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October 10, 2006

BY HAND DELIVERY

Mark B. McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington DC 20202

Re: Comments on CMS-1506-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

By this letter commenting on the 2006 hospital outpatient prospective payment system ("OPPS") final rule, Curon Medical Inc. ("Curon") respectfully requests that the agency revise the proposed payment rate assigned to the Current Procedural Terminology ("CPT") code, 43257.[1] This code includes both the Stretta procedure and esophagogastroduodenoscopy ("EGD") procedures within a single code. The code, however, did not exist in 2004, which is the period from which the Centers for Medicare & Medicaid Services ("CMS") is drawing claims for purposes of setting the 2006 OPPS rates. Instead, hospitals billed separate codes for the Stretta and EGD procedures. While the agency made some accommodations in the Proposed Rule to account for the coding differences between 2004 and 2006, Curon believes that the proposed rate considerably underestimates the costs of providing this service. We believe that the agency must take further steps to ensure that it is establishing a median cost for CPT code 43257 in a way that takes into account the full set of resources used in furnishing this procedure, and that CMS should establish a new ambulatory payment classification ("APC") to ensure that all of the procedures proposed to be assigned to APC 422 are paid more appropriately.

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[1] 70 Fed. Reg. 42674 (Jul. 25, 2005) (the "Proposed Rule").

I. BACKGROUND

A. The Stretta System

The Stretta System, cleared for marketing by the Food and Drug Administration in April of 2000, provides a minimally invasive outpatient procedure for the treatment of gastroesophageal reflux ("GERD") that is both clinically effective and less expensive than the surgical procedure alternative. Gastroesophageal reflux is the term used to describe a backflow of acid from the stomach into the esophagus. GERD is a clinical condition that occurs when reflux is frequent, sustained and symptomatic. Using the Stretta Catheter, a sophisticated, single use flexible catheter with needle electrodes, and the Curon Control Module, the physician delivers precisely controlled radiofrequency energy, contracting the lower esophageal sphincter and creating thermal lesions in the muscle of the sphincter as a treatment for GERD. As these lesions heal, the tissue remodels, reducing reflux episodes and improving GERD symptoms. The patient returns home on the same day as the procedure. Thus, the Stretta procedure avoids the risk and expense of general anesthesia, hospitalization, and prolonged post-operative recovery associated with the surgical anti-reflux procedure alternative.

B. Treatment of the Stretta System Under OPPS Through 2004

CMS approved the Stretta System as a new technology effective January 1, 2001 and assigned it to Healthcare Common Procedure Coding System ("HCPCS") code C9701. Through 2004, this service continued to be billed under OPPS using C9701, with a payment rate of $1850.[2] While hospitals performing the Stretta procedure during that time billed using the C9701 code, hospitals also billed for the EGD procedures furnished concurrently. Based on our review of the 2004 OPPS claims data that CMS released with the Proposed Rule, some hospitals that billed HCPCS code C9701 also billed CPT code 43234 or 43235 or other endoscopy codes. These CPT codes are assigned to APC 141, with a current payment rate of $460.00.

C. A New CPT Code

Effective January 1, 2005, the American Medical Association ("AMA") established a new Category I CPT code (43257) to be used to bill for the Stretta System. The language of this code is:

> *Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease.*

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[2] 68 Fed. Reg. 63398, 63611 (Nov. 7, 2003). We note that a Category III CPT code was effective January 1, 2004, but CMS listed this as a non-payable code while continuing to identify C9701 as a payable code under OPPS. 68 Fed. Reg. at 63490, 63611.

The details of the procedure and the services involved are reflected in the "Clinical Example" included in the AMA's *CPT Changes 2005* (pertinent pages attached). With the patient under conscious sedation, an EGD is performed to visualize the esophagus and determine appropriate placement locations. The Stretta Catheter is then inserted into the patient's mouth and advanced to the junction of the esophagus and stomach as determined by the endoscopic measurements. A balloon is inflated and needle electrodes are deployed into the tissue. Radiofrequency energy is delivered through the electrodes, heating the tissue to create thermal lesions in the muscle of the LES and gastric cardia to induce contraction of the sphincter musculature, creating two rings of eight lesions. A second EGD is then performed to confirm the positioning of the first two rings. Further thermal energy is then delivered creating additional rings. At the end of the procedure, a third EGD is performed to confirm the placement of the lesions.

CPT code 43257 represents a significant departure from the prior coding scheme in which hospitals billed C9701 for the Stretta procedure and one of a number of endoscopy CPT codes for the EGD procedure. This CPT code contemplates the billing of a single code for the EGD procedures and the Stretta procedure, which the prior coding scheme did not.

D. The 2005 OPPS Rulemaking

In 2005, CMS both incorporated the new CPT code as a payable code under OPPS and discontinued paying for the Stretta procedure as a new technology APC, assigning 43257 to APC 422 (Level II Upper GI Procedures). Initially, the agency set a payment rate of $1,264.79.[3] Subsequently, the agency revised the payment rate for this APC to $1335.65.[4]

E. Proposed Treatment of the Stretta Procedure in 2006

In the Proposed Rule, CMS again proposes to assign CPT code 43257 into APC 422. Concurrent with the release of the Proposed Rule, the agency issued a median cost file, which included the median costs for the procedures in that APC. That file included a median cost for the Stretta C code used in 2004 (C9701) of $1382.54, which was calculated by looking solely at 2004 claims that included just the C9701 code and no code for an endoscopic procedure. Recognizing that the CPT code now used to bill for the Stretta procedure (43257) includes the Stretta procedure and endoscopic procedures, CMS proposes adding 2004 claims that included the C9701 code and one of two endoscopy CPT codes to the set of claims used to calculate median cost. As a result, the median cost for this clearly device-dependent procedure increased

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[3] 69 Fed. Reg. 65682, 65873 (Nov. 15, 2004).

[4] *See* CMS Transmittal # 514, available at http://www.cms.hhs.gov/manuals/pm_trans/R514CP.pdf.

to $1669.43, and the proposed payment rate for APC 422 is $1356.78.[5] The table below identifies the median cost of the codes in APC 422:

Code	Frequency	Median Cost
0008T	4	$1372.53
43228	220	$1093.22
43830	204	$1378.57
C9701/43257	Unknown	$1669.43
C9703	12	$1838.41

II. DISCUSSION

Curon appreciates CMS' recognition that the 2004 claims data in the released median cost file does not provide an accurate basis for setting the payment rate for CPT code 43257 because this code combines the Stretta procedure and the endoscopy procedures, whereas hospitals billed for these services in separate codes in 2004. The agency's inclusion of claims that contained the codes for the Stretta procedure and an endoscopy code increased the median cost by about $300. Yet, the result still includes numerous claims that do not reflect the resources of the endoscopic procedure that, clinically, must be done with every Stretta procedure. Accordingly, we believe that CMS' median cost calculation for CPT code 43257 needs further refinement. In addition, even under the above listed median cost figures, Curon believes that CMS should create a new APC to break apart the codes in APC 422 so that more accurate payment rates for all of the procedures proposed to be in that APC can be determined.

A. Recomputing the Median Cost for CPT Code 43257

As just noted, the median cost used for CPT code 43257 increased when CMS added in the claims that also reflected the resources of the endoscopic procedures that must be done with the Stretta procedure. That demonstrates that continued inclusion of claims containing only C9701 artificially devalues the median cost CMS will use for CPT code 43257. Curon believes that there are different options that CMS could utilize to compute a median cost for this code that truly reflects the resources for the endoscopic and Stretta procedures.

CMS could adjust the cost of each claim that was billed only with C9701 by the median cost for CPT code 43235 - $406.13 (the lower of the median costs CMS identified for 43234 or 43235) and use these claims in the median cost calculation. Putting these adjusted claims together with 2004 claims in which C9701 and 43234 or 43235 or another endoscopy code were billed would ensure that the claims used to determine the median cost for 43257 reflect the resources of both the Stretta and endoscopic procedures. Curon believes that this is the most appropriate means of determining the median cost for 43257.

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[5] 70 Fed. Reg. at 42711.

Conceptually, CMS also could ensure that only claims reflecting the resources of the endoscopic and Stretta procedures are utilized by considering only 2004 claims in which C9701 and either 43234 or 43235, or another endoscopy code were billed when computing median cost. Because this does not yield as complete a claims set as the above suggested methodology, we view this as a lesser alternative to using the claims that included both the claims containing only C9701 adjusted by the median cost for CPT code 43235, and the claims containing C9701 and either 43234 or 43235 or another endoscopy code.

B. Creating a Level III Upper GI Procedures APC

Curon believes it is apparent that a new APC must be created to group the procedures currently assigned to APC 422 more appropriately, irrespective of whether the median cost in the Proposed Rule or a revised median cost developed as we recommend in Section II(A) above is used for CPT code 43257. Given that the median cost for this code in the Proposed Rule is $1669.43 and that the median cost for the lower cost endoscopy code is over $400, ensuring the claims used to set median cost reflect the resources of the endoscopic procedures, as CMS should, likely would generate a median cost for 43257 that is higher than the highest median cost for a code in APC 422 in the data released by CMS - $1838.41 for C9703 (the Bard endoscopic suturing system).[6] As a result, there will be a very significant difference in median cost levels between the endoscopic suturing system code and the Stretta code (43257) compared to the other two codes (43228 and 43830). Indeed, the median cost for C9703 is as much as 68% higher than that of CPT codes 43228 and 43830, and the higher revised median cost for CPT code 43257 would create an even greater gap. We, therefore, recommend that CMS leave 43228 and 43830 in APC 422, and create a Level III Upper GI Procedures APC, assigning 43257 and 0008T into that new APC.

The frequency of the various procedures in APC 422 also supports the creation of a new APC. The two procedures with the lower median costs (43228 and 43830) have significantly greater frequency values (220 and 204, respectively) than the Stretta and endoscopic suturing system codes, which collectively do not total 75. As a result, the continued inclusion of 43257 and 0008T in APC 422 pulls up the payment rate for a greater number of procedures. If 43228 and 43830 remained in APC 422 and 43257 and 0008T were moved to a new APC, the rate for APC 422 could be set more accurately, as would the rate for the new APC. For these reasons, we recommend that CMS create a new APC for Level III Upper GI Procedures and assign 43257 and 0008T to that APC.

This recommendation is consistent with the agency's treatment of vascular access procedures in the Proposed Rule. CMS has proposed creating new APCs for vascular access

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[6] As of January 1, 2005, CMS instructed hospitals to bill 0008T instead of C9703 for the endoscopic suturing system. The median cost file CMS released indicates that, in 2004, hospitals were billing using C9703 and 0008T. Given that, in 2004, hospitals were supposed to bill for the service using C9703, and 0008T was then a nonpayable code (68 Fed. Reg. 63398, 63489 (Nov. 7, 2003)), it is inappropriate to utilize the 4 claims for 0008T in determining the median cost for this service. In addition, because C9724 was first established in April 2005 and assigned directly to APC 422, there are no 2004 claims data to consider in determining the median cost for that code. Since there are no 2004 claims data for C9724, we do not discuss the assignment of this code to an APC.

procedures, assigning procedures to the new APCs "based on median cost and clinical homogeneity."[7] As explained above, creating a new Level III Upper GI Procedures APC and assigning 43257 and 0008T to that APC would provide greater median cost homogeneity for the affected procedures.

III. CONCLUSION

The Stretta procedure represents a remarkable treatment breakthrough that offers excellent results to patients at lower costs than traditional surgical procedures. Thus, creating economic disincentives to the utilization of this procedure, as the Proposed Rule does, ultimately may impose greater costs on the Medicare program and its beneficiaries. For the reasons detailed above, Curon respectfully urges CMS to:

1. revise the median cost computed for CPT code 43257 to ensure that all claims contributing to that median cost reflect the resources of the endoscopic procedures that are a necessary part of this code; and
2. create a new APC and assign 43257 and 0008T to that APC.

Thank you for the opportunity to comment on this important issue. We look forward to the appropriate resolution of the 2006 OPPS payment rate for new CPT code 43257 effective January 1, 2006. Please contact me at 510-661-1801 if you have any questions concerning regarding this comment letter.

Sincerely,

Larry C. Heaton II
President and
Chief Executive Officer

Attachment

[7] 70 Fed. Reg. at 42711.

NCQDIS
National Coalition for Quality Diagnostic Imaging Services

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October 10, 2006

HAND DELIVERED

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P

Dear Dr. McClellan:

The National Coalition for Quality Diagnostic Services ("NCQDIS") would like to thank you for the opportunity to comment on the Proposed Rule CMS-1506-P, "The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule" (the "Proposed Rule") published in the *Federal Register* on August 23, 2006.[1] We hope our comments will facilitate the development of a Hospital Outpatient Prospective Payment System Final Rule that will ensure continued access to safe and quality imaging services for the Medicare beneficiaries in 2007.

As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

NEW TECHNOLOGY APCs

I. CMS SHOULD ASSIGN PET/CTs TO AMBULATORY PAYMENT CLASSIFICATION (APC) 1514 FOR 2007 AND 2008

CMS proposed to move PET/CT scans from a new technology APC (APC 1514) to a clinical APC (APC 308) for 2007. NCQDIS strongly urges CMS to rescind this proposal and accept the recommendation of the APC Panel and keep PET/CT scans in APC 1514. Furthermore, NCQDIS recommends that CMS keep PET/CT scans in APC 1514 for a minimum of two years to ensure that the cancer patients will continue to have access to this critical imaging service.

The proposed OPPS payment amount of $862.29 represents a drastic payment cut of over 31%. PET/CT is a critically important part of the treatment plan for many cancer patients. As numerous studies have shown, PET/CT yields numerous clinical and patient benefits because of the short scan times (less patient movement) and the ability to see both a metabolic and anatomical image set acquired in the same setting. We are concerned that at the proposed reimbursement rate Medicare beneficiaries will not have access to PET/CT scans which largely have replaced PET as the standard of care. The cost of performing PET/CT is underestimated in

[1] 71 *Fed. Reg.* 49504 (Aug. 23, 2006).

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the OPPS fee schedule because the capital equipment cost is spread out over all procedures in the revenue center. We note that hospitals allocate the costs of expensive capital equipment over all procedures with costs attributable to a specific revenue center. In the case of PET/CT, the cost of a PET/CT scanner is allocated over all procedures in the diagnostic radiology (or nuclear medicine) revenue center. The hospital "cost" of providing a PET/CT scan is underestimated because the cost of the scanner is spread out over all radiologic services. In essence, hospital cost reporting results in the cost of non-PET/CT services being overestimated and the cost of PET/CT underestimated.

Furthermore, we suspect the claims data being used to set the payment rates under the Proposed Rule are flawed because we understand many hospitals have not yet updated their chargemasters to separate charges for PET and PET/CT and more accurately reflect the cost of the newer technology. We recommend that PET/CT remain in the new technology APC for a minimum of two years to allow hospitals time to establish PET/CT-specific charges that more accurately reflect the costs associated with the services. On a number of occasions, CMS has mitigated significant decreases in reimbursement by transitioning payment reductions over several years to allow providers to take steps to minimize the effect of reduced reimbursement on their ability to provide care to Medicare beneficiaries. In fact, CMS is doing precisely that with regard to transitioning in physician fee schedule (PFS) payments under the new practice expense (PE) methodology from 2007 to 2010.

Lastly, this significant flaw in the claims data should be addressed in setting the payment rate for PET/CT. In the past CMS has used external data when setting payments for OPPS services (e.g., insertion of defibrillators, cochlear implants) when the claims data are flawed. Therefore, we believe there is precedent for CMS to use its own external data (from the refined direct cost inputs used to establish practice expense RVUs under the PFS) to set payment rates for PET/CT. If that external data is blended with OPPS claims data the payment rate would be significantly higher than the payment rate in the Proposed Rule. Such a result lends additional support to placing PET/CT in APC 1514.

II. CMS SHOULD REVISE CERTAIN IMAGING APCS

NCQDIS strongly urges CMS to revise the CT, MRI, and MRA APC groupings to create greater internal clinical and resource consistency. Attached as Appendix I is a listing of the proposed APC imaging groupings. The current APC groupings are not clinically coherent. Diagnostic services performed in the same anatomical region have similar resource utilization and therefore should be in the same APC grouping. NCQDIS is prepared to work with CMS, on an ongoing basis, to develop clinically coherent APC groupings as innovative imaging procedures continue to emerge.

The Deficit Reduction Act § 5102(b) provision capping physician payments for the technical component of imaging services in IDTFs and radiology physician offices at the rates paid under OPPS inextricably link the two payment systems. Furthermore, it is critical that the imaging APCs be as refined as possible because the OPPS system is being used as the benchmark to limit reimbursement for imaging services under the PFS. We believe that refinement is appropriate

for imaging services to ensure resource similarity of the procedures within imaging APCs and establish a more accurate payment rate for imaging services under both the PFS and OPPS.

Given the linkage between the OPPS and PFS with regard to payment for imaging services, we believe that CMS should refine the APCs for CT, MRI and MRA in a manner that more accurately reflects resource use than the current APC structure. In other words, because APC relative weights will now determine physician payment, and because physicians can not spread costs over unrelated procedures or make up payment shortfalls for CT, MRI and MRA by profits on other services like hospitals do, CMS should make every effort to restructure the CT, MRI and MRA APCs to take into account resource differences that are smaller than they have in the past.

We also ask that CMS consider using external data (from the refined direct cost inputs used to establish practice expense RVUs under the PFS) and indirect PE allocation methodology to determine relative weights for imaging APCs.

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NCQDIS would again like to thank CMS for the opportunity to submit formal comments on the Proposed Rule. We urge CMS to adopt the recommendations set forth in this comment letter so that Medicare beneficiaries continue to have access to safe and quality imaging services.

Sincerely,

Cherrill Farnsworth
President, NCQDIS

Liz Quam
Policy Chair, NCQDIS

Appendix I

(Proposed APC Imaging Groupings)

CT APC Groupings

CPT	Proposed APC Grouping	Current APC
	CT EXTREMITIES/OTHER w/DYE	
70481	Ct orbit/ear/fossa w/dye	283
70487	Ct maxillofacial w/dye	283
70491	Ct soft tissue neck w/dye	283
73201	Ct upper extremity w/dye	283
73701	Ct lower extremity w/dye	283
76355	Ct scan for localization	283
76360	Ct scan for needle biopsy	283
	CT CORE w/DYE	
71260	Ct thorax w/dye	283
72193	Ct pelvis w/dye	283
74160	Ct abdomen w/dye	283
70460	Ct head/brain w/dye	283
72126	Ct neck spine w/dye	283
72129	Ct chest spine w/dye	283
72132	Ct lumbar spine w/dye	283
	CT EXTREMITIES/OTHER w/o DYE	
70480	Ct orbit/ear/fossa w/o dye	332
70486	Ct maxillofacial w/o dye	332
70490	Ct soft tissue neck w/o dye	332
73200	Ct upper extremity w/o dye	332
73700	Ct lower extremity w/o dye	332
	CT CORE w/o DYE	
70450	Ct head/brain w/o dye	332
71250	Ct thorax w/o dye	332
72192	Ct pelvis w/o dye	332
74150	Ct abdomen w/o dye	332
72125	Ct neck spine w/o dye	332
72128	Ct chest spine w/o dye	332
72131	Ct lumbar spine w/o dye	332
	CT CORE w/o & w/ DYE	
74170	Ct abdomen w/o & w/dye	333
71270	Ct thorax w/o & w/dye	333
70470	Ct head/brain w/o & w/dye	333
72127	Ct neck spine w/o & w/dye	333
72130	Ct chest spine w/o & w/dye	333
72133	Ct lumbar spine w/o & w/dye	333
72194	Ct pelvis w/o & w/dye	333

CT APC Groupings (continued)

CPT	Proposed APC Grouping	Current APC
	CT EXTREMITIES/OTHER w/o & w/DYE	
70482	Ct orbit/ear/fossa w/o&w/dye	333
70488	Ct maxillofacial w/o & w/dye	333
70492	Ct sft tsue nck w/o & w/dye	333
73202	Ct uppr extremity w/o&w/dye	333
73702	Ct lwr extremity w/o&w/dye	333
76362	Ct guide for tissue ablation	333
0067T	CT colongraphy; dx	333

MRA APC Groupings

CPT	Proposed APC Grouping	Current APC
	MRA CORE w/o DYE	
C8910	MRA w/o cont, chest	336
C8919	MRA w/o cont, pelvis	336
70547	Mr angiography neck w/o dye	336
70544	Mr angiography head w/o dye	336
	MRA EXTREMITIES/OTHER W/O DYE	
C8913	MRA w/o cont, lwr ext.	336
	MRA EXTREMITIES/OTHER W/DYE	
C8912	MRA w/cont, lwr ext	0284
	MRA EXTREMITIES/OTHER W/O & W/DYE	
C8914	MRA w/o fol w/ cont, lwr ext	337
	MRA CORE w/ & w/o DYE	
70546	Mr angiograph head w/o&w/dye	337
70549	Mr angiograph neck w/o&w/dye	337
C8902	MRA w/o fol w/cont, abd	337
C8920	MRA w/o fol w/cont, pelvis	337
C8911	MRA w/o fol w/cont, chest	337
	MRA CORE w/ DYE	
C8900	MRA w/cont, abd	0284
C8909	MRA w/cont, chest	0284
C8918	MRA w/cont, pelvis	0284
C8901	MRA w/cont, abd	336
70545	Mr angiography head w/dye	0284
70548	Mr angiography neck w/dye	0284

MRI APC Groupings

CPT	Proposed APC Grouping	Current APC
	MRI EXTREMITIES/OTHER w/o DYE	
C8908	MRI w/o cont, breast	337
C8904	MRI w/o cont, breast, uni	336
C8907	MRI w/o cont, breast, bi	336
73221	Mri joint upr extrem w/o dye	336
73721	Mri jnt of lwr extre w/o dye	336
73218	Mri upper extremity w/o dye	336
73718	Mri lower extremity w/o dye	336
	MRI CORE w/o DYE	
74181	Mri abdomen w/o dye	336
70557	Mri brain w/o dye	336
71550	Mri chest w/o dye	336
72195	Mri pelvis w/o dye	336
70551	Mri brain w/o dye	336
72141	Mri neck spine w/o dye	336
72146	Mri chest spine w/o dye	336
72148	Mri lumbar spine w/o dye	336
	MRI EXTREMITIES/OTHER w/o & w/ DYE	
73220	Mri uppr extremity w/o&w/dye	337
73223	Mri joint upr extr w/o&w/dye	337
73720	Mri lwr extremity w/o&w/dye	337
73723	Mri joint lwr extr w/o&w/dye	337
C8905	MRI w/o fol w/cont, brst, un.	337
	MRI CORE w/o & w/ DYE	
70543	Mri orbt/fac/nck w/o & w/dye	337
74183	Mri abdomen w/o & w/dye	337
70553	Mri brain w/o & w/dye	337
72156	Mri neck spine w/o & w/dye	337
72157	Mri chest spine w/o & w/dye	337
72158	Mri lumbar spine w/o & w/dye	337
70559	Mri brain w/o & w/dye	337
71552	Mri chest w/o & w/dye	337
72197	Mri pelvis w/o & w/dye	337
	MRI EXTREMITIES/OTHER w/ DYE	
73219	Mri upper extremity w/dye	0284
73222	Mri joint upr extrem w/dye	0284
73719	Mri lower extremity w/dye	0284
73722	Mri joint of lwr extr w/dye	0284
C8903	MRI w/cont, breast, uni	0284
C8906	MRI w/cont, breast, bi	0284

MRI APC Groupings (continued)

CPT	Proposed APC Grouping	Current APC
	MRI CORE w/ DYE	
70542	Mri orbit/face/neck w/dye	0284
70552	Mri brain w/dye	0284
70558	Mri brain w/dye	0284
71551	Mri chest w/dye	0284
72142	Mri neck spine w/dye	0284
72147	Mri chest spine w/dye	0284
72149	Mri lumbar spine w/dye	0284
72196	Mri pelvis w/dye	0284
74182	Mri abdomen w/dye	0284

Society of Diagnostic Medical Sonography

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
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RE: CMS-1506-P: Medicare: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator McClellan:

On behalf of the Society of Diagnostic Medical Sonography ("SDMS"), thank you for the opportunity to comment on the proposed rule released by the Centers for Medicare and Medicaid Services ("CMS") regarding the proposed Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (the "Proposed Rule").[1]

We are generally very supportive of the proposed addition of ultrasound screening for Abdominal Aortic Aneurysm ("AAA"). SDMS commends CMS for this fine proposal. We thank you for acting in the best interests of beneficiaries and in a fashion that supports adequate and appropriate access to important health care services. SDMS and its members are very grateful for CMS' commitment to beneficiary access.

Founded in 1970, SDMS has remained committed to the advancement of diagnostic medical sonography, the education of the medical community, and the delivery of echocardiography, obstetrical and abdominal ultrasound, and vascular ultrasound services of the highest quality. As the largest professional sonography organization in the country, SDMS represents 18,000 physician and sonographer members whose interests are directly impacted by these proposals.

We thank you in advance for consideration of our comments regarding the proposed reimbursement and the definition of "ultrasound screening for an Abdominal Aortic Aneurysm".

I. Appropriate Reimbursement

We write in support of the proposed addition of ultrasound screening for Abdominal Aortic Aneurysm ("AAA"). SDMS commends CMS for proposing to pay for ultrasound screening for AAAs through the use of a new HCPCS code GXXXX (Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening) on equivalent hospital resources and intensity to those

[1] 71 Fed. Reg. 49,506 (Aug. 23, 2006).

contained in CPT code 76775, which is assigned to APC 0266 (Level II Diagnostic and Screening Ultrasound) for CY 2007. We agree that the hospital costs associated with the screening study are very similar to those of the limited retroperitoneal ultrasound diagnostic examination. Therefore, SDMS supports the proposal to assign the screening and diagnostic studies to the same clinical APC for reasons of clinical and resource homogeneity.

II. Definition of "ultrasound screening for an Abdominal Aortic Aneurysm"

Section 5112(a)(2) of the DRA defines the term "ultrasound screening for an Abdominal Aortic Aneurysm" as "(1) a procedure using sound waves (or other procedures using alternative technologies, of commensurate accuracy and cost, that the Secretary may specify) provided for the early detection of abdominal aortic aneurysm; and (2) includes a physician's interpretation of the results of the procedure." The statute remains silent with regard to the qualifications of individuals and facilities who perform the ultrasound screening, but in February of 2005, the United States Preventative Services Task Force ("USPSTF") recommended that screenings be performed in an accredited facility with credentialed technologists.[2] As a result, we strongly encourage CMS to consider including language aimed at improving the quality of ultrasound screenings provided.

We cannot overstate the importance of requiring that screenings be performed in an accredited facility with credentialed technologists. Clinical research has demonstrated that ultrasounds can be wrong as often as they are correct—upwards of a fifty percent error rate—where they are not performed with adequate quality standards in place.[3] Ultrasound credentialing and accreditation are well-established standards within the Medicare program, with 37 jurisdictions requiring the credentialing of sonographers or vascular technologists.

The accuracy of noninvasive vascular diagnostic studies, like ultrasound screening, depends on the knowledge, skill and experience of the technologist or sonographer, the interpreter, and the laboratory in which the service is provided. Consequently, the providers must be capable of demonstrating documented training and experience and maintain documentation for post-payment review purposes.

The addition of language regarding accreditation and/or credentialing would take an important step in protecting the health of Medicare beneficiaries, requiring

[2] U.S. Preventive Services Task Force. *Screening for Abdominal Aortic Aneurysm: Recommendation Statement.* AHRQ Publication No. 05-0569-A, February 2005. Agency for Healthcare Research and Quality, Rockville, MD.

[3] O. William Brown et. al., *Reliability of extracranial carotid artery duplex ultrasound scanning: Value of vascular laboratory accreditation*, 39 Journal of Vascular Surgery 2, at 366 (2004); David G. Stanley, *The Importance of Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) Certification for Non-invasive Peripheral Vascular Tests: The Tennessee Experience*, 28 Journal of Vascular Ultrasound 2, at 65 (2004).

that anyone performing an "ultrasound screening for an Abdominal Aortic Aneurysm" with the intention of receiving Medicare reimbursement must either be credentialed or work in an accredited laboratory. The credentialing process ensures a minimum standard of competence and experience by the individual performing the ultrasound. Accreditation of laboratories, which is an alternative to credentialing under this language, provides a means of ensuring that the ultrasound laboratory operates under appropriate standards.

Accordingly, we encourage CMS to include in the definition of "ultrasound screening for an Abdominal Aortic Aneurysm" a requirement that all studies must meet one of the two following standards: "(a) the services are performed in facilities with laboratories accredited by an appropriate national accreditation body, and/or (b) the services are performed by non-physician personnel who have demonstrated minimum entry level competency by being credentialed by an appropriate national credentialing body in vascular technology or abdominal sonography." This language would have no application to physicians who provide the technical component of an ultrasound screening for a AAA, but it would significantly improve the quality of the screening provided and ultimately the accuracy of physicians' diagnosis. On behalf of Medicare beneficiaries, we urge you to consider its inclusion.

III. Conclusion

Thank you again for your consideration of our comments regarding the Proposed Rule. Again, we commend your proposal regarding reimbursement and urge you to consider language to improve the quality of ultrasound screenings provided as part of the AAA benefit. CMS and its staff continue to act in the best interests of beneficiaries and in a fashion that supports adequate and appropriate access to important health care services. Our organization and its members are very grateful for CMS' commitment to act in the best interests of beneficiaries and their access needs.

We appreciate your thorough review of our comments and hope that you will consider these in addition to those we included in our comments regarding the Medicare Physician Fee Schedule for CY 2007. SDMS would be happy to provide additional information on any or all of the aforementioned issues. We look forward to continuing to work with you to improve the health of Medicare beneficiaries and thank you in advance for your thoughtful consideration of our comments.

Respectfully submitted,

Jean Lea Spitz jsm

Jean Lea Spitz, MPH, RDMS
President
Society of Diagnostic Medical Sonography

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SVU

SOCIETY FOR VASCULAR ULTRASOUND

October 10, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1506-P: Medicare: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

On behalf of the Society for Vascular Ultrasound ("SVU"), thank you for the opportunity to comment on the proposed rule released by the Centers for Medicare and Medicaid Services ("CMS") regarding the proposed Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (the "Proposed Rule").[1] The SVU is a professional society comprised of over 4,100 registered vascular technologists, sonographers, nurses, and physicians. SVU members provide a variety of high-quality vascular ultrasound services to Medicare beneficiaries, but primarily the procedures described by Current Procedural Terminology ("CPT") codes 92922-93990.

Ultrasound is a critical diagnostic imaging modality that uses sound waves to obtain images of the interior of the body. It offers a highly sensitive, non-invasive, low-cost means of looking into the body of a patient to examine structures such as organs, vessels, or a fetus. As a result, both primary care and specialty physicians rely on ultrasound as their chief, and often definitive, diagnostic tool in many instances. Increasingly, physicians employ ultrasound testing as the sole examination prior to surgical intervention, saving not only Medicare dollars but reducing the risks involved in other invasive modalities. We are pleased that Medicare will be covering ultrasound screening for AAA.

[1] 71 Fed. Reg. 49,506 (Aug. 23, 2006).

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We thank you in advance for consideration of our comments regarding the proposed reimbursement and the definition of "ultrasound screening for an Abdominal Aortic Aneurysm".

I. Appropriate Reimbursement

We write in support of the proposed addition of ultrasound screening for Abdominal Aortic Aneurysm ("AAA"). SVU commends CMS for proposing to pay for ultrasound screening for AAAs through the use of a new HCPCS code GXXXX (Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening) on equivalent hospital resources and intensity to those contained in CPT code 76775, which is assigned to APC 0266 (Level II Diagnostic and Screening Ultrasound) for CY 2007. We agree that the hospital costs associated with the screening study are very similar to those of the limited retroperitoneal ultrasound diagnostic examination. Therefore, SVU supports the proposal to assign the screening and diagnostic studies to the same clinical APC for reasons of clinical and resource homogeneity.

II. Definition of "ultrasound screening for an Abdominal Aortic Aneurysm"

Section 5112(a)(2) of the DRA defines the term "ultrasound screening for an Abdominal Aortic Aneurysm" as "(1) a procedure using sound waves (or other procedures using alternative technologies, of commensurate accuracy and cost, that the Secretary may specify) provided for the early detection of abdominal aortic aneurysm; and (2) includes a physician's interpretation of the results of the procedure." The statute remains silent with regard to the qualifications of individuals and facilities who perform the ultrasound screening, but in February of 2005, the United States Preventative Services Task Force ("USPSTF") recommended that screenings be performed in an accredited facility with credentialed technologists.[2] As a result, we strongly encourage CMS to consider including language aimed at improving the quality of ultrasound screenings provided.

We cannot overstate the importance of requiring that screenings be performed in an accredited facility with credentialed technologists. Clinical research has demonstrated that ultrasounds can be wrong as often as they are correct—upwards of a fifty percent error rate—where they are not performed with adequate quality standards in place.[3] Ultrasound credentialing and accreditation are well-established

[2] U.S. Preventive Services Task Force. *Screening for Abdominal Aortic Aneurysm: Recommendation Statement.* AHRQ Publication No. 05-0569-A, February 2005. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/uspstf05/aaascr/aaars.htm.

[3] O. William Brown et. al., *Reliability of extracranial carotid artery duplex ultrasound scanning: Value of vascular laboratory accreditation*, 39 Journal of Vascular Surgery 2, at 366 (2004); David G. Stanley, *The Importance of Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) Certification for Non-invasive Peripheral Vascular Tests: The Tennessee Experience*, 28 Journal of Vascular Ultrasound 2, at 65 (2004).

standards within the Medicare program, with 37 jurisdictions requiring the credentialing of sonographers or vascular technologists.

The accuracy of noninvasive vascular diagnostic studies, like ultrasound screening, depends on the knowledge, skill and experience of the vascular technologist or sonographer, the interpreter, and the laboratory in which the service is provided. Consequently, the providers must be capable of demonstrating documented academic training and educational experience and maintain documentation for post-payment review purposes.

The addition of language regarding accreditation and/or credentialing would take an important step in protecting the health of Medicare beneficiaries, requiring that anyone performing an "ultrasound screening for an Abdominal Aortic Aneurysm" with the intention of receiving Medicare reimbursement must either be credentialed or work in an accredited laboratory. The credentialing process ensures a minimum standard of competence and experience by the individual performing the ultrasound. Accreditation of laboratories, which is an alternative to credentialing under this language, provides a means of ensuring that the ultrasound laboratory operates under appropriate standards.

Accordingly, we encourage CMS to include in the definition of "ultrasound screening for an Abdominal Aortic Aneurysm" a requirement that all studies must meet one of the two following standards: "(a) the services are performed in facilities with laboratories accredited by an appropriate national accreditation body, and/or (b) the services are performed by non-physician personnel who have demonstrated minimum entry level competency by being credentialed by an appropriate national credentialing body in vascular technology or abdominal sonography." This language would have no application to physicians who provide the technical component of an ultrasound screening for a AAA, but it would significantly improve the quality of the screening provided and ultimately the accuracy of physicians' diagnosis. On behalf of Medicare beneficiaries, we urge you to consider its inclusion.

III. Conclusion

Thank you again for your consideration of our comments regarding the Proposed Rule. Again, we commend your proposal regarding reimbursement and urge you to consider language to improve the quality of ultrasound screenings provided as part of the AAA benefit. CMS and its staff continue to act in the best interests of beneficiaries and in a fashion that supports adequate and appropriate access to important health care services. Our organization and its members are very grateful for CMS' commitment to act in the best interests of beneficiaries and their access needs.

We appreciate your thorough review of our comments and hope that you will consider these in addition to those we included in our comments regarding the

Medicare Physician Fee Schedule for CY 2007. SVU would be happy to provide additional information on ultrasound screening for AAAs. We look forward to continuing to work with you to improve the health of Medicare beneficiaries.

Respectfully submitted,

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October 10, 2006

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Washington, DC 20201

RE: CMS-1506-P: Medicare: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

Thank you for the opportunity to provide the following comments in response to the proposed Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (the "Proposed Rule").[1] We focus our remarks on the proposed payment for drugs, biologicals, and radiopharmaceuticals without pass-through status that are not packaged. In particular, we are concerned that the proposal to pay for specified covered outpatient drugs ("SCODs") at 105 percent of the average sales price ("ASP") would unnecessarily compromise beneficiary access to care and is contrary to the plain language of the Medicare Modernization Act ("MMA").[2]

Talecris Biotherapeutics ("Talecris") is a young company proud to have inherited a legacy of its predecessor's having provided lifesaving and life-enhancing plasma-derived therapeutic proteins for more than sixty years. By virtue of its acquisition of the assets of Bayer Biological Products' plasma business, Talecris has laid claim to a heritage of patient care innovations in therapeutic proteins dating back to the early 1940s. We have long been recognized in the industry as producers of innovative products. Talecris, having inherited this solid foundation of unparalleled expertise and experience, is now uniquely positioned to create a new standard of excellence in the field of biotherapeutics.

We manufacture a host of plasma-derived therapeutic proteins. Included among those products is Gamunex®, an intravenous immunoglobulin ("IVIG") product, critically important for thousands of beneficiaries. We aim to be the recognized global leader in developing and delivering IVIG and other premium protein therapies. Talecris strives to provide the known and trusted therapeutic protein products and services that

[1] 71 Fed. Reg. 49,506 (Aug. 23, 2006).
[2] Pub. L. No. 108-173 (2003).

meet our patients' needs. We are committed to ensuring access to these life-saving therapies. We offer our comments with a focus on IVIG, though certainly we appreciate the impact of this proposal on our entire product line.

As we discuss below, we believe that the use of multiple source ASPs in the physician fee schedule and OPPS environments has been substantially responsible for the movement of IVIG patients from physician office settings to hospital outpatient department ("HOPD") settings and for significant issues in the access of IVIG therapy for Medicare beneficiaries. Further, we fear that the reduction of IVIG reimbursement to 105 percent in the HOPD setting will lead even more HOPDs to (1) eliminate treatments for Medicare beneficiaries, (2) reduce the frequency of treatment, (3) switch patients to different IVIG treatments (with the attendant clinical risks), or (4) reduce the number of grams of IVIG provided in the course of treatments. Perhaps even more fundamentally, however, the Agency's proposal is simply inconsistent with the plain language of the MMA. Finally, because of the Agency's use of a multiple source ASP for various, clinically distinct IVIG products, the Agency cannot accurately conclude that 105 percent of ASP will cover the acquisition cost and handling costs of IVIG treatment for HOPDs.

We are committed to working openly with the Centers for Medicare and Medicaid Services ("CMS") because your work will have such an important effect on health care access for so many Medicare beneficiaries. Thank you in advance for your attention to our concerns.

I. About IVIG

Normal human blood contains antibodies, which help to protect us from a wide spectrum of pathogens. However, some individuals are unable to make functional antibodies, which renders them susceptible to recurrent and life-threatening infections. Treatment with IVIG provides immune-deficient individuals with the antibodies needed to prevent potentially fatal infections. IVIG is produced from plasma pooled from thousands of blood plasma donors, which is processed to provide a high concentration of antibodies. Talecris is one of a handful of manufacturers who produce IVIG.

We have taken extraordinary steps to increase substantially production of IVIG, dramatically increase investment in production facilities, ensure the availability of an emergency supply of product for needy patients, and conduct important scientific research. Despite the incredible costs involved in these efforts, which have exceeded more than a quarter of a billion dollars, we have not, over the last five years, increased our prices at a rate that has even kept pace with the rate of inflation. Talecris has also approached pricing issues with restraint and a sincere interest in limiting price increases. That is an extraordinary commitment to our patients, and we are justifiably proud of our record.

We are committed to facilitating IVIG access to Medicare patients in every appropriate site of service. We support the ASP methodology as a means to reimburse adequately physicians for the cost of acquiring the therapy. Unfortunately, two coding-related IVIG reimbursement issues are contributing in a substantial manner to situations where providers and patients are not able to acquire some IVIG products at a price that is consistent with the Medicare reimbursement. We fear that the proposal to reduce the

reimbursement for drugs and biologics to 105 percent of ASP will exacerbate the issues already troubling Medicare beneficiaries being treated with IVIG.

II. Beneficiary Impact of a Reduction to 105 Percent of ASP

Section 1833(t)(14)(A)(iii) of the Social Security Act (the "Act") requires that payment for SCODs be equal to the average acquisition cost of the drug for that year in CY 2006 and subsequent years, as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office. We understand that the Agency has concluded that for CY 2007, on average, hospitals could acquire a range of drugs at 105 percent of ASP. In our opinion, this proposal raises significant policy, analytical, and legal concerns.

A. Beneficiary Access to IVIG and Reimbursement: The Link

The chronology of the development of the IVIG access issue reveals its substantial link to Medicare reimbursement. Pursuant to the MMA, the ASP payment system first became the basis of Medicare reimbursement for services in physicians' offices in January 2005. Reports of beneficiary IVIG access problems in physicians' offices surfaced shortly thereafter and were, based on the information that we have received from patient groups, essentially localized in that site of service and essentially limited to Medicare beneficiaries.

Significantly, throughout 2005, Medicare continued to reimburse hospital outpatient facilities without using the ASP methodology, while Medicare services in the physician office setting were being transitioned to the ASP methodology. It is important to note that the patient groups did not report any significant access issues at the time in the hospital outpatient setting. Indeed, the patient groups reported a migration of a significant number of patients from the physician office setting to the hospital outpatient setting.

As you know, however, in 2006 Medicare hospital outpatient reimbursement did transition to the ASP payment system. Soon after, patient groups began to report that Medicare beneficiaries were experiencing IVIG access problems in hospital outpatient departments. It is important to note that reports of IVIG access issues have continued to be primarily focused on Medicare beneficiaries, although some commercial payer coverage changes have been responsible for some additional issues.

We continue to take reports of IVIG access issues seriously. Although some appear to be inclined to see the access issues as supply-driven, and not reimbursement-related, we do not believe that this is correct, particularly when we examine the evidence related to our product. We want to make clear that we are not aware of an IVIG shortage. The Food and Drug Administration ("FDA") Center for Biologics Evaluation and Research ("CBER") agrees. CBER has not identified a shortage of IVIG, and Herb Kuhn of CMS recently corroborated that point in testimony before the U.S. House of Representatives Committee on Ways and Means Subcommittee on Health. Given our appreciation of the continuing access issue for Medicare beneficiaries, we were struck by the fact that CMS would consider putting

further pressure on beneficiary access by proposing to reduce reimbursement in the HOPD setting, particularly where, as noted above, the effect of prior reimbursement decisions has been to move patients into that site of service.

B. Questionable Analytical Strength

In addition to our policy concerns, we question CMS' analysis, which fails, we fear, to differentiate between costs and charges. CMS appears to be operating based on the premise that charges are adequate to cover acquisition and related drug costs. We question, however, the accuracy of this assumption and challenge the validity of the Medicare Payment Advisory Commission ("MedPAC") data cited to corroborate this assertion.[3] MedPAC's conclusions on their face appear unsound. We are disturbed that those conclusions seem to be based on a number of informal consultations. As a result, we doubt the statistical significance of survey results that claim to reflect charging practices. We fear that this proposal, when applied to individual drugs, provides no assurance that the payment covers the acquisition cost for the drug and related costs, given the concerns about the nature of the data used and the methodology employed.

Talecris is also troubled by the Agency's reasoning. It appears to conclude that a payment rate determined by reducing charges to costs would be appropriate to cover handling and acquisition costs simply because hospitals set charges for drugs high enough to reflect handling costs and acquisition costs. We disagree and believe, at best, CMS' analysis suggests that payment at charges may be adequate.

CMS appears to conclude that its proposed methodology is appropriate because the Agency believes the methodology to be consistent with the OPPS claims data. Given the well-established concerns that have been articulated with CMS' OPPS methodology generally and the accuracy of the cost data used, we believe that the OPPS claims data provides insufficient support for CMS' methodology. Significantly, Congress has directed CMS to use data beyond the OPPS claims data in determining SCOD costs. As a consequence, we are concerned that the use of the OPPS claims data in this fashion is ultimately inconsistent with the Congressional mandate.

C. Deviation from the Plain Language of Statute

As noted above, we have significant questions the legality of this proposal. Essentially, we find the Agency's application of section 1833(t)(14)(A)(iii) of the Act to be inconsistent with a plain reading of the statute. Talecris is troubled deeply because the Act does not contemplate the calculation of ambulatory payment classification ("APC") payment rates on a composite basis. Section 1833(t)(14) refers to the payment for "a specified covered outpatient drug" covered as part of a hospital outpatient department service, going on to define the amount of payment as "the average acquisition cost for the drug."[4] With references to "a . . . drug" and "the drug" in

[3] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, Ch 6, Payment for Pharmacy Handling Costs in Hospital Outpatient Departments," 141 (Jun. 2005).
[4] Emphasis added.

the singular form, it is apparent to us that the plain language of the Act reveals that CMS must determine drug APC payment rates on an individualized basis.

Even assuming the accuracy of the Agency's conclusion that, on average, hospitals may acquire all 500 drugs and biologicals at 105 percent of ASP, that fact is irrelevant in determining the drug APC payment rates prescribed by the Act. Congress could have required CMS to take into account the average price at which hospitals acquire all drugs. It did not, and we can find no evidence that Congress intended that CMS determine drug APC payments rates on anything other than a drug-by-drug basis.

In a series of cases dating back more than 20 years, the courts have been clear that regulatory agencies lack the discretion to deviate from the plain language of a statute.[5] Because we see no ambiguity or flaws, perceived or otherwise, with the basic language of this provision, we are concerned that the Proposed Rule appears to misconstrue section 1833(t)(14). We are troubled by the Agency's interpretation of this language and urge CMS to review it carefully prior to finalizing this proposal.

III. Proposed Solutions

We are particularly concerned about this proposed reduction because it would likely exacerbate the Medicare reimbursement issues already associated with IVIG. Talecris has urged CMS to issue separate HCPCS codes to IVIG products and to increase the payment for IVIG administration services. The background regarding these proposals and our rationale is outlined below. These issues play a significant role in the appropriateness of reimbursement of IVIG in the hospital outpatient department setting and get to the heart of the problems with the proposal to reimburse IVIG at 105 percent of ASP.

A. HCPCS Coding

CMS calculates the ASP for drugs based in part on what HCPCS code those drugs are assigned to using the standardized coding system utilized for outpatient billing. Each quarter, CMS computes an ASP for each HCPCS code typically based on the volume-weighted average of the applicable manufacturer's average sales prices. Where there is only one product in a HCPCS code, which is the case for the vast majority of drugs, ASP is equal to the price of that product's manufacturer reported ASP. This system generally makes ASP predictable and the resulting reimbursement stable

[5] "[N]o matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161, 120 S.Ct. 1291, 1315 (2000) (internal quotations and citations omitted). Accordingly, a regulatory agency "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 2781 (1984) (footnote omitted). Indeed, a regulatory agency "has no power to correct flaws that it perceives in the statute it is empowered to administer. Its rulemaking power is limited to adopting regulations to carry into effect the will of Congress as expressed in the statute." *Board of Governors of Federal Reserve System v. Dimension Financial Corp.*, 474 U.S. 361, 374, 106 S.Ct. 681, 689 (1986) (footnote omitted). However, even putting this point to the side, it is not a flawed policy to require, as Congress did, that costs be determined on a drug by drug basis. Indeed, this is the best means of ensuring appropriate payment.

and consistent with acquisition prices. This is, we believe, exactly what Congress intended when it mandated ASP as a methodology in some settings.

Unfortunately, because all of the IVIG products are treated as multiple source products by CMS, notwithstanding that they are not in any way bioequivalent, IVIG reimbursement is based on the weighted average of the ASPs of multiple IVIG products. Accordingly, this necessarily means that some IVIG products will have reimbursements that are based on a class ASP that is below the product's actual ASP. The inevitable consequence of this, we believe, is that HOPDs are forced to provide critically necessary IVIG services at a reimbursement rate that is below the provider's acquisition cost. CMS normally groups only products into one HCPCS code when the affected products are rated therapeutically equivalent, pharmaceutically equivalent, and bioequivalent by the FDA. The IVIG products, however, are not therapeutically equivalent, pharmaceutically equivalent, or bioequivalent. There is no debate about this critical point.

IVIG products differ in terms of the amount of sugar, osmolality, volume, sucrose, immunoglobulin A, and pH. In addition, products differ according to donor pools, manufacturing process, and final product formulation. These differences provide the clinical basis for physicians to prescribe specific brands of IVIG. When a patient is administered a brand that is not appropriate for him or her, problems can arise. This is particularly true for patients with diabetes, congestive heart failure, and compromised renal function, among other conditions.

Fortunately, CMS has the authority to code and reimburse all IVIG products separately. We believe that this change is integral to solving the IVIG access issue, and we believe it is entirely consistent with the ASP methodology. We ask that IVIG products be treated like the vast majority of other drugs and the way that any unique, distinct product should be treated. Given the strain that these products are already under, a further reduction in the level of reimbursement would seem fundamentally unwise.

B. Payment for IVIG Administration Services

In addition to the coding problem, we believe that IVIG access is also compromised due to inadequate reimbursement for administration services. Where some have suggested that the ASP multiplier should be increased above 106 percent to address this issue, we do not support this option because we do not believe that it is consistent with the rationale behind the ASP methodology. We cannot, however, support a reduction to 105 percent of ASP, and we also believe that this proposal, particularly where it is based on a composite approach for all SCODs taken together, is inconsistent with the ASP methodology and the MMA.

In decreasing drug reimbursement, the MMA clearly contemplated that administration service reimbursement could and should be altered where additional administration reimbursement was shown to be necessary. We ask that CMS do only what Congress contemplated as part of its consideration of the MMA. We ask that CMS work with the AMA to review the extraordinary costs inherent in the administration of

IVIG and make all appropriate adjustments that are supported by the evidence presented. The Proposed Rule fails to do this.

The safe and effective administration of IVIG is extremely complex. We understand that the infusion times for IVIG range from 2 to 8 hours. A nurse to patient ratio is set at 1:1, with immediate availability of a physician for assessment of potential complications. In addition to a physician's evaluation of a patient, the administration service includes the complete evaluation of vital signs and neurological status by a highly trained infusion nurse, pre-medication by an infusion nurse, and complete assessment of vital signs and neurological status every 15 minutes. To account for all of these factors, we support an increase in the payment for administration services. We urge CMS to consider this issue in its final rule.

IV. Commitment to Long-term Solution

One of the most important aspects of a solution to the IVIG access issue is a long-term commitment by Congress and CMS to keep a constant methodology in place for IVIG reimbursement. This includes a stable payment rate. We believe that the proposal to pay for SCODs at 105 percent of the ASP will serve to undermine the work being done to improve access to this important therapy and lead some to question the wisdom of additional investments in IVIG production capacity.

We do appreciate that supply of IVIG is tight, and over the last five years we have increased the amount of IVIG we make available to patients in the United States by 75 percent. In anticipation of, and in response to, the considerable need for IVIG over the last decade, Talecris has dedicated significant resources to meet the needs of the IVIG community. Talecris, for instance, has invested more than $250 million to build a highly efficient, state-of-the-art manufacturing facility in Clayton, North Carolina—the only facility of its size dedicated to IVIG production.

Various factors make a stable market critical to the decision to invest in increased production. The manufacture of IVIG includes more than 400 steps from pooling through fractionation, purification, inspection, and packaging. To ensure additional investment in IVIG capacity to meet the increasing demand for this life-saving therapy, predictable demand and long lead times are required because the manufacture of IVIG takes approximately 8 months from plasma collection at a donor center to lot release, and purchase commitments for raw plasma must be made 1 to 2 years in advance. Furthermore, in order to ensure compliance and regulatory approval, manufacturers must allow up to 5 years to expand production facilities and modify processes.

Talecris may not continue to make additional investments to increase IVIG production in an environment where reimbursement is uncertain or subject to change. We fear that a number of the temporary or emergency solutions being discussed will only add to unpredictability of the marketplace, having the unintended result of discouraging future investments by manufacturers, like Talecris. We believe that a reduction in reimbursement for the hospital outpatient department setting will have a similar effect.

Many immunocompromised patients rely on this essential therapy to treat and prevent fatal infections. Accordingly, we ask CMS to proceed with caution as it considers the proposed reduction in reimbursement and to weigh heavily the long-term implications on an often life-saving therapy.

V. Conclusion

On behalf of IVIG patients and all beneficiaries undergoing premium protein therapies, we thank you for your ongoing work. We urge you to seriously consider the impact of your proposal to pay for SCODs, including IVIG, at 105 percent of the ASP. Please let us know how we might be of further assistance to you in developing the final rule.

Respectfully submitted,

Bruce Bunyan
Vice President
Corporate Communications and Public Policy

cc: William A. Sarraille, Sidley Austin LLP
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