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September 2, 2014

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**RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015. (CMS-1612-P)**

Dear Administrator Tavenner:

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1612-P), published on July 11, 2014 in the *Federal Register*, regarding the proposed policy revisions to the 2015 Medicare physician fee schedule (PFS).

NASPGHAN offers its support of comments submitted by the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), and the American Society for Gastrointestinal Endoscopy (ASGE) regarding CMS' interim final determinations for the valuation of upper endoscopy codes. We also offer comments on CMS' proposal to eliminate the reporting exception for continuing education (CE) under the Open Payments system.

**Valuation of Upper Endoscopy Codes**

While reductions in Medicare reimbursement do not directly affect pediatric gastroenterologists, the downstream implications of drastic reductions by Medicare of upper endoscopy codes are disconcerting, as private payers often base their rates off Medicare. In adult patients, endoscopy procedures are commonly performed on the most complex and sickest patients. The same can be said for pediatric patients requiring endoscopy. It is critical that Medicare reimbursement rates accurately reflect the judgment, skill, and time required for performing highly technical endoscopy procedures. Failure of CMS to accurately value these services could lead to complementary and unjustified payment reductions for pediatric endoscopy services by other payers.

NASPGHAN shares the key concerns that have been articulated by ACG, AGA and ASGE and asks that CMS carefully consider the evidence these societies have provided in support of the physician work recommendations of the American Medical Association/Specialty Society Relative Value System/RVS Update Committee (RUC), as well as their explanation of the intensity and

complexity of the upper GI endoscopy codes, 43200 - 43278. Among the upper endoscopy services most commonly billed by pediatric gastroenterologists include the following and for which CMS did not accept the work relative value units (RVUs) recommended by the RUC

- 43239 - Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
- 43246 - Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube
- 43247 -- Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body

#### CMS' rationale for applying its new methodology of 10 minutes of physician time = 1.00 wRVU

CMS' application of its new methodology of 10 minutes of physician time=1.00 wRVU does not take into consideration the range of intensities across all gastrointestinal endoscopic procedures and services. This approach is markedly different from the methodology used to determine the values of other codes in the physician fee schedule and ignores that intensity can vary significantly across codes with identical intra-service times. Use of the survey minimum, the response of one individual, is not a statistically valid methodology. The survey data for code 43200 (Esophagoscopy, flexible, transoral; diagnostic includes brushing or washing when performed) was based on 121 responses, well above the 30 response minimum required. The median survey total time for code 43200 was 60 minutes (35 minutes pre-service /15 minutes intraservice / 10 minutes post-service), five minutes above the previous time of 55 minutes. This demonstrates that the procedure time did not decrease. CMS' assignment of 1.50 RVUs to 43200 based on a methodology that uses a survey minimum RVU from another specialty's code is neither accurate nor justifiable considering that the survey data for 43200 show that the procedure has not decreased in time or intensity from the previous valuation.

#### Accurate Comparison of Time Inputs

Achieving an accurate comparison of previous to current time is essential when reviewing a code's work value. The Agency made time comparisons without adjusting for the following factors:

- Movement of moderate sedation from intra-service to pre-service time.
- Application of a 5 minute decrease in intra-service time across the EGD code family.
- The recent application of the RUC pre-service and post-service time packages.

#### *Movement of Moderate Sedation*

When these codes were previously valued, whether by Harvard or by the RUC, administration of moderate sedation was included in the intra-service time. The time for administration of moderate sedation is now included in the pre-service time. CMS' failure to adjust the previous intra-service times for the movement of moderate sedation from intra-service to pre-service ignores the shift (and unbundling from intra-service work) of moderate sedation, which has created a new value of 0.02 wRVUs per minute for the work of the administration of moderate sedation. Movement of moderate sedation from intraservice to pre-service time should be accounted for when comparing previous to current times in order to construct an accurate comparison.

#### *Adjustment of Time for EGD Codes*

In 2005, code 43235 (Esophagogastroduodenoscopy, flexible, transoral; diagnostic includes brushing or washing when performed) was valued by the RUC as part of the Five-Year review. CMS agreed with maintaining the work RVU of this service, while accepting survey data that included a 5 minute decrease in intra-service time. This decrease in intra-service time was never applied to the rest of the codes in the EGD family. CMS' failure to adjust the previous intra-service times for these codes by the 5 minute reduction in the base code, when comparing the previous time to current time, creates an inaccurate

comparison which de-values the remaining work. Before making any assumption about a change in the work of performance of these procedures, the intra-service and total time of all codes in the EGD family (43236-43259) should be adjusted (without a reduction in wRVUs) for the decrease of 5 minutes in the intra-service time.

#### *Impact of RUC Time Packages*

Codes reviewed prior to the application of the RUC pre-service and post-service time packages should be appropriately adjusted by either applying the package times to the previous times or using the data that came directly from the survey participants rather than the RUC recommendations. Simply comparing previous total time to the total RUC recommended time will result in the erroneous conclusion that the time of the procedure has decreased when it has not. The recent application of pre-service and post-service time packages should be taken into account so that time comparisons are made using the same definitions. Again, the work has not decreased.

Failure to make comparisons using the same definitions creates a flawed analysis and, subsequently, flawed RVU determinations. In its analysis of time in the Final Rule, the Agency did not acknowledge that definitions/requirements in other reviews may differ, impacting important input values. When the Agency performs its own independent analysis of codes that have recently gone through the RUC process, the Agency must take into consideration the movement of time for moderate sedation, the history of each base code, and the impact of RUC-mandated pre- and post-time packages when addressing the correlation between total time and intensity associated with performing these procedures.

#### Intensity

The intensity of endoscopic services has not decreased compared to when endoscopic services were surveyed almost two decades ago. The RUC uses 11 measures of intensity of physician work in evaluating the relative differences in work among services. Our societies believe it is important to note that the measures of intensity of work are no less for each of the endoscopic services surveyed as part of this most recent review. ACG, AGA and ASGE have provided the Agency with information about the intensity involved in performing endoscopic ultrasound (43231) and injection procedures (43201, 43204). We urge CMS to re-evaluate its methodology in valuing the injection and endoscopic ultrasound codes by considering the intensity of the work for these services within all GI code families.

#### **Reports of Payments or Other Transfers of Value to Covered Recipients Under Open Payments**

NASPGHAN opposes CMS' proposal to remove the current exclusion [§ 403.904(g)(1)] from the Open Payments system the reporting of payments associated with continuing education (CE). We acknowledge an unintended consequence of current regulation has been CMS' apparent endorsement or support to organizations sponsoring continuing education events. However, we believe removing the exclusion entirely and redesignating CE payments under the exclusion in §403.904(i)(1) leaves CE speakers/faculty vulnerable to reporting by manufacturers or applicable group purchasing organizations (GPOs), which could have a chilling effect on CE in this country.

Under §403.904(i)(1), indirect payments or other transfers of value are excluded from reporting where the applicable manufacturer is "unaware" of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year. This means that manufacturers who fund CE must be unaware of a speaker, who is a covered recipient, for essentially up to a year and a half after the indirect payment has been made. We believe this standard of "unaware" is wholly unrealistic because it would not be uncommon for industry to learn the identities of speakers/faculty, and potentially participants, through brochures, programs, and other publications after funds have been transferred.

CMS states in the proposed rule, “When an applicable manufacturer or applicable GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under §403.904(i)(1).” We believe this exclusion should be made explicit under §403.904(i)(1). However, we hold the position that any standard based on the time at which a manufacturer or GPO becomes aware of a CE speaker/faculty is unreasonable and will prevent covered recipients from serving as speakers/faculty, and potentially participating, in CE programs. Clarifying that reporting for CE activities would only be triggered where the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity is a necessary improvement to CMS’ proposal. However, the “before” standard does not account for the common practice of continued solicitation of industry support for a CE program after the program course and faculty have been confirmed and publicized.

Given the ramifications of deleting § 403.904(g)(1), we ask the section be maintained until CMS can arrive at an alternative solution that will provide the same level of exclusion as currently offered to CE activities under § 403.904(g)(1).

### **Conclusion**

NASPGHAN appreciates the Agency’s consideration of its comments. Any questions or requests for additional information can be directed to NASPGHAN’s Washington representative Camille Bonta at (202) 320-3658 or [cbonta@summithealthconsulting.com](mailto:cbonta@summithealthconsulting.com).

Sincerely,

A handwritten signature in cursive script that reads "Athos Bousvaros".

Athos Bousvaros, M.D.  
NASPGHAN President