SOCIETY OF
INTERVENTIONAL
RADIOLOGY
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August 23, 2010

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1503-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule; CMS-1503-P

Dear Administrator Berwick:

The Society of Interventional Radiology (SIR) is a physician association of over 4,700 members that represents the majority of practicing vascular and interventional radiologists in the United States. SIR appreciates the opportunity to submit comments on to the Centers for Medicare and Medicaid Services (CMS) in response to the July 13, 2010 Federal Register notice regarding the 2011 Medicare Physician Fee Schedule (MPFS) proposed rule. Our comments focus on the multiple procedure payment reduction (MPPR), physician practice information survey (PPIS), equipment utilization rates, potentially misvalued codes, updating equipment and supply price inputs for existing codes, self-referral and current direct clinical inputs for CPT code 37210.

Multiple Procedure Payment Reduction

CMS currently has a policy of reducing payment for multiple surgical procedures performed on the same patient, by the same physician, on the same day. Over the years, the multiple procedure payment reduction (MPPR) policy has been extended to a number of nuclear diagnostic and diagnostic imaging procedures. The Accountable Care Act (ACA) increased the established MPPR for the technical component of certain single-session imaging studies provided on contiguous body parts within families of codes from 25 percent to 50 percent as of July 1, 2010. Now, CMS is also proposing to expand the MPPR policy.

CMS is proposing to expand their policy and apply the MPPR regardless of family, that is, the policy would apply to multiple imaging services furnished within the same family of codes or across families. Therefore, the MPPR would apply to CT and CTA, MRI and MRA, and ultrasound procedures services furnished to the same patient in the same session, regardless of the imaging modality, and not limited to contiguous body areas.

The proposed expansion of the imaging MPPR policy to include all of the current codes in a single family to which the standard 50 percent reduction for second and subsequent procedures

would apply would reduce payment for 20 percent more services than the current MPPR policy under the PFS.

SIR strongly urges CMS not to extend the 50% multiple procedure payment reduction for services beyond the most recent Congressional mandate.

CMS looks at the current surgical discount methodology while considering this imaging MPPR expansion. SIR does not feel that is an appropriate comparison. The imaging procedures generally have XXX global periods. The surgical codes generally have global periods of 010 or 090 days. This difference is important when considering an MPPR expansion. If two surgical procedures are done at the same time and have a global period of 10 or 90 days (as most surgical procedures do) there is great potential for overlap in the post operative visits (follow up care in the global period) thus necessitating the MPPR. That is not the case with imaging studies. Since they do not have a global period (XXX) the need to dramatically discount follow up visits is not there.

It is important to stress that any efficiencies that may occur when two procedures are performed on contiguous body parts in the same session (a few minutes of clinical time for greeting the patient or retrieving medical records) would NOT be present when two services are performed in separate sessions. There would be negligible or no duplication of clinical activities in those situations. Certainly a 50% reduction in the payment for performing the second service would absolutely be unwarranted.

The radiology community has been working with the RUC to address concerns of potential duplication of work when services are performed together at a high rate (i.e. >75%). If there is a particular concern regarding sets of procedures being billed together and a possible overlap in resources, then we recommend looking at those particular situations, through the RUC/PEAC process. An across the board, arbitrary reduction is not appropriate.

CMS also references the HOPPS composite APCs as a justification for extending this MPPR policy. SIR does not feel that is an appropriate comparison either. The payment methodologies in the HOPPS systems are vastly different than the MFS. And interestingly if you look closely at the multiple imagine composite APCs it demonstrates **no** need for a 50% reduction. ACR analysis revealed that CMS pays hospitals for the second imaging study at nearly 100% of the APC for the single study and it is not until the third study that there are reductions in payment.

Finally, CMS stated that they will continue to review other possible expansions of the MPPR policy to the TC and/or PC of imaging procedures or other diagnostic tests for the future. SIR strongly discourages CMS from expanding the MPPR policies.

CMS states that this expansion of the MPPR will save the Medicare program of $160 million for FY 2011. However, this proposal is inappropriate and not the way to score savings to the Medicare program. SIR strongly urges CMS to withdraw this proposal.

Lower Extremity Revascularization

SIR continues to have strong concerns that the application of the 50 percent multiple procedure discount results in reimbursement levels for device-intensive services far below the resources used by the physician in the non-facility setting, particularly with the new *lower extremity revascularization* codes will go into effect January 1, 2011. We believe reasonable and viable solutions could be enacted to provide adequate reimbursement for practice expense when multiple, device-intensive procedures performed in the non-facility setting are paid under the MPFS. We propose the creation of a "device-intensive multiple procedures discount" modifier/alpha-numeric HCPCS level II code, that when reported on a claim would trigger an exemption for practice expense from the 50% discount. We urge CMS to explore this issue and enact a solution for CY2011.

Physician Practice Information Survey (PPIS)

SIR continues to have serious concerns about the AMA PPIS data. Only 33 PPIS surveys were used in the PE/HR calculations for Interventional Radiologists, 21 of which reported no equipment expenses. The PPIS data are **not** representative of the population of interventional radiology.

The interventional radiology data available from the SIR 2006-2007 Socio-Economic Survey illustrates several disparities between the two surveys. For instance the SIR 2006-2007 report indicates the number of solo practitioners is 6%, compared to 3% in the PPIS survey. The SIR 2006-2007 survey reports teaching hospitals at 14% while the PPIS data has the percentage at 23%. The SIR 2006-2007 reveals 80% of the group practices have 1-5 interventional radiologists (IRs) and 20% have greater than 6 IRs. While, the PPIS data suggest 31% of practices have 1-5 radiologists and 69% have greater than or equal to 6 radiologists.

We highlight these differences to illustrate the importance of having a robust number of respondents and appropriate weighting measures. The SIR 2006-2007 had a sample size of 250 respondents for a population of 1,713 has a margin of error of plus or minus 5.73% at a 95% level of confidence, while the PPIS survey had only 33 IR responses.

It is reckless to base Medicare reimbursement rates on data that we know are not accurate. These issues need to be addressed. SIR strongly urges CMS to work with the radiology community to collect more PPIS surveys for radiology specialties and to develop a methodology by which to develop the sample and weight the responses.

In the meantime, an attempt should be made to re-weight the respondents to produce a more accurate representation of the population of radiologists. Weighting the data by AMA Membership and a two-step Size of Practice classification fails to adequately address a number of deviations from the population of radiology practices, such as equipment ownership and practice setting.

The factors used to weight the PPIS survey results do not adequately compensate for some of the major settings for radiology practices, such as multispecialty practices and office-based, private practices that are responsible for all of their own expenses. There are too many teaching and non-teaching hospital practices represented in the PPIS results, which may have caused physicians outside of private practice to have greater influence on the PE/HR than their numbers justify.

In order to address these weighting issues, SIR recommends that PPIS practices with no medical equipment expenses should be weighted down to 44% of the total, while those practices in the sample that have medical equipment expense should be weighted up to 56%. This would insure that practices that are functionally independent of hospitals are adequately represented in the PE/HR calculations.

Next PPIS practices with a corresponding classification to the 2007 ACR Survey should be weighted to the proportions of the 2007 ACR Survey of Radiologists, and that the sum of these three practice settings (Solo Practice, Multispecialty Group and Teaching Hospitals) should account for 43% of the total. The remaining PPIS practices without corresponding classification to the 2007 ACR Survey should be weighted down to sum to 57% of the total.

Finally, since it appears likely that six main expense categories are under-reported in the PPIS sample, the SPE survey results, updated to the 2007 level accepted by CMS, should be blended with the combined Radiology and Interventional Radiology PPIS results. The SPE records would provide sufficient responses from the full spectrum of radiology practices that will allow the resulting PE/HR to adequately compensate for the expenses incurred in delivering radiology services to Medicare eligible patients.

Equipment Utilization Rates

An equipment utilization assumption rate of 75 percent will be applied to expensive diagnostic imaging equipment in a nonbudget neutral manner for CY 2011, as required in the ACA. The changes to PE RVUs will not be transitioned over a period of years. CMS will apply the 75 percent utilization rate assumption in CY 2011 to all of the services to which they currently apply the transitional 90 percent utilization rate assumption in CY 2010.

Additionally, for CY 2011, CMS is proposing to expand the list of services to which the higher equipment utilization rate assumption applies to all other diagnostic imaging services that utilize

similar expensive CT and MRI scanners. The additional 24 CPT codes (listed in Table 4) to which they are proposing to apply the 75 percent equipment utilization rate assumption also have expensive diagnostic imaging equipment (priced at over $1 million) included in their PE inputs. The codes included in this expansion are predominantly MRA and CTA services.

Therapeutic interventional radiology procedures that utilize an angiography room remain subject to a 50% equipment utilization assumption rate. Therapeutic interventional radiology services like transluminal balloon angioplasty, selective catheter placement, TIPS, transluminal mechanical thrombectomy and embolizations should not be subjected to the 75% equipment utilization assumption rate. SIR appreciates CMS' policy to maintain therapeutic interventional radiology procedures at a 50% equipment utilization assumption rate.

Potentially Misvalued Codes RUC issues

CMS, in conjunction with the AMA RUC, has identified and reviewed numerous potentially misvalued codes. CMS plans to continue their work examining potentially misvalued codes, consistent with the new legislative mandate on this issue. SIR agrees that it is appropriate for CMS to continue to work in conjunction with the AMA RUC on issues related to potentially misvalued codes. SIR believes this is the right approach and we are happy to continue to be part of the process.

For CY 2011, CMS is identifying codes with low work RVUs but are high volume, based on claims data, as another category of potentially misvalued codes and are referring these codes to the AMA RUC for review. In addition, for CY 2011 they are newly targeting the "multispecialty points of comparison" services (MPCs) and referring these to the AMA RUC for review as potentially misvalued codes. CMS also plans to pay particular attention to the work values and direct PE inputs for new services and the AMA RUC's periodic review process to ensure that any efficiencies are captured under the PFS over time.

The AMA RUC has established screens to identify potentially misvalued codes in additional categories, including codes with a high intraservice work per unit of time (IWPUT) and codes representing services that had been surveyed by one specialty, but are now performed by a different specialty. CMS will continue to review AMA RUC recommendations for revised work RVUs and/or direct PE inputs for codes that fall into the identified categories.

While it is understandable that CMS would like to examine various approaches to discover potentially misvalued codes, it is important to note that these reviews come with it a tremendous price tag for specialty societies. SIR urges CMS to establish reasonable timelines for these additional reviews, which come on top of the numerous requests already in progress. Finally, it is critical that any such reviews include all specialties and services equally, applying screening criteria equally to all services in the fee schedule.

Validating RVUs of Potentially Misvalued Codes

While CMS does assess the AMA RUC recommended work RVUs to determine if the recommendations constitute appropriate adjustments to the RVUs under the PFS, they intend to establish a more extensive validation process of RVUs in the future. SIR strongly encourages CMS to continue to work with the RUC on validating work RVUs. SIR strongly discourages CMS from using alternative methodologies in an inconsistent manner.

The MPFS is a "relative" payment system. It is not appropriate to use a special approach for validating one or two pieces of the code valuation process and then only apply that to some of

the 7500+ services in the fee schedule. If that approach is taken, then the system fails to be a ***relative*** system anymore.

If CMS has concerns with how codes are being examined/valued, they should discuss that with the RUC and specialty societies so they can be addressed in a uniform and fair manner.

Updating High-Cost Supplies

CMS is considering a process to regularly update prices for high-cost supplies under the PFS, possibly on a two year cycle, beginning as soon as CY 2013. CMS would propose the refined process through rulemaking before revising the prices for any high-cost supply item based on the United States General Services Administration (GSA) schedule.

CMS states that the medical community would have several years to examine the GSA medical supply schedule before the refined process would be adopted. This extended time period will also give stakeholders the opportunity to ensure that any items missing from the GSA medical supply schedule would be included. CMS states that if a supply price were not publicly available on the GSA medical supply schedule by the time they need to access the price, they would propose to reduce the current price input for the supply by a percentage that would be based on the relationship between GSA prices at that time and the existing PE database prices for similar supplies (currently an average 23 percent reduction).

SIR believes this proposal is dangerous and should be examined carefully before moving forward with a proposal. Many privately held companies selling radiology supplies do not have GSA schedules. The likelihood that all these companies will move forward to establish a GSA schedule is unrealistic. Why would a company sign up for the added regulatory burden of having a GSA schedule when they don't have to? So, really what CMS is proposing is an across the board reduction in reimbursement for physicians who perform Medicare procedures in an office setting.

SIR encourages CMS to continue to use the current approach of pricing supplies and equipment which includes providing copies of recently paid invoices from various offices (NF setting) in different demographics areas. Introducing another level of complexity to an already complex process is not a good idea. If CMS has concerns about particular items, they should continue to publish them in the Federal Register, notify the RUC/PEAC and request documentation. SIR does not support CMS using the GSA schedule to price items for the MFS.

Updating Equipment and Supply Price Inputs for Existing Codes

CMS is proposing to update equipment and supply price inputs annually through rulemaking by following a regular and consistent process. They are proposing to use the annual PFS proposed rule released in the summer and the final rule released on or about November 1 each year as the vehicle for making these changes.

CMS will accept requests for updating the price inputs for supplies and equipment on an ongoing basis; requests must be received no later than December 31 of each CY to be considered for inclusion in the next proposed rule. In that next proposed rule, they would present their review of submitted requests to update price inputs for specific equipment or supplies and their proposals for the subsequent calendar year. They would then finalize changes in the final rule for the upcoming calendar year.

SIR supports this proposed process for updating equipment and supply costs. We support the current documentation criteria, which includes providing copies of recently paid invoices from various offices (NF setting) in different demographics areas.

Self Referral

The Affordable Care Act (ACA) imposed a new disclosure requirement on physicians who self-refer for MRI, CT, PET and other imaging services that CMS determines appropriate. Under this legislation, physicians who provide certain imaging services to Medicare patients through their group practices, under the group practice exception, are required to provide a list of alternative suppliers to the patient.

Under the PFS Proposed Rule, physicians who refer patients to their own group practice for MRI, CT or PET services would be required to:

- Inform the patient in writing at the time of the referral that he or she may obtain the service from a person other than the referring physician or someone in the physician's group practice. The disclosure notice is required to be written in a manner that can be understood by all patients and must be given to the patient at the time of the referral.
- Provide the patient with a list of at least ten suppliers who furnish the service in the 25-mile radius of the physician's office (not in the "area in which the patient resides" as

stated in the governing legislation). CMS is proposing to require physicians with fewer than ten other suppliers within a 25-mile radius to list all the suppliers that are within the 25-mile radius. The list must include the name of the suppliers and their addresses, phone numbers, and distance from the physician's office location at the time of the referral. Furthermore, the referring physician is prohibited from including on the disclosure or list of suppliers anything indicating to the patient that he or she must receive imaging from a supplier on the list or from the referring physician's practice. Significantly, CMS is proposing that only suppliers (and not "providers of services", *e.g.*, hospitals) are to be included on the list.

- A record of the patient's signature on the disclosure notification must be maintained as an element of the patient's medical record.

While interventional radiology procedures are not designated health services, interventional radiologists may on occasion refer to others within their practices for MRI, CT, and PET procedures and in these instances, may rely on the Stark Law's group practice exception.

SIR recommends that CMS provide clear language to providers regarding the language that should be included on their patient alternative supplier letter in order to meet the disclosure requirements.

If CMS moves forward with requiring an actual list of suppliers, SIR feels that 10 alternative supplies is more than enough and that the proposed 25-mile radius is appropriate for both urban and rural practices.

SIR believes that maintaining a copy of the patient's signed disclosure notification in the medical record is burdensome. SIR recommends CMS accept a note in the patients chart that a member of the staff provided the letter and explained it to the patient should as sufficient documentation.

SIR believes these requirements should **not** be expanded to radiology services other than MRI, CT, or PET and that CMS should allow for an exception for services furnished on an emergency or time-sensitive basis.

CPT Code 37210

CPT code 37210 *Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure* was reviewed at the April and October 2006 RUC meetings. The AMA forwarded PE recommendations for CY2007. In reviewing the CY 2011 Direct Practice Expense File (CY_2011_NPRM_Direct_PE) it appears 10 minutes of RN/LPN/MTA pre time are missing

from the CMS direct inputs. The total RN/LPN/MTA time should be 13 minutes for this procedure.

SIR appreciates the opportunity to provide comments to CMS on the proposed policies for CY2011. If you have any questions, please contact Trisha Crishock, MSW at (703)934-8272.

Sincerely,

James F. Benenati, MD, FSIR
SIR President