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September 8, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for Calendar Year (CY) 2016

Dear Mr. Slavitt:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016* (proposed rule) that was published in the *Federal Register* on July 15, 2015.

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. Our comments below are presented in the order in which they appear in the proposed rule.

PROVISIONS OF THE PROPOSED RULE FOR PFS

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

Practice Expense Methodology

The Centers for Medicare and Medicaid Services (CMS) propose a modification to Step 7 of its practice expense (PE) relative value unit (RVU) methodology: calculation of direct and indirect PE percentages at the service level, which takes a weighted average of the specialties that furnish the service. Historically, CMS has used the specialties that furnish the service in the most



recent full year of Medicare claims data to determine which specialties furnish individual procedures. To create more stability and mitigate code-level fluctuations, particularly for new and low-volume codes, CMS proposes to refine this step of the PE methodology to use an average of the three most recent years of available Medicare claims data to determine the specialty mix assigned to each code.

We understand that averaging three years of specialty mix data may mitigate code-level fluctuations for most codes and the ACS generally supports this approach. However, this does not address the concern of how misreporting the specialty on claims data affects low volume codes. There could be situations where data, even from the average of three years, misrepresent the dominant specialty that could be reasonably expected to furnish the service, and these erroneous data result in incorrect PE RVUs. In these situations, **we urge CMS to maintain a flexible approach and use dominant specialties for certain low volume codes and further suggest that CMS utilize the expertise of the American Medical Association/ Specialty Society Relative Value Scale Update Committee (RUC) to assist with identifying dominant specialties.**

With regards to calculating equipment cost per minute, CMS notes that it solicited comments in 2015 rulemaking on whether the maintenance factor should be variable rather than the current, uniform 0.05. CMS notes that the data it received were limited and may not reflect typical costs. Thus, CMS continues to seek a source of publicly available data on actual maintenance costs for medical equipment to improve the accuracy of the equipment costs used in developing PE RVUs. CMS does not propose any changes to the factor for maintenance in 2016. The ACS supports the Society for Vascular Surgery's (SVS) separately submitted comments that the 5 percent allowance in the current PE methodology often does not account for expensive maintenance contracts on pieces of highly technical equipment. **The ACS supports SVS' recommendation to increase the allowance for equipment maintenance to 10 percent to help offset the actual direct expense for equipment maintenance incurred by providers.** We believe that specialty societies and other stakeholders should be allowed to provide documentation to CMS (as they do for pricing new supplies and equipment) to apply for an increase in maintenance costs. The ACS encourages CMS to work with specialty societies to ensure that data they find online are valid, reliable, and up-to-date prior to using them to change its methodology.

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Changes to Direct PE Inputs for Specific Services

CMS invites comment on the appropriate standard minutes for clinical labor tasks associated with services that use digital technology (listed in Table 5 of the proposed rule). **The ACS supports SVS' separately submitted recommendation that CMS generalize the staff types in the tasks (i.e. technologist to clinical staff, radiologist to physician).** Specialty societies should be afforded the opportunity to request deviations from the standard (i.e. increase). Finally, we support the SVS in its ask that CMS work with the RUC and specialty societies before adjusting the existing times for current codes.

Determination of Malpractice RVUs

Malpractice RVU Methodology Refinements

CMS proposes to determine the specialty mix assigned to each code using the same process as in the PE methodology. This includes the CMS proposal to use the three most recent years of available data instead of a single year of data, to determine the specialty mix. CMS also proposes to no longer apply the dominant specialty for low volume services, because the primary rationale for the policy has been mitigated by this proposed change in methodology. CMS, however, plans to maintain the code-specific overrides established in prior rulemaking for codes where the claims data are inconsistent with a specialty that could be reasonably expected to furnish the service.

Similar to our discussion above regarding changes to Step 7 of the PE RVU calculation, averaging three years of data will mitigate some fluctuation for most codes. However, if CMS can create code-specific overrides for codes with erroneous claims, we do not understand why code-specific assignment of dominant specialties for low volume codes is problematic. **The ACS urges CMS to continue using dominant specialties for low volume codes. We also suggest that CMS utilize the expertise of the RUC to assist with identifying dominant specialties for low volume services.**

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Potentially Misvalued Services under the Physician Fee Schedule (PFS)

CY 2016 Identification of Potentially Misvalued Services for Review - CPT 92002

Section 220(c) of the Protecting Access to Medicare Act of 2014 (PAMA) expanded the list of categories of codes the Secretary is directed to examine, and included codes that account for the majority of spending under the PFS. Table 8 of the proposed rule lists the 118 codes identified through the high expenditure specialty screen. CMS identified the top 20 codes by specialty in terms of allowed charges and excluded codes that have been reviewed since 2010, codes with fewer than \$10 million in allowed charges, and codes that describe anesthesia or evaluation and management (E/M) services. **The ACS supports the American Academy of Ophthalmology's separately submitted comment that Current Procedural Terminology (CPT) code 92002 was erroneously identified and should be removed from this list.** CPT code 92002 is considered an Ophthalmological E/M service and should be excluded from this query along with all other E/M services.

Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

CMS observed that practice patterns for endoscopic procedures where moderate sedation is inherent are changing, and anesthesia is increasingly being reported separately for these procedures, which are included in Appendix G of the CPT manual. CMS is considering establishing a uniform approach to valuation of all Appendix G services for which moderate sedation is no longer inherent, and seeks recommendations from the RUC and other interested stakeholders on approaches to address the appropriate valuation of the work associated with moderate sedation.

The ACS asks CMS to ensure that any methodology be designed to accurately capture all the work being done by the physician performing the procedure. There are many areas of America where endoscopy is performed by general surgeons in an office or other outpatient setting without using a separate provider for anesthesia. As CMS considers paying separately for moderate sedation services and makes adjustments in work RVUs for different components of performing an endoscopy, it is critical that physicians who are delivering both moderate sedation services to the patient and

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performing a procedure, are appropriately reimbursed for the actual work performed. Please also note that the RUC and the CPT Editorial Panel established the Joint CPT/RUC Moderate Sedation Workgroup in 2014. The collaborating specialties will present their survey data and joint recommendations at upcoming RUC meetings, and the RUC will submit its recommendations to CMS for consideration for the CY 2017 PFS proposed rule.

Improving the Valuation and Coding of the Global Package

Section 523 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS to use rulemaking to obtain information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery, as appropriate. This information must be reported on claims or in another manner specified by the Secretary. The Secretary is also authorized through rulemaking, to delay up to 5 percent of the PFS payment for services, for which a physician is required to report information, until the required information is reported. Beginning in 2019, the information collected, along with any other available data, must be used to improve the accuracy of the valuation of surgical services.

CMS seeks feedback on a number of issues related to the data collection and valuation of global services. We provide high-level comments on each issue below, and we plan to communicate further with CMS in the coming months to discuss in more detail CMS' plan for data collection and valuation of surgical services. We very much appreciate that CMS plans to seek comments, in addition to the rulemaking process, for developing a proposal for CY 2017 to collect data needed to value surgical services. We urge CMS to utilize any available means to obtain comments including open door forums and town hall meetings with the public, amongst other avenues. We also urge CMS to allow stakeholders to provide additional written comments on policies that CMS is developing for collecting these 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.

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Types of data and how to acquire the data

CMS is soliciting comments from the public regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished by the practitioner reporting the procedure code during the current post-operative periods) needed to increase the accuracy of the values for surgical services. CMS is also seeking comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, CMS seeks information on the extent to which individual practitioners or practices may currently maintain their own data on services, including those furnished during the post-operative period, and how the agency might collect and objectively evaluate those data for use in increasing the accuracy of the values beginning in CY 2019.

We urge CMS to utilize a number of different data sources to collect data for increasing the accuracy of the values for surgical services. Different data sources will be needed to capture information on the procedure itself, the postoperative visits, preoperative services, and other services provided. **We also stress that the data must be truly representative and must include information from geographically diverse large and small practices.** It will not be possible to obtain all the needed information that is representative of services delivered to patients across our country from a single data source or even two or three large institutions.

Valuing individual components of the global surgical package

CMS is seeking public comment on potential methods of valuing the individual components of the global surgical package, including the procedure itself, and the pre- and postoperative care, including the follow-up care during post-operative days. CMS is particularly interested in stakeholder input regarding the overall accuracy of the values and descriptions of the component services within the global packages. For example, CMS seeks information from stakeholders on whether (both qualitatively and quantitatively) postoperative visits differ from other E/M services.

There are many issues to take into consideration as CMS plans to value the individual components of the global packages.

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- **Physician work:** We urge CMS to collaborate with the RUC to evaluate physician work. We believe that the RUC is in the best position for surveying, vetting, and valuing these services.

In addition, for the reasons below, we also stress that CMS should not rely exclusively on the recent RAND report titled “Development of a Model for Validation of Work Relative Value Units for the Physician Fee Schedule”¹ for a methodology for valuing physician work RVUs. This report investigated the feasibility, methodological issues, and limitations involved in developing a model for valuing physician services that uses data from existing databases independent of the current RUC valuation process.

- RAND stated that the results presented in its report should be considered exploratory analyses that examine the overall feasibility of the model and the sensitivity of the model results to alternative methodological approaches and assumptions. The report did not produce a completed validation model for physician work values.
- The report indicated that it should not be used beyond two limited applications: (1) to flag codes as potentially misvalued if the CMS and RAND model estimates are notably different; and (2) as an independent estimate of the work RVUs to consider when assessing a RUC recommendation.
- While the report attempts to remedy data issues, the lack of available external data makes the utility of the findings limited. Specifically, the report states that there were no external databases with information on pre-service and immediate post-service times that could be used as a gold standard to build prediction models.
- The current RAND models contain methodological inconsistencies that make them impossible to use consistently across all codes. For example, the report acknowledges that the methods sometimes resulted in negative or implausibly low intra-service work. Most importantly the results of the RAND analysis do not provide a

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¹ Wynn, et. al. “Development of a Model for the Validation of Work Relative Value Units for the Medicare Physician Fee Schedule” 2014. Available at:

http://www.rand.org/content/dam/rand/pubs/research_reports/RR600/RR662/RAND_RR662.pdf.



reliable and reproducible mechanism to maintain values that are relative across all CPT codes.

- The RAND methodology focuses only on surgical procedures and excludes E/M visits from the models. The report does not provide a rationale for excluding E/M services, but states that significant effort will be necessary to develop new models for the nonsurgical aspects of the resource-based relative value scale. We are concerned that excluding E/M codes from the model is a fatal flaw to the RAND methodology and results because E/M codes make up a significant proportion of Medicare spending. Thus, maintaining a fair relativity across all CPT codes is not possible using this methodology.

As such, we do not believe the RAND models described in the report should be used for valuing physician work.

- **Practice expense:** As CMS values the procedure itself, separate from the global code, **the agency should incorporate the PE value that is unique to follow up visits in the base or “parent” code.** This will prevent an unfair devaluation of the cost of supplies, labor, and equipment that is consumed in caring for the Medicare patient in the post-operative outpatient visits. CMS has previously stated that a disparity exists between E/M visits included in global surgical work and E/M visits that are discrete. Based on our analysis, the PE in separately reportable E/Ms is insufficient to account for the specialized supplies, equipment, and labor required for post-operative E/M care. The E/M services performed in a surgical global period often include additional and more expensive supplies and equipment relative to standard, separately reported E/M services. Examples of supplies that fall into this category are specialized bandages and dressings, staple and suture removal kits, and different postoperative incision care packs. Examples of equipment that fall into this category include specialized examination tables, cast cutters, surgical and exam lights, ultrasound units, and endoscopy equipment. Certain surgical E/M services also include additional clinical staff time relative to the clinical staff time for separately reported E/M visits. Examples include the additional clinical labor time required to care for stomas or for the setup and cleaning of scope equipment required at a post-op visit.

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In addition, **there are a number of post-operative services included in 10- and 90-day global codes that cannot be reimbursed using the current separately billable E/M codes.** These post-operative services represent real dollar cost outlays by surgeons, both for supplies as well as labor, that are fairly paid for using the existing methodology in the 10- and 90- day global codes, but would be unpaid if surgeons were left to bill for them by using E/M codes. Examples of these services are listed in the Medicare Claims Processing Manual² and include items such as: dressing changes; local incision care; removal of operative packing; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters; routine peripheral intravenous lines; nasogastric and rectal tubes; and changes and removal of tracheostomy tubes.

- **Malpractice:** In valuing the individual components of a global service separately, it is important that CMS prevent potential artificial reductions in professional liability insurance (PLI) RVUs for some specialties. The PLI RVUs for each service are calculated by multiplying the work RVU by the specialty risk factor of the specialty or specialties that perform the service. Currently, the work RVUs of the proxy E/M services contained in the global period for 10- and 90-day global codes are part of the PLI calculation. If the surgical procedure component is valued alone, CMS should not allow the surgical risk payment that is currently included in a 90-day global period to be removed and transferred to a diluted pool of non-surgical risk E/Ms. Similar to the PE formula, the PLI RVU formula was designed for a system where different global periods existed, and discrete services with high liability costs were delivered as part of the 90-day global surgical package. Any changes to how the E/Ms are included as part of the 10-and 90-day global periods would necessitate CMS reexamining how PLI is calculated and allocated for the surgical procedure. This may involve increasing the amount of recognized PLI for the remaining 0-day global service to ensure that surgeons are held

² *Medicare Claims Processing Manual*, Chapter 12, Physicians/Nonphysician Practitioners, 40.1 A. Components of a Global Surgical Package (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>, accessed August 18, 2015).

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harmless. We urge CMS not to use a methodology that redistributes the PLI associated with the global period to other specialties. A revised PLI formula should also properly and fairly credit resource-based specialty PLI costs to each specialty proportional to their own unique PLI costs.

Overall Accuracy

CMS also is interested in stakeholder input regarding the overall accuracy of the values and descriptions of the component services within the global packages. For example, CMS seeks information from stakeholders on whether postoperative visits differ from other E/M services (both qualitatively and quantitatively).

Postoperative visits that are valued in global codes differ substantially from other E/M services. As described above, there could be direct PE in the form of specialized supplies, equipment, and labor that are included in postoperative visits, but not in separately reportable E/Ms. Additional examples include:

- Cardiac surgery post-surgical office visits require RN staff-type
- Ophthalmology post-surgical office visits require COMT/COT/RN/CST staff-type
- Otolaryngology post-surgical office visits require suction machines, reclining chairs, loupes, or operating microscopes

Another issue related to the accuracy of global services is the application of the multiple procedure payment reduction policy. This policy applies to multiple surgeries performed by a single physician or same group practice on the same patient at the same operative session or on the same day. The MPPR pays at 100 percent of the fee schedule amount for the highest valued procedure, 50 percent for the second highest valued procedure, 25 percent for the third through fifth highest valued procedures, and “by report” for six or more procedures. The vast majority of the efficiency between multiple surgeries is due to the overlap of bundled E/M services between the surgeries. **Continuing to apply the same reduction percentage to the procedure component of the 10- and 90-day global code alone would inappropriately reduce the payment for second and subsequent surgical services.**

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Other items and services

CMS is also interested in stakeholder input on what other items and services related to the surgery, aside from postoperative visits, are furnished to beneficiaries during post-operative care. As the practice of medicine evolves and CMS recognizes codes to capture collaboration of care for other specialties, we urge CMS to also recognize the collaborative work performed by surgeons (such as extensive collaboration with primary care), which is not captured in the global surgical package. As an example, if a patient were referred to a surgeon for colon or rectal cancer, the surgeon, for the majority of these patients, coordinates radiation and medical oncology appointments, coordinates preoperative imaging, and arranges for the patient to be presented to the Multidisciplinary Tumor Board after all imaging is performed. The surgeon explains all the images and laboratory tests and the intended therapy for the colon surgery and the timing of surgery after neoadjuvant therapy for rectal cancer. The surgeon also coordinates with a stomal therapy nurse, who is employed by the hospital, to meet with the patient and discuss management of an ostomy. Post-operatively, the surgeon works closely with the case manager for home health to discuss wound care and, if required, ostomy care with nursing visits and physical therapy. The surgeon also coordinates with the medical oncologist to ensure that patients follow up with that specialist. This is just one example of a case where a surgeon would provide a substantial amount of collaborative care that is not valued in the global surgical package. **We urge CMS to acknowledge this extra work that surgeons provide and to consider ways to include this work in the global code.**

As described in the example above, surgeons also perform transitional care management (TCM); however, TCM codes (99495 and 99496) cannot be billed in combination with a global code. **We urge CMS to allow surgeons to report 99495 and 99496 along with a global procedure when appropriate transitional care is delivered to the Medicare patient, as a way to properly and fairly account for this additional work.** In addition to collaborative care and transitional care, surgeons engage in advance care planning, which is not included in global codes. When a surgeon discusses a potential major surgical procedure with a patient prior to surgery or discusses the results following surgery within the global period (for example if a non-resectable tumor was found during surgery), there is a strong likelihood that the conversation will include advance care planning and advance directives, so we ask that these

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services be allowed to be billed in conjunction with global procedures, when appropriate and documented.

Improving Payment Accuracy for Primary Care and Care Management Services

Improved Payment for the Professional Work of Care Management Services

CMS seeks specific comments on ways to recognize the different resources, particularly cognitive work, involved in delivering comprehensive, coordinated care management beyond those resources involved in the current codes. CMS is particularly interested in codes that could be used in addition to, not instead of, the current E/M codes. CMS notes that such add-on codes would require an established relationship between the patient and the billing professional. CMS also notes that the add-on codes might apply broadly to patients in a number of different circumstances and they would not make reporting the codes contingent on a particular business model or technology. CMS anticipates developing potential proposals to address these issues through 2016 rulemaking for implementation in 2017.

The work of comprehensive and coordinated care management services pertains to many surgeons. Surgeons spend substantial time working toward optimal outcomes for patients with chronic conditions and patients they treat episodically, which often involve additional work not reflected in current codes. As outlined in the examples above and below, this work includes coordination of care among physicians, collaboration with team members, continuous development and modification of care plans, and patient or caregiver education. Surgeons working in more rural communities, in particular, deliver comprehensive and primary care-focused services due to a lack of providers and other resources. **The ACS urges CMS to allow surgeons to bill for these services, as appropriate, in addition to “primary care and other cognitive specialties.”**

Establishing Separate Payment for Collaborative Care

CMS believes that care management for Medicare beneficiaries with multiple chronic conditions can require extensive discussion, information-sharing and planning between a primary care physician and a specialist. CMS seeks comments on ways to more accurately account for the resource costs of a more robust interpersonal consultation involved in care coordination for patients

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requiring more extensive care. CMS anticipates developing proposals to address these issues through 2016 rulemaking for implementation in 2017.

Multidisciplinary coordination of care is key and essential to the work of surgeons and this is readily apparent with cancer patients and trauma patients. For example, a breast cancer patient may present with an undetermined diagnosis and the surgeon will coordinate with radiologists for pre-operative imaging and pathologists for review of clinical information and the development of a diagnosis. Once a tissue diagnosis is made, the surgeon coordinates a treatment plan that includes appropriately timing the various treatment modalities and arranging relevant consultations that will assist with patient-centered care and decision making. This may include multi-disciplinary tumor board reviews, arranging for genetic testing, social services, emotional and nutritional support, and directed education. Referrals to radiation oncologists, medical oncologists, and plastic and reconstructive surgeons are made. The patient will then return to discuss with the surgeon, consultant recommendations, additional imaging results, and/or her response to neoadjuvant therapy; the surgeon subsequently arranges for surgical care. The surgeon will coordinate with a plastic surgeon prior to definitive surgery to discuss immediate versus delayed reconstruction, potential symmetry surgery and impact on lifestyle, as well as projected return to employment and pre-diagnosis functional level. The surgeon coordinates with the radiation oncologist to ensure that the plan is acceptable and appropriately timed with the patient's surgical recovery and adjuvant chemotherapy requirements as indicated. Ongoing surgical follow-up care entails monitoring patient response to physical therapy or decompressive therapy for lymphedema, and ordering restorative prosthetics. Surgeons determine the correct sequence of the above activities, in conjunction with other specialists.

To cite another example, trauma patients who present in some of the most severe of circumstances rely on the trauma surgeon to be their coordinator of care. The trauma surgeon works closely with Anesthesia and other surgical specialties to ensure that the neurosurgical, orthopedic, craniofacial, urological, and other subspecialty injuries are appropriately addressed. The trauma surgeon coordinates the timing of all activities and procedures to ensure that the most critical injuries are swiftly addressed, while those that can wait are addressed in a timely fashion. During hospitalization and stabilization of the

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patient, the trauma surgeon also coordinates with physical therapists, occupational therapists, speech therapists, psychologists, inpatient pharmacists, dietitians, and other hospital allied health providers to ensure that the patient's recovery is optimized. Additionally, trauma surgeons often coordinate with the legal system and social services as a component of ongoing patient advocacy.

As evidenced by the above examples, general surgeons and other surgical specialists participate extensively in interpersonal consultation and care management activities for their patients, and the ACS urges CMS to recognize this work and allow surgeons to bill for these services, as appropriate.

Target for Relative Value Adjustments for Misvalued Services

PAMA established an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under this provision, if the estimated net reduction in expenditures for a year is equal to or greater than the target for the year, then these adjustments would be redistributed in a budget-neutral manner within the PFS. If net reduction in expenditure is greater than the target, then the difference is applied to the next year for purposes of meeting that year's target. On the other hand, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, then the amount equal to the target recapture amount or the difference between the target and the amount of expenditures reduced would not be applied in a budget-neutral manner. PAMA applied a 0.5 percent target for reductions for 2017 through 2020 under the PFS. These target amounts were subsequently revised by the Achieving a Better Life Experience Act of 2014 (ABLE), which accelerated the application of the PFS expenditure reduction target to 2016, 2017, and 2018, and set a 1 percent target for 2016 and 0.5 percent target for 2017 and 2018. CMS proposes a methodology to implement this statutory provision and seeks comment on all aspects of its proposal.

Distinguishing "Misvalued Code" Adjustments from Other RVU Adjustments

CMS believes the best approach to identifying a subset of misvalued code adjustments in RVUs for a year to reflect an estimated "net reduction," is to include the estimated pool of all services with revised input values. This would limit the pool of RVU adjustments to those services for which individual,

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comprehensive review or broader proposed adjustments resulted in changes to service-level inputs of work RVUs, direct PE inputs, or PLI RVUs, as well as services directly affected by changes to coding for related services. **Individual components of the PFS (i.e., work, PE, and PLI) have been reviewed as potentially misvalued, and therefore, we agree with the proposal to use total RVU changes and / or individual component RVU changes when considering codes to include in calculating the net reduction in expenditures.**

CMS also proposes to use three years of change to determine “net” reduction:

- Year 1 = current value
- Year 2 = interim final value
- Year 3 = final value

For CY 2016, CMS proposes to exclude code-level input changes for all potentially misvalued codes that were interim final in CY 2015 (i.e., Year 2 to Year 3 change) and only include 309 codes that will be listed as interim final for CY 2016 (i.e., Year 1 to Year 2 change). This transition period proposal to include this set of approximately 309 codes identified in the proposed rule (and we assume any interim codes included in the final rule) is necessary because CMS must identify a subset of the adjustments in RVUs for “one year” to reflect an estimated “net reduction” in expenditures.

We appreciate the thorough consideration given to this process through the transition years and agree with the methodology proposed by CMS. **However, we disagree with some of the codes CMS proposes for inclusion as misvalued codes, for the purposes of the 1 percent target reduction in misvalued services. To improve transparency, CMS should also publish the criteria it uses for identifying codes for the calculation of the annual target.**

New technology codes 21811-21813 (rib fracture fixation) should not be included as misvalued codes for net reduction calculations. These three codes were never part of any potentially misvalued consideration and instead are the result of transitioning Category III codes (0245T-0248T) to Category I status per a request by industry stakeholders. We do agree, however, that three other rib fracture treatment codes (21800, 21805, 21810) were identified as potentially misvalued and were submitted for deletion. This action was

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completely independent of the industry requested Category I status for new technology codes and none of these three deleted Category I codes were referred to the new technology codes. **Therefore, codes 21811, 21812 and 21813 should not be included in the list of codes defined as misvalued for the target; however codes 21800, 21805, and 21810 should be included in the list.**

Similarly, codes 46601 and 46607 (high resolution anoscopy) were transitioned from Category III codes (0226T and 0227T) to Category I codes after literature became available to meet Category I requirements. These two new codes had no relevance to any potentially misvalued codes. **Therefore, codes 46601 and 46607 should not be included on the list of codes defined as misvalued for the target.**

Finally, advance care planning codes 99497 and 99498 were new codes for CY 2015 and are, for the first time in CY 2016, being proposed for payment. It is impossible for these codes to be potentially misvalued, and therefore, **codes 99497 and 99498 should be removed from the list of codes defined as misvalued for the target because they are new codes not previously valued.**

Measuring the Adjustments

CMS notes that code-level PE RVUs and PLI RVUs can increase or decrease due to redistribution from other services and that the value for all RVUs (work, PE, and PLI) will be adjusted through annual adjustments to the conversion factor. CMS simulated two approaches for measuring net reduction using prior PFS years: one approach compared changes before applying any scaling factors or neutrality adjustments and a second approach compared changes after applying scaling factors and adjustments. CMS found that both approaches generally resulted in similar estimated net reductions. CMS is proposing to calculate net reduction using only codes identified as potentially misvalued for the target, as follows:

$$\text{Net Reduction} = \frac{(\text{Total RVUs*utilization})_{\text{update year}} - (\text{Total RVUs*utilization})_{\text{current year}}}{(\text{Total RVUs*utilization})_{\text{current year}}}$$

CMS seeks comment on whether comparing the update year's work RVUs, direct PE RVUs, indirect PE RVUs, and PLI RVUs for the relevant set of codes (by volume) prior to the application of any scaling factors or adjustments

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for the current year would be a preferable methodology for determining the estimated net reduction.

We believe the intent of the law is to show net reduction in total RVUs after scaling and adjustments are made. This is a more straightforward approach and will be easier for stakeholders to replicate. We also agree that using volume (RVU*utilization) is more appropriate than using value (or price) that takes into account changes to the conversion factor, as the latter creates potential circularity.

Estimating the Target for CY 2016

CY 2016 is a transition year for estimating a target. Codes with RUC recommendations submitted by February 10, 2015 were published as interim final in this proposed rule and will be final for the final rule. Codes with recommendations submitted after February 10, 2015 (i.e., codes reviewed at the April 2015 RUC meeting) will be considered interim final in the final rule. In future years, all codes will be considered interim final in the proposed rule of the subsequent year and final in the final rule of the subsequent year. CMS notes that it cannot calculate a realistic estimate of the CY 2016 target amount in this proposed rule because of the significant number of codes that will be interim final in the final rule. However, CMS estimates that the net reduction is approximately 0.25 percent for the codes defined as misvalued for target in this proposed rule.

We appreciate the difficulty in calculating a realistic estimate of the CY 2016 target through transition years. **We advocate against using calculations for changes in time or visits for any codes where the global period has also changed (e.g., from 90-day to 0-day or 90-day to ZZZ) because work RVUs are based on magnitude estimation and not a calculation of time and visit components.**

Phase-in of Significant RVU Reductions

PAMA specifies that for services that are not new or revised codes, applicable adjustments in work, PE, and PLI RVUs shall be phased-in over a 2-year period if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. The ABLE Act requires that the phase-in begin in 2016 rather than 2017. CMS also proposes to estimate whether a particular code meets the

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20 percent threshold for change in total RVUs of a particular component (e.g., PE RVUs).

We agree that for most of the codes identified, the difference between with and without phase-in is minor in terms of RVUs. However, for codes with very expensive supplies, a 19 percent reduction will still significantly overpay for the supplies of the procedures for one more year. The RUC and many societies have suggested several times that high dollar supplies (e.g. over \$500) should be separately reportable. **The ACS believes it is appropriate to exclude from this phase-in provision, any code that has a decrease of over 20 percent due to repricing of expensive supplies (e.g. over \$500).**

Valuation of Specific Codes

CY 2016 Valuation of Specific Codes

CMS reviewed the RUC recommendations for work RVUs and direct PE inputs for new, revised, and potentially misvalued codes. All proposed values are subject to public comment. Table 13 contains CMS' refinements to the RUC's direct PE recommendations. CMS notes that for each refinement, they indicate the impact on direct costs for that service; in any case where the impact on the direct cost for a particular refinement is \$0.32 or less, the refinement has no impact on the final PE RVUs. CMS notes that nearly half of the refinements listed in Table 13 result in changes under this \$0.32 threshold.

Code 46500, clinical staff facility

We disagree with the proposed refinement of pre-service clinical staff time for the facility setting as indicated in the table below. The fact that code 46500 is rarely performed in the facility setting is rationale enough that these patients are "different" and will require more than standard 10-day global pre-service clinical staff work. Patients that cannot be treated in an office setting will typically require special care and more than local anesthesia. For example, learning impaired adults or patients with physical disabilities will require special equipment and/or sedation.

We urge CMS to recognize that there is a special population that will require this service in a facility and this will require clinical staff pre-service time. We request that CMS accept the RUC recommended clinical staff pre-service minutes.

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Input Code	Input code description	N F/ F	Labor Activity (where applicable)	RUC Rec or current value	CMS Refinement	CMS Comment
L037D	RN/LPN /MTA	F	Complete pre-service diagnostic and referral forms	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility
L037D	RN/LPN /MTA	F	Coordinate pre-surgery services	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility
L037D	RN/LPN /MTA	F	Follow-up phone calls and prescriptions	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility
L037D	RN/LPN /MTA	F	Schedule space and equipment in facility	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility

Code 46500, clinical staff for scope set up

We disagree with the proposed refinement of clinical staff time related to setting up endoscopy equipment for code 46500 as indicated in the table below. The standard two minutes allotted for “preparing room, equipment, supplies” is related to the two minutes allotted for stand-alone E/M services that require minimal work to set up the exam table, lay out patient gown, and confirm exam supplies are available. These two minutes do not include the additional time to set up anoscopy equipment that is utilized on the day of the procedure and at follow up visits.

The intra-service work description indicates that: *Visual inspection is performed through the anoscope, rotating as needed, to identify all hemorrhoids. Fecal matter is removed with suction as needed. Each hemorrhoid is injected at the superior pole, the submucosa in the central part, the mucous lamina propria*



in the central part and the submucosa at the inferior pole of hemorrhoid. At the end of the exam, the anoscope is removed.

The post-operative office visit work description indicates that: *At return visit, anoscopic exam is performed to determine effectiveness of treatment. In addition, because the treatment is meant to cause necrosis, it is important to monitor for infection or sepsis.*

Diagnostic anoscopy is performed both on the day of the procedure and at the follow-up visit and is not separately reportable. Although this is well understood by surgeons who perform 46500, CPT 2016 will add instructional guidelines that state: *Do not report 46600 in conjunction with 46020-46942, 0184T, 0249T, 0377T during the same operative session.*

Input Code	Input code description	N F/ F	Labor Activity (where applicable)	RUC Rec or current value	CMS Refinement	CMS Comment
L037 D	RN/LP N/MTA	N F	Setup scope (non facility setting only)	5	0	Included in clinical labor task "Prepare room, equipment, supplies"
L037 D	RN/LP N/MTA	N F	Setup scope at POV	5	0	Included in clinical labor task "Clean room, equipment, and supplies" included in post-operative visit
L037 D	RN/LP N/MTA	F	Setup scope at POV	5	0	Included in clinical labor task "Prepare room, equipment, supplies" included in post-operative visit

We urge CMS to recognize this additional work and request that CMS accept the RUC recommended clinical staff minutes for setting up endoscopic equipment.

Code 46500, clinical staff and supplies for scope cleaning

We disagree with the proposed refinement of clinical staff time and supplies related to cleaning endoscopy equipment for code 46500 as indicated in the table below. The standard three minutes allotted for "clean room, equipment, supplies" is related to the three minutes allotted for stand-alone E/M services



that require minimal work to clean up the exam table, exam room counters, and dispose of exam supplies such as thermometer/otoscope covers and gloves. These three minutes do not include the additional time to clean endoscopic equipment. Code 46500 includes diagnostic endoscopy as inherent. The post-operative office visit will also require a diagnostic anoscopy, which cannot be separately reported.

The RUC and CMS have agreed to standards for cleaning endoscopy equipment; 5 minutes for a disposable scope; 10 minutes for a rigid scope, and 30 minutes for a flexible scope. Although the anoscopy equipment is typically not disposable and is rigid, the RUC (and CMS) have determined that anoscopy cleaning will only require 5 minutes. This is an example of specialized work that is required in addition to work described for a stand-alone E/M services.

Cleaning of the equipment is an important step to prevent cross contamination of bacteria or viruses between patients. *Anoscope cleaning instructions:* Using a soft bristle brush, scrub the item submerged in the cleaning solution for a minimum of 5 minutes then rinse with sterile water for 5 minutes. *Light handle cleaning instructions:* Prepare an enzymatic detergent formulated for endoscopic instruments. Submerge the rectal light handle outer sleeve in the cleaning solution. Using a soft bristle brush, scrub the item submerged in the cleaning solution for a minimum of 5 minutes then rinse with sterile water for 5 minutes. Wet the rectal light handle body and cord with the cleaning solution. Using a soft bristle brush, scrub the cord with the cleaning solution for a minimum of 5 minutes then rinse the cord with sterile water for 5 minutes. *Power cord cleaning instructions:* Prepare an enzymatic detergent formulated for endoscopic instruments. Wet the cord with the cleaning solution. Using a soft bristle brush, scrub the cord with the cleaning solution for a minimum of 5 minutes then rinse the cord with sterile water for 5 minutes.³

We urge CMS to recognize this additional work and request that CMS accept the RUC recommended clinical staff minutes supplies for cleaning endoscopic equipment.

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http://intl.welchallyn.com/documents/Endoscopy/Cleaning_Instructions_20100224_Endo_Faxable_English_only.pdf.



Input Code	Input code description	N F/ F	Labor Activity (where applicable)	RUC Rec or current value	CMS Refinement	CMS Comment
L037D	RN/LPN/MT A	N F	Clean scope	5	0	Included in clinical labor task "Clean room, equipment, and supplies"
L037D	RN/LPN/MT A	N F	Cleaning scope at POV	5	0	Included in clinical labor task "Clean room, equipment, and supplies" included in post-operative visit
L037D	RN/LPN/MT A	F	Cleaning scope at POV	5	0	Included in clinical labor task "Clean room, equipment, and supplies" included in post-operative visit
SA042	pack, cleaning and disinfecting, endoscope	N F		2	0	Removed supply associated with equipment item not typically used in this service

Code 46500, equipment time

We disagree with the proposed refinement of time for equipment item ES002 for code 46500 as indicated in the table below. **We request that CMS reinstate the endoscopy equipment set up and cleaning time should be reinstated.**

Input Code	Input code description	N F / F	Labor Activity (where applicable)	RUC Rec or current value	CMS Refinement	CMS Comment
ES002	anoscope with light source	N F		78	60	Refined equipment time to conform to established policies for non-highly technical equipment



Codes 46601 and 46607, equipment time

We disagree with the proposed refinement of time for equipment items EF031 for codes 46601 and 46607 as indicated in the table below. CMS has basically subtracted the time related to greeting/gowning, obtaining vital signs, and providing education/obtain consent. Once the patient is gowned, they are in the procedure room where the power table resides. These patients are not “held” in other rooms sitting in a chair or standing in the hallway for these activities. Nor is the power table moved out of the room and used somewhere else while these activities are being performed.

Input Code	Input code description	N F/ F	Labor Activity (where applicable)	RUC Rec or current value	CMS Refinement	CMS Comment
EF031	table, power	N F		41	33	Refined equipment time to conform to established policies for non-highly technical equipment
EF031	table, power	N F		49	38	Refined equipment time to conform to established policies for non-highly technical equipment

We request that CMS reinstate the RUC recommended time for EF031 for these two codes.

Gastrointestinal (GI) Endoscopy (CPT codes 44380-45391)

In the CY 2014 PFS final rule with comment period, CMS agreed with the RUC in applying an “incremental difference methodology” in valuing the upper GI codes. For this proposed rule, CMS also used this methodology but did not accept the RUC recommendations for several codes.

CPT Code 45378: CMS utilized the RUC recommended incremental difference of 1.10 work RVUs between code 45378 (diagnostic colonoscopy) and code 43235 (diagnostic esophagogastroduodenoscopy), but applied this difference to the CMS proposed work RVU for code 43235 (not the RUC recommendation) to calculate a proposed work RVU value of 3.29 for code



45378. We disagree with the RUC recommendation of 3.36 work RVUs for code 45378 and also disagree with the CMS proposed work RVU of 3.29. We urge CMS to accept 3.51 work RVUs as a correct value for CPT code 45378 and as the base code value for the colonoscopy family of codes.

Code 45378 was reviewed by the RUC twice prior to the recent survey. Our multispecialty expert panel⁴ agrees that total physician work for this service has not decreased since the 2005 RUC review. The previous survey included the physician work related to administration of moderate sedation in the intra-service period. For all gastrointestinal endoscopy services reviewed by the RUC since 2012, administration time for moderate sedation has been moved from intra-service to pre-service time. We noted on our RUC Summary of Recommendation form (which was submitted to CMS) that when the previous intra-service time is adjusted for the movement of moderate sedation from intra-time to pre-service time, the current intra-service time is consistent with the intra-service time in the 2005 Five-Year review.

CMS' proposed value based on the RUC recommended difference of 1.10 work RVUs between 43235 and 45378 is an artificial factor. The RUC never compared these two codes during its review and in fact, the work RVU difference between these two codes for 20 years has been over 1.30 work RVUs. There is no rationale for reducing the incremental difference between these codes. In fact, if the recommended work RVU of 3.51 was accepted, the differential that was established by CMS and has been in place for over 20 years, would be maintained.

It is also important to note that since this procedure was last surveyed, there has been a change in technology and guidelines which has impacted the intensity of work. Changes in the multi-society task force recommendations on colorectal cancer (CRC) surveillance intervals based on polyp anatomy, morphology, and number have been impacted by the movement from fiberoptic to video endoscopic systems with high-definition viewing screens, which has improved the ability of the endoscopist to examine the mucosa and identify pre-malignant lesions, such as flat adenomas. Thus, the current survey validates the previous review and valuation, with a reduction in RVW to account for the movement of moderate sedation and changes to the pre-service package.

⁴ Includes the ACS, SAGES, ASCRS, AGA, ACG, and ASGE.

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CRC is the second leading cause of cancer-related deaths in the United States. More than 140,000 new cases of CRC are diagnosed in the United States, with more than 50,000 deaths from the disease each year.⁵ Experts believe that more than half of the annual deaths are preventable. Of those diagnosed with CRC, at least two-thirds are Medicare-eligible. In addition to the pain, suffering, and death, the economic costs of CRC treatment are staggering. The annual expenditure for CRC was estimated at \$14 billion by the National Institutes of Health in 2010. That same year, Medicare spent an estimated \$7.4 billion dollars on CRC treatment, which is 85 percent of the National Cancer Institute's estimate for expenditures for those 65 and over.⁶

Colonoscopy is a life-saving procedure. Data recently published in *The New England Journal of Medicine* provide some of the clearest evidence that colonoscopy has advantages over sigmoidoscopy for the prevention of CRC.⁷ Researchers followed 88,902 study participants for 22 years and found that 1,815 developed CRC. Forty percent of those cancers could have been prevented if all of the patients in the study had received colonoscopy, and colonoscopy was associated with reduced death from cancer in the proximal colon.³ A study published in 2012 highlights the ability to reduce CRC deaths through polyp detection and removal, underscoring the value of colonoscopy and polypectomy.⁸ Following removal of adenomatous polyps during colonoscopy, a 53 percent reduction in CRC deaths was reported compared to the risk in the general population.⁴

An estimated 14.2 million screening, diagnostic, and therapeutic colonoscopies are performed annually in the United States and 1.6 million of these procedures are for screening.⁹ While work, time, and effort for colonoscopy is based on average-risk patients receiving a routine test, colonoscopy often identifies multiple, large, and/or flat polyps which are challenging to identify, and require greater time, effort, and skill to remove.

⁵ <http://www.cancer.org/research/cancerfactsfigures/cancerfactsfigures/cancer-facts-figures-2013>

⁶ <http://costprojections.cancer.gov/>

⁷ Nishihara R, Wu K, Lochhead MB, et al. Long-Term Colorectal-Cancer Incidence and Mortality after Lower Endoscopy. *N Engl J Med* 2013;369:1095-105.

⁸ Zauber AG, Winawer SJ, O'Brien MJ, et al. Colonoscopic polypectomy and long-term prevention of colorectal-cancer deaths. *N Engl J Med* 2012;366:687-96.

⁹ Seeff LC, Richards, TB, Shaprio JA, et.al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. *Gastroenterology* 2004; 127(6):1670-7.

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The incidence of CRC has been declining in the United States since 1985, and the rate of decline increased in 2001, coincident with the beginning of Medicare coverage for screening colonoscopy.^{10,11,12} Much of the decline in CRC incidence and mortality is directly attributable to the widespread use of colonoscopy in the United States.^{6,7,8} Colonoscopy screening is a unique service because it can both detect and resect precancerous lesions,⁴ reducing CRC incidence and mortality.¹³ Despite research showing that CRC screening saves lives, a November 2013 Centers for Disease Control and Prevention (CDC) Vital Signs report found that 23 million adults in the United States have not had the recommended screening. Experts believe that more lives could be saved each year with more awareness and screening.

Screening with colonoscopy translates into Medicare savings of \$15 billion, greater than the savings achieved with a stool blood testing model.¹⁴ The Lewin Group, in collaboration with the National Colorectal Cancer Roundtable established by the American Cancer Society and the CDC, developed a cost model that explored how increased CRC screening among pre-Medicare individuals (aged 50-64 years) could translate into Medicare savings through earlier detection and treatment, specifically polypectomy and treatment of early stage cancer. The model, published in 2007, concluded that the earlier regular screening begins, the greater the benefit to Medicare.

Colonoscopy has significant value to both patients and society. **In an era of value-based reimbursement, de-valuing a service of such high value for CRC prevention carries the significant risk of adversely affecting access and quality of care to Medicare beneficiaries.** We must continue to encourage safe, high quality, meticulous inspection of the colonic mucosa,

¹⁰ Edwards BK, Ward E, Kohler BA, et al. Annual report to the nation on the status of cancer, 1975-2006, featuring colorectal cancer trends and impact of interventions (risk factors, screening, and treatment) to reduce future rates. *Cancer* 2010;116:544-73.

¹¹ Myer PA, Mannalithara A, Singh G, Ladabaum U. Proximal and distal colorectal cancer resection rates in the United States since widespread screening by colonoscopy. *Gastroenterology* 2012;143:1227-36.

¹² Cheng L, Eng C, Nieman LZ, Kapadia AS, Du XL. Trends in colorectal cancer incidence by anatomic site and disease stage in the United States from 1976 to 2005. *American journal of clinical oncology* 2011;34:573-80.

¹³ Kahi CJ, Imperiale TF, Juliar BE, Rex DK. Effect of screening colonoscopy on colorectal cancer incidence and mortality. *Clin Gastroenterol Hepatol* 2009;7:770-5.

¹⁴ Dobson A, Sen N. Methodology for Estimating the Potential Cost Savings to Medicare from Increased Colorectal Cancer Screening of the Pre-Medicare Population. <http://nccrt.org/wp-content/plugins/download-monitor/download.php?id=42>. Accessed December 31, 2013.

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which demonstrates the established value of colonoscopy for the prevention of CRC and the associated suffering and cost of preventable CRC.

Our recommended work RVU of 3.51 reflects an adjustment to the current work RVU of 3.69 to account for less pre-service time compared with the pre-service time from the 2005 RUC review, and the movement of the time for administration of moderate sedation from intra-service to pre-service time. This work RVU results in the same intra-operative intensity as the previous value, in support that work has not changed.

CPT	SOURCE	RVW	Total time	EVAL	POSIT	SDW	INTRA	POST
45378	2005 survey data with 5 min moved from intra-time to pre-time to account for change in reporting moderate sedation	3.69	75	25	5	5	25	15
45378	2013 survey data with Pre-time pkg 1B	3.51	67	19	3	5	25	15

Recommended RVW 3.51	=	Current RVW 3.69	-	Evaluation difference x intensity [(25 min – 19 min)*0.0224]	-	Positioning x intensity [(5 min – 3 min)*0.0224]
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Both the RUC and CMS have utilized this methodology of using assigned pre- and immediate post-time intensities (i.e., 0.0224) to reduce an RVW when there is a reduction in pre and/or post-service time (e.g., for overlap with concurrent E/M service).

We urge CMS to accept 3.51 work RVUs as a correct value for CPT code 45378 and as the base code value for the colonoscopy family of codes. In conjunction with the recommendation above, we request that all family and related codes be adjusted using 3.51 work RVUs as the base and then add in the appropriate increment.



Incomplete Colonoscopy (CPT codes 44388, 45378, G0105, and G0121)

For CY 2015, the definition of an incomplete colonoscopy will change from the scope not passing the splenic flexure to not reaching the cecum. In recognition of the more resource intensive work described by the new definition, CMS proposes to value codes 44388, 45378, G0105, and G0121 when reported with modifier 53 at 50 percent of the values for the complete procedures. **We agree with CMS' proposal to value an incomplete colonoscopy at 50 percent of the value for the complete procedure.**

CMS is also seeking comment on how to address the disparity of resource costs for incomplete colonoscopies that do not pass the splenic flexure. They believe it may be appropriate for practitioners to report sigmoidoscopy.

The "Colonoscopy Decision Tree" in CPT 2015 already indicates that CPT code 45330 (*flexible sigmoidoscopy*) should be reported if the endoscope does not pass the splenic flexure for patients undergoing diagnostic colonoscopy. However, as CMS points out, there may be a disparity between the resource costs for patients undergoing a planned diagnostic colonoscopy versus a planned flexible sigmoidoscopy; most notably related to sedation. Patients undergoing colonoscopy will require moderate sedation, while minimal sedation is used for those undergoing flexible sigmoidoscopy. The physician work for pre-service evaluation and initiation of moderate sedation will not be accounted for if code 45330 is reported. **We request that CMS keep this question open as the RUC continues to work on the valuation and reporting of moderate sedation.**

In addition, CMS is asking for information regarding the number of colonoscopies that will be considered incomplete under the new CPT definition.

The change in definition for an incomplete colonoscopy has been effective since January 1, 2015. Therefore, the percentage of all diagnostic colonoscopies reported with modifier 53 in the most current 2015 utilization file should provide a reasonable estimate of the percentage of colonoscopies that will be considered incomplete under the new CPT definition.

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Malpractice (MP) Crosswalk (CPT codes 43775, 44407, 44408, 46601 and 46607)

CMS notes that the RUC-recommended PLI crosswalks for CPT codes 43775, 44407, 44408, 46601 and 46607 are inconsistent with CMS' analysis of the specialties likely to furnish these services. CMS proposes using a specialty mix derived from the claims data of the predecessor codes and when claims data with the new codes is available to incorporate this information into the calculation of the PLI RVUs for these services.

Code 43775 has been a CPT Category I code since 2010. The 2014 Medicare utilization for this code is over 9,000 and information regarding the specialty mix is available. For this code, we suggest that CMS use these data for calculation of PLI RVUs, with the caveat that specialties that are inconsistent with CMS' analysis of the specialties likely to furnish this service are deleted. We are most concerned with the almost 2 percent of claims for 2014 reported by general practice providers.

Similarly, codes 46601 and 46607 are not new codes. These codes were previously reported by CPT Category III codes 0226T and 0227T, for which there are Medicare claims data. In addition, CMS should have eight months of data for the CPT Category I codes for 2015 for all five codes that would help identify the specialty mix for calculation of PLI RVUs.

Advance Care Planning

CMS proposes to recognize and provide separate payment for CPT codes 99497 and 99498, two codes describing advance care planning services. CMS also proposes to adopt the RUC-recommended values for these codes. The ACS notes that general surgeons, amongst other types of physicians, currently engage in advanced care planning discussions. **The ACS supports assigning these advance care planning codes a status indicator of "A" (active code) and urges CMS to allow surgeons to use these codes, in addition to billing for the global surgical codes.** There are many situations where it is necessary for the surgeon to discuss advance care planning with the patient prior to performing a surgical procedure.

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Laparoscopic Lymphadenectomy (CPT Codes 38570, 38571 and 38572)

CMS agrees with the RUC work RVU decreases for 38571 and 38572, but does not agree with maintaining the value for 38570, *Lap retroperitoneal lymph node biopsy*. The agency proposes to reduce the work RVU for 38570 to 8.49 to reflect the ratio of the reduction in total time and to maintain rank order among the three codes.

We disagree with the proposed reduction in the work RVU for code 38570 from 9.34 to 8.49. CMS states this reduction was calculated to reflect the ratio of the reduction in total time. The current total time for 38570 is 242 minutes. The new survey time is greater (not less) at 280 minutes. In addition, there currently are no hospital visits included in work time details for this inpatient procedure. The survey data now correctly include a hospital visit and discharge visit for this service that is typically inpatient. In addition, the post-operative follow up visits are now correctly at a higher level. Although the survey showed a decrease in intra-time, the RUC determined this was offset by the addition of significant post-operative hospital work and correction of office visits. **We urge CMS to review the RUC submission and maintain the current value for 38570 at 9.34 work RVUs.**

Hemorrhoid(s) Injection (CPT Code 46500)

CMS disagrees with the RUC recommendation to maintain the current value for code 46500. CMS notes a significant decrease in work times and proposes to decrease the work RVU from 1.69 to 1.42 by the same ratio as the reduction in total time.

CMS discussion of this code in this proposed rule is not complete. On the RUC Summary of Recommendation form (that was submitted to CMS), it was noted that intra-time for code 46500 is Harvard-based and that it is not clear if the Harvard estimated intra-time included time for applying and waiting for the effect of anesthesia since there were no Harvard definitions for intra-work other than “skin-to-skin.” Therefore, it is possible that the intra-work included local anesthesia work that is currently reported as pre-service work. We also noted that the pre- and post-times were predicted and not surveyed during the Harvard study. The RUC presentation and documentation noted that the Harvard work RVU and work times resulted in an intensity of 0.019 and that maintaining the current work RVU with corrections to time and visits resulted

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in nearly the same intensity (0.018). The CMS proposed work RVU of 1.42 is not valid as it dismisses the evidence and discussion presented at the RUC and submitted to CMS and results in a negative intensity of -0.009. **We urge CMS to review the RUC submission and maintain the current value for 46500 at 1.69 work RVUs.**

The CMS proposed work RVU of 1.42 is not valid as it dismisses the evidence and discussion presented at the RUC and submitted to CMS and results in a negative intensity of -0.009. **We urge CMS to review the RUC submission and maintain the current value for 46500 at 1.69 work RVUs.**

CMS also proposes to delete the direct PE inputs related to cleaning the anoscope based on the rationale that the scope is disposable.

The PE recommendation submitted to CMS does not include a disposable anoscope, but instead, the equipment item ES002, *anoscope with light source* is included. This equipment item would typically be in a colorectal surgeon's practice. We refer CMS to our comments above regarding refinement of direct practice expense inputs where we provide information about the set-up and cleaning of anoscopy equipment. We request that CMS maintain the equipment item and equipment set-up and cleaning time and supplies as recommended by the RUC.

OTHER PROVISIONS OF THE PROPOSED REGULATIONS

Physician Compare Website

Timeline and Selection of Publicly Reported Data

CMS reports on the progress of public reporting and reconfirms its goal of reporting performance data across all reporting mechanisms (including Qualified Clinical Data Registries (QCDRs)) and for all size groups and individual practitioners by late 2016 based on 2015 data.

As finalized last year, CMS will only make available to the public measures that prove to be:

- Valid, reliable, and accurate upon analysis (discussed in the 2015 rule);
- Deemed statistically comparable;
- Meet a minimum sample size of 20 patients;

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- Are not first year measures

Not all of these data would necessarily be posted on a physician or group practice's profile page, but rather in a downloadable data file. CMS' analysis of these data, along with consumer testing and stakeholder feedback, will determine which measures are published on physician profile pages.

The ACS supports efforts to provide consumers with tools to make them better healthcare decision-makers. We also appreciate the steps CMS is taking to ensure that only accurate and meaningful data are made available to the public. However, we continue to have concerns about CMS' rapid timeline for releasing these data and fear that if they are released too prematurely and without adequate testing, it could mislead and confuse the public and even inappropriately harm the reputation of physicians. As such, **we urge CMS to apply the aforementioned criteria very carefully and thoughtfully and to work closely with professional societies and their clinical experts throughout this process.** Transparency is also key and to date, we know little about the extent to which CMS has conducted consumer testing and if consumers are even turning to the site for health care decision-making. Furthermore, **we urge CMS to release data incrementally in order to give CMS and the public a chance to learn from and improve upon the underlying measures data and reporting formats before further expanding the publicly reported data set.** A gradual release of data will also ensure that consumers are not overwhelmed and confused by an abundance of unnecessary information.

In regards to minimum thresholds for reporting performance data on Physician Compare, the ACS requests that CMS increase the 20 patient minimum to at least 30 patients. A higher threshold will help to ensure that the validity of the data is not compromised and that performance scores are meaningful to both physicians and consumers.

CMS clarifies that it will make most of the data it deems suitable for public reporting available through a downloadable data file geared towards health care professionals, industry insiders, and researchers who are more able to accurately use more complex data. Only select data will be deemed appropriate for consumers and actually posted on a physician's profile page. CMS' analysis of the data, along with consumer testing and stakeholder feedback, will determine specifically which measures are published on physician profile

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pages versus the database. **While the ACS supports transparency, we recommend against making performance data available through a downloadable database.** If measure data prove to be too complex for posting on physician profile pages, they are likely also not suitable for posting in a raw data file. Furthermore, giving the general public access to this data could result in widely variable interpretations of the data and even misuse by industry insiders, including payers, attorneys and watchdog groups. In the end, research or other “report cards” issued by these stakeholders could further confuse or misinform consumers.

The ACS also recommends that CMS re-examine its policy to exclude first year measures from public reporting. While we appreciate this policy, **we are concerned that QCDRs might not be ready for public reporting beyond a measure’s first year.** Since QCDRs have the flexibility to determine the manner in which they publicly report their own data, it is important that they are given the same opportunity as CMS to conduct careful analyses regarding the validity, reliability, and accuracy of measures data, as well as utility to consumers. QCDRs may need more than one year to conduct these analyses and to develop evidence-informed benchmarks that make measures data suitable for public consumption. QCDRs also need time to gain experience with collecting and reporting data to CMS and resolving any inaccuracies in the data before releasing data to the public. This issue recently came to light when CMS announced that it had identified multiple errors and inaccuracies related to the Performance Year (PY) 2014 submission data. As a result, CMS cannot use these data to determine quality performance and/or establish benchmarks for the 2014 reporting year.

In general, as CMS transitions to more widespread reporting of physician performance data on Physician Compare it is critical that it improve current explanations regarding the data, descriptions about calculations and benchmarks, and disclaimers about the limitations of the data. Since CMS plans to only display performance data for select measures that it feels are ready for public reporting, it is important that CMS also add language to the Physician Compare site explaining why certain professionals might not yet have performance data that is suitable for public reporting and that this is not a reflection of the level of their quality. CMS will also need to continuously evaluate and update these data in a transparent manner and based on physician input and consumer testing. CMS must work with all relevant stakeholders to

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find a balance between full transparency and not overwhelming or confusing the public.

Value Modifier Indicators

As early as late 2017 based on 2016 data, CMS proposes to include a green check mark on individual and group practice profile pages who received an upward adjustment as a result of the Value Modifier (VM). This check mark would indicate that a physician achieved one of the following: higher quality care at a lower cost; higher quality care at an average cost; or average quality care at a lower cost. Currently, CMS uses a green check mark on physician profile pages only to indicate which quality programs reporting requirements have been satisfied.

CMS also proposes to add to the Physician Compare *downloadable database* (but not the individual profile pages) which will include the 2018 VM quality tiers for cost and quality, based on the 2016 data, for group practices and individual eligible professionals (EPs). The database would indicate if the group practice or EP is high, low, or average on cost and quality per the VM. CMS also proposes to include a notation of the payment adjustment received based on the cost and quality tiers, and an indication if the individual EP or group practice was eligible but did not report quality measures to CMS.

The ACS remains concerned about the relevancy of the quality and cost measures used to calculate the VM, the ongoing disconnect between what is being measured on the quality side and cost side of the equation, and the inadequacy of the program's attribution and risk adjustment methodologies. In regards to the disconnect, CMS relies on PQRS measures to calculate a portion of the quality composite, which focuses on very specific procedures or services (e.g., such as discontinuation of prophylactic antibiotics) while the cost measures are broad and evaluate total costs (i.e., total per capita costs, as well as the cost of services performed during an episode that comprises the period immediately prior to, during, and following a patient's hospital stay). **Given our ongoing concerns, the ACS opposes any effort to provide the public with information about VM adjustments or tiers, regardless of whether this information is posted on physician profile pages or a downloadable database.**

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Without significant changes, which are not proposed in this rule, the VM remains a poor proxy for value, and we do not believe that providing this information to the public will assist consumers in any meaningful way with healthcare choices. As we mentioned earlier, this simply increases the chance of data being misused by members of the public. **We recommend that CMS continue to provide these data confidentially to physicians so that they can help CMS to refine these measures and methodologies going forward.** We also recommend that CMS work with professional societies, such as ACS, to identify examples of where the cost and quality measure disconnect is most problematic and to how to resolve those disconnects so that patients can make a better informed value judgment about physicians. For example, a surgeon may have excellent quality metrics, but live in a community of high cost co-providers who have excessive use of unwarranted imaging. Under the current VM program, these costs could be inappropriately attributed to the surgeon and impact their payment adjustment.

Benchmarking

In addition, CMS proposes to apply a measure-level benchmarking methodology known as the Achievable Benchmark of Care (ABC™) to publicly reported PQRS measures. CMS claims this is a well-tested, data driven model that evaluates who the top performers are, and then uses that to set a point of comparison for all of those groups or individual EPs who report the same measure. Under the ABC methodology, a benchmark for a measure or item is calculated as the performance score among the subset of top performers (EPs or groups, as appropriate for the measure) that account for 10 percent of the patient population. The performance score would equal the total number of patients among the top performers receiving the intervention/desired level of care/desired outcome assessed under the measure divided by the total number of all patients measured by these top performers. The methodology includes adjustments to account for low denominators and CMS notes that it is designed to account for all the data collected for a quality measure in the benchmark. In contrast, PQRS measures have been historically (and are currently) reported as a percentage of the time an EP satisfies a given PQRS measure.

CMS also proposes to use this benchmark to assign stars for the Physician Compare 5 star rating. Currently, for select measures reported by group practice reporting option (GPRO) (Diabetes Mellitus and CAD), CMS displays

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quality measure scores using stars, where each star represents 20 percentage points. But these stars simply represent how each group practice performed on a measure (e.g. if a group practice performed the appropriate care process 80 percent of the time, it receives four fully-filled stars). They are not currently used as a rating or ranking system because they do not benchmark group practices against each other.

While the ACS appreciates CMS' efforts to put performance data into context so that it is more useful for both consumers and physicians, we have multiple concerns and questions about the ABC methodology's ability to accomplish this goal. For one, we seek clarity regarding the ABC methodology's benchmark, which is based on the mean of the best performers on a given measure representing at least 10 percent of the patient population. Specifically, how was validity and reliability determined for the best performers across all PQRS measures? Does the 10 percent cut point represent statistically significant differences in performance and account for the strength of adequate confidence intervals? We also seek further clarity on how the cut point of 10 percent was determined—does this indicate that the 10 percent includes the minimum value for inclusion as a “best performer,” and all other EPs would otherwise be penalized with a poor rating?

The ACS is also unsure to what extent the ABC methodology would adequately account for patient mix and ensure apples-to-apples comparisons of physician performance. Unlike cost measures used under the VM, there are currently no adjustments applied to PQRS quality measures to account for the specialty mix of those reporting the measure. CMS simply compares performance across any and all physicians who report the same measure, regardless of their specialty, practice setting, or patient mix. When calculating performance benchmarks, it is critical that CMS account for the varying circumstances of physicians who may choose to report the same measure, including their specialty (and sometimes even their subspecialty, such as in the case of trauma vs. non-trauma surgeons), patient mix, practice setting, and the care/procedure they are actually providing. Since these are not simple tasks, **we recommend that CMS begin by testing benchmarking methodologies on measures for which there is little variability in the patient population to which the measure applies and the physicians who report the measure. Another alternative would be for CMS to initially focus only on individual physician or group practice self-improvement over time rather than**

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attempting to solve all of these issues associated with more complex benchmarks that attempt to compare performance across a potentially diverse population of providers.

Fundamentally, our concern is that this is a strategic decision without a determination of what the correct proxy for quality should be across all PQRS measures within the Medicare population. **ACS agrees that CMS should have a high target for quality improvement. However, it is important to note that even with high validity and reliability, ACS supports methods to incentivize providers to improve, not penalize providers with poor performance ratings on Physician Compare.**

Additionally, it is also unclear to what extent the ABC benchmarking methodology aligns with the benchmarking methodology used for Quality and Resource Use Reports (QRURs) and VM calculations. CMS seems to employ multiple, distinct methodologies for identifying poor performers across its federal quality programs—whether it be programs targeting physicians or programs affecting other settings (Hospital-Acquired Condition Reduction Program, Hospital Value-Based Purchasing Program, etc.). **To ensure that these methodologies are easily understood by physicians and the public, CMS should aim to use consistent methodologies across programs to the greatest extent possible.** This alignment is especially important for Physician Compare and the VM/QRURs, which rely on the same PQRS quality measures. In situations where CMS feels it is necessary to adopt an alternative methodology, it should at least clearly explain the differences and the reasons for that decision.

In regards to translating these benchmarks into a 5-star rating system, ACS supports efforts to make performance data more digestible for consumers, but warns against over simplifying the data. If the underlying benchmarks are flawed, a 5-star rating system could result in arbitrary cut offs that do not necessarily represent significant differences in performance. **We recommend that CMS proceed cautiously down this path by applying the 5 star rating system to only select measures and studying them carefully before expanding it to other measures.** CMS should also keep in mind that a star rating system might only be appropriate for certain measures, and not others. It is also important that CMS provide clear explanations to the public about how to interpret the star ratings.

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Finally, regardless of what benchmarking approach CMS ultimately adopts for traditional PQRs measures, **it is very important that CMS preserve the freedom it has afforded to QCDRs up until this point to determine the best mechanism for benchmarking and publicly reporting its own measure data, which may differ from CMS' methodology.**

Utilization Data

As required under MACRA, beginning with 2016, CMS would also make utilization data available to the public (i.e., counts of services/procedures provided to Medicare beneficiaries and generated from Medicare Part B claims). The ACS appreciates that CMS acknowledges that these data are less immediately useable in their raw form by the average consumer and that they are not appropriate for posting on physician profile pages. However, we reiterate our concerns about CMS' proposal to make these data available to the general public through a downloadable database. **We again request that CMS instead limit the release of this data to professional societies, which can work with researchers to determine the most appropriate use(s).**

Preview Period

While CMS is not proposing any changes to its 30-day preview period, the **ACS recommends that CMS offer physicians at least 60 days to review data prior to its publication on Physician Compare.** Physicians are currently inundated with information related to quality reporting program requirements and feedback. With these competing demands and the concerns highlighted earlier, 30 days is simply too short of a time period for physicians to access reports, review their data, identify any potential errors or other misinformation, and gather the evidence needed to refute erroneous data. A 60-day period would also align with the informal review submission period that CMS offers physicians following the release of QRURs for determinations related to the 2016 VM.

Potential Future Proposals

CMS also seeks feedback on potential future proposals related to Physician Compare, including the posting of Open Payments data on individual EP profile pages, as well as stratifying publicly reported measure data by race, ethnicity, and gender or posting other types of measures that monitor trends in health equity. On the first issue, CMS is already required to make data

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detailing the financial relationships between drug and device manufacturers and health care providers available to the public. However, **we believe it would be inappropriate and misleading to post Open Payments data alongside data that is supposed to reflect the “quality” of physician care.** We strongly urge CMS to keep the Open Payments data separate and not post it on Physician Compare.

In regards to the second issue, ACS supports efforts to ensure more accurate and actionable data, including stratifying publicly reported data, where appropriate. However, we remind CMS that we still do not have a sufficient foundation of robust quality data across all specialties. Therefore, **stratifying at this point in time might over-dilute the data and result in sample sizes that are insufficient for public reporting.**

Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

Proposed Changes Related to Qualified Clinical Data Registries (QCDRs)

In this rule, CMS proposes multiple modifications to the requirements for becoming a QCDR.

Self-Nomination Requirements

The ACS appreciates CMS’ attempt to give QCDRs more time to self-nominate by opening the nomination period a month earlier (i.e., December 1 through January 31). We also appreciate CMS’ proposal to require that an entity be in existence as of January 1 of the year for which the entity seeks to become a QCDR rather than the year prior to. This provides more flexibility and provides a wider variety of registries in various stages of implementation the opportunity to become a QCDR.

Nevertheless, we are concerned about CMS’ proposal to move up the date by which an entity must submit all documents to CMS for purposes of being considered a qualified QCDR to no later than January 31 of the reporting year. Under current policy, vendors have until March 31 to provide CMS with such information. Documentation includes, but is not limited to, submission of the vendor’s data validation plan as well as the measure specifications for the non-PQRS measures the entity intends to report. Under this latest proposal, after the entity submits this information on January 31, it cannot later change any of the

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information it submitted for purposes of qualification (e.g., it cannot later modify the measures specifications the entity submitted). However, CMS could still request supplemental information from the entity after this date. Getting this documentation in order by January 31 could be a challenge, especially for entities that are applying to become a QCDR for the first time or entities that have decided to submit new measures. Many QCDRs used the first three months of 2015 to ask CMS important questions about the QCDR requirements and the adequacy of their measures and methodologies before submitting their final nomination. **We request that CMS preserve this important opportunity by maintaining the March 31 deadline.**

Group Practice Reporting via QCDR

The ACS has previously urged CMS to recognize group practice reporting via a QCDR. As such, we are pleased that MACRA includes language requiring CMS to create an option for EPs participating in the GPRO to report quality measures via a QCDR. In accordance with this mandate, CMS proposes that QCDRs have the ability to submit quality measure data for group practices, in addition to individuals, starting in 2016. **The ACS supports permitting group practices to report via QCDRs and believes it will provide physicians with a greater choice of options when selecting PQRS reporting mechanisms.**

QCDR Data Reporting Criteria

Although CMS is not proposing any changes to the reporting criterion for EPs using QCDRs in 2016 (i.e., 9 measures, including 2 outcomes measures, for at least 50 percent of all applicable Medicare and non-Medicare patients), the ACS reminds CMS of its concerns that the 50 percent requirement may pose too large of a reporting burden than what is truly necessary to ensure a valid and reliable reporting sample. The appropriate size of a sample will vary based on the type of clinical procedure and what is actually being measured. The ACS has always sought to strengthen data reliability and validity through adequate registry design and appropriate sample size. By using a robust validation strategy and regular audits to verify the rigor of the data, the ACS has been able to maintain highly effective measurement in its registries using less than 50 percent of patients in the sample. As such, **we request that QCDRs have the flexibility to determine, on a case-by-case basis, what is the most appropriate sample size to produce a statistically valid sample of patients.**

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We also request that CMS permit QCDRs to report on PQRS and non-PQRS measures groups. EPs who use qualified registries are currently able to report on a single measures group rather than individual measures. We urge CMS to extend this policy to QCDRs and to maintain the requirement that EPs report on one measures group for a twenty patient sample over the twelve-month reporting period. Allowing QCDRs to report on measures groups would be less burdensome and would also align two PQRS reporting options for specialty EPs and provide them with a greater choice of potentially relevant PQRS reporting options.

The ACS recognizes the value of larger sample sizes measured over longer periods of time. However, the main purpose of QCDRs is to provide EPs who were previously unable to participate in a meaningful manner with an opportunity to report more relevant measures. At this early stage, achieving highly reliable data is a secondary goal. We stand ready to work with CMS to find ways to arrive at an alternative reporting mechanism that achieves a high sample size with minimal burden (e.g., automated data flow).

The Consumer Assessment of Healthcare Providers Survey (CAHPS) for PQRS

Currently, group practices of 100 or more participating in GPRO under any reporting mechanism must also use and bear the cost of a CMS-certified survey vendor to report the CAHPS for PQRS survey to CMS. For the 2016 reporting year, groups with 25 or more that register for the GPRO Web Interface would also have to report CAHPS for PQRS measures. The ACS appreciates CMS' recognition of the fact that groups reporting through other GPRO reporting mechanisms (e.g., registry, EHR) are more likely to be highly specialized and that the CAHPS for PQRS is likely not relevant to them. **As such, we support CMS' proposal to exclude certain GPRO reporting mechanisms from this requirement.**

However, the ACS continues to urge CMS to consider including the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey measure (S-CAHPS) as an individual, voluntary PQRS measure. CMS acknowledges in this rule that the CAHPS for PQRS does not accurately reflect the care provided by single- or multispecialty surgical or anesthesia groups. The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality, which are important from the patient's perspective and for which the patient is the best source of information. We remind CMS that the

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National Quality Forum (NQF) Measure Applications Partnership (MAP) recommended the inclusion of S-CAHPS in PQRS for two consecutive years, starting in 2013, yet CMS still continues to claim that it is not technically feasible to include the S-CAHPS measure in PQRS. We do not believe this delay is in the best interest of the surgical patient.

The surgery community has invested considerable resources to develop, test, and shepherd the measure through NQF-endorsement to ensure that surgical patients have a mechanism to accurately capture their care experience. Furthermore, the S-CAHPS has broad support across surgical specialties—the S-CAHPS Technical Advisory Panel (TAP) included 21 members from various specialty societies, and nine surgical specialties participated in the main field test conducted during the development of the survey, which included colon and rectal, ophthalmology, general surgery, orthopaedic, plastic surgery, otolaryngology, thoracic, urology, and vascular. Since the S-CAHPS follows the same collection mechanism as the CG-CAHPS, we strongly encourage CMS to prioritize the time and resources needed to include the S-CAHPS as a PQRS measure. The ACS continues to offer to assist CMS to any extent possible to implement this valid instrument of the surgical patient's voice.

New PQRS Measures Proposed for 2016

The ACS appreciates CMS' proposal to add a considerable number of measures to the 2016 PQRS measures set that might be applicable to our members. However, we still feel it is important to track gap analyses within surgical specialties (e.g., surgical oncologists pediatric surgeons, breast surgeons, bariatric surgeons, otolaryngologists, urologists, transplant surgeons, trauma surgeons, and rural surgeons). CMS has done a lot to close this gap, but it is still something CMS and/or the Measures Application Partnership should monitor closely.

Potential Future Policies

CMS intends to require the collection of quality data, stratified by race, ethnicity, sex, primary language and disability status, within each of the PQRS reporting mechanisms. CMS seeks comments on facilitators and obstacles to collecting and reporting these attributes. As previously noted, the ACS supports adjustments to data that make them more meaningful and actionable for both consumers and physicians. However, we are concerned that the

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underlying foundation of PQRS data is not yet robust enough to stratify by all of these factors. **As CMS determines how best to stratify, we request that it keep in mind the unique limitations of each PQRS reporting mechanism, which might make it difficult to collect this information.** For example, claims data might not adequately capture the breadth of socio-demographic factors that CMS would like to account for. And while a clinical data registry might have more flexibility to customize its data points, doing so could create an additional data collection burden on participants if the registry cannot easily extract this additional information from an EHR or other source due to lack of interoperability or uniformity of data definitions.

Value-Based Payment Modifier and Physician Feedback Program

Payment Adjustments

For the 2018 payment year (based on 2016 reporting) CMS will continue its two-category approach where groups and solo practitioners who do not satisfy PQRS fall into Category 2 and receive automatic cuts in addition to PQRS penalties. Those who do satisfy PQRS would fall into Category 1 and would be subject to performance based payment adjustments under CMS' quality tiering approach. Unlike in 2015, where groups with 2-9 EPs and solo practitioners are held harmless from downward adjustments, *all groups and solo practitioners* would be subject to upward, neutral, or *downward* adjustments derived under the quality-tiering methodology in 2016. The maximum payment at risk under Category 1 would be -4 percent for groups with 10 or more EPs and -2 percent for groups with between 2 to 9 EPs and physician solo practitioners. The automatic penalty under Category 2 would be structured similarly, with groups of 10 or more EPs subject to a -4 percent penalty and groups with 2-9 EPs and solo practitioners subject to a -2 percent penalty for non-compliance with PQRS.

The ACS appreciates that CMS is not proposing to raise the ceiling on potential penalties under this program. Nevertheless, **we have serious ongoing concerns about the appropriateness of the measures and methodologies used to calculate the VM and request that CMS continue to hold smaller groups of physicians and solo practitioners harmless from downward adjustments since this cohort has the greatest chance of receiving an inaccurate “value” determination under this program.**

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CMS also proposes to modify the “50 percent rule” that it applies under the VM. Under current policy, CMS looks at groups that *did not register for the PQRS GPRO* to see if at least 50 percent of a group’s individuals satisfied PQRS. In this case, the group would not be subject to an automatic downward adjustment under the VM. In this rule, CMS proposes to apply this 50 percent rule even in cases where a group practice did register for GPRO, but still failed to satisfy PQRS. **The ACS supports modifying the 50 percent rule since it would assist EPs who might experience difficulty reporting through the mechanism they had originally chosen at the time of PQRS GPRO registration due to issues outside their control** (e.g., a group registered for the EHR reporting mechanism and was subsequently informed that their EHR vendor could not support submission of data).

Quality/Cost Measures

CMS proposes no changes to the set of quality or cost measures currently used to calculate the VM. However, CMS is proposing to increase the minimum number of attributed episodes needed for CMS to include the Medicare Spending Per Beneficiary measure in the cost composite from 20 to 100 episodes. In the past, ACS has voiced concern about this measure holding physicians accountable for care decisions beyond their control. We therefore appreciate CMS’ attempt to minimize the inappropriate application of this measures. However, **we request that CMS employ a 200 case minimum for the MSPB measure to further ensure that physicians are not erroneously held accountable for this measure.** A 200 case minimum also aligns with the case minimum used for the all-cause hospital readmission measure evaluated under the VM’s quality composite. **We also request that CMS hold harmless from downward payment adjustments any EP or group practice for which CMS is unable to calculate a cost score due to an insufficient number of attributed patients under this measure.** These EPs should not be penalized for failing to meet the minimum sample size of patients needed to ensure high reliability for this measure.

The ACS has ongoing concerns with CMS’ continued reliance on broad cost measures, which assess the total amount billed per patient and not the treatment of the individual provider. While holding physicians accountable for spending may be appropriate, in some instances, for achieving better overall value, these general metrics incorrectly assume that physicians have

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control over the care plan and treatment decisions of other physicians who might have also treated a patient over the reporting period. It is critical that each physician caring for a patient to understand how he/she contributed to the patient's total cost of care, but it is not necessarily appropriate to hold each of these physicians *accountable* for the patient's *total* cost of care. Doing so could have unintended consequences, such as skimping on care or patient access issues that result from physicians choosing to avoid high risk patients.

Furthermore, **it is critical that cost measures have a more direct link to the quality measures used to assess value.** The current set of cost measures has little to no relevance to the more condition/procedure-specific quality measures used to calculate the value modifier. If quality and cost measures focus on different elements of care, they should not be used to make determinations about overall value. We also would like to point out the difficulty that our members have had trying to understand the relevance of the three outcome indicators that CMS automatically calculates as part of the VM's quality composite. Because this is done automatically and without sufficient explanation from CMS, it is difficult to determine the accuracy of these calculations.

For all of these reasons, we ideally would like to see CMS use the current set of cost and non-PQRS quality measures for educational purposes only (i.e., via confidential feedback reports). **Physicians should not be held accountable for cost performance, in particular, until CMS has developed and carefully tested more focused episode-based cost measures that more accurately evaluate care over which a physician has control and allow for more equal comparisons of patient populations.** The ACS is very involved in this work and looks forward to assisting CMS with the implementation of more specialty-specific episode-based cost measures.

Benchmarks under the VM

CMS also proposes to separately benchmark the PQRS *electronic* clinical quality measures (eCQMs) beginning with the CY 2018 VM. Currently, CMS calculates a case-weighted mean of a measure's prior year's performance rates inclusive of ALL PQRS reporting mechanisms for the measure. **The ACS supports CMS' proposal to separately benchmark eCQMs based on the fact that measures are typically calculated differently when collected via EHR versus via other reporting mechanisms (such as claims or registries)**

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and often include private payer data.

Although CMS does not propose any other specific changes to the benchmarking methodology used to determine physician performance under the VM, it cites the following previously finalized policy: “Once we have historical data from measures submitted via QCDRs, the benchmark for quality of care measures will be the national mean for the measure’s performance rate during the year prior to the performance period (79 FR 67956).” The ACS was under the impression that QCDRs would have the flexibility to develop their own performance benchmarks so long as the methodology is able to compare the quality of care an EP provides to his or her patients to other EPs performing the same or similar functions. However, the language in the rule seems to indicate that CMS will automatically use a national mean to determine QCDR participant performance. We therefore **request that CMS provide clarification on how it will use QCDR data to calculate performance-based payment adjustments under the VM.**

We are further confused by the fact that CMS seems to be proposing in this rule a separate benchmarking methodology (i.e., the ABC methodology) for quality measure reported via Physician Compare. This methodology sets a benchmark that represents the best care provided to the top 10 percent of patients, which appears to be different than the national mean performance on a measure. As we noted earlier, these are the same measures, yet it appears that they will be benchmarked differently under the VM (and in QRURs) versus when publicly reported on Physician Compare.

We reiterate our request that CMS employ consistent benchmarking methodologies across programs, especially programs that rely on the same measures. It is confusing and inappropriate to analyze the same quality measure data using one method for a physician’s confidential QRUR (and for subsequent payment determinations) and using another method for public reports.

Informal Inquiry Process

CMS proposes to continue the approach of the initial corrections process to classify a TIN as “average quality” in the event it determines CMS or a third-party vendor made an error in the calculation of the quality composite. CMS proposes to continue this policy for the CY 2017 payment adjustment and

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future adjustment periods or until such a time that the operational infrastructure is in place to allow the re-computation of data. We caution CMS about over-reliance on this automatic “average quality” designation since it may not accurately reflect the quality of truly high performers and may penalize physicians for errors that might have been outside of their control. For example, if a physician is average or low cost, an average quality designation would result in a lower or no bonus payment versus if a physician received a high quality designation, which would result in a bonus payment. **In situations where CMS cannot determine the quality or cost of a physician, it should exempt the physician from the VM program altogether and hold them harmless from any downward payment adjustments.**

Potential Future Policies

In response to public concerns that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost measures for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries, CMS is seeking feedback, but not making any proposals at this time, on potential future approaches. One option would be to stratify the cost measure benchmarks so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with similar risk profiles. We support efforts to stratify cost measures so that comparisons could be made between physicians whose patients have similar risk profiles. However, we oppose CMS’ efforts to make improvements to the total per capita cost measure since this measure is fundamentally flawed. We believe that **CMS should instead spend its time and resources on developing more specific episode-based cost measures, which will help ensure more fair comparisons and alleviate the need for many of the complex adjustments to data that are required when looking at total per capita costs.**

In this section, CMS reminds the public that starting this year, VM cost measures are adjusted to account for the specialty makeup of the group and the fact that certain specialties might routinely treat more complex and consequently more costly beneficiaries. For the last two years, ACS has raised concerns about these adjustments not sufficiently accounting for certain subspecialties. For example, trauma surgeons are more expensive than non-trauma general surgeons, but would be compared with non-trauma general

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surgeons under the VM. **The ACS suggests that CMS develop better ways to account for the specialty of the physician.** One recommendation would be to identify the top 15 codes that specialists within a specialty bill and create additional benchmarks if needed within a specialty.

Quality and Resource Use Reports (QRURs)

The accuracy, format, and usability of these reports has never been more important now that all physicians will receive payment adjustments based on these data. While the ACS appreciates CMS' efforts to refine these reports and enhance the timeliness and frequency of their distribution, **we continue to question the utility of these tools given the fact that very few of the underlying measures are relevant or meaningful to a surgeon and the calculations are often perceived as highly flawed.** As mentioned, we are strong proponents of and actively engaged in efforts to develop more specific episode-based cost measures. These measures should more accurately capture costs over which surgeons have direct control provide and provide surgeons with a better understanding and appreciation for the cost of their care. As this work proceeds, the ACS urges CMS to keep in mind that each episode should be treated as a unique situation, with potentially different parameters depending on the specific condition or procedure.

Provisions Related to the Medicare Access and CHIP Reauthorization Act (MACRA)

Merit-based Incentive Payment System (MIPS)

MIPS is applicable beginning with payments for items and services furnished on or after January 1, 2019. In this rule CMS seeks input on multiple provisions of the legislation to guide future policymaking.

Low-Volume threshold

CMS is required to select a low-volume threshold to apply for purposes of excluding certain EPs from the definition of a MIPS EP. CMS seeks comment on what would be an appropriate low-volume threshold for purposes of excluding certain EPs. As we noted previously, we recognize that to get at truly reliable outcomes data we need a very high sample size. However, **we ask CMS to keep in mind that the sample size needs may vary depending on the situation.** In the initial years of MIPS, the main goal will be to get

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physicians to participate in a meaningful manner and not necessarily to show differences in clinically reliable data. Therefore, lower standards may be appropriate to encourage participation in MIPS.

Clinical Practice Improvement Activities

CMS seeks comments on what activities could be classified as clinical practice improvement activities under MIPS. The ACS is currently working through the most appropriate activities that surgeons should be recognized for under this category and plans to submit more detailed comments in response to CMS' future RFI. However, we believe that the process by which physicians demonstrate compliance with Clinical Practice Improvement Activities should be as simple as possible to minimize the reporting burden and to reflect the broad diversity of activities that should be recognized under this category. **We recommend that CMS adopt a simple attestation process, potentially through an online form that physicians already must submit to CMS.**

Alternative Payment Models (APMs)

The statutory amendments related to APMs have payment implications beginning in 2019. In this rule, CMS is broadly seeking comment on: the criteria for assessing physician-focused payment models; the criteria and process for the submission of physician-focused payment models eligible APMs, qualifying APM participants; the Medicare payment threshold option and the combination all-payer and Medicare payment threshold option for qualifying and partial qualifying APM participants; the time period to use to calculate eligibility for qualifying and partial-qualifying APM participants, eligible APM entities, quality measures and EHR use requirements; and the definition of nominal financial risk for eligible APM entities.

The ACS reminds CMS of the challenge that this policy will pose for many surgical specialties that have not yet had a chance to develop or test APMs. Much of the work to date has focused on models that are relevant to primary care or non-acute care. The other challenge to keep in mind is that the more focused the payment model and the more discrete the payment bundle, the more difficult it will be for a physician to meet the revenue threshold for becoming a qualified APM participant.

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Physician Self-Referral Updates

Assistance to Employ a Nonphysician Practitioner

CMS proposes a new limited exception for hospitals, Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs) to provide remuneration to a physician to assist with the employment of a non-physician practitioner (NPP) in a geographic area served by the hospital, FQCH, or RHC (hereinafter referred to collectively as “hospital”). This proposed exception would protect both direct compensation arrangements between the hospital and an individual physician and indirect compensation arrangements between the hospital and a physician “standing in the shoes” of a physician organization to which the hospital provided remuneration. The exception would apply for NPPs who furnish only primary care services, and specialty care services would not be protected.

While it is not clear how CMS is defining primary care services of an NPP relative to the services being provided by the physician employer, we urge CMS to extend this exception to arrangements where hospitals provide remuneration to physicians providing specialty care who employ NPPs. Given that NPPs do not have a specialty designation, it is not always clear whether they are providing primary care, specialty care, or primary care services related to physician provided specialty care. But most importantly, we do not believe that CMS should use the physician self-referral statute to support a particular specialty over another. This law is intended to govern self-referral for Medicare and Medicaid patients. The exceptions to the self-referral statute were created to protect certain compensation arrangements that do not pose a risk of Medicare program abuse. In this case, expanding the exception to cover employment of NPPs who provide services in the context of a specialty physician practice poses no risk of program abuse. For these reasons, we urge CMS to expand this exception to apply to NPPs who might be considered to be providing specialty care.

New Exception for Timeshare Arrangements

CMS also proposes a new arrangement for timeshare agreements. Under a timeshare agreement, a hospital or local physician practice may ask a specialist from a neighboring community to provide specialty services in a space owned by the hospital or practice on a limited basis. We appreciate that CMS has

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recognized the need for these agreements and that they support specialists who would like to provide services in rural areas that cannot maintain a full time specialists. As such, we support this new exception.

We appreciate the opportunity to comment on this proposed rule. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Ollapally, Regulatory Affairs Manager in the ACS Division of Advocacy and Health Policy. She may be reached at vollapally@facs.org or at (202) 672-1510.

Sincerely,

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