



September 6, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Comments on the Physician Fee Schedule and Other Revisions to Part B for CY 2017 (CMS-1654-P)

Dear Acting Administrator Slavitt:

The American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), and the American Society for Gastrointestinal Endoscopy (ASGE) appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1654-P), published on July 15, 2016 in the *Federal Register*, regarding the proposed policy revisions to the 2017 Medicare Physician Fee Schedule (PFS). Our three societies represent virtually all practicing gastroenterologists in the United States.

There are a number of provisions in the proposed rule that impact practicing gastroenterologists and the Medicare beneficiaries they treat. We offer comments in the following areas:

- Moderate Sedation
- Technical Corrections to Direct Practice Expense (PE) Input Database
- Standardization of Clinical Labor Tasks and Equipment for Scope Systems
- Direct PE Inputs for Procedures Involving Endoscopes
- Target for Relative Value Adjustments for Misvalued Services
- Esophagogastric Fundoplasty, Transoral Approach (CPT Code 43210)
- Refinement Panel
- Phase-In of Significant RVU Reductions
- Improving Payment Accuracy for Primary Care, Care Management, and Patient-Centered Services

- Appropriate Use Criteria for Advanced Diagnostic Imaging

PROPOSED VALUATION OF SERVICES WHERE MODERATE SEDATION IS AN INHERENT PART OF THE PROCEDURE AND PROPOSED VALUATION OF MODERATE SEDATION SERVICES

Moderate Sedation Code GMMM1 Physician Work RVUs

We thank CMS for taking into consideration the survey data from various specialties regarding the work involved in furnishing moderate sedation services by the same physician performing the procedure, as described by CPT code 991X2. The survey data showed a significant bimodal distribution between endoscopic procedural services furnished by gastroenterologists and surgeons and non-endoscopic procedures provided by other specialties. We appreciate the proposal by CMS to create a new HCPCS code, GMMM1, to be used for certain gastrointestinal (GI) endoscopy-specific moderate sedation services in lieu of code 991X2. We also appreciate the proposal to value GMMM1 at 0.10 wRVUs, which is consistent with the physician work survey data which our societies presented to the RUC and to CMS.

GMMM1 Moderate sedation services provided by the same physician or other qualified health-care professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient age 5 years or older.

However, we are concerned that, as CMS has recognized, there is a difference in moderate sedation by the same professional for endoscopic and non-endoscopic services. Specifically, we respectfully submit that using the survey data from gastroenterologists in the valuation of both GMMM1 and 991X2 is inappropriate, causes a mis-valuation of 991X2, and will lead to a loss of relativity between the two procedures. We respectfully ask CMS to reconsider its decision to include the survey data from gastroenterologists in the valuation of 991X2.

We are also concerned about the rationale to exclude esophageal dilation codes and biliary endoscopy specifically endoscopic retrograde cholangiopancreatography (ERCP) procedures from reporting with GMMM1 and to instead report these procedures using code 991X2. The procedures in question are:

- 43450 Dilation of esophagus, by unguided sound or bougie, single or multiple passes
- 43453 Dilation of esophagus, over guide wire
- 43260 Endoscopic retrograde cholangiopancreatography (ERCP); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
- 43261 Endoscopic retrograde cholangiopancreatography (ERCP); with biopsy, single or multiple

- 43262 Endoscopic retrograde cholangiopancreatography (ERCP); with sphincterotomy/papillotomy
- 43263 Endoscopic retrograde cholangiopancreatography (ERCP); with pressure measurement of sphincter of Oddi
- 43264 Endoscopic retrograde cholangiopancreatography (ERCP); with removal of calculi/debris from biliary/pancreatic duct(s)
- 43265 Endoscopic retrograde cholangiopancreatography (ERCP); with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)
- 43273 Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s) (List separately in addition to code(s) for primary procedure)
- 43274 Endoscopic retrograde cholangiopancreatography (ERCP); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent
- 43275 Endoscopic retrograde cholangiopancreatography (ERCP); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)
- 43276 Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged
- 43277 Endoscopic retrograde cholangiopancreatography (ERCP); with trans-endoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct
- 43278 Endoscopic retrograde cholangiopancreatography (ERCP); with ablation of tumor(s), polyp(s), or other lesion(s), including pre- and post-dilation and guide wire passage, when performed

During the multi-year review of more than 120 GI endoscopic procedures, and on the occasion when the physician work of moderate sedation for GI endoscopic procedures was presented to the RUC, we note that all GI endoscopy procedures were treated equally. Neither ERCP nor esophageal dilation procedures were excluded from the moderate sedation survey. In the proposed rule, CMS did not cite any survey data or other rationale in support of the appraisal that the physician work involved in providing moderate sedation for esophageal dilation or biliary endoscopy procedures by the same individual is different than the physician work of the endoscopist in providing moderate sedation for other GI endoscopic and esophageal dilation services. Therefore, we strongly urge CMS to include the esophageal dilation and ERCP procedures listed above as appropriate to report using GMMM1.

Moderate Sedation Practice Expense

CMS has proposed the following moderate practice expense (PE) inputs for moderate sedation:

Moderate Sedation Equipment

EF018	Stretcher
EF027	table, instrument, mobile
EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)
EQ032	IV infusion pump

We note that the stretcher (EF018) and mobile instrument table (EF027) are part of the underlying procedure and not specific to moderate sedation monitoring. Removing these items from the underlying procedure would impact the PE for endoscopic services provided in the non-facility setting. As endoscopic services are performed with the patient in the prone position, the stretcher (EF018) must be part of the PE of the endoscopic service. We respectfully inform CMS that even if a patient undergoes endoscopy or esophageal dilation without sedation, the accreditation and state regulatory standards of office-based surgical practice include the requirement for the patient to receive monitoring using ECG, 3-channel (with SpO2, NIBP, temp, resp) (EQ011) or equivalent, which needs to reside on the EF027 table, instrument, mobile. For these patient safety and procedure performance reasons, PE inputs EF018, EQ011 and EF027 should remain in the PE for the endoscopic procedure.

The equipment time for the stretcher (EF018) was calculated using total service period clinical labor time, which includes the following inputs. The highlighted inputs are those associated with moderate sedation. It would be appropriate to assign the associated times for the (yellow) highlighted tasks to moderate sedation while keeping the associated staff time and PE for the stretcher in the underlying procedure.

Service Period Clinical Labor Time Inputs for EF018

Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA
Obtain vital signs	L037D	RN/LPN/MTA
Provide pre-service education/obtain consent	L037D	RN/LPN/MTA
Prepare room, equipment, supplies	L037D	RN/LPN/MTA
Setup scope (non-facility setting only)	L037D	RN/LPN/MTA
Prepare and position patient	L037D	RN/LPN/MTA
Sedate/apply anesthesia	L037D	RN/LPN/MTA
*Other Clinical Activity - specify: Review History, systems and medications	L037D	RN/LPN/MTA

Assist physician in performing procedure	L037D	RN/LPN/MTA
Monitor pt. following service/check tubes, monitors, drains	L051A	RN
Clean room/equipment by physician staff	L037D	RN/LPN/MTA
Clean Scope	L037D	RN/LPN/MTA

The equipment time for the mobile instrument table (EF027) was calculated using the following inputs. The highlighted inputs are associated with moderate sedation. It would be appropriate to assign the associated times for the (yellow) highlighted tasks to moderate sedation while keeping the associated staff time and PE for the table in the underlying procedure.

Clinical Labor Time Inputs for EF027

Obtain vital signs	L037D	RN/LPN/MTA
Provide pre-service education/obtain consent	L037D	RN/LPN/MTA
Prepare room, equipment, supplies	L037D	RN/LPN/MTA
Prepare and position patient	L037D	RN/LPN/MTA
Sedate/apply anesthesia	L051A	RN
Assist physician/moderate sedation (% of physician time)	L051A	RN
Monitor pt. following service/check tubes, monitors, drains	L051A	RN

The equipment time for ECG, 3-channel (with SpO2, NIBP, temp, resp) (EQ011) was calculated using the following inputs. The highlighted inputs are associated with moderate sedation. It would be appropriate to assign the associated times for the (yellow) highlighted tasks to moderate sedation while keeping the associated staff time and PE for the ECG in the underlying procedure.

Clinical Labor Time Inputs for EQ011

Obtain vital signs	L037D	RN/LPN/MTA
Provide pre-service education/obtain consent	L037D	RN/LPN/MTA
Prepare room, equipment, supplies	L037D	RN/LPN/MTA

Prepare and position patient	L037D	RN/LPN/MTA
Sedate/apply anesthesia	L051A	RN
Assist physician/moderate sedation (% of physician time)	L051A	RN
Monitor pt. following service/check tubes, monitors, drains	L051A	RN

We concur with CMS' proposal to remove the moderate sedation supplies SA044 and staff labor L051A from the procedure and include those in the GMMM1, 991X1-991X3 codes as appropriate.

Upon our review of the PE inputs in the proposed rule, we note that the following codes still include moderate sedation equipment or labor, and recommend that the PE inputs be adjusted as appropriate to maintain consistency with other endoscopic procedures.

Includes moderate sedation equipment: 43201, 43202, 43231, 43232, 43453

Includes moderate sedation RN staff: G0121

Please note that G0121 does not include the RN/LPN/MTA blend for the staff work associated with the procedure as do CPT codes 45378 and HCPCS code G0105. We believe this was removed in error and should be restored.

TECHNICAL CORRECTIONS TO DIRECT PE INPUT DATABASE

We thank CMS for restoring the Gomco suction machine (EQ235) and associated times to ileoscopy codes 44380, 44381 and 44382. We appreciate that CMS recognized this error and has taken steps to correct and update these inputs.

PROPOSED CHANGES TO DIRECT PE INPUTS FOR SPECIFIC SERVICES: STANDARDIZATION OF CLINICAL LABOR TASKS (EQUIPMENT RECOMMENDATIONS FOR SCOPE SYSTEMS)

We support CMS' desire to standardize clinical labor tasks and equipment for scope systems. However, we question CMS' proposal to reduce by half the price of the endoscopy video system (ES031). In the proposed rule CMS states, "We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we are proposing to use for this re-pricing." However, CMS has not provided invoice data that would support the \$15,045 figure as the price of the endoscopy video system.

We do not believe this proposed amount accurately reflects the current price of GI endoscopy video systems and note that CMS has not recommended this change to endoscopy video systems in other specialties (e.g., orthopedics, pulmonary, ENT, urology, gynecology, etc.) that might perform video endoscopic procedures in the non-facility setting. We are obtaining invoices that reflect current prices paid across the country for this equipment from multiple manufacturers and we will provide them to CMS as we receive them. In the meantime, we urge CMS to maintain the existing value for ES031 in CY 2017 and, as discussed below, recommend that CMS invite the RUC to perform a comprehensive multi-society review of the PE for ‘scopes’ and associated equipment and make recommendations before CMS makes any unilateral changes in the absence of evidence.

Year	CMS Code	Description	Useful Life in Years	Price
2016	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	5	\$33,232.50
2017	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	5	\$15,045.00

CMS also proposes standardizing refinements to the way scopes have been defined in the direct PE input database. “We believe that there are four general types of scopes: non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the video scope systems, while the nonvideo scopes would not. The flexible scopes can be further divided into diagnostic (or nonchanneled) and therapeutic (or channeled) scopes. We are proposing to identify for each anatomical application: (1) a rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We are proposing to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services.”

ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)
ES034	videoscope, gastroscopy
ES038	videoscope, endoscopic ultrasound
ES043	video sigmoidoscope

ES033	videoscope, colonoscopy
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Because of the complexity of this issue and the need to incorporate input from all specialty societies, the RUC plans to form a Workgroup of the PE Subcommittee and review this issue and appropriate direct PE inputs involved in procedures involving endoscopes at the same time. We look forward to participating in the RUC PE Subcommittee workgroup as part of the RUC process as it develops recommendations for consideration in CMS' 2018 Proposed Rule, and we urge CMS to not finalize the proposed changes to ES031 at this time.

DIRECT PE INPUT DISCREPANCIES - APPROPRIATE DIRECT PE INPUTS INVOLVED IN PROCEDURES INVOLVING ENDOSCOPES

CMS notes there are 45 different pieces of endoscopy equipment and 25 different pieces of endoscope related-supplies that are currently associated with endoscopic services. Therefore, CMS has requested that stakeholders “make recommendations on the appropriate endoscopic equipment and supplies typically provided in all endoscopic procedures for each anatomical body region, along with their appropriate prices.”

In addition to the traditional forms of endoscopy equipment, in recent years the Food and Drug Administration (FDA) has approved a number of disposable, one-time use endoscopes to be used for upper and lower endoscopic procedures. Patient safety and the prevention of infections are a top priority for our societies. Recognizing there have been case reports of antibiotic-resistant infections following the use of duodenoscopes used in ERCP procedures and in echoendoscopes used in endoscopic ultrasound (EUS) procedures, our societies are collaborating with other stakeholders on updated guidelines¹ for safe reprocessing of endoscopes. Changes to FDA recommendations and manufacturers' sterilization instructions to address infections may require changes to the practice expense for endoscopic procedures given evolution in the definition of “typical.” We look forward to working with the RUC to provide data regarding both single-use and multiple-use equipment, and to provide accurate recommendations to CMS and the Department of Health and Human Services.

Because of the complexity of this issue and the need to incorporate input from all specialty societies, the RUC plans to form a Workgroup of the PE Subcommittee and review this issue and the equipment recommendations for scope systems at once. We look forward to participating in the Workgroup as part of the RUC process as it develops recommendations for consideration in CMS' 2018 Proposed Rule, and urge CMS to not finalize recommendations for this equipment at this time.

¹ Petersen BT, Cohen J, et al. Multi-Society Guideline on Reprocessing Flexible Gastrointestinal Endoscopes—2016. *Gastrointest Endosc* 2016, In Press.

GLOBAL SERVICES

We support the premise under which CMS proposes to collect data on the resources used and care delivered to patients during the 010 and 090 day global periods. To maintain the accuracy and validity of the physician fee schedule, CMS' payment policies must be based on a well-constructed, valid and representative knowledge base. Therefore, we similarly propose that CMS commit to developing an evidence base from which evaluation and management (E/M) services can be redefined and valued to more accurately describe and value the work performed by physicians whose participation in patients' care involves cognitive rather than exclusively procedural skills. This character of care will be summarized as the work of "cognitive physicians".

The proposed rule states, "It is essential that the RVUs under the PFS be based as closely and accurately as possible on the actual resources involved in furnishing the typical occurrence of specific services." To ensure this is the case, evidence based research founded on health services research is necessary; this applies equally to the services delivered as part of the global periods as to E/M services delivered by cognitive physicians.

As the agency appropriately notes, the global periods rely on crosswalks to E/M services based on the assumption that the resources, including work, are similar. The follow-up work performed within the global periods and the continuity work performed by cognitive physicians should not be represented by the same codes. The care required by a patient recovering from a procedure is fundamentally different from the typical follow-up of an established outpatient, especially when there are multiple simultaneous interacting conditions or a single metastable chronic illness. We anticipate that the data collected as part of this research initiative will demonstrate that E/M codes are the only set of codes being used to represent substantially different types of work.

With respect to this data collection and research effort, the proposed rule states, "To the extent that such mechanisms prove valuable, they may be used to collect data for valuing other services." We believe that research focused on the global E/M should in fact anticipate the very specific E/M research we have proposed, focusing initially on the new and established outpatient E/M service codes, 99201-99205 and 99211-99215).

CMS proposes to collect the pre- and post-operative visits included in the global surgical bundle primarily through the mandatory reporting of newly created HCPCS level II G codes. These G codes will be reported by all physicians performing procedural services in Medicare to collect the pre- and post-operative activities based on place of service, complexity of patient and the completion time in increments of 10 minutes.

Inpatient	GXXX1	Inpatient visit, typical, per 10 minutes, included in surgical package
	GXXX2	Inpatient visit, complex, per 10 minutes, included in surgical package

	GXXX3	Inpatient visit, critical illness, per 10 minutes, included in surgical package
Office or Other Outpatient	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package
	GXXX5	Office or other outpatient visit, typical, per 10 minutes, included in surgical package
	GXXX6	Office or other outpatient visit, complex, per 10 minutes, included in surgical package
Via Phone or Internet	GXXX7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package
	GXXX8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package

However, as data collection must begin by January 1, 2017, there would be little time for physician education on how to report the G codes and for the necessary changes to electronic health record (EHR) systems and billing software to support the new codes. We recommend using existing CPT code 99024 (*Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure*). Code 99024 is already in widespread use to verify that required postoperative visits have been provided.

Revising the reporting period from 10 to 15 minute increments, and using existing category I CPT codes, may assist in decreasing the administrative burden of this proposal. Timed services in 15 minute increments are a familiar concept to coders, physicians and health care professionals, EHR systems and clearinghouses. CMS may consider instructing providers to report these services as follows:

1. Inpatient, office, or other outpatient: one unit of 99024 for each 15-minute interval of post-operative E/M services
2. Via internet or phone; one unit of code 99444 (*Online evaluation and management service provided by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient or guardian*) for each 15-minute interval of post-operative patient interactions by electronic means

We urge CMS to clearly define how time is to be reported. We recommend using the eight-minute rule as it is already a familiar concept for therapy and other time based codes. That is, each unit of 99024 or 99444 may only be reported after at least eight minutes of post-operative E/M service. CMS may wish to set a maximum number of units per date of service.

CMS' proposal also seeks to capture the complexity of each visit via a classification of typical, complex or critical illness. We believe that this level of granularity adds unnecessary complexity for practitioners. Time is a sufficient proxy for work relativity in post-operative visits. The number units of 99024 will reflect the complexity involved.

As we stated earlier, we believe that research focused on the global E/M should focus on the new and established outpatient E/M service codes (99201-99205 and 99211-99215) to determine if the nature of the work involved in a post-operative E/M visit is the same.

We urge CMS to heavily weigh the input of the medical community as it engages in this effort and in the future as a research study is proposed for the rest of the E/M code set.

GEOGRAPHIC PRACTICE COST INDEX (GPCI)

We support CMS' implementation of H.R. 4302, the "Protecting Access to Medicare Act" (PAMA) to move California's Medicare physician payment localities to the same Metropolitan Statistical Areas used to pay hospitals, which more accurately reflect the cost of practicing medicine. We appreciate that CMS has taken the steps to update these inputs.

TARGET FOR RELATIVE VALUE ADJUSTMENTS FOR MISVALUED SERVICES

For the final two years (CYs 2017 and 2018) to which the congressionally mandated target for relative value adjustments for misvalued services applies, we support the continuation of CMS' methodology to calculate changes in values for misvalued services across three full years. Consequently, for the CY 2017 0.5 percent target, changes in values would be measured across: the original value in the first year (CY 2015); the interim final value in the second year (CY 2016); and the finalized value in the third year (CY 2017).

ESOPHAGOGASTRIC FUNDOPLASTY, TRANSORAL APPROACH (CPT CODE 43210)

We are very disappointed that CMS rejected the recommendations of the RUC and the Refinement Panel for the physician work RVUs of code 43210 (*Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed*). The RUC recommended a work RVU of 9.00 for code 43210. The CY 2016 multi-specialty refinement panel recommended that the Agency accept the RUC-recommended value of 9.00 work RVUs, acknowledging that the RUC recommended value compared well with the key reference service code 43276

(Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged), which has a work RVU of 8.94 and an intra-service time of 60 minutes. The esophagogastric fundoplasty procedure involves the performance of two esophagogastroduodenoscopies (EGDs) during this service. Not only are the intra-service times and intensities similar between codes 43210 and 43276, the majority of survey participants indicated that CPT code 43210 is somewhat more complex than code 43276. For these data-driven reasons, we implore CMS to accept the recommendations of the Refinement Panel and to establish a work RVU of 9.00 for code 43210.

REFINEMENT PANEL

In the CY 2016 notice of proposed rulemaking, CMS proposed to permanently eliminate its Refinement Panel process. In the CY 2016 Final Rule, instead of finalizing the exact language of that proposal, CMS announced it would “...retain the ability to convene Refinement Panels for codes with interim final values” and that “...CY 2016 is the final year for which we anticipate establishing interim final values for existing services.” We object to the CMS intention to make this vital process obsolete. We strongly urge CMS to open Refinement Panel review to all procedures and services that are under CMS review during the current rulemaking process. The original Refinement Panel process, coupled with the input from the RUC, would provide the best mechanism to utilize the expertise from physicians and other health care professionals to determine the resources utilized in the provision of a service to a Medicare beneficiary. Recognizing that the timing of the Refinement Panel could be problematic, we recommend that the Panel meeting be moved to September, which would allow all stakeholders to provide recommendations to CMS prior to finalizing values.

PHASE-IN OF SIGNIFICANT RVU REDUCTIONS

By statute, if total RVUs for a service, except for new or revised codes, are decreased by an estimated 20 percent or more, the adjustments shall be phased-in over a two-year period. In the CY 2016 Medicare PFS Final Rule, CMS stated it did not have the authority to extend the phase-in period beyond two years as specified in statute. We are pleased that CMS has re-evaluated its authority and has proposed to continue its policy of a maximum 19 percent reduction for those codes with phase-in values in the previous year, which allows services with steep reductions to be phased in over a longer period of time.

Consistent with our comments to the CY 2016 Medicare PFS Proposed Rule, we are disappointed with CMS' decision to exclude from the phase-in codes with a reduction of 20 percent or more that fall within a family with significant coding revisions. We ask CMS to reconsider this policy, despite its concerns about maintaining rank-order among codes in the family. Current policy particularly disadvantages physician practices when a cut of more than 20 percent is applied to a specialty's high-volume procedures.

IMPROVING PAYMENT ACCURACY FOR PRIMARY CARE, CARE MANAGEMENT, AND PATIENT-CENTERED SERVICES

Comprehensive Assessment and Care Planning for Patients Requiring Chronic Care Management (HCPCS code GPPP7)

Our societies appreciate CMS' recognition that coordinated cognitive services require a significant amount of physician time not currently reflected in the work RVU of evaluation and management services. Thus, we commend CMS for proposing GPPP7 and believe this should be finalized for all specialists performing E/M services for a chronic condition and/or multiple chronic care management services. CMS proposes that a provider may use GPPP7 as an add-on code for beneficiaries who require extensive face-to-face assessment and care planning by the billing practitioner through an add-on code to the initiating visit. As proposed, GPPP7 would be used to account for the additional work and effort described by an E/M code, or chronic care management codes if these requirements are also met.

Our societies agree with these stakeholders and appreciate CMS' recognizing this complex cognitive work in the valuations of new codes. We are encouraged that CMS recognizes these cognitive care issues persist in other specialties, such as gastroenterology. For example, the growing complexity of the diagnosis and management of inflammatory bowel disease (IBD) patients highlights the challenges of grappling with extraordinarily complicated disease features of bleeding, abdominal pain, diarrhea, fistula, abscess, obstruction, postoperative sequelae, biologic therapies, and changing paradigms of therapy. This is further confounded in the Medicare patient population. All of these efforts are essential to ensure a correct diagnosis with subsequent management. These services are vital to intelligent and coordinated care, but are not reflected in the current E/M services gastroenterologists provide their patients. This includes the investment of time required for discussion with each patient and/or caregivers.

Thus, our societies commend CMS for this proposal for such complex and cognitive services. While we do not believe these codes as proposed are restricted to one specialty, we do believe it is necessary to emphasize that the codes should not be limited to primary care or a particular specialty.

Non-Face-To-Face Prolonged Evaluation & Management Services

Beginning in CY 2017, CMS proposes to recognize CPT codes 99358 (*Prolonged evaluation and management service before and/or after direct patient care, first hour*) and 99359 (*Prolonged evaluation and management service before and/or after direct patient care, each additional 30 minutes*) for separate payment under the physician fee schedule. We appreciate and support this proposal with revisions. We also appreciate the opportunity to comment on CMS' request for feedback regarding potential intersection of the prolonged service CPT codes 99358 and 99359 with proposed code GPPP7.

While we thank CMS for proposing to recognize CPT codes 99358 and 99359 for CY 2017, we urge CMS to revise this proposal by not requiring these services to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code. As noted in the proposed rule, CPT guidance for CPT codes 99358 and 99359 stipulates these codes should not be reported during the same service period as complex chronic care management services, as these services include substantial non-face-to-face work by the billing physician or other practitioner. This guidance is consistent with our members' experience when treating complex IBD patients as described above.

We are concerned that requiring 99358 and 99359 services to be provided the same day as a complex E/M encounter does not match the reality of many practitioners and the challenges of busy practices. The completion of the service commonly requires time and work to obtain and review medical records, imaging, pathology or other data not necessarily available the same day, yet closely linked to the underlying service. This is the distinction from GPPP7 or chronic care management, which is carried out over time related to ongoing management consistent with the plan set up at an initial encounter or between subsequent encounters. CMS states in the proposed rule "we note that PFS coding, in general, does not dictate how physicians practice medicine and believe that it should, instead, reflect the practice of medicine." However, the proposal to require 99358 and 99359 on the same date as a complex E/M encounter appears to do just that. We recommend that CMS allow codes 99358 and 99359 to be reported for total physician time with a single patient over the course of a calendar month, rather than during a single day. We also plan to recommend to the RUC/CPT Emerging Issues Workgroup that CPT consider revising the code definition similarly and in an expeditious manner for CPT 2018.

Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) services

We support that CMS is proposing several changes in the payment rules for CCM services to improve the use of CPT code 99490. We also appreciate that CMS is proposing to more appropriately recognize and pay for the other codes in the CPT family of CCM services (CPT codes 99487 and 99489) and that the same scope of service elements for CCM, as amended, would apply to these codes, as well as to 99490, beginning in 2017.

In our September 2013 comments to CMS in response to the CY 2014 Medicare PFS Proposed Rule, we cautioned that the proposed CCM requirements, most specifically the 24/7 access requirement, would be difficult for many physician practices to meet, particularly small group practices. We support, as proposed, the removal of a number of the EHR requirements from various scope of service elements, as well as other modifications.

- Initiating Visit: Support replacing "all patients" with "new patients or those not seen within one year."

- **Structured Recording of Patient Information Using Certified EHR Technology:** Support removal of the requirement that a structured clinical summary record must be created using certified EHR technology.
- **24/7 Access to Care:** Support removal of the requirement that health care practitioners in the practice must have access to a patient's electronic care plan to address his or her urgent care needs. We also support the revision in this requirement to replace "urgent chronic care needs" with "urgent needs."
- **Electronic Sharing of Care Plan:** Support the removal of the requirement that care plan information would need to be available 24/7 to all practitioners within the practice whose time counts toward the time requirement for the practice to bill the CCM code. Support that care plan information would be provided in a timely manner when appropriate to providers within and outside the billing practice. Support that care plan information could be shared by fax, and not just in extenuating circumstances.
- **Beneficiary Receipt of Care Plan:** Support that the care plan can be provided to a caregiver, rather than exclusively to the beneficiary.
- **Documentation of Care Plan Provision to Beneficiary using Certified EHR Technology:** Support removal of this requirement.
- **Management of Care Transitions:** We request clarification on what the expectation is for this criterion, specifically to ensure that a follow-up visit after an emergency department visit or hospital discharge is not required, but rather coordinated communication. Support removal of the requirement that clinical summaries must be formatted according to certified EHR technology (content standard). Support the requirement to "create and exchange/transmit continuity of care document(s) timely with other practitioners and providers" in lieu of the current requirement to "exchange/transmit clinical summaries, as long as they are transmitted electronically (by fax in extenuating circumstance)."
- **Documentation of Home- and Community-Based Care Coordination:** Support the removal of the requirement that such documentation must take place using certified EHR technology.
- **Beneficiary Consent:** Support the removal of the requirement that the provider must obtain the beneficiary's written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers, and documentation of consent in the medical record.

We also request CMS modify its proposal with respect to the following requirements:

- **Electronic Comprehensive Care Plan:** Request further modification to this requirement, which can be burdensome for non-primary care physicians. We request that the care plan should be specific to the areas pertinent to the patient's condition being managed.

- Continuity of Care: Oppose removal of the “or member of the care team,” from this requirement. It is essential that "member of the care team" stays part of this requirement, especially considering that in underserved areas there may not be a designated practitioner available year-round. Rather, coverage is provided by locum tenens whereby routine appointments are made with midlevel provider but the physician may vary.

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING

There are many clinical situations in which gastroenterologists order advanced diagnostic imaging services, thereby subjecting them to the requirements of the Medicare Appropriate Use Criteria (AUC) Program as set forth in PAMA. Regrettably, this law was enacted with little regard to its complexity and administrative burdens. Our societies recognize that agreed-upon AUCs serve a valuable purpose for education or for quality of care studies. We are, however, dismayed that the law is overly prescriptive with regard to the manner in which AUC must be consulted service-by-service, thereby conferring new costs and administrative burdens onto providers without evidence the savings or quality improvement envisioned would justify these complex procedures and burdens. Furthermore, we fear the demand for clinical decision support mechanism (CDSM) modules for EHRs will be a major distraction to Electronic Medical Record (EMR) vendors that should be focused on clinical content development and interoperability.

In our comments to CMS in response to the CY 2016 Medicare PFS proposed rule we expressed serious concerns with the compressed timeline allowed for implementation of the AUC Program, reflecting the statutory deadline of Jan. 1, 2017. We thank CMS for recognizing the complexity associated with implementing the law and for the decision by CMS to delay implementation. We also appreciate that CMS is taking a phased approach to rulemaking for the AUC program given its many components and complexities. CMS states in this proposed rule that the AUC consultation and reporting requirements may begin Jan. 1, 2018. We believe the implementation date must be dictated not only by the availability of CDSMs but also by their integration into EHR systems, as well as by physician readiness, as demonstrated by sufficient pilot testing. Toward this end, we have significant concern with a January 2018 implementation date and ask CMS to further delay implementation to no earlier than January 2019.

Hardship Exemptions

Compliance with the AUC program will be least disruptive to practice workflow when a CDSM is integrated into a practice's EHR. Therefore, we support CMS' proposal to automatically grant an ordering professional a hardship exemption from consulting AUC if the ordering professional is granted a significant hardship exception for purposes of the Medicare EHR Incentive Program payment. We believe there must be an expedited mechanism for a real time, rapid turnaround acknowledgement of hardship that arises during the year. Otherwise an ordering professional may be unable to get orders for

imaging studies accepted by furnishing professionals and their patients may be denied services. We also request that CMS consider exempting ordering physicians based on a low-volume threshold of advanced imaging test ordering and for those who participate in alternative payment models (APMs). We believe the incentive to order only appropriate imaging tests (i.e., assessment of resource use) is inherent in APMs.

Clinical Priority Areas

We acknowledge that CMS is proposing the top eight clinical groupings (by volume of procedures) as the initial list of priority clinical areas. Even though, as CMS states, the eight clinical areas account for roughly 40 percent of Part B advanced diagnostic imaging services paid for by Medicare in 2014, this does not necessarily mean that these priority clinical areas are accompanied by disproportionately inappropriate utilization. We believe that fewer than eight priority clinical areas may lead to better acceptance of this program and create a better user experience and that revising, based on stakeholder feedback, to target areas of known or suspected inappropriate use will lead to improved engagement by providers by making the AUC consultation task clinically meaningful. Initiating the program with priority clinical areas where inappropriate use is not pervasive may result in a skewed analysis of the program if utilization of advanced imaging tests remains constant, in addition to the large burdens placed on clinicians where outcomes won't improve.

Clinical Decision Support Mechanisms

CDSMs are the “hook and ladder” by which providers will consult AUC. Therefore, the requirements for CDSMs constitute a critical component of successful implementation of the law. We are pleased to offer our thoughts on the following proposed CDSM requirements.

— *Qualified CDSMs must make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas. However, every qualified CDSM does not need to make available every specified applicable AUC.*

We appreciate the importance of reducing administrative burden on professionals who will order advanced imaging tests across a wide range of conditions. We also recognize the challenges inherent in establishing minimum AUC requirements by specialty. However, we believe there needs to be flexibility for specialty physicians to purchase and utilize CDSMs that are specific to their scope of practice. We believe a limited CDSM might allow for modules to be more readily incorporated into certain software, which would be easier for gastroenterologists to navigate, potentially keying off a diagnosis code entered in the encounter as soon as an order was being prepared for an advanced imaging test. We suggest that practices that acquire and use a more narrow CDSM could fulfill the consultation requirements for clinical priority areas by consulting a web-based CDSM or the free CDSM for tests that they order infrequently. For ordering professionals who utilize a more narrow CDSM, CMS could also conduct a retrospective review of claims to determine if physicians are frequently ordering advanced imaging outside their specialty's

normal services. Then, additional steps could be taken, including potentially requiring physicians with more than some specified number of such claims for services not normally provided by this specialty to consult a product that included all the priority areas.

We strongly support CMS' proposal that every qualified CDSM does not need to make available every specified applicable AUC. We believe requiring every CDSM to make available every specified applicable AUC will drive up the cost of CDSMs by limiting market competition.

— *Qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified Provider-Led Entity (PLE).*

We appreciate CMS' proposal to require that CDSMs must be able to incorporate AUC from more than one PLE. However, because a CDSM is not required to incorporate specified applicable AUC from more than one qualified PLE, the likely result is that some AUC from qualified PLEs will not be incorporated into CDSMs. We appreciate, from CMS' perspective, that requiring CDSMs to incorporate AUC from more than one PLE would involve costs that could ultimately be passed down to the provider and could limit the number of CDSMs in the marketplace. While CMS has said it will not develop its own CDSM, we encourage CMS to consider requiring any free CDSM to include more than one AUC for each clinical priority area. This is a particularly importance consideration if there is only one free CDSM from which providers can choose. Furthermore, we believe that it was the intent of Congress to allow health professionals to choose which AUC to consult when there are more than one AUC developed by PLEs. Sec. 218 (q)(2)(D) of PAMA states, "In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service."

— *Specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered must be made available within the qualified CDSM.*

We believe this is an important requirement and should be retained in the final rule.

— *The qualified CDSM must clearly identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.*

CMS states in the proposed rule that it is important that the ordering professional knows which appropriate use criterion is being consulted and has the option to choose one over another if more than one criterion applies to the clinical scenario. We agree, and, therefore, support this requirement.

— *The qualified CDSM must provide to the ordering professional a determination, for each consultation, of the extent to which an applicable imaging service is consistent with specified applicable AUC or a determination of "not applicable" when the mechanism does not contain a criterion that would apply to the consultation.*

We believe that consultation of applicable AUC not included in a physician's CDSM should be optional. We suggest that the AUC consultation and reporting requirements be limited to the priority clinical areas regardless of the applicable AUC contained in a physician's CDSM. We believe the consultation requirements as proposed will require physicians and their staffs to spend considerable time keying information into a CDSM just to find that the AUC is not included in their CDSM for a particular clinical scenario.

— *The qualified CDSM must generate and provide to the ordering professional certification or documentation that documents which qualified CDSM was consulted, the name and NPI of the ordering professional that consulted the CDSM and whether the service ordered would adhere to applicable AUC, whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable for the service ordered.*

We understand the above documentation requirements are specified in law. We encourage CMS, however, to provide the ordering professional the option to document that the criteria is "sometimes applicable" or "uncertain" as not all clinical scenarios result in a clear-cut determination of appropriate or inappropriate.

— *The documentation or certification provided by the qualified CDSM must include a unique consultation identifier. This would be a unique code issued by the CDSM that is specific to each consultation by an ordering professional. CMS believes that for the CDSM to be able to provide meaningful feedback to ordering professionals, information regarding consultations that do not result in imaging is just as important as information on consultations that do result in an order for advanced imaging.*

As proposed, this requirement appears to preclude providers from simply reviewing criteria for their own education outside a patient specific session involving ordering. We ask CMS to reconsider this requirement or require that the CDSM allow a pathway for ordering professionals to consult AUC outside a patient visit.

— *All qualified CDSMs must reapply every 5 years.*

We believe that reapplication every five years provides some predictability for practices that invest in CDSMs. However, professionals ordering the tests need to understand the implications if a qualified CDSM is not re-qualified. In such cases, a provider should be considered exempt from the program while procuring a new CDSM. For EHR-based CDSMs, a one-year exemption may not suffice.

Summary of Recommendations

Proposed Valuation of Services Where Moderate Sedation is an Inherent Part of the Procedure and Proposed Valuation of Moderate Sedation Services

- Remove the survey data for gastroenterologists in the valuation of 991X2, as including it causes a mis-valuation of 991X2 which will lead to a loss of relativity between 991X2 and GMMM1.
- Include the esophageal dilation (43450, 43453) and ERCP (43260-43265, 43273-43278) procedures as appropriate to report using GMMM1.

Moderate Sedation Practice Expense

- Retain equipment codes EF018, EQ011 and EF027 for moderate sedation practice expense in GMMM1.
- Attribute the time associated with moderate sedation tasks for equipment codes EF018, EQ011 and EF027 to GMMM1 and remove that time from the underlying endoscopic procedures.
- Remove the following PE inputs from the codes listed below to maintain consistency with other endoscopic procedures:
 - Remove moderate sedation equipment: 43201, 43202, 43231, 43232, 43453
 - Remove moderate sedation RN staff: G0121

Proposed Changes to Direct PE Inputs for Specific Services: Standardization of Clinical Labor Tasks (Equipment Recommendations for Scope Systems)

- Maintain the existing value for ES031 in CY 2017 and invite the RUC to perform a comprehensive multi-society review of the PE for 'scopes' and associated equipment and make recommendations before CMS makes any unilateral changes in the absence of evidence.

Direct PE Input Discrepancies – Appropriate Direct PE Inputs Involved in Procedures Involving Endoscopes

- Delay finalizing proposed recommendations for equipment until the RUC forms a workgroup of the PE Subcommittee to review this issue and the equipment recommendations for scope systems and provides recommendations for consideration in CMS' 2018 Proposed Rule.

Global Services

- Reconsider how pre- and post-operative visits included in the global surgical bundle are proposed to be reported.
- Use of existing CPT code 99024 (*Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure*) and revision of the reporting period from 10 to 15 minute increments may assist in decreasing the administrative burden of this proposal.
- Heavily weigh the input of the medical community as it engages in this effort and in the future as a research study is proposed for the rest of the E/M code set.

Esophagogastric Fundoplasty, Transoral Approach (CPT Code 43210)

- Accept the recommendations of the Refinement Panel to establish a work RVU of 9.00 for code 43210.

Refinement Panel

- Open Refinement Panel review to all procedures and services that are under CMS review during the current rulemaking process.
- Move the Refinement Panel meeting to September in order to allow all stakeholders to provide recommendations to CMS prior to finalizing values.

Phase-in of Significant RVU Reductions

- Reconsider excluding from the phase-in code policy codes with a reduction of 20 percent or more that fall within a family with significant coding revisions. Current policy particularly disadvantages physician practices when a cut of more than 20 percent is applied to a specialty's high-volume procedures.

Comprehensive Assessment and Care Planning for Patients Requiring Chronic Care Management (HCPCS code GPPP7)

- Finalize code GPPP7 for all specialists performing E/M services for a chronic condition and/or multiple chronic care management services.
- Emphasize that the comprehensive assessment and care planning for patients requiring chronic care management services should not be limited to primary care or a particular specialty.

Non-Face-To-Face Prolonged Evaluation & Management Services

- Revise the proposal to recognize CPT codes 99358 and 99359 for CY 2017 so that these services are not required to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code.
- Allow codes 99358 and 99359 to be reported for total physician time with a single patient over the course of a calendar month, rather than during a single day.

Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) services

- Modify the proposal with respect to the following requirements:
 - **Electronic Comprehensive Care Plan:** Request further modification to this requirement, which can be burdensome for non-primary care physicians. We request that the care plan should be specific to the areas pertinent to the patient's condition being managed.
 - **Continuity of Care:** Oppose removal of the "or member of the care team," from this requirement.

Appropriate Use Criteria for Advanced Diagnostic Imaging

- Delay implementation to no earlier than January 2019.
- Hardship Exemptions
 - Create an expedited mechanism for a real time, rapid turnaround acknowledgement of hardship that arises during the year.
 - Consider exempting ordering physicians based on a low-volume threshold of advanced imaging test ordering and for those who participate in APMs.

- Clinical Priority Areas
 - Consider implementing fewer than eight priority clinical areas as this may lead to better acceptance of this program and create a better user experience. Revising these areas to target areas of known or suspected inappropriate use will lead to improved engagement by providers by making the AUC consultation task clinically meaningful.
- Clinical Decision Support Mechanisms
 - Our societies believe that requirements for CDSMs constitute critical component of successful implementation of AUC. Please consider our recommended changes for the proposed CDSM requirements.

Conclusion

The ACG, AGA, and ASGE appreciate the opportunity to provide comments on the 2017 Physician Fee Schedule Proposed Rule. If we may provide any additional information, please contact Brad Conway, Vice President of Public Policy, ACG, at 301-263-9000 or bconway@gi.org; Leslie Narramore, Director of Reimbursement, AGA, at (410) 349-7455 or Lnarramore@gastro.org; or Lakitia Mayo, Director of Health Policy and Quality, ASGE, at (630) 570- 5641 or lmayo@asge.org.

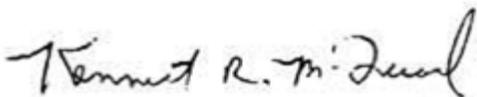
Sincerely,



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