Dear Dr. Berwick:

The Society of Nuclear Medicine (SNM) is pleased to provide comments on the proposed rule for Medicare payments in the Physician Fee Schedule (PFS) for calendar year 2012, released on July 1, 2011 by the Centers for Medicare & Medicaid Services (CMS). The SNM’s more than 17,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice.

We offer comments and recommendations on the following topics addressed in this final rule:

- Sustainable Growth Rate
- Physician Practice Information Survey
- RUC Five Year Review – Gastric Emptying Study
- Multiple Procedure Reduction
- General Comments Transparency
  - CMS Assignment for CPT Code 78808
  - Physician Work for CPT Code 78459 Changed In 2003
- Physician Quality Reporting System (PQRS)
- eRx Incentive Program
- Maintenance of Certification Incentive Program
- Availability of Medicare Data for Performance Measurement
Sustainable Growth Rate - SGR

In the CY 2012 Proposed Rule, CMS proposed a 29.5 percent reduction to the conversion factor absent congressional action. The SNM is deeply concerned with implementation of such an action regarding its impact on patient access to care. We strongly encourage CMS to consider alternative administrative opportunities (e.g. capping, phasing-in) to eliminate such a reduction.

Physician Practice Information Survey

In the CY 2012 Proposed Rule, CMS states that they used survey data for indirect practice expenses incurred per hour worked, to develop the indirect portion of the practice expense (PE) RVUs. Specifically, CMS used data from the Physician Practice Expense Information Survey (PPIS) conducted by the AMA. The SNM must reiterate concerns that were shared in comments for the CY 2011 Final Rule and more specific recommendations supplied in the Five Year Review proposed rule, regarding the validity of the PPIS data as it relates to the practice of nuclear medicine. The SNM continues to have doubt about the validity of the PPIS data as it relates to the practice of nuclear medicine. As we stated in our April 11, 2011 letter:

- Nuclear Medicine has too few PPIS data points to adequately represent this medical profession. The results should be set aside and Nuclear Medicine should be crosswalked to the results obtained for Radiology.
- Current PPIS data should be weighted to accurately represent radiology practices to adequately compensate for the expenses incurred in delivering radiology services to Medicare beneficiaries using the “2007 Survey of Radiologists: Practice Characteristics, Ownership and Affiliation with Imaging Centers.”
- The six main expense categories are under-reported in the PPIS sample. A minimal cost per hour ($5.00 PE/HR) in each direct cost category should be used to define office-based practices and the proportion that these practices represent should be set to 30%. This would increase the total PE/HR to $162, a more representative figure.
- The $162 PE/HR value recommended above should be blended with the supplemental practice expense survey results, updated to the 2007 level (a PE/HR value of $204).
- CMS should resurvey and replace current PPIS data with stratified PPIS data by CY 2013.
  - Stratify the survey sample by non-hospital and hospital practice settings and blend based on distribution of volume.
  - Allow collection of more accurate practice cost data of physician practices in different settings.
At the request of the American Society for Radiation Oncology (ASTRO), CMS accepted stratified data for radiation oncology and should do the same for diagnostic radiology.

- The PPIS data for radiology should be collected at the practice level (not the individual physician level) as previously recommended by The Lewin Group.
- Ensure appropriate representation of the various practice types in radiology in the PPIS data.
- Conduct a physician practice expense survey and update practice expense data at least every three years.
- CMS should work with specialty societies to determine the best methods of obtaining accurate and representative practice cost data from physicians.
- CMS should disclose all formulas that are used for calculating the PE/HR and revised practice expense RVUs to ensure transparency.
- Flawed PPIS data cannot be the last word for valuing office based radiology services, including imaging, nuclear medicine and interventional radiology. This is especially important given the rapid evolution of new payment systems and the presumed reference to existing MPFS payment schedules. Radiology services will cease to exist in the office setting and patients will suffer the consequences of limited access and higher cost through higher cost-sharing when services are obtained in non-office settings.

The SNM again offers to work with CMS to ensure that the data and PE/HR calculations are truly representative of diagnostic radiology and nuclear medicine practices. Currently, the data clearly underestimate nuclear medicine practice expenses. This problem must be addressed by CMS. **We urge that CMS reevaluate the use of clearly flawed PPIS data and implement solutions as outlined in this letter to resolve inaccuracies within the payment system.**

**RUC Five Year Review – Gastric Emptying Study**

CPT 78264 Gastric Emptying Study was submitted by CMS to be reviewed by the AMA RUC due to Harvard valuation. In the proposed rule, CMS stated, “for CPT code 78264 Gastric Emptying Study, the AMA RUC reviewed the survey results and recommended the survey median work RVU of 0.95 for CPT code 78264. We (CMS) disagreed with the AMA RUC recommended work RVU for CPT code 78264. We (CMS) believe the 25th percentile survey value is more appropriate based on its similarity in the physician work to other diagnostic tests.”

The SNM and the American College of Radiology (ACR) presented substantial supporting data to the AMA RUC, with guidelines, medical expert testimony and additional information in response to
questions raised from the RUC survey. It met the rigor of the RUC compelling evidence standard that the service 78264 Gastric Emptying Study had changed since its last valuation 20 years ago at the Harvard evaluation.

In 2005 and 2006, a collaborative effort between the SNM and the American Neurogastroenterological and Motility Association resulted in a position paper which was published in the nuclear medicine and gastroenterology literature, and subsequently adopted into SNM procedure guidelines. This established a standard procedure for gastric emptying scintigraphy (GES), a procedure considered by many to be the gold standard for physiologic measurement of gastric motor function in the management of gastric motility disorders. This protocol noted the importance of a standardized meal and patient preparation, including attention to medications, blood glucose levels, allergies, symptoms prior to the procedure, prior surgeries and previous testing.

The change in work for the procedure was thoroughly discussed with the RUC. Patient preparation requires a patient questionnaire (reviewed by the physician), assessment of the patient’s glucose level, assessment of patient’s current medications to avoid an adverse reaction, and determination of a patient’s menstrual cycle. During the procedure itself, the ability of the patient to consume the entire meal (repeated imaging hourly for up to a maximum of four hours or until less than 10% of the meal remains), and the symptoms during the study are noted. Imaging has been lengthened to 4 hours, and includes more data points for analysis than in the former procedure, which translates to additional physician time for review. The physician performing the test is closely involved with the acquisition and processing of this information, especially assuring accurate regions of interest. The specifics of the standardized protocol have resulted in increased interaction between the physician and technologist performing the procedure, particularly when any deviation from the standardized protocol is noted. The study is reviewed for completeness prior to the patient leaving the department, and the images are reviewed, compared to prior results, and any deviation from the standard protocol recorded and incorporated into the study report. Finally, the interpretation is more complex requiring both greater knowledge of the clinical conditions leading to the procedure, as well as the limitations and causes of errors in the results. In summary, the standardized procedure requires more physician work and the RUC concluded that there was compelling evidence that the physician work and time required to perform this service had changed.

The SNM and ACR presented the joint results from the AMA surveys of CPT 78264 to the RUC. The RUC reviewed the survey results from 168 radiologists and nuclear medicine physicians and determined that the median work RVU of 0.95 appropriately maintained relativity among similar services. The RUC compared 78264 to key reference service CPT code 78707 *Kidney imaging morphology; with vascular flow and function, single study without pharmacological intervention* (work RVU = 0.96 and total time = 22 minutes) and concluded that this is an equivalent comparison because the total physician time is the same, 22 minutes.

Additionally, for CMS’s consideration, the survey results showed very little differences between the respondents selected key reference code CPT 78707(Question 3) and the survey code CPT 78264.
There was no more than a 0.22 difference for pre, intra and post intensity complexity rankings by the survey respondents. In summary, of questions 3 and 4 combined, (rating average complexity/intensity based on the universe of codes the specialty performs) key reference code CPT 78707 compared directly to CPT 78264, eight (8) of the comparison questions ranked less than a 0.5 difference between these services and three (3) ranked between a .6 and 0.86 difference, supporting the fact that these codes are indeed comparable by the survey results.

In further analysis, the SNM, ACR and the RUC compared this service to CPT code 78453 *Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic) (work RVU = 1.00 and total time = 20 minutes)* and determined that the total physician time is similar to the surveyed service 22 and 20 minutes, respectively, and that the survey median work RVU of 0.95 is appropriate in relation to this service. In further support of the median survey work values, we offer CMS the RUC surveyed code CPT 78306 *Bone/joint imaging whole body* with an RVW of 0.86 pre time 5 minutes, intra time 8 minutes and 5 minutes of post time, which has less patient and physician interaction including less processing than the gastric emptying study, therefore maintaining relativity among the procedures.

In reviewing Five-Year Review specific questions, 58% of our respondents told us that this procedure had changed in the past five years, and the typical threshold established by the AMA CPT and RUC. Of those respondents who said that the procedure had changed (1) 42% stated that it is new technology (of which 95% stated that the new technology was more work). The majority did not believe the service reflects a new technology that had become more familiar. To our surprise, only 42% stated that it was new technology. Therefore we went back to the 56 respondents who answered No to question 6A asking them, “What does question 6.A mean to you specifically regarding new technology?”, and 83% said this meant new equipment or software. These results supported our notion that many of our members in the nuclear medicine and radiology community view new technology not as a new protocol but rather as a new piece of equipment or service. We believe some of our membership simply misunderstood the question as it was posed and as it related to imaging procedures.

The RUC recommended to CMS a work RVU of 0.95 for CPT code 78264 which is the survey median. We remain convinced there is substantial evidence to support this value as noted by the AMA RUC recommendations and with the supporting information provided in this letter. Therefore, we respectfully request CMS experts consider all the evidence presented and accept the mean work RVU of 0.95 for CPT 78264. Regarding the CMS proposed times of 5-12-10 the SNM can accept the median times as reasonable when accepting the median physician work RVU.

Multiple Procedure Reduction

The SNM has serious concerns with CMS’ proposal to extend the multiple procedure payment reduction (MPPR) policy to the professional component (PC) of advanced imaging services – specifically, computed tomography (CT) scans, magnetic resonance imaging (MRI), and ultrasound.
Under this proposed policy, the procedures with the highest PC payment would be paid in full. While the extension of this policy is meant to increase the efficiencies in physician work, the SNM disagrees with this arbitrary notion. This is a necessity rather than efficiency. Therefore, the SNM understands MedPAC’s and now CMS’s position, but strongly disagrees with their conclusions. **The extension of the MPPR policy to the professional component is arbitrary and should not be implemented. Regarding further expansion of the MPPR for future years, we believe that any additional proposed cuts must be accompanied with data and rationale to support any future recommendations.**

**CMS Responses to Prior Comments - Transparency**

As we commented in the 2011 final rule, we reiterate comments and respectfully request CMS provide responses in the 2012 rule. We are deeply concerned that specific comments in rules are not addressed or mentioned in proposed or final rules. We understand CMS has many comments to address, however we grow concerned that our societies spend significant time bringing issues to CMSs attention with no mention in any rules. **In the spirit of transparency we request CMS provide a response with rationale for each issue that is brought to their attention in rule.** We understand that some issues which are repeating themes from many providers may be addressed in bulk when appropriate. However, the SNM is concerned with the lack of a transparent CMS decision making and official response process. The paucity of details of how or why CMS devalued one third of the codes, and did not increase the value any code, is of major concern to us. The SNM does not dispute CMS’s broad authority to implement policies related to physician reimbursement under the Medicare program. We believe CMS did not provide example or rationale which would rise to the level of the RUC standards for its decisions including that for the Gastric Emptying Study. Additionally, CMS did not provide any comment or rationale for CPT 78808 and CPT 78459 outstanding issues, details of those issues provided below.

**CMS Assignment for CPT Code 78808**

The AMA introduced a new CPT code 78808 Injection procedure for radiopharmaceutical localization by non-imaging probe study, intravenous (eg, parathyroid adenoma), which was effective January 1, 2009. CMS has assigned a PC/TC (professional component/technical component) Indicator (5)i to CPT code 78808 and therefore, it is not separately payable under HOPPS. The SNM believes that CMS is treating this procedure as they do other injection codes such as CPT code 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour. The SNM instead suggests that CMS treat this code like CPT code 38792 Injection procedure; for identification of sentinel node or CPT code 36000 Introduction of needle or intracatheter, vein and assign an indicator (0) or (1). This procedure is a stand-alone procedure when performed by nuclear medicine; that is, the nuclear medicine physician and department do NOT perform any additional service other than those services required for physician supervision and technical work for ordering, monitoring, and injection of a regulated radioactive pharmaceutical, and completing a formal written report for the record. The CPT code was requested to not only identify those PC and TC services, but to facilitate the reporting
and reimbursement for the radiopharmaceutical when performed in the hospital or physician office outpatient setting. We request CMS treat this procedure the same as other nuclear medicine procedures by assigning CPT code 78808 with an indicator (0) or (1). Additionally, we respectfully request CMS define a PC and TC payment for this CPT code.

Physician Work for CPT Code 78459 Changed In 2003

In reviewing the history of RVWs for PET (positron emission tomography) procedures we became aware of a change in RVUs implemented by CMS in 2003 for CPT code 78459 Myocardial imaging; positron emission tomography (PET), metabolic evaluation. This change was arbitrary with no rationale that we are aware of, and we are also unaware of notification of this change. Typically if CMS does not agree with a RUC approved value, detailed discussion is available. In September of 1994 the RUC approved a physician work value of 1.9, and this was subsequently approved by CMS and published in 1995. A change occurred in 2003 when in the final rule the RVUs suddenly changed to 1.50 with no explanation. We respectfully request CMS look into this change, and if a technical error, to please correct as soon as possible.

Physician Quality Reporting System (PQRS)

SNM supports the development of additional measure groups to provide greater options for individual eligible professionals reporting in the PQRS and therefore increasing participation in the program. SNM encourages CMS to focus efforts on measures that are clinically meaningful and feasible. Therefore, SNM recommends that CMS remove cardiac nuclear medicine scans from the proposed measure in the Radiology group. As CMS has indicated that measure groups proposed for 2012 cannot be reported individually, this action will allow for the measure denominator to be consistent to CT scans alone.

eRx Incentive Program

SNM commends CMS for efforts to improve the quality of patient care through the e-prescribing incentive program to measure a prescriber’s ability to electronically send accurate and understandable prescription directly to a pharmacy. CMS states that the payment adjustment should not penalize those for whom the adoption and use of electronic prescribing system may be impractical given the low volume of prescribing. CMS has proposed a waiver for eligible professionals who prescribe fewer than 100 prescriptions during a 6-month payment adjustment reporting period. Additionally, CMS states that an eligible professional will be subject to the payment adjustment if:

- An eligible professional reports that at least one prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified system at least 25 times during the 12-month payment period adjustment reporting period OR
An eligible professional reports the electronic prescribing measure’s numerator at least 10 times during the 6-month payment adjustment period.

The denominator for the electronic prescribing quality measure consists of specific billing codes that nuclear medicine professionals do not report. SNM believes nuclear medicine professionals will neither be subject to the payment adjustment because they will not meet a minimum threshold to be considered eligible professionals under this program, but it is not clear if these professionals will need to submit the hardship waiver. SNM requests CMS clearly state in the MPFS Final Rule that physicians who do not meet the minimum threshold to be considered eligible professionals under this program do not need to submit the hardship waiver to avoid a payment adjustment.

**Maintenance of Certification Incentive Program**

SNM supports the Maintenance of Certification Incentive Program through which physicians will have the opportunity to earn a PQRS incentive plus the additional 0.5%. SNM encourages CMS to utilize existing nuclear medicine measures to ensure specialty physicians are not excluded from this incentive program.

**Availability of Medicare Data for Performance Measurement**

SNM supports CMS efforts to provide beneficiaries with resources to find health care providers and make comparisons of their quality of care. However, we have serious concerns with the data provided by the Physician Compare website because much of the data is incorrect. SNM encourages CMS to allow providers at least a six-month period for prior review and comment, along with the right to appeal, with regard to any data or its use that is part of the public review process before it is made available to the public. Additionally, SNM is troubled by the inability of the general public to understand the data and interpret the information appropriately. Therefore, CMS should develop and implement a detailed educational program for the public to explain the Medicare data and address the program limitations including barriers to physician participation and the fact that the quality measures program takes into account only a small fraction of overall physician performance.

The SNM appreciates the opportunity to comment on this MPFS 2012 Proposed Rule to the CMS. As always, the SNM is ready to discuss any of its comments or meet with CMS on the above issues. In this regard, please contact Susan Bunning, Vice President, Government Affairs, by email at sbunning@snm.org or by phone at 703-326-1182.
Respectfully Submitted,

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