS discusses the opportunities presented by the implementation of TEFCA in the *Advancing the Trusted Exchange Framework and Common Agreement RFI*. To provide clinicians opportunities to earn additional credit for the HIE objective, CMS proposes to add a new optional *Enabling Exchange Under TEFCA* measure under the PI performance category of MIPS. This new measure would be reported by attesting “yes/no” to the following attestation statements. If a clinician attests “yes” they would earn the total points allotted for the HIE objective:

- Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the Federal Register and on ONC’s website) (in good standing that is not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy.
- Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.

**The ACS has been a strong supporter of the TEFCA efforts for many years. From the ACS’ perspective, the Framework will offer benefits to both patients and providers.** Widespread exchange with QHINs opens doors to greater access and exchange of important clinical data that can be applied across the entire healthcare spectrum. **We applaud CMS for taking steps to incentivize bi-directional exchange with QHINs. With these data, providers can longitudinally track patients’ comorbidities, risk factors, and past treatments, regardless of where the patient was treated, to better inform care decisions.** We also see opportunities in the near future for these networks to be leveraged to generate knowledge that supports the development of digital tools, such as CDS, that can be applied to achieve more patient-centric healthcare delivery. **However, as mentioned in our comments in the Advancing TEFCA – RFI, TEFCA is not mature enough to measure at this time. As TEFCA implementation matures, CMS should consider a measure that will lead to incentives for participation in exchange networks.**

## **RFI on Patient Access to Health Information Measure**

In this RFI, CMS discusses the benefits associated with patients using their portals to access their health information, such as improvements in access, quality of care, health outcomes, and reductions in healthcare expenditures. The Agency also cited findings from a 2020 Health Information National Trends Survey Report that showed that health care providers and staff have a substantial role in influencing patients' use of their portals.

In the past, CMS attempted to promote patient access to their health information through measuring the number of patients who actively engaged with the EHR through the View, Download, Transmit (VDT) measure. Recognizing the concerns and barriers with the previous VDT measure (e.g., the measure requires patient action for successful submission), but acknowledging the advancements made within the health IT industry over the past few years, this RFI seeks comments regarding how to further promote equitable patient access and use of their health information without adding unnecessary burden on the MIPS eligible clinician or group.

First, it is important to note that patients' readiness to utilize portals and other technologies is variable. The ACS is supportive of the goal to increase patient's access to health and healthcare knowledge through portals and other applications. Patient portals are a tool that should be designed to support patients' ability to track their health and guide them to resources that align with their expectations and goals for their care. **We agree that creating opportunities for patients to easily access their personal healthcare knowledge is important to promoting better health and healthcare, but due to the complicated nature of care, we need to conduct more research to learn about patients' readiness to interface with their healthcare information in this way before implementing measures of physicians' facilitation.** In addition, CMS must also consider digital literacy and patients without reliable access to digital information. This should be explored and identified as a barrier to patient portal use. Without understanding patient readiness, access, literacy, etc., and creating solutions to fill the gaps, we could inadvertently increase burden on physicians. **Instead of creating a measure that would potentially penalize physicians for how often a patient accesses their personal health information, CMS should explore ways they can reward physicians that are using innovation to increase patient readiness and engagement with sources of their health and healthcare information.**

**In addition, creating an interface that allows patients to access all their information in one place would reduce barriers to access.** No single EHR fully reflects the patient's health and healthcare. The ACS encourages the federal agencies to collaborate to create patient profiles that are all inclusive. The HIE environment would be effective in building these resources because of its ability to aggregate and exchange information across

healthcare systems and settings. **Designing a patient portal that would be available through the HIE and could interconnect to other HIEs would provide patients with a better reflection of their total health and healthcare history.** We envision in the future, HIEs might also be able to help support the delivery of remote care by creating pathways to capture patient generated data, and data from other care settings, such as skilled nursing facilities, home health, rural clinics, and more.

### **Calculating the Final Score**

#### *Complex Patient Bonus*

In the CY 2018 QPP final rule, CMS finalized the complex patient bonus for MIPS eligible clinicians, groups, APM entities, and virtual groups and established facility-based measurement for certain MIPS eligible clinicians. When these policies were established, CMS did not address whether facility-based MIPS eligible clinicians would be eligible to receive the complex patient bonus. In this proposed rule, CMS states while individual facility-based clinicians are not required to submit data for at least one MIPS performance category, they believe these clinicians should be eligible to receive the complex patient bonus. Thus, CMS proposes beginning with the 2023 performance period/2025 payment year, a facility-based MIPS eligible clinician would be eligible to receive the complex patient bonus, even if they do not submit data for at least one MIPS performance category. **The ACS supports this proposal as an effort that recognizes the increased resources needed to care for complex and unstable patient populations.** Efforts that attempt to compensate for some of the increased cost to care for this population are a step in the right direction toward increasing access to care. However, **we seek further information from CMS on how well this bonus will account for the increased cost associated with complex patients and how appropriately it levels the playing field for clinicians who care for complex patients—this is especially critical for the transition to value-based care.** Clinicians and hospitals will need to be equipped with the knowledge to understand if their system or practice can take on the cost of a complicated population as they enter risk-bearing contracts.

#### ***RFI on Risk Indicators for the Complex Patient Bonus Formula***

CMS is requesting feedback on additional risk indicators that it should consider updating or supplementing the existing complex patient bonus formula. In this RFI, CMS discusses its proposal to offer a positive adjustment to the quality performance score for an ACO that achieves a specified level of quality performance and serves beneficiaries in areas with a high Area Deprivation Index (ADI) or serves a large proportion of dual eligible beneficiaries. The Agency is not proposing to use the ADI measure within the MIPS complex patient bonus, but it requests public comment on the potential future incorporation of the measures.

The ACS strongly supports these efforts to evaluate various socioeconomic status (SES) indices to identify socially at-risk populations and the degree of their risk. The ACS has analyzed SES indices for sensitivity in the ACS National Surgical Quality Improvement Program (NSQIP) and other ACS registries. The findings indicated for surgery, ADI is the most sensitive SES index currently available. However, it is important to note that ADI and the other SES indices are developed by combining American Community Survey data points (housing, education, job, income, transportation, etc.), which does not consider the outcome to be predicted. In that regard, these indices are generic for assessing risk. **A better approach would be to construct an index (e.g., using regression) that is tuned for predictive strength with respect to the outcome of interest.** This will require a dynamic process that is regularly updated and responds to different needs. The ACS is currently investigating the development of an index for surgical care.

### **Public Reporting on the Compare Tools hosted by HHS**

#### ***Telehealth Indicator***

CMS proposes to add a telehealth indicator to clinician and group profile pages on its Care Compare tool website, as technically feasible. CMS proposes to identify clinicians who perform telehealth services using Place of Service Code 02 (indicating telehealth) on paid physician & ancillary service (i.e., carrier) claims, or modifier 95 appended on paid claims, and develop an indicator that would display this information on physician profile pages. To keep the indicator current and address concerns that some telehealth codes are time-limited, CMS would use a 6-month lookback period and refresh the telehealth indicator on clinician profile pages bi-monthly, which is the same cadence in which CMS updates other clinician directory information. Along with the indicator, CMS would include a statement on the profile page caveating, in a user-friendly way based on consumer testing, that the clinician or group only provides some, not all, services via telehealth. **The ACS supports the addition of a telehealth indicator on the Care Compare website. The expansion of telehealth services has increased patient access to care and will continue to do so as technology advances.** Patients, especially those who live in rural areas, who do not always have access to certain specialty care may prefer telehealth visits, and will benefit from a clear indicator that shows which physicians actively participate in telehealth visits.

#### ***Publicly Reporting Utilization Data on Profile Pages***

CMS proposes to publicly report Medicare procedural utilization data on the Care Compare tool's clinician and group profile pages in a way that is understandable to patients and caregivers, based on user testing, and helps them make healthcare decisions.

CMS would begin publicly reporting procedural utilization data no earlier than CY 2023 and would use a 12-month lookback period and bi-monthly data refresh frequency, as technically feasible. CMS would include a disclaimer on profile pages that the utilization data only represents the care that has been provided to Medicare beneficiaries and does not include those of patients with other forms of insurance.

**The ACS does not support this proposal to publicly report utilization data because measuring procedure volume does not reliably predict high quality care and is therefore an outdated proxy—essentially this is a step backwards in the identification of high-quality care. Measuring volume in the absence of quality is a mixed signal as the nation transitions to appreciating value-driven care and moves away from volume-driven care. Without quality measures, patients will use volume information in isolation and may be misinformed. This may also have the unintended consequence of perverse incentives to increase volume.** This is supported by the following points:

- **Quality measurement systems at the surgeon-specific level remain underdeveloped, especially for uncommon complex procedures. It is difficult to determine a volume threshold that indicates high quality with meaningful statistical power at the individual clinician level, and the volume threshold will typically differ from procedure to procedure.** In fact, achieving reliability at the hospital level is often not achieved. A minimal case number threshold for the required experience of rarely performed operations or those performed for rare diseases is likely impossible to define or be meaningful.<sup>27</sup>
- **The ACS Statement on Credentialing and Privileging and Volume Performance Issues notes for some complex procedures, high case volume could be associated with improvement in surgical outcomes, however, “these outcomes may reflect not only the knowledge, 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 of patients.”** It is also well documented that some surgeons performing a relatively low volume of these procedures also achieve excellent outcomes.<sup>28</sup>
- In our work running verification programs, we know that using standards of care established as part of a quality program will align facility and providers for continuous, reliable, and standardized care. In other words, it takes much more than just a single surgeon’s volume of cases that goes into optimal outcomes. In

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<sup>27</sup> The American College of Surgeons. (2018, April 1). *Statement on credentialing and privileging and volume performance issues*. <https://www.facs.org/about-ac/s/statements/credentialing-and-privileging-and-volume-performance-issues/>

<sup>28</sup> The American College of Surgeons. (2018, April 1). *Statement on credentialing and privileging and volume performance issues*. <https://www.facs.org/about-ac/s/statements/credentialing-and-privileging-and-volume-performance-issues/>

addition to good outcomes, adhering to clinical protocols, having the correct personnel and equipment, and good organization are good indicators of quality. It is for these reasons the ACS advocates for the full quality program needed to organize around the patient to deliver optimal care.

- The dataset would not include any utilization for Medicare Advantage, Medicaid, Veteran Affairs, or private payor beneficiaries, and therefore would often erroneously repress providers as having no experience with procedures that they regularly perform.

**In conclusion, publicly reporting volume data will be misleading and confusing to patients who are using the Care Compare site to determine where they will receive the best care. It is not appropriate to assume that performing a high case volume of certain procedures always equates to better outcomes, especially when considering data integrity issues outlined above. It is important to understand volume, patient risk profiles, price, and quality to make an informed decision. If CMS goes forward, it should be inclusive of an asterisk that makes these points. However, the ACS does not support volume as a proxy for value without being more informed by these other parameters.**

### ***RFI on Incorporating Health Equity into Public Reporting***

CMS solicits comment on ways to incorporate health equity into public reporting on both doctor and clinician profile pages with the goal of ensuring that all patients and caregivers can easily access meaningful information to assist with their healthcare decisions. Overall, the ACS is supportive of efforts that provide patients with information that will help them seek trusted care based on their own values, goals, and preferences. We believe public reporting should include information on key structural measures that show practices have processes in place to increase patient access to care and should include information on programs for underinsured patients to access services for prevention, screening, and early detection.

The ACS is currently working to develop a quality framework for health equity that will inform the development and implementation of equity standards in our ACS Quality Verification and Accreditation Programs. The ACS is taking an incremental approach to developing these standards, first focusing on equity standards at the leadership level of a healthcare institution, surgical department, etc. Standards at this level will first be focused on who is accountable for the policy, workforce culture, etc. The next iteration of standards will focus on the environment: whether it is safe, comfortable, inclusive, and so on. The final two iterations will be focused on the workforce and equity standards in patient care. Our strategy is to first focus on developing health equity standards for surgical practices, but in the future the standards could be expanded beyond surgery into

additional areas of health care. This information could be made publicly available to show which institutions and clinicians are prioritizing closing the health equity gap.

As these efforts progress, greater emphasis should be put on how to best capture and display patient experience of care and PROs. Transparently reporting these measures can help patients seek out care based on their personal circumstances and values. Patient experience data will reflect whether patients felt they were treated respectfully, whether they felt their voice was heard and personal goals understood, and if they experienced a trusting relationship with the care team. However, **CMS should not publicly report outcomes until the measure science for reporting outcomes in at-risk patient populations is further developed, and this should be done in the aggregate, not at the individual clinician level.**

### **RFI on Quality Payment Program Incentives beginning in Performance Year 2023 Advanced APMs**

*CMS seeks public comment on whether administrative action is needed beginning in the 2024 performance period/2026 payment year, and if so, what would be the best approach to address the multi-faceted issues that arise with the end of statutory authority for an APM Incentive Payment for QPs and the transition to the differential QP and general conversion factors.*

The ACS welcomes CMS' acknowledgement of the potential adverse incentives created by payment policies included in the MACRA law. The expiration of incentives, lack of updates for a multi-year window, and splitting of the Conversion Factor through differential updates seem to create incentives counter to the goals of the law 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 longer-term incentives for physicians to adopt these models. The gap between the expiration of the early APM Incentive Payments and the higher updates for qualifying APM participants (QPs) are only one factor limiting the success of the transition to value.

In 2022, we are unfortunately reaching the end of the early incentives for participation in APMs before the pathway participation is clear for many specialist physicians. 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 complete reliance by CMS to use 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 that provide actionable information on how to 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 backlog 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.

**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.**

*What are your primary considerations going forward as you choose whether to participate in an Advanced APM or be subject to MIPS reporting requirements and payment adjustments? What factors are the most important as you make this decision?*

For many Fellows of the ACS, opportunities for participation in APMs are dictated by the location in which they practice or the patients or conditions they typically treat. While many surgeons are QPs in ACOs, few feel that these models improve patient care. This is because these models fail to measure surgical quality, instead relying on population measures that provide no actionable information for the improvement of surgical patient care. In fact, surgeons are sometimes surprised to learn that they are included on ACO participant lists and are therefore QPs. Surgeons as employed professionals are measured for their clinical contributions and have left prior private practice business models to attract various revenue streams to their employing system. The incentives, therefore, change from direct compensation for delivery of a service or set of services a surgeon performs to more align with the needs of the employer and hopefully the total care needs of the patients they treat. Systems participating in ACO models may have a different perspective and incentives. Ideally, models with incentives more specifically targeted toward specialty care could improve care for these patients. Clearly, models that focus

more on improving care to surgical patients and which provide timely, actionable information would be a more attractive option for surgeons.

Another factor to consider is the change in practice patterns occurring in recent decades. As noted above, in surgery as in many areas of medicine, there is an ongoing shift from private practice to employment. This shift has, to an extent, limited the freedom of surgeons to self-determine which models they will participate in. An employed surgeon's options may be limited by the models in which the employer sees value and chooses to adopt.

***If you are participating in an Advanced APM now and have been or could be a QP for a year, will the end of the 5 percent lump-sum APM Incentive Payments beginning in the 2023 performance period/2025 payment year cause you to consider dropping your participation in the APM, which would mean forgoing QP determinations, thereby ensuring you are subject to MIPS reporting requirements and payment adjustments?***

This is a complex question, as there are a number of factors beyond the APM Incentive Payments which go into the decision of whether to participate in, or leave, a given payment model. That said, a de-facto five percent decrease in reimbursements will certainly factor into that decision. The five percent incentive can help to fill gaps in the resources needed to invest in an APM (e.g., staffing, data analysis, administration).

***Going forward, attaining QP status for a year through sufficient participation in one or more Advanced APMs will enable an eligible clinician to, for a year: (1) continue receiving any financial incentive payments available under the Advanced APM(s) in which they participate, subject to the terms and conditions applicable to the specific Advanced APM(s); (2) be paid under the PFS in the payment year using the higher QP conversion factor (0.75 percent rather than 0.25 percent) beginning in payment year 2026; and (3) not be subject to MIPS reporting requirements or payment adjustments. Do these three conditions provide sufficient incentives for you to participate in an Advanced APM, or would you instead decide to be subject to MIPS reporting requirements and payment adjustments?***

As noted previously, there are considerations between financial incentives that factor into the decision to participate in APMs. The lack of focus on surgical patients and the lack of meaningful and actionable quality metrics can lead to a lack of buy-in and perceived burden of participating in certain models. Given enough time, the divergence of payments between the conversion factors for QPs and non-QPs will become so great that one will no longer be sustainable. However, it would be better to create affirmative reasons to participate in a model (either financial, or because they are seen as providing higher-value care, or both) than forcing a decision through making one option increasingly uncomfortable.

*Are there other advantages of MIPS participation that might lead a clinician to prefer MIPS over participation in an Advanced APM, such as: (1) quality measurement that may be specific to a particular practice area or specialty area; or (2) the desire for more precise accountability through public reporting of quality measure performance in the future?*

As currently implemented, most surgeons report MIPS measures as part of a large group and therefore receive little specific information related to surgical patients. There is some promise that MVPs could provide an opportunity for more meaningful MIPS participation, as well as help to create a steppingstone toward APM participation by providing more insight needed to take on more risk. If such MVPs were to develop, rather than detract from APM participation, they may help to build the confidence and knowledge necessary for physicians and teams to make the transition to APMs.

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](mailto:vmujumdar@facs.org), or Jill Sage, Chief of Quality Affairs, at [jsage@facs.org](mailto:jsage@facs.org).

Sincerely,



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