SOCIETY OF INTERVENTIONAL RADIOLOGY
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Society of Interventional Radiology
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August 29, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1403-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via http://www.regulations.gov

RE: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; Proposed Rule. [CMS-1403-P]"

Dear Mr. Weems:

The Society of Interventional Radiology (SIR) is a physician association with over 4,300 members that represents the majority of practicing vascular and interventional radiologists in the United States. SIR having reviewed the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; Proposed Rule. [CMS-1403-P]" offers the following general and specific comments:

General Comments

SIR commends CMS staff for their dedication and commitment to the continual improvement to the Medicare Physician Fee Schedule (MPFS), which is again evident in the production of this proposed rule. In general, SIR is committed to continuing to work through the AMA RBRVS Update Committee (RUC) process, which supports the development of valuations and reexamination of existing values for physician services. CMS' continued support and acceptance of this continually evolving process is truly appreciated. SIR does ask CMS to acknowledge the societal resources required to support this process and urges CMS to not overburden this system. SIR had taken great strides to adhere with CMS' request for current pricing of a significant number of supplies. SIR finds that the costs of many of the devices on the CMS list have increased. We anticipate that CMS will act to appropriately increase the practice expense values of these supplies. Finally, SIR has concern that the implementation of the proposal to require all offices providing imaging services to register as Independent Diagnostic Testing Facilities (IDTF) could be truly problematic and urge CMS to delay this proposal until it is more fully developed.

Specific Comments

"INDEPENDENT DIAGNOSTIC TESTING FACILITIES"

SIR Opposes CMS Proposal to Require All Offices Providing Imaging Services to Register as IDTFs

Interventional radiologists are board-certified physicians with additional advanced training in minimally invasive, targeted treatments performed using imaging guidance. Their unique board certification, administered by the American Board of Radiology, includes both Vascular and Interventional Radiology and Diagnostic Radiology. With their roots in diagnostic radiology, SIR members are strongly committed to assuring quality of imaging services. However, SIR has significant concern regarding the potential implementation of CMS' proposal to require all offices providing imaging services to enroll as independent diagnostic testing facilities (IDTFs). We are concerned that requiring offices to register as IDTFs will overwhelm carrier provider application processing systems. We also believe there are significant claims processing issues that may result from this proposal that have not been fully considered by CMS. SIR finds this proposal to be premature, but is committed to working with CMS to identify a mechanism to ensure quality of imaging services provided in the non-hospital setting.

Potential Ramifications to Claims Processing

IDTFs have unique claims processing requirements that differ from those of general physician offices. Moreover, there are limitations on the specific procedure codes that IDTFs are approved to submit for reimbursement. Requiring general physician offices to register as IDTFs, while still reporting currently allowed services for non-imaging services, would require CMS to lessen the current restrictions placed on IDTF claim submission. SIR assumes CMS had sound rationales for implementing these restrictions and we sincerely doubt that this would be a desirable outcome. Additionally, there are non-"diagnostic" imaging services that may performed in the "office" setting that are not currently supported for the IDTF setting, such as radiological supervision & interpretation codes. These are commonly reported in support of the performance of diagnostic and therapeutic interventional radiology procedures. SIR recommends that CMS fully explore the claims processing ramifications that may result from registering physician offices providing imaging services as IDTFs, prior to moving forward with this proposal.

Imaging Accreditation Requirements by 2012

CMS' desire to ensure quality of imaging for the office setting is clearly aligned with the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which requires accreditation for the technical component of advanced imaging services provided in the office setting. Again, SIR is committed to working with CMS to ensure this legislation is effectively and appropriately implemented.

"POTENTIALLY MISVALUED SERVICES UNDER THE PFS"

SIR Supports the RUC Process and Urges CMS to Establish Limitations
SIR supports the American Medical Association's RBRVS Update Committee (RUC process), which continues to act to address concerns raised by CMS regarding potentially misvalued services under the MPFS. CMS' continued support and acceptance of this evolving process is truly appreciated. SIR does ask CMS to acknowledge the societal resources required by this process and urges CMS to not overburden this system. The RUC process, particularly the RUC survey process required for the development of physician work RVU recommendations and the consideration of practice expense inputs, requires a substantial outlay of societal resources. Therefore, in order to not overburden any one given specialty, SIR recommends that CMS consider placing limitations on the number of codes, during a given period of time that any given specialty may have targeted for revaluation.

Differences in Current Coding Systems
Per the 2009 MPFS proposed rule, concerns have been raised by "some observers" that "there may be inequities between specialties in the current coding and payment system regarding the extent to which there are opportunities for additional coding and payment for services performed on the same day." SIR does find that there are significant differences in the coding systems amongst some specialties. However, mere variation amongst coding systems does not necessarily translate to inequities in payment.

Just as this group of observers is apprehensive about the coding conventions that support detailed accurate accounting and reporting of services, SIR is apprehensive of some E&M coding conventions. Specifically, these appear to be highly subjective and difficult to audit, as compared to the very detailed and exact coding conventions that require the reporting of smaller, very precise and more clearly defined units of physician work.

SIR Urges CMS to Examine the Accuracy of the Number of E&M Services Bundled into Global Surgical Packages
Additionally, SIR is apprehensive regarding services reported using "comprehensive surgical global policies." SIR has concern that clinical practice patterns may have changed significantly since the initial valuation of many of the codes for reporting these services. We are concerned that the large number of follow-up visits included in the valuation of these services, may no longer be applicable. In addition to CMS' comprehensive study of services commonly reported together, SIR urges CMS to study all codes that contain more than two follow up visits within their global period to see if the patients' records support the large number of E&M visits that have been built into valuation for codes valued using "comprehensive surgical global policies".

Updating High Cost Supplies
As anticipated, the collection of cost information for supplies has been burdensome. SIR has made every reasonable effort, with the resources available to us, to adhere to CMS' request in this regard. Many manufactures cited numerous concerns in providing this data. Many are unfamiliar with the practice expense valuation process despite CMS'

fairly clear discussion of the methodology for these calculations. Regretfully, there are too many variables for which the data is not available or has not been provided to the public to support external verification of this methodology.

Additionally, CMS citied the impetus for this initiative as a desire to identify supplies that have experienced a price reduction. However, the cost information collected by SIR supports prices, typically, do not decrease, but rather increase over time. Like other technology, SIR finds that often there may be initial high prices that then experience a significant drop once the market becomes fairly saturated. Moreover, SIR finds that for medical procedures – typically, this cycle of high then lower pricing occurs prior to the medical procedure receiving a CPT code and going through the valuation process. By the time a medical procedure and its corresponding devices become eligible for a specific CPT code, the procedure has become fairly widely established and the pricing for the devices involved have already hit their plateau.

Out of respect for the device manufacturers that submitted pricing information to SIR, SIR has forwarded this information directly to CMS staff responsible for the oversight of this information and we are only presenting a summary table confirming the dates of submission within these comments. If there are any questions regarding any of this data submitted under separate cover, please feel free to contact SIR staff using the contact information presented in the closing paragraph of this letter.

SIR strongly recommends that CMS extend the time frame for examining the cost if "high priced" supplies from the proposed "every two years" to intervals of every three years. Additionally, CMS uses external sources to establish the average pricing for drugs under HOPPS (Hospital Outpatient Prospective Payment System). Perhaps CMS should consider using external sources, such as that provided by IMS Health (www.imshealth.com) in updating "high cost supplies".

High Utilization

As CMS is aware, the RUC has already taken action regarding the list of high utilization codes identified by CMS in the 2009 MPFS proposed rule. SIR, in concert with other stakeholders, will be working through the RUC process to address codes 10022, 35470, 35474, and 36248.

Review of Harvard-Valued Codes

SIR agrees with the RUC that reviewing all 2,856 Harvard-valued codes is a daunting task that would require an unreasonable amount of time and resources. Again, SIR asks that CMS acknowledge the societal resources required to support the RUC process. We urge CMS to not overburden this system, and we recommend CMS consider placing limitations on the number of codes, during a given period of time that any given specialty may have targeted for revaluation.

SIR appreciates the opportunity to provide comment to CMS regarding the valuation of interventional radiology services under the Medicare Physician Fee Schedule. If SIR can be of any assistance as CMS continues to consider and review the 2009 Medicare Physician Fee Schedule, please do not hesitate to contact Dawn R. Hopkins, Director of Reimbursement & Health Policy at (800) 488-7284, ext. 588, Hopkins@SIRweb.org,

Sincerely,

Ezequiel Silva III, MD
Chair, Economics Committee
SIR

Cc: Ken Simon, MD, CMS
Pamela West, CMS
Michael Brunner, MD
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Society of Interventional Radiology
Attachment A

TABLE 24: Top 65 High Cost Supplies Over $150--Supplies Needing Specialty Input for Price Update

CMS Supply Code	Supply Description	Unit	Quantity per Procedure	CPT I Code(s)	Manufacturer	Cost information submitted to CMS
SD109	probe, radiofrequency, 3 array (StarBurstSDE)	item	1	50592, 32998, 20982	AngioDynamics (previously RITA)	**insufficent documentation (ie, pricing without any product numbers) received - request again submitted to manufacturer for complete documentation**
	catheter, CVA, system, tunneled w-port, dual (LifeSite)	item	2	36566	Unable to locate device manufacturer	
	stent, vascular, deployment system, Cordis SMART	kit	1.5	37205, 37206	Cordis	**8/26/2008**
	probe, cryoablation, renal	item	2.5	50593	Endocare	**8/28/2008**
SD155	catheter, RF endovenous occlusion	item	1	36475	VNUS	**8/27/2008**
SA039	kit, vertebroplasty (LP2, CDO)	kit	1.5	22520, 22521	Arthrocare	**8/28/2008**
SA025	kit, PICC with subcut port	kit	1	36570, 36571, 36585	**ACR able to obtain cost info; SIR supports their findings**	
SA074	kit, endovascular laser treatment	kit	1	36478	**ACR able to obtain cost info; SIR supports their findings**	
SA011	kit, CVA catheter, tunneled, with subcut port	kit	1	36560, 36561, 36563, 36582, 36583	Bard	**8/22/2008**
SA015	kit, for percutaneous thrombolytic device (Trerotola)	kit	1	36870, 37184, 37186, 37187, 37188	**ACR able to obtain cost info; SIR supports their findings**	
SD151	catheter, balloon, low profile PTA	item	2	35470, 35471, 35474	Bard	**8/22/2008**
SD154	catheter, microcatheter (selective 3rd order)	item	1	36217, 36247, 37210	Boston Scientific (Fast tracker 325)	**8/29/2008**
SA077	kit, pleural catheter insertion	kit	1	32550	Cardinal	**8/8/2008**
SA010	kit, CVA catheter, tunneled, without port-pump	kit	1	36557, 36558, 36581	Bard	**8/22/2008**
SA020	kit, loop snare (Microvena)	kit	1	36595, 37203	Angiotech	**8/29/2008**
	agent, embolic, 2 ml uou	unit	5	37210	Biosphere	**8/29/2008**
SD152	catheter, balloon, PTA	item	2	35472, 35473, 35475, 35476, G0392, G0393	Bard	**8/22/2008**

TABLE 24: Top 65 High Cost Supplies Over $150--Supplies Needing Specialty Input for Price Update

CMS Supply Code	Supply Description	Unit	Quantity per Procedure	CPT I Code(s)	Manufacturer	Cost information submitted to CMS
SD207	suture device for vessel closure (Perclose A-T)	item	1	37184, 37205 (35470, 35471, 35472, 35473, 35474, 35475, 37187, 37188, G0392)	**ACR able to obtain cost info; SIR supports their findings**	
	tube, jejunostomy	item	1	49441, 49446, 49451, 49452	Bard	**8/22/2008**
SD175	guidewire, steerable (Transcend)	item	1	36217, 36247, 37205, 37206, 37210, 49440, 49441, 49442, 49446, 49450, 49451, 49452, 49460	BSCI	**8/29/2008**
SD218	stent, ureteral, without guidewire	item	1	50382, 50385	Bard	**8/22/2008**
SD020	catheter, CVA, tunneled, dual (Tesio)	item	1	36565	Bard	**8/22/2008**