Submitter : Dr. Brett Coldiron **Date:** 01/02/2007

Organization : American Academy of Dermatology Assn

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1321-FC-37-Attach-1.DOC

American Academy of Dermatology Association

Physicians Dedicated to Excellence in Dermatology™

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Executive Director & CEO

January 2, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1321-FC**

Dear Administrator Norwalk:

On behalf of the 15,000 members of the American Academy of Dermatology Association (AADA), I appreciate the opportunity to submit written comments regarding the 2007 Medicare Physician Fee Schedule. As advocates for dermatologists and their patients, the AADA believes that an adequate physician fee schedule ensures fairness and continued beneficiary access to quality, specialty health care services.

Modifier 51 Exemption for Mohs Micrographic Surgery

We are deeply concerned that the Centers for Medicare and Medicaid Services (CMS) has withdrawn the specific exemption for Mohs Micrographic Surgery (Mohs) codes from the multiple surgery reduction rule payment adjustment in the 2007 Medicare Physician Fee Schedule. This CMS action takes away the specific exemption accorded to the Mohs codes in the 1992 Medicare Physician Fee Schedule and maintained by CMS within all subsequent fee schedules since 1992 (see Federal Register, Vol. 56, No. 227, Nov 25, 1991, pgs 59541 and 59602).

Mohs micrographic surgery is a specialized technique for the removal of certain complex or ill-defined skin cancers. The Mohs codes, CPT Codes 17311-17315, include both excision of cancer and the precise pathologic examination of tissue margins by the operating surgeon. Following determination of clear margins, reconstructive procedures are then undertaken, if necessary. The Mohs surgery excisions are performed independently at separate operative sessions from reconstructive procedures. In its review of the Mohs codes in 1992, CMS agreed that Mohs excisions are "separate staged procedures; they will be paid separately with no multiple surgery reductions."

The Mohs surgery codes were placed in the RUC Five Year Review and subsequent to that process the codes were split into site specific families but otherwise went through the RUC refinement process with no fundamental changes that would justify their removal from the multiple surgery reduction rule list.

Withdrawal of the longstanding exemption for Mohs Micrographic Surgery from the multiple surgery reduction rule unduly impacts the many physicians who provide these services without affording any opportunity to comment on the impact of this significant change in Medicare reimbursement for their services. The proposed rule for 2007 neither proposed to change this policy nor suggested in any way that CMS was considering such a change. Both the Administrative Procedures Act and the Medicare statute's own rulemaking provisions impose clear-cut requirements; CMS cannot

comply with those requirements by issuing a final rule with little connection to the proposed rule. Thus, a final CMS decision to revoke the modifier 51 exemption for Mohs surgery could only be made through a future notice and comment process in which all interested parties had the opportunity to present CMS with evidence and arguments on this issue. The AADA has contacted CMS several times since early November on this issue and we are disappointed that our requests have been ignored.

Drug Management Codes
CPT Code 99363 -- *Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; initial 90 days of therapy (must include a minimum of 8 INR measurements* - The recommendation of the AMA/Specialty Society Relative Value Update Committee (RUC) is a value of 1.65 relative value units (RVUs) for this code.

CPT Code 99364 -- *Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; each subsequent 90 days of therapy (must include a minimum of three INR measurements)* - The RUC recommended value is 0.63 RVUs

CMS has determined that these codes should be bundled into the evaluation and management services and has offered no rationale for this decision. The AADA supports the AMA RUC comment which respectfully disagrees with this determination and strongly believes that each of these procedures is a separate and distinct service not adequately described in the evaluation and management services.

Specifically, the anti-coagulant management codes were created to address a concern from 2001 when CMS stated that the standard of care for anticoagulant services was suboptimal and the current payment policy requires the physician to have the beneficiary make an office visit to discuss prothrombin time tests results and necessary adjustments to receive separate payment. Although it is clinically optimal for a physician to discuss results with a patient and make an adjustment during a face-to-face encounter under some circumstances, physicians often engage in these activities outside of a face-to-face encounter with the patient.

The CPT Editorial Panel agreed that bundling this post service time into the payment for the visit is unfair when physicians are managing patients on long-term anticoagulants. In addition, the Panel believed that CMS policy provides inadequate avenues for physicians to be paid for managing patients on long term anticoagulant may contribute to the problem of underutilization of anticoagulant drugs that has adverse effects on the health of patients. Failure to receive anticoagulant drugs when indicated can increase patient risk of thrombosis and embolism, and under- or over-anticoagulation can increase patient risk of bleeding. The CPT Editorial Panel discussed the issue at its February 2006 meeting and created two new codes to allow the reporting of anticoagulant management services. The AADA joins the AMA RUC in strongly urging CMS to change the status indicator for all of the aforementioned codes to "active" and accept the associated RUC recommendations.

Payment for Splint and Cast Supplies
We appreciate that CMS has indicated that it intends to reimburse separately via HCPCS Q codes for splint and casting supplies. We agree that costs for these should be extracted from the practice expense direct inputs for those code ranges listed within the proposed rule. However, as supplies for CPT 29580 - Unna boot applications have been specifically excluded in the past and now appear to be included within the listed code ranges, we request that Unna boot supplies be extracted from the practice expense direct inputs, appropriately re-categorized within the HCPCS

Q codes and specifically included in the list of supplies that will now be separately billable using HCPCS Q code(s).

Practice Expense
The Academy appreciates CMS incorporating our practice expense supplemental survey data into the 2007 fee schedule. The Academy dedicated considerable physician and staff volunteer time and significant financial resources to submitting supplemental survey data, as provided by the Balanced Budget Refinement Act of 1999 (BBRA) and requested by CMS. Incorporating this data into the CY2007 fee schedule increases the accuracy in determining the practice expense RVUs (PE RVUs) for the services our members provide and improves the overall accuracy of the practice expense component of the fee schedule.

As you know, the AMA is sponsoring a multi-specialty supplemental study of practice expense costs. The AADA has already agreed to participate in and contribute to this additional practice expense survey. However, we are concerned that the design and structure of the new survey in fact as proposed does not focus on practice expense costs, as originally communicated to the physician community. The additional survey should be in compliance with all of the criteria established for the specialty specific practice expense supplemental surveys already accepted by CMS. For consistency's sake, the new multi-specialty practice expense survey results must be held to the same statistical standards relating to the level of precision as the supplemental surveys already accepted by CMS.

Telehealth Services
The AADA would appreciate CMS incorporating additional telehealth services to the Medicare program. Besides increasing access for patients, telemedicine can also reduce overall costs. Patients with skin disease who participate in telemedicine receive more accurate diagnoses earlier in their disease course than they would if evaluated and treated only by a non-dermatologist. Their diseases can be treated effectively and at earlier stages than they would be if a patient waited until complications forced them to make a long trip to see a dermatologist. While it will never replace the face to face patient visit, the Academy considers telemedicine a viable method of treatment and one important component of an overall plan to improve patient access to dermatology. Therefore, the AADA believes that dermatologic office visits conducted via live interactive or store and forward telemedicine should be covered under the Medicare program.

Thank you for the opportunity to comment on this proposed notice. For further information, please contact Jayna Bonfini at jbonfini@aad.org or 202-842-3555 or Norma Border at nborder@aad.org or 847-330-0230.

Sincerely,

Brett M. Coldiron MD

Brett Coldiron, MD, FAAD
Chairman, Health Care Finance Committee

Cc: Stephen P. Stone, MD, FAAD, President
Diane R. Baker, MD, FAAD, President-Elect
David M. Pariser, MD, FAAD, Secretary-Treasurer
Ronald A. Henrichs, CAE, Executive Director and CEO
Daniel Siegel, MD, FAAD, AADA RUC Representative
Michael Bigby, MD, FAAD, AADA RUC Representative

Bruce Deitchman, MD, FAAD, AADA RUC Representative
John Zitelli, MD, FAAD, Chair, AADA CPT Committee
John D. Barnes, Deputy Executive Director, AADA
Judy Magel, PhD, Senior Director, Practice, Science & Research
Laura Saul Edwards, Director, Federal Affairs
Cyndi Del Boccio, Director, Executive Office
Jayna Bonfini, Assistant Director, Federal Affairs
Norma Border, Senior Manager, Coding and Reimbursement
Sandra Peters, Senior Manager, Workforce, Insurance & Practice Issues
William Brady, Manager, Practice Management
Vernell St. John, Senior Coding and Reimbursement Specialist
Peggy Eiden, Coding & Reimbursement Specialist

Submitter : **Dr. Dennis Sheehan** **Date: 01/02/2007**

Organization : **Cardiovascular Medicine & Coronary Interventions**

Category : **Physician**

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

COMMENT TO: Provisions Issues

File Code CMS-1321-FC: Comments Related to Final Rule re: Medicare Program; Revisions to Payment Policies Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule for Calendar Year 2007.

I am writing to express my concern about the proposed reductions for Home INR Monitoring Services. The Home INR Monitoring program is considered by CMS as a lifesaving service designed to 'prevent strokes and bleeding' for selected individuals on anticoagulation therapy. My concern is that the proposed reductions for G-0248 and G-0249 under the proposed Fully Implemented PE RVUs will result in reimbursement far below the cost of providing these services. As a practicing cardiologist, I believe that access to this important service can be increased by modifying the way in which the cost of INR monitoring equipment is reimbursed.

Specifically, I would like to see the $2,000 cost of the INR monitor deleted from G-0249 (a recurring charge) and added to G-0248 (a once in a lifetime charge). Under the current structure, the cost of the INR monitor is reimbursed over time as the provider bills for the ongoing G-0249 services. Under the proposed Fully Implemented PE RVUs for G-0249, the 2.44 total RVUs for this service will not even cover the cost of the direct supplies for the service. As a result, the cost of the equipment will never be recovered. As an alternative, I am recommending that the $2,000 cost of the INR monitor be moved to the G-0248 code and covered in total at the time the G-0248 services are initially provided. This alternative structure would actually result in lower total costs to CMS over time while at the same time eliminating the unreasonable risk that Providers incur in order to provide this service. Because G-0248 services are only billable only once in a beneficiary s lifetime, Providers would be less apt to abuse the ongoing G-0249 services as a means of recovering the initial cost of the INR monitor.

Submitter : **Mrs. ste Dyson** **Date: 01/02/2007**

Organization : **DaVita**

Category : **End-Stage Renal Disease Facility**

Issue Areas/Comments

GENERAL

GENERAL

DaVita is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with technical correction comments as the RVU assignments for CY 2007 PFS are being finalized. DaVita is a leading kidney care provider serving patients with high-quality, specialized prevention and treatment services, spanning 42 states and the District of Columbia. The DaVita network includes more than 1,250 outpatient facilities as well as acute inpatient units in over 750 hospitals. RMS Lifeline , a subsidiary of DaVita, provides management services to physician outpatient offices that offer vascular access repair and maintenance procedures exclusively to hemodialysis patients.
As always, we appreciate CMS review of these technical corrections and look forward to working with you as you finalize this regulation. Please feel free to contact Stephanie Dyson (202) 457-0417 or Terry Litchfield (847)388-2038 if you have any questions.

Sincerely,

Charles J. McAllister, M.D., FACP Gerald Beathard, M.D.
Chief Medical Officer VP, Provider Development
DaVita RMS Lifeline, Inc.

cc: Kent Thiry, Mayor and CEO, DaVita
Eric Berger, Senior Vice President, DaVita
Terry Litchfield, Vice-President, RMS
Stephanie Dyson, Director Public Policy, DaVita

Interim Relative Value Units

Interim Relative Value Units

We are pleased that CMS recognizes the importance of expanding the types of procedures performed in the ASC setting to include those related to the repair and maintenance of AV fistula and grafts, as evidenced by the inclusion of G0392 and G0393 in the November 1, 2006 Final Rule for the Hospital Outpatient Prospective Payment System (OPPS). In reviewing the public use files of supplies, labor and equipment for the most common dialysis access procedures, we find there appear to be some errors. We would like to request that the technical group review the data files (equipment and supplies) for the 35475, 35476 and 36870 codes. Be advised that 35475 and 35476 are the map codes for the new G codes in 2007:
G0393-Dialysis Access Angioplasty-venous (35476 old code)
G0392-Dialysis Access Angioplasty-arterial (35475 old code)

Specifically, we are asking for consideration of the following:
? RVU adjustment for new G codes (G0392 and G0393) - The corresponding CPT codes (35475 and 35476) were last reviewed in 2004. Since then, technology advances, particularly in the advent of angioplasty balloons, have improved success rates as well as decreased complications. The low profile, high pressure balloons are routine in these types of angioplasties.
? Adjustment to equipment and supply items for common dialysis access procedures In reviewing the public use files, we found several missing items on the angioplasty procedure list, as well as missing items pertaining to the declot code that were included in last years public use files. In the dialysis access declot code (36870), there is nothing in the cost files to note the use of a room with angiographic equipment, table and imaging. In addition, the angioplasty procedures would need a power table in the angio room.

CMS-1321-FC-39-Attach-1.PDF

CMS-1321-FC-39-Attach-2.PDF

CMS-1321-FC-39-Attach-3.PDF

This is the data from the public use files on equipment

SOURCE	CPEP	PROCCODE	Equip_Category_05	Equip_Code_05	Description	LIFE	PRICE	EQTI	EQTO	Valued_NF	Valued_FAC	SOURCECD	GLOB	PEAC_mtg	PEAC_tab	2004_code
PEAC	RUC	35475	FURNITURE	EF019	stretcher chair	10	3133	120	0	Y	Y		000	Jan04	9	
PEAC	RUC	35475	ROOM - LANE	EL011	room, angiography	5	1386816	92	0	Y	Y		000	Jan04	9	E51084
PEAC	RUC	35475	OTHER EQUIPMENT	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	7	4322.5	212	0	Y	Y		000	Jan04	9	E55005
PEAC	RUC	35475	OTHER EQUIPMENT	EQ032	IV infusion pump	10	2384.45	212	0	Y	Y		000	Jan04	9	E91001
PEAC	RUC	35475	OTHER EQUIPMENT	EQ168	light, exam	10	1630.12	120	0	Y	Y		000	Jan04	9	E30006
PEAC	RUC	35475	OTHER EQUIPMENT	EQ211	pulse oximeter w-printer	7	1207.18	212	0	Y	Y		000	Jan04	9	E55003
PEAC	RUC	35476	FURNITURE	EF019	stretcher chair	10	3133	120	0	Y	Y		000	Jan04	9	
PEAC	RUC	35476	ROOM - LANE	EL011	room, angiography	5	1386816	77	0	Y	Y		000	Jan04	9	E51084
PEAC	RUC	35476	OTHER EQUIPMENT	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	7	4322.5	197	0	Y	Y		000	Jan04	9	E55005
PEAC	RUC	35476	OTHER EQUIPMENT	EQ032	IV infusion pump	10	2384.45	197	0	Y	Y		000	Jan04	9	E91001
PEAC	RUC	35476	OTHER EQUIPMENT	EQ168	light, exam	10	1630.12	120	0	Y	Y		000	Jan04	9	E30006
PEAC	RUC	35476	OTHER EQUIPMENT	EQ211	pulse oximeter w-printer	7	1207.18	197	0	Y	Y		000	Jan04	9	E55003
RUC	RUC	36870	FURNITURE	EF023	table, exam	15	1338.17	142	27	Y	Y		090			E11001

The following items are either missing or the public use files have inaccurate information/items:

PEAC	RUC	35475	OTHER EQUIPMENT	EQ235	suction machine (Gomco)	10	743.21	57	0	Y	Y		000			E30001
PEAC	RUC	35475	FURNITURE	EF031	table, power	10	6153.63	30	0	Y	Y		000			E11003
PEAC	RUC	35476	OTHER EQUIPMENT	EQ235	suction machine (Gomco)	10	743.21	57	0	Y	Y		000			E30001
PEAC	RUC	35476	FURNITURE	EF031	table, power	10	6153.63	30	0	Y	Y		000			E11003
PEAC	RUC	36870	ROOM - LANE	EL011	room, angiography	5	1386816	92	0	Y	Y		000	Jan04	9	E51084
PEAC	RUC	36870	OTHER EQUIPMENT	EQ235	suction machine (Gomco)	10	743.21	57	0	Y	Y		000			E30001
PEAC	RUC	36870	FURNITURE	EF031	table, power	10	6153.63	30	0	Y	Y		000			E11003

Supplies from Public Use Files

PROCCODE	SOURCE	CPEP	CATEGORY_07	Supply_Code_07	DESCRIPTION	QTY_07	UNIT_07	PRICE	QTY_NF	QTY_FAC	in_cost	out_cost	GLOBAL	Post_Op_Visits	Source_for_Xwalk	PEAC_mtg	PEAC_Tab
35475	PEAC	RUC	Accessory, Procedure	SD089	guidewire, hydrophilic	1	item	35.5	1	0	35.5	0	000			Jan04	9
35475	PEAC	RUC	Accessory, Procedure	SD149	catheter, balloon inflation device	1	item	24.9	1	0	24.9	0	000			Jan04	9
35475	PEAC	RUC	Accessory, Procedure	SD152	catheter, balloon, PTA	1	item	243.5	2	0	487	0	000			Jan04	9
35475	PEAC	RUC	Accessory, Procedure	SD174	guidewire, steerable (Hi-Torque)	1	item	90	1	0	90	0	000			Jan04	9
35475	PEAC	RUC	Accessory, Procedure	SD176	guidewire, torque	1	item	41	1	0	41	0	000			Jan04	9
35475	PEAC	RUC	Accessory, Procedure	SD207	suture device for vessel closure (Perclose A-T)	1	item	225	1	0	225	0	000			Jan04	9
35475	PEAC	RUC	Gown, Drape	SB001	cap, surgical	1	item	0.209	2	0	0.418	0	000			Jan04	9
35475	PEAC	RUC	Gown, Drape	SB011	drape, sterile, fenestrated 16in x 29in	1	item	0.557	1	0	0.557	0	000			Jan04	9
35475	PEAC	RUC	Gown, Drape	SB014	drape, sterile, three-quarter sheet	1	item	3.83	1	0	3.83	0	000			Jan04	9
35475	PEAC	RUC	Gown, Drape	SB019	drape-towel, sterile 18in x 26in	1	item	0.282	4	0	1.128	0	000			Jan04	9
35475	PEAC	RUC	Gown, Drape	SB024	gloves, sterile	1	pair	0.84	1	0	0.84	0	000			Jan04	9
35475	PEAC	RUC	Gown, Drape	SB028	gown, surgical, sterile	1	item	4.671	1	0	4.671	0	000			Jan04	9
35475	PEAC	RUC	Gown, Drape	SB034	mask, surgical, with face shield	1	item	1.199	2	0	2.398	0	000			Jan04	9
35475	PEAC	RUC	Gown, Drape	SB039	shoe covers, surgical	1	pair	0.338	2	0	0.676	0	000			Jan04	9
35475	PEAC	RUC	Kit, Pack, Tray	SA044	pack, conscious sedation	1	pack	17.311	1	0	17.311	0	000			Jan04	9
35475	PEAC	RUC	Kit, Pack, Tray	SA048	pack, minimum multi-specialty visit	1	pack	1.143	1	0	1.143	0	000			Jan04	9
35475	PEAC	RUC	Pharmacy, NonRx	SJ041	povidone soln (Betadine)	1	ml	0.008	10	0	0.08	0	000			Jan04	9
35475	PEAC	RUC	Wound Care, Dressings	SGD55	gauze, sterile 4in x 4in	1	item	0.159	2	0	0.318	0	000			Jan04	9
35475	PEAC	RUC	Wound Care, Dressings	SG079	tape, surgical paper 1in (Micropore)	1	inch	0.002	6	0	0.012	0	000			Jan04	9
35476	PEAC	RUC	Accessory, Procedure	SD089	guidewire, hydrophilic	1	item	35.5	1	0	35.5	0	000			Jan04	9
35476	PEAC	RUC	Accessory, Procedure	SD149	catheter, balloon inflation device	1	item	24.9	1	0	24.9	0	000			Jan04	9
35476	PEAC	RUC	Accessory, Procedure	SD152	catheter, balloon, PTA	1	item	243.5	2	0	487	0	000			Jan04	9
35476	PEAC	RUC	Accessory, Procedure	SD174	guidewire, steerable (Hi-Torque)	1	item	90	1	0	90	0	000			Jan04	9
35476	PEAC	RUC	Accessory, Procedure	SD176	guidewire, torque	1	item	41	1	0	41	0	000			Jan04	9
35476	PEAC	RUC	Gown, Drape	SB001	cap, surgical	1	item	0.209	3	0	0.627	0	000			Jan04	9
35476	PEAC	RUC	Gown, Drape	SB011	drape, sterile, fenestrated 16in x 29in	1	item	0.557	1	0	0.557	0	000			Jan04	9
35476	PEAC	RUC	Gown, Drape	SB014	drape, sterile, three-quarter sheet	1	item	3.83	1	0	3.83	0	000			Jan04	9
35476	PEAC	RUC	Gown, Drape	SB019	drape-towel, sterile 18in x 26in	1	item	0.282	2	0	0.564	0	000			Jan04	9
35476	PEAC	RUC	Gown, Drape	SB024	gloves, sterile	1	pair	0.84	2	0	1.68	0	000			Jan04	9
35476	PEAC	RUC	Gown, Drape	SB028	gown, surgical, sterile	1	item	4.671	2	0	9.342	0	000			Jan04	9
35476	PEAC	RUC	Gown, Drape	SB034	mask, surgical, with face shield	1	item	1.199	3	0	3.597	0	000			Jan04	9
35476	PEAC	RUC	Gown, Drape	SB039	shoe covers, surgical	1	pair	0.338	3	0	1.014	0	000			Jan04	9
35476	PEAC	RUC	Kit, Pack, Tray	SA044	pack, conscious sedation	1	pack	17.311	1	0	17.311	0	000			Jan04	9
35476	PEAC	RUC	Kit, Pack, Tray	SA048	pack, minimum multi-specialty visit	1	pack	1.143	1	0	1.143	0	000			Jan04	9
35476	PEAC	RUC	Pharmacy, NonRx	SJ041	povidone soln (Betadine)	1	ml	0.008	10	0	0.08	0	000			Jan04	9
35476	PEAC	RUC	Wound Care, Dressings	SGD55	gauze, sterile 4in x 4in	1	item	0.159	2	0	0.318	0	000			Jan04	9
35476	PEAC	RUC	Wound Care, Dressings	SG079	tape, surgical paper 1in (Micropore)	1	inch	0.002	6	0	0.012	0	000			Jan04	9

Add: Items Missing from CPEP file but used in Dialysis Access Angioplasties Arterial and Venous

	35475		Accessory, Procedure	SD151	catheter, balloon, low profile PTA	1	item	431.5	2	0	863	0	000			Jan04	9
	35475		Hypodermic, IV	SC029	needle, 18-27g	1	item	0.089	1	0	0.089	0	010				
	35475		Hypodermic, IV	SC052	syringe 1ml	1	item	0.14	1	0	0.14	0	010				
	35475		Hypodermic, IV	SC055	syringe 3ml	1	item	0.096	1	0	0.096	0	010				
	35475		Hypodermic, IV	SC054	syringe 30 ml	1	item	0.63	1	0	0.63	0	000				
	35475		Kit, Pack, Tray	SA016	kit, guidewire introducer (Micro-Stick)	1	kit	23	2	0	46	0	010				
	35475		Office Supply, Grocery	SK058	paper, photo printing (8.5 x 11)	1	item	0.45	10	0	4.5	0	000				
	35475		Office Supply, Grocery	SK075	skin marking pen, sterile (Skin Scribe)	1	item	1.048	1	0	1.048	0	000				
	35475		Pharmacy, Rx	SH039	heperin 1,000 units-ml inj	1	ml	0.193	5	0	0.965	0	010				
	35475		Pharmacy, Rx	SH047	lidocaine 1%-2% inj (Xylocaine)	1	ml	0.035	1	0	0.035	0	010				
	35475		Pharmacy, Rx	SH069	sodium chloride 0.9% irrigation (500-1000ml uou)	1	item	2.074	1	0	2.074	0	000				

	35476		Accessory, Procedure	SD151	catheter, balloon, low profile PTA	1 item	431.5	2	0	863	0 000		Jan04	9
	35476		Hypodermic, IV	SC029	needle, 18-27g	1 item	0.089	1	0	0.089	0 010			
	35476		Hypodermic, IV	SC052	syringe 1ml	1 item	0.14	1	0	0.14	0 010			
	35476		Hypodermic, IV	SC055	syringe 3ml	1 item	0.096	1	0	0.096	0 010			
	35476		Hypodermic, IV	SC054	syringe 30 ml	1 item	0.63	1	0	0.63	0 000			
	35476		Kit, Pack, Tray	SA016	kit, guidewire introducer (Micro-Stick)	1 kit	23	2	0	46	0 010			
	35476		Office Supply, Grocery	SK058	paper, photo printing (8.5 x 11)	1 item	0.45	10	0	4.5	0 000			
	35476		Office Supply, Grocery	SK075	skin marking pen, sterile (Skin Skribe)	1 item	1.048	1	0	1.048	0 000			
	35476		Pharmacy, Rx	SH039	heparin 1,000 units-ml inj	1 ml	0.193	5	0	0.965	0 010			
	35476		Pharmacy, Rx	SH047	lidocaine 1%-2% inj (Xylocaine)	1 ml	0.035	1	0	0.035	0 010			
	35476		Pharmacy, Rx	SH069	sodium chloride 0.9% irrigation (500-1000ml uou)	1 item	2.074	1	0	2.074	0 000			

Delete: Items not used in Dialysis Access Angioplasties due to improved technology SD 151

35475		PEAC	RUC	Accessory, Procedure	SD152	catheter, balloon, PTA	1 item	243.5	2	0	487	0 000		Jan04	9
	35476	PEAC	RUC	Accessory, Procedure	SD152	catheter, balloon, PTA	1 item	243.5	2	0	487	0 000		Jan04	9

This is the data from the public use files on equipment

SOURCE	CPEP	PROCCODE	Equip_Category_05	Equip_Code_05	Description	LIFE	PRICE	EQTI	EQTO	Valued_NF	Valued_FAC	SOURCECD	GLOB	PEAC_mtg	PEAC_tab	2004_code
PEAC	RUC	35475	FURNITURE	EF019	stretcher chair	10	3133	120	0	Y	Y		000	Jan04	9	
PEAC	RUC	35475	ROOM - LANE	EL011	room, angiography	5	1386816	92	0	Y	Y		000	Jan04	9	E51084
PEAC	RUC	35475	OTHER EQUIPMENT	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	7	4322.5	212	0	Y	Y		000	Jan04	9	E55005
PEAC	RUC	35475	OTHER EQUIPMENT	EQ032	IV infusion pump	10	2384.45	212	0	Y	Y		000	Jan04	9	E91001
PEAC	RUC	35475	OTHER EQUIPMENT	EQ168	light, exam	10	1630.12	120	0	Y	Y		000	Jan04	9	E30006
PEAC	RUC	35475	OTHER EQUIPMENT	EQ211	pulse oximeter w-printer	7	1207.18	212	0	Y	Y		000	Jan04	9	E55003
PEAC	RUC	35476	FURNITURE	EF019	stretcher chair	10	3133	120	0	Y	Y		000	Jan04	9	
PEAC	RUC	35476	ROOM - LANE	EL011	room, angiography	5	1386816	77	0	Y	Y		000	Jan04	9	E51084
PEAC	RUC	35476	OTHER EQUIPMENT	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	7	4322.5	197	0	Y	Y		000	Jan04	9	E55005
PEAC	RUC	35476	OTHER EQUIPMENT	EQ032	IV infusion pump	10	2384.45	197	0	Y	Y		000	Jan04	9	E91001
PEAC	RUC	35476	OTHER EQUIPMENT	EQ168	light, exam	10	1630.12	120	0	Y	Y		000	Jan04	9	E30006
PEAC	RUC	35476	OTHER EQUIPMENT	EQ211	pulse oximeter w-printer	7	1207.18	197	0	Y	Y		000	Jan04	9	E55003
RUC	RUC	36870	FURNITURE	EF023	table, exam	15	1338.17	142	27	Y	Y		090			E11001

The following items are either missing or the public use files have inaccurate information/items:

PEAC	RUC	35475	OTHER EQUIPMENT	EQ235	suction machine (Gomco)	10	743.21	57	0	Y	Y		000			E30001
PEAC	RUC	35475	FURNITURE	EF031	table, power	10	6153.63	30	0	Y	Y		000			E11003
PEAC	RUC	35476	OTHER EQUIPMENT	EQ235	suction machine (Gomco)	10	743.21	57	0	Y	Y		000			E30001
PEAC	RUC	35476	FURNITURE	EF031	table, power	10	6153.63	30	0	Y	Y		000			E11003
PEAC	RUC	36870	ROOM - LANE	EL011	room, angiography	5	1386816	92	0	Y	Y		000	Jan04	9	E51084
PEAC	RUC	36870	OTHER EQUIPMENT	EQ235	suction machine (Gomco)	10	743.21	57	0	Y	Y		000			E30001
PEAC	RUC	36870	FURNITURE	EF031	table, power	10	6153.63	30	0	Y	Y		000			E11003

Submitter : **Ms. Shari Kipp** **Date: 01/02/2007**

Organization : **Patient Selfcare Providers Association**

Category : **Other Association**

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

We were disappointed to see no change to the proposed Fully Implemented PE RVUs for G-0248 and G-0249 despite our comments and detailed analysis based on input from the nation s largest providers of these services. This analysis was an updated version of the analysis that CMS originally used to determine the PE RVUs when the Home INR Monitoring program was first implemented in 2002. As we outlined in our earlier comments to the Proposed Rule (CMS -1321-P) the proposed reductions will result in reimbursement levels which are far below the actual cost of providing these important services.

Our updated analysis shows that a more appropriate PE RVU level for:
1. G-0248 should be in the range of 5.99 (minimum) and 9.26 (maximum). Our recommendation of 7.63 is based on a simple average of the minimum and maximums supported by our analysis.
2. G-0249 should be in the range of 4.71 (minimum) and 7.28 (maximum). Our recommendation of 5.99 is based on a simple average of the minimum and maximums supported by our analysis.

We respectfully, request that CMS reconsider the updated analysis (see attached) that we provided when preparing the Final Fully Implemented PE RVUS for these two codes.

Sincerely,

Shari Kipp
Executive Director
skipp@inrcare.com

CMS-1321-FC-40-Attach-1.PDF

CMS-1321-FC-40-Attach-2.PDF

Patient Selfcare Providers Association
2020 Pennsylvania Ave NW Suite 863
Washington DC 20006

October 9, 2006

Hon. Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

COMMENT TO: "Provisions Issues"

SUMMARY: We believe that the RVUs for G-0248 and G-0249 included in the Proposed Rule § II.A.5.(k) do not reflect the cost of providing these services. We recommend that the PE RVUs be set at 7.63 and 5.99 for G-0248 and G-0249 respectively. Our recommendation is based on an updated version of the detailed analysis that was presented to CMS in 2002 when the original payment rates for this code were first established. The original analysis was based on input provided by several product manufacturers and experienced Medicare providers of diagnostic services. In addition, the resource requirements were based on best estimates of what it should take to perform the activities according to best practice guidelines. For this we used the second edition of "Managing Oral Anticoagulation Therapy", the recognized best care practice guide for Home INR Monitoring. The updated version of the original analysis has been updated for changes in product prices and other variables based on field experience over the past several years. The updated version of this original analysis is attached.

Dear Ms. Norwalk:

Patient Selfcare Providers Association (PSP) is pleased to provide this comment letter to the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B" ("Proposed Rule"). We wish to comment specifically on proposed § II.A.5.(k) as it relates to the Resource-Based Practice Expense (PE) RVU Proposals for CMS Billing Codes G-0248 and G-0249. PSP is a non-profit association organized under section 501(c)(3) of the Internal Revenue Code, with a mission to promote quality standards and patient self care treatment options including Home INR Monitoring for patients on anticoagulation therapy.

In a former capacity with a major manufacturer, I was personally involved in the original estimation of resources requirements when the Home INR Monitoring Program was first

implemented. At the time, we provided CMS with a comprehensive analysis which was based on our best estimate of the resources requirements needed to fulfill the activities outlined in the second edition of "Managing Oral Anticoagulation Therapy". This book, written by Jack Ansell, M.D. from Boston University School of Medicine and others, is recognized as the best practice guide for Home INR Monitoring. The updated version of our original analysis remains consistent with these best care guidelines and the experience we have collected from PSP members who have serviced Medicare beneficiaries over the past three years.

The updated analysis that we have prepared to support these recommendations evaluates four variables for each code; Clinical Labor, Administrative Labor, Supplies and Equipment. Each variable was cross-referenced to the relevant section of best care guidelines and then analyzed according to assumptions that have been drawn from our previous or other publicly available data. The 14-page analysis, which is summarized on page 1, shows that the updated resource requirements for G-0248 are $351.09 and for G-0249 are $275.83. We recognize that these codes are atypical and therefore have calculated these resource requirements based on the direct practice expenses plus an additional 25% for indirect practice expenses. Our recommended PE RVUs have been calculated by dividing the dollar-based resource requirements by the proposed 2007 conversion factor of 37.8975. The minimums and maximums are in turn calculated by the range of GPCIs used by CMS. Based on our analysis, we believe that the proposed reductions in PE RVUs for these two codes will be inadequate for providers to offer these services. Our updated analysis shows that a more appropriate PE RVU level for:

1. **G-0248** should be in the range of 5.99 (minimum) and 9.26 (maximum). Our recommendation of 7.63 is based on a simple average of the minimum and maximums supported by our analysis.
2. **G-0249** should be in the range of 4.71 (minimum) and 7.28 (maximum). Our recommendation of 5.99 is based on a simple average of the minimum and maximums supported by our analysis.

We believe that maintaining appropriate PE RVU levels are particularly important for G-0248 and G-0249 because of the significant supply and equipment component in each code. Therefore, we request that CMS reevaluate the proposed PE RVUs included in the Proposed Rule and consider the updated analysis that we have provided. If needed, I would welcome the opportunity to provide you further information.

Sincerely,

Shari Kipp
Executive Director
skipp@inrcare.com

CMS
Home INR Monitoring
Practice Expense RVU's

CMS
Home INR Monitoring
Practice Expense RVU's

Recurring Technical - Clinical (RT-C) (G-0249) Home prothrombin time (INR) monitoring for anticoagulation management; report of results and report only. Case Guidelines / Details	Assumptions: Staff Type	Time in Minutes	Per Event	Occurrence Rate	Clinical Labor: Labor Rate/Hr / Time	$ / Cost/INR Value
1 Process Order						
2 Dispense Supplies & Equipment for Monitoring INR						
a) Fulfill Prescription According to Physician Orders	Pharmacist	10.00	Prescription		0.95	$ 0.30
3 Manage Patient Compliance / Provide Consultation						
a) Receive and review INR values	RN/LPN/MA	5.00	Reported Test	1.00	5.00	$ 1.59
b) Follow-up with patient to ensure INR values reported as prescribed	RN/LPN/MA	5.00	Missed Test	20%	1.00	$ 0.32
c) Follow-up with patient to ensure re-testing following Physician-directed dosing change	RN/LPN/MA	10.00	Dosing Change	4.00	0.95	$ 0.30
d) Provide ongoing technical support for use of equipment.	RN/LPN/MA	20.00	Call	2.00	0.95	$ 0.30
e) Provide technical support related to specific test errors	RN/LPN/MA	20.00	Call	2.00	0.95	$ 0.30
f) Update Changes to Patient Clinical Profile	RN/LPN/MA	20.00	Year	20%	0.10	$ 0.03
4 Manage Anticipated Changes in Anticoagulant Change						
a) Follow-up with patient to ensure INR values reported prior to invasive procedure	RN/LPN/MA	10.00	Procedure	20%	0.05	$ 0.02
5 Communication & Documentation						
a) Contact physician directly regarding out of range INR Values	RN/LPN/MA	2.00	Out of Range INR	20%	0.40	$ 0.13
b) Contact physician directly regarding non-adherent patients	RN/LPN/MA	10.00	Year	17%	1.70	$ 0.54
6 Claim filing with Medicare						
7 Accounts receivable mgmt. & collection						
Total Clinical Costs to Generate:						
1 Controlled, Billable INR Value					**12.05**	**$ 3.82**
4 Controlled, Billable INR Values					**48.21**	**$ 15.28**

		Comments	Reference	Best Care Guidelines
2	a)	Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/02	5.1
3	a)	Information provided to ensure physician that patient's condition is properly managed	Estimation by Raytel Medical Inc.	10.3
3	b)	% Patients fail to report INR value without reminder	Estimation based on '2 Year Transitional Study @ Loma	10.3
3	c)	# Times physician changes warfarin dose during course of year	Linda VA Medical Center:	8.2
3	d)	# Times patients call during course of year	" "	8.1
3	e)	# Times patients call during course of year	" "	8.1
3	f)	% Patients who have some form of clinical change during course of year	" "	8.3
4	a)	% Patients who undergo some invasive procedure each year	" "	10.2
5	a)	% INR results outside of target range	" "	4.1
5	b)	% Patients who will be repeatedly non-compliant during course of year.	" "	

CMS
Home INR Monitoring
Practice Expense RVU's

Recurring Technical - Administrative (RT-A) (G-0249) Home prothrombin time (INR) monitoring for anticoagulation management, receipt of results and report only Care Guidelines / Details	Assumptions Staff Type	Time in Minutes	Per Event	Occurrence Rate	Administrative Labor Labor Rate/Hr Time/INR Value	$ Cost/INR Value
1 Process Order						
a) Receive and enter order	Admin Staff	7.50	Prescription	4.00	0.71	$ 0.17
2 Dispense Supplies & Equipment for Monitoring INR						
3 Manage Patient Compliance / Provide Consultation						
a) Update Changes to Patient Data Profile	Admin Staff	15.00	Year	20%	0.07	$ 0.02
4 Manage Anticipated Changes in Anticoagulant Change						
5 Communication & Documentation						
a) Send report of patient's INR Value to physician	Admin Staff	2.00	Test Reported	1.00	2.00	$ 0.48
b) Send report of patient's INR trends for past quarter to support physician's evaluation	Admin Staff	3.00	Quarter	4.00	0.29	$ 0.07
c) Document & Archive all INR Results & patient interaction	Admin Staff	5.00	Test Reported	1.00	5.00	$ 1.21
d) Send report of annual report to support physician's annual outcomes assessment	Admin Staff	3.00	Year	1.00	0.07	$ 0.02
6 Claim filing with Medicare						
a) Submit claims for New & Re-Initiated Patients	Admin Staff	5.00	Per Month	1.00	5.00	$ 1.21
7 Accounts receivable mgmt. & collection				1.00		
a) Bill Patient Co-Pay	Admin Staff	5.00	Month	1.00	1.43	$ 0.35
b) Follow-up on Past Due Accounts	Admin Staff	5.00	Month	16%	0.23	$ 0.06
c) Write-off for Non-collectable Accounts	Admin Staff			8%		$ 1.01
Total Clerical Costs to Generate:						
1 Controlled, Billable INR Value					**14.80**	**$ 4.58**
4 Controlled, Billable INR Values					**59.20**	**$ 18.33**

		Comments	Reference	Best Care Guidelines
1	a)	Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/02	5.1
3	a)	20% of Patients have some element of demographic or insurance change	Estimation by Raytel Medical Inc.	4.1
5	a)	Assumes semi-automated data handling systems	Estimation by Raytel Medical Inc.	4.1
5	b)	Assumes semi-automated data handling systems	Estimation by Raytel Medical Inc.	12.1
5	c)	Assumes semi-automated data handling systems	Estimation by Raytel Medical Inc.	4.1
5	d)	Assumes semi-automated data handling systems	Estimation by Raytel Medical Inc.	12.1
6	a)	IDTF submits monthly claims for INR Values reported in month	Proposed Gxxx4 work instructions	5.1
7	a)	IDTF bills patient co-pay for INR Values reported in month	Proposed Gxxx4 work instructions	5.1
7	b)	% Patients who are diligent in co-pay payment	Estimation by Raytel Medical Inc.	5.1
7	c)	% of Non-collectable Co-Pay Amounts	Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

Recurring Technical - Supplies (RT-S) (G-0249) Home prothrombin time (INR) monitoring for anticoagulation management, receipt of results and report only. Care Guidelines / Details	Assumptions: Unit Value	Per Event	Occurrence Rate	Supplies: Units/Test	Cost/INR Value
Average					
1 Process Order					
2 Dispense Supplies & Equipment for Monitoring INR					
a) Test Strips to Generate 1 Controlled INR Value	$ 16.39	Per Strip	1.0	1.0	$ 16.39
b) Re-test due to Reconfirm Extreme Out of Ranges	$ 16.39	Year	4.0	0.1	$ 1.56
c) Product Spoilage	$ 16.39	Year	3.5	0.1	$ 1.44
d) Re-test due to Testing Errors (e.g.. Insufficient Blood,Temperatures, Insertion, QC Checks, etc.)	$ 16.39	Year	2.8	0.1	$ 1.02
e) Express ship strips to patients	$ 10.00	Prescription	4.0	0.1	$ 0.95
f) Insurance on Product Shipments	$ 0.50	Prescription	4.0	0.1	$ 0.05
3 Manage Patient Compliance / Provide Consultation				-	$ -
4 Manage Anticipated Changes in Anticoagulant Change				-	$ -
5 Communication & Documentation				-	$ -
6 Claim filing with Medicare				-	$ -
7 Accounts receivable mgmt. & collection				-	$ -
Total Supply Costs to Generate:					
1 Controlled, Billable INR Value				**1.4**	**$ 21.42**
4 Controlled, Billable INR Values				**5.7**	**$ 85.66**

		Comments	Reference	Best Care Guidelines
2	a)	Adjusted to account for QC controls	Roche, ITC & LifeScan Estimated Averages	5.1
2	a)	Expected # of INR Values Reported Per Year (Avg. of 8-13 Values / Prescription)	42 Per CMS Meeting 2/28/02	5.1
2	b)	Patients instructed to re-test prior to physician action whenever INR significantly out of range	Estimation based on 2 Year Transitional	10.1
2	c)	Accidental product spoilage due to abuse, storage, environmental conditions, etc.	Study @ Loma Linda VA Medical Center:	5.1
2	d)	Patients instructed to re-test whenever error is generated (e.g. insufficient blood, temperature)	" "	5.1
2	e)	Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/02	5.1
2	f)	Quarterly Rx for 8-13 INR Values	Per CMS Meeting 2/28/03	5.1
7	a)	% of Non-collectable Co-Pay Amounts	Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

Recurring Technical - Equipment (R-T-E) (G-0249) Home prothrombin time (INR) monitoring for anticoagulant dose management, receipt of results and report only; Care Guidelines / Details	Assumptions: Unit Value	Per Event	Occurrence Rate	Equipment: Units/Test	Cost/Unit	Value
Est. Avg.						
1 **Process Order**						
2 **Dispense Supplies & Equipment for Monitoring INR**						
a) Provide Home INR Monitoring Equipment	$2,341.67	Per New or Re-Initiated Patient	48	0.006	$	14.74
b) Adjustment for Patient Fall-Out	$2,341.67	Year	15.3%	0.001	$	2.25
c) Financing Cost of Meter	16%	Year			$	4.93
3 **Manage Patient Compliance / Provide Consultation**				-	$	-
4 **Manage Anticipated Changes in Anticoagulant Change**				-	$	-
5 **Communication & Documentation**				-	$	-
6 **Claim filing with Medicare**				-	$	-
7 **Accounts receivable mgmt. & collection**				-	$	-
				-	$	-
Total Equipment Costs to Generate:						
1 Controlled, Billable INR Value				**0.007**	**$**	**21.92**
4 Controlled, Billable INR Values				**0.029**	**$**	**87.66**

Comments	Reference	Best Clinic Guidelines
2 a) Expected useful life of equipment	Roche, ITC & LifeScan Estimated Averages	5.1
2 b) Patient Fall-Out :		5.1
Mortality	2.5% St. Jude Medical: 5% 1st Year, 1.25% Years 2 -3	
Other (Incapacitation/Relocation/Etc.)	12.8% Ann Thorac Surg 2001;72:1523-7	
Total % Meters Whose Acquisition Costs Not Fully Recovered by IDTF	15.3%	
2 c) Average consumer credit charge		5.1
7 a) % of Non-collectable Co-Pay Amounts	Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

	Recurring Technical - Summary (RT) (G-0248) Home prothrombin time (INR) monitoring (pt. anticoagulation management), receipt of results and report only. Care Guidelines / Details	Cost / INR Value Clinical RT - C	Admin RT - A	Supplies RT - S	Equipment RT - E	Summary RT	Required by Best Practice	Required by Medicare Coverage Determination
RT-	1 **Process Order**	$ -	$ 0.17	$ -	$ -	$ 0.17	5	
RT-	2 **Dispense Supplies & Equipment for Monitoring INR**	$ 0.30	$ -	$ 21.42	$ 21.92	$ 43.63	5	√
RT-	3 **Manage Patient Compliance / Provide Consultation**	$ 2.84	$ 0.02	$ -	$ -	$ 2.86	8,10	√
RT-	4 **Manage Anticipated Changes in Anticoagulant Response**	$ 0.02	$ -	$ -	$ -	$ 0.02	8	√
RT-	5 **Communication & Documentation**	$ 0.67	$ 1.76	$ -	$ -	$ 2.43	4	√
RT-	6 **Claim filing with Medicare**	$ -	$ 1.21	$ -	$ -	$ 1.21	5	
RT-	7 **Accounts receivable mgmt. & collection**	$ -	$ 1.41	$ -	$ -	$ 1.41	5	
AVG Based	**Total Recurring Technical Costs to Generate 1 Controlled, Billable INR Value**	$ 3.82	$ 4.57	$ 21.42	$ 21.92	$ 51.72		
	+ Overhead @ 25%	$ 1.27	$ 1.52	$ 7.14	$ 7.31	$ 17.24		
	Total	$ 5.09	$ 6.09	$ 28.55	$ 29.22	$ 68.96		
	Total Recurring Technical Costs to Generate 4 Controlled, Billable INR Values	$ 15.28	$ 18.26	$ 85.66	$ 87.66	$ 206.87		
	+ Overhead @ 25%	$ 5.09	$ 6.09	$ 28.55	$ 29.22	$ 68.96		
	Total	$ 20.38	$ 24.35	$ 114.22	$ 116.88	$ 275.83		

CMS
Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Clinical (IT-C)		Assumptions			Clinical Labor	
(G-0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training test transmissions.	Staff Type	Time in Minutes	Per Event	Occurrence Rate	Labor Rate/Hr.	$ 30.00
Care Guideline / Activity					Units/Initiation	Cost/Initiation
1 Patient Selection & Assessment						
a) Verify & document Patient has received required training before releasing equipment & strips	Pharmacist	5.00	Per Initiation		5.00	$ 2.50
2 Initiation of Therapy						
a) Contact patient to explain IDTF service	RN/LPN/MA	10.00	Per Initiation		10.00	$ 5.00
b) Contact Physician Office to review patient instructions (Therapeutic Range & Notification)	RN/LPN/MA	5.00	Per Initiation		5.00	$ 2.50
3 Patient Education	RN/LPN/MA	120.00	Per Initiation		120.00	$ 60.00
4 Claim filing with Medicare						
5 Accounts receivable mgmt. & collection						
Total Initiation Technical - Clinical Costs for New or Re-Initiated Patient					**140.00**	**$ 70.00**

		Comments	Reference	Best Care Guidelines
1	a)	Prescription product required dispensing in accordance with FDA requirements.	510(k) Clearance	4.1
2	a)	Similar to Initiation of EKG & Holter Monitoring Services	Estimation by Raytel Medical Inc.	9.1
2	b)	Similar to Initiation of EKG & Holter Monitoring Services	Estimation by Raytel Medical Inc.	7.1

CMS
Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Administrative (TA)	Assumptions				Administrative Labor		
(G0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training and transmissions.	Staff Type	Time in Minutes	Per Event	Occurrence Rate	Labor Rate/Hr	$	38.50
Care Guidelines / Details					Units/Initiation	$	Cost/Initiation
1 Patient Selection & Assessment							
2 Initiation of Therapy							
a) Create Patient Record (Demographic & Insurance Data)	Admin Staff	15.00	Per Initiation		15.00	$	3.63
b) Send copy of Patient Record to Physician's Office for final review & confirmation	Admin Staff	5.00	Per Initiation		5.00	$	1.21
3 Patient Education							
4 Claim filing with Medicare							
a) Submit claims for New & Re-Initiated Patients in month	Admin Staff	5.00	Per Initiation		5.00	$	1.21
5 Accounts receivable mgmt. & collection							
a) Bill Patient Co-Pay	Admin Staff	5.00	Per Initiation		1.43	$	0.35
b) Follow-up on Past Due Accounts	Admin Staff	5.00	Per Initiation	16%	0.23	$	0.06
c) Write-off for Non-collectible Accounts				8%		$	3.82
Total Initiation Technical - Administrative Costs for New or Re-Initiated Patient					**26.66**	**$**	**10.26**

	Comments	Reference	Best Care Guidelines
2	a) Process similar to other Cardiovascular Monitoring Services	Estimation by Raytel Medical Inc.	7.1
2	b) Process similar to other Cardiovascular Monitoring Services	Estimation by Raytel Medical Inc.	7.1
4	a) Process similar to other Cardiovascular Monitoring Services	Estimation by Raytel Medical Inc.	5.1
5	a) Process similar to other Cardiovascular Monitoring Services	Estimation by Raytel Medical Inc.	5.1
5	b) % of Patients who do not pay on schedule	Estimation by Raytel Medical Inc.	5.1
5	c) % of Non-collectible Co-Pay Amounts	Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Supplies (IT-S) (G-0248) Home prothrombin time (INR) monitoring for anticoagulation management; provision of home monitor and initial test strips, with training test transmissions. Care Guidelines & Details	Assumptions Unit Value	Per Event	Occurrence Rate	Supplies Units/Initiation		Cost/Initiation
1 Patient Selection & Assessment						
a) Test Strips required to support & validate Patient Training	$ 16.39	Per Strip	4	4.00	$	65.56
b) Express ship strips to patients	$ 29.00	Per Initiation	1	1.00	$	29.00
2 Initiation of Therapy						
a) Provide Spring-Powered Device for Lancing	$ 17.21	Per Initiation	1	1.00	$	17.21
b) Provide Lancets per Box of 200	$ 24.30	Per Initiation	1	1.00	$	24.30
c) Provide Batteries	$ 0.64	Per Initiation	3	3.00	$	1.92
d) Provide for Refurbishment & Re-qualification of Meters for Non-Compliant Patients	$ 250.00	Per Refurbishment	10.8%	0.11	$	27.00
3 Patient Education						
a) Provide Printed Education & Training Materials	$ 1.00	Per Initiation	1	1.00	$	1.00
b) Provide Video/CDRom Education & Training Materials	$ 2.50	Per Initiation	1	1.00	$	2.50
4 Claim filing with Medicare						
5 Accounts receivable mgmt. & collection						
Total Initiation Technical - Supply Costs for New or Re-Initiated Patient				**12.11**	**$**	**168.49**

		Comments		Reference	Best Care Guidelines
1	a)	1 for trainer demo, 3 for patient confirmation		Roche, ITC & LifeScan	6.1
1	b)	Quarterly Rx for 8-13 INR Values		Per CMS Meeting 2/28/02	6.1
2	a)	Upfront materials needed to initiate therapy (can not be refurbished)		Cross-Walk to A4258	7.3
2	b)	Upfront materials needed to initiate therapy (can not be refurbished)		Cross-Walk to A4259	7.3
2	c)	Upfront materials needed to initiate therapy (can not be refurbished)		Cross-Walk to A4254	7.3
2	d)	Meters Which Can Be Refurbished:			10.3
		Failure to Complete Training	6.8%	Ann Thorac Surg 2001;72:1523-7	
		Non-Compliance (Meter Is Retrievable from Patient)	4.0%	LifeScan Clinical Trials shows ~4% discontinuation.	
		Allowance for Refurbishment	10.8%		
3	a)	FDA Clearance requires appropriate training material		ITC & Roche	9.1
3	b)	FDA Clearance requires appropriate training material		ITC & Roche	9.1

CMS
Home INR Monitoring
Practice Expense RVU's

Initiation Technical - Equipment (IT-E)	Assumptions			Equipment	
(G-0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training, test transmissions.	Unit	Per	Occurrence		
Care Guidelines / Details	Value	Event	Rate	Units / Test	Cost/UNIT Value
Est. Avg.					
1 Patient Education					
2 Initiation of Therapy					
a) Provide Home INR Monitoring Equipment	$2,341.67	Per New or Re-Initiated Patient	4	0.006	$ 14.74
b) Adjustment for Patient Fall-Out	$2,341.67	Year	15.3%	0.001	$ 2.25
3 Patient Selection & Assessment					
4 Care Guidelines / Details					
5 Patient Selection & Assessment					
Total Initiation Technical - Equipment Costs for New or Re-Initiated Patient				**0.007**	**$ 16.99**

		Comments	Reference	Best Care Guidelines
2	a)	Expected useful life of equipment	Roche, ITC & LifeScan Estimated Averages	5.1
2	b)	Patient Fall-Out :		5.1
		Mortality 2.5%	St. Jude Medical: 5% 1st Year, 1.25% Years 2 -3	
		Other (Incapacitation/Relocation/Etc.) 12.8%	Ann Thorac Surg 2001;72:1523-7	
		Total % Meters Whose Acquisition Costs Not Fully Recovered by IDTF 15.3%		
2	c)	Average consumer credit charge		5.1
7	a)	% of Non-collectable Co-Pay Amounts	Estimation by Raytel Medical Inc.	5.1

CMS
Home INR Monitoring
Practice Expense RVU's

	Initiation Technical - Summary (IT) (G-0248) Home prothrombin time (INR) monitoring for anticoagulation management, provision of home monitor and initial test strips, with training, test transmissions, Care Guidelines / Details	Cost / Initiation: Clinical IT - C	Admin IT - A	Supplies IT - S	Equipment IT - E	Summary IT	Required By: Best Care Guidelines	Required By: 9/18/2001 Coverage Memorandum
IT -	1 **Patient Selection & Assessment**	$ 2.50	$ -	$ 94.56	$ -	$ 97.06	6	√
IT -	2 **Initiation of Therapy**	$ 7.50	$ 3.63	$ 70.43	$ 16.99	$ 98.54	7,10	√
IT -	3 **Patient Education**	$ 60.00	$ -	$ 3.50	$ -	$ 63.50	9	√
IT -	4 **Claim filing with Medicare**	$ -	$ -	$ -	$ -	$ -	5	
IT -	5 **Accounts receivable mgmt. & collection**	$ -	$ 4.22	$ -	$ -	$ 4.22	5	
	Total Initiation Technical Costs for New or Re-Initiated Patient	**$ 70.00**	**$ 7.84**	**$ 168.49**	**$ 16.99**	**$ 263.32**		
AVG Based	**Total Recurring Technical Costs to Generate 1 Controlled, Billable INR**	$ 70.00	$ 7.84	$ 168.49	$ 16.99	$ 263.32		
	+ Overhead @ 25%	$ 23.33	$ 2.61	$ 56.16	$ 5.66	$ 87.77		
	Total	$ 93.33	$ 10.45	$ 224.65	$ 22.65	$ 351.09		

CMS
Home INR Monitoring
Best Care Guidelines

1. Qualifications of Personnel					
1.1 Anticoagulation providers should meet minimum competencies and hold a license in a patient-oriented health-related field (e.g., medicine, nursing, pharmacy).	X				
2. Supervision					
2.1 The physician or health care provider with ultimate responsibility for therapeutic decisions should develop an agreed-upon policy and procedure for personnel supervision and oversight of those health care providers actually managing the anticoagulation therapy.	X				
3. Care Management and Coordination					
3.1 Written protocols for the management of anticoagulation should be established.	X				
3.2 The anticoagulation provider should have a systematic process to identify patients who need to be scheduled for a blood sample and/or medical assessment, to schedule the necessary appointments, to retrieve laboratory results, and to provide patient instruction and follow-up.	X				
4. Communication and Documentation					
4.1 The anticoagulation provider should have policies and procedures regarding communications with the patient, primary care physician or health care providers, laboratory, and designated pharmacy(ies). Documentation of these interactions, as well as documentation of outcomes assessment, should be recorded in the database of the patient.			X		X
5. Laboratory Monitoring					
5.1 The anticoagulation provider should use the INR to assess patient anticoagulation control.					X
6. Patient Selection and Assessment					
6.1 The referring physician or health care provider recommending anticoagulation therapy shall determine the appropriateness of anticoagulation therapy for a particular patient. The actual anticoagulation provider or director of the service, in order to manage the care, must agree on the appropriateness of the therapy.		X			
6.2 The anticoagulation provider should assess the patient's current medical, medication, dietary, and lifestyle history; level of understanding and literacy; health beliefs and attitudes; motivation for self-care behavior; and other environmental or behavioral barriers to learning and adherence when therapy is instituted.		X			
7. Initiation of Therapy					
7.1 A patient-specific INR range based on the medical literature and other patient specific-information, should be established.		X	X		
7.2 The anticoagulation provider should base dosage adjustments on INR and other pertinent laboratory results, individual assessment, patient-specific response, and guidelines approved by the anticoagulation service as part of its policies and procedures.				X	
7.3 Initial monitoring should occur every week or more frequently following initiation of therapy or hospital discharge, depending on the stability of the patient. After the patient's anticoagulation has been stabilized, follow-up evaluation should occur at least every four weeks.					X
8. Maintenance and Management of Therapy					
8.1 The anticoagulation provider should have a systematic process for follow-up evaluations focused on patient assessment for potential side effects of therapy; recurrent disease; hemmorrhagic complications; drug-drug/drug-disease state and drug-food interactions; lifestyle changes; review of laboratory results; adherence issues; and patient education.				X	X
8.2 The anticoagulation provider should have a policy on the interval for follow-up blood testing after a dosage adjustment has been made. The determination should consider the magnitude of the nontherapeutic INR and dosage change, as well as other variables influencing patient responsiveness and stability.				X	X
8.3 Anticoagulation providers should develop guidelines regarding management of anticipated changes in anticoagulant response that result from a change in patient status, medication use, diet, or other factors.				X	X
9. Patient Education					
9.1 The anticoagulation provider should have a policy and procedure pertaining to the desired goals and objectives of its educational program. Patient education should be individualized according to the initial assessment, based on the patient's level of understanding; be accompanied by written information as a reinforcement; and be reviewed on a regular basis.		X	X		
10. Management and Triage of Therapy-Related and Unrelated Problems					
10.1 Anticoagulation providers should have a policy and procedure for the management of major and minor bleeding episodes, signs and symptoms of thromboembolism, other potential anticoagulation side effects, or other medical problems not related to anticoagulation therapy. This should include the use of vitamin K or fresh-frozen plasma to correct an excessively prolonged INR or to treat serious hemorrhage.				X	
10.2 Anticoagulation providers should have a policy and procedure for the management of anticoagulation when the patient requires and invasive procedure.				X	X
10.3 Anticoagulation providers should have a policy and procedure for the management of patients who are nonadherent with therapy, appointments, or other aspects of anticoagulation treatment. This policy should include guidelines for termination of anticoagulation management by the anticoagulation service.					X
11. Organizational components					
11.1 The anticoagulation provider should perform a program evaluation of organizational components on an annual basis or more often as deemed necessary. Anticoagulation providers should analyze the contribution of various processes to patient outcomes.	X				
12. Patient Outcomes					
12.1 The anticoagulation provider should perform an outcomes evaluation on an annual basis or more often as deemed necessary. This outcome assessment should include, as a minimum, information pertaining to degree of therapeutic effectiveness as determined by the INR, hemorrhagic complication rates, thromboembolism rates, and other complications resulting from anticoagulant therapy.	X				X

CMS
Home INR Monitoring
Practice Expense RVU's

Required Technical - Supplies (RT-S) (G0248) Home INR monitoring for anticoagulation management, ... of results and report only		Assumptions: Unit Value	Per Basis	Conservative Value	Comments	Supplies: Units/Test	Cost Value
Company Specific Assumptions							
Roche - CoaguChek							
1	**Process Order**						
2	**Dispense Supplies & Equipment for Monitoring INR**						
a)	Test Strips to Generate 1 Controlled INR Value	$ 23.00	Per Strip	1.0		1.00	$ 23.00
b)	Re-test due to Reconfirm Extreme Out of Ranges	$ 23.00	Year	4.0		0.10	$ 2.19
c)	Re-test due to Testing Errors (e.g.. Insufficient Blood, Temperatures, Insertion, QC Checks, etc.)	$ 23.00	Year	4.3	Patient Error Rate during LifeScan 2 Yr. Transition Study	0.10	$ 2.37
d)	Product Spoilage	$ 23.00	Year	2.0	Estimated waste due to spoilage	0.05	$ 1.10
e)	Express ship strips to patients	$ 10.00	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.95
f)	Insurance on Product Shipments	0.50	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.05
3	**Manage Patient Compliance / Provide Consultation**						
4	**Manage Anticipated Changes in Anticoagulant Change**						
5	**Communication & Documentation**						
6	**Claim filing with Medicare**						
7	**Accounts receivable mgmt. & collection**						
	Total Supply Costs to Generate 1 Controlled, Billable INR Value					1.44	$ 29.65
ITC - ProTime							
1	**Process Order**						
2	**Dispense Supplies & Equipment for Monitoring INR**						
a)	Test Strips to Generate 1 Controlled INR Value	$ 13.00	Per Strip	1.0		1.00	$ 13.00
b)	Re-test due to Reconfirm Extreme Out of Ranges	$ 13.00	Year	4.0		0.10	$ 1.24
c)	Re-test due to Testing Errors (e.g.. Insufficient Blood, Temperatures, Insertion, QC Checks, etc.)	$ 13.00	Year	4.3	Patient Error Rate during LifeScan 2 Yr. Transition Study	0.10	$ 1.34
d)	Product Spoilage	$ 13.00	Year	2.0	Estimated waste due to spoilage	0.05	$ 0.62
e)	Express ship strips to patients	$ 10.00	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.95
f)	Insurance on Product Shipments	0.50	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.05
3	**Manage Patient Compliance / Provide Consultation**						
4	**Manage Anticipated Changes in Anticoagulant Change**						
5	**Communication & Documentation**						
6	**Claim filing with Medicare**						
7	**Accounts receivable mgmt. & collection**						
	Total Supply Costs to Generate 1 Controlled, Billable INR Value					1.44	$ 17.19
HemoSense - INRatio							
1	**Process Order**						
2	**Dispense Supplies & Equipment for Monitoring INR**						
a)	Test Strips to Generate 1 Controlled INR Value	$ 13.17	Per Strip	1.0		1.00	$ 13.17
b)	Re-test due to Reconfirm Extreme Out of Ranges	$ 13.17	Year	4.0		0.10	$ 1.25
c)	Re-test due to Testing Errors (e.g.. Insufficient Blood, Temperatures, Insertion, QC Checks, etc.)	$ 13.17	Year	4.3	Patient Error Rate during LifeScan 2 Yr. Transition Study	0.10	$ 1.35
d)	Product Spoilage	$ 13.17	Year	2.0	Estimated waste due to spoilage	0.05	$ 0.63
e)	Express ship strips to patients	$ 10.00	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.95
f)	Insurance on Product Shipments	0.50	Prescription	4.0	Quarterly Rx for 8-13 INR Values	0.10	$ 0.05
3	**Manage Patient Compliance / Provide Consultation**						
4	**Manage Anticipated Changes in Anticoagulant Change**						
5	**Communication & Documentation**						
6	**Claim filing with Medicare**						
7	**Accounts receivable mgmt. & collection**						
	Total Supply Costs to Generate 1 Controlled, Billable INR Value					1.44	$ 17.40

CMS
Home INR Monitoring
Practice RVU's

[illegible] Technical - Equipment (RVU) — (G-0249) [illegible] (INR) monitoring for anticoagulation [illegible], receipt of results and report only. — [illegible] / Details	Unit Cost	Per Event	Occurrence Rate		Equipment Units	Equipment Cost/INR Value	Required By Best Practice	Required By [illegible] Coverage [illegible]
Roche - CoaguChek								
1 Process Order								
2 Dispense Supplies & Equipment for Monitoring INR								
a) Provide Home INR Monitoring Equipment	$ 2,135.00	Per New or Re-Initiated Patient	60	Expected useful life of equipment	0.005	$ 10.17	5.1	
b) Adjustment for Patient Fall-Out	$ 2,135.00	Year	15.3%	Patients who discontinue each year.	0.001	$ 1.55	5.1	
c) Financing Cost of Meter	10%	Year	36	Expected useful life of equipment		$3.69	5.1	
3 Manage Patient Compliance / Provide Consultation								
4 Manage Anticipated Changes in Anticoagulant Change								
5 Communication & Documentation								
6 Claim filing with Medicare								
7 Accounts receivable mgmt. & collection								
Total Equipment Costs to Generate 1 Controlled, Billable INR Value					0.005	$ 15.40		
ITC - ProTime								
1 Process Order								
2 Dispense Supplies & Equipment for Monitoring INR								
a) Provide Home INR Monitoring Equipment	$ 2,495.00	Per New or Re-Initiated Patient	36	Expected useful life of equipment	0.008	$ 19.80	5.1	
b) Adjustment for Patient Fall-Out	$ 2,495.00	Year	15.3%	Patients who discontinue each year.	0.001	$ 3.02	5.1	
c) Financing Cost of Meter	10%	Year	36	Expected useful life of equipment		$4.31	5.1	
3 Manage Patient Compliance / Provide Consultation								
4 Manage Anticipated Changes in Anticoagulant Change								
5 Communication & Documentation								
6 Claim filing with Medicare								
7 Accounts receivable mgmt. & collection								
Total Equipment Costs to Generate 1 Controlled, Billable INR Value					0.009	$ 27.13		
HemoSense - INRatio								
1 Process Order								
2 Dispense Supplies & Equipment for Monitoring INR								
a) Provide Home INR Monitoring Equipment	$ 2,395.00	Per New or Re-Initiated Patient	48	Expected useful life of equipment	0.006	$ 14.26	5.1	
b) Adjustment for Patient Fall-Out	$ 2,395.00	Year	15.3%	Patients who discontinue use	0.001	$ 2.17	5.1	
c) Financing Cost of Meter	16%	Year	36	Expected useful life of equipment		$6.76	5.1	
3 Manage Patient Compliance / Provide Consultation								
4 Manage Anticipated Changes in Anticoagulant Change								
5 Communication & Documentation								
6 Claim filing with Medicare								
7 Accounts receivable mgmt. & collection								
Total Equipment Costs to Generate 1 Controlled, Billable INR Value					0.007	$ 23.21		

Submitter : **Diane Millman** **Date: 01/02/2007**

Organization : **Diane Millman**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-FC-41-Attach-1.DOC

CMS-1321-FC-41-Attach-2.DOC

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS 1321-FC
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS File Code: CMS-1321-FC; Comments on 2007 Medicare Physician Fee Schedule

Dear Ms. Norwalk:

On behalf of Philips Medical ("Philips" or "Philips Medical"), I am delighted to have this opportunity to provide these comments regarding the final Physician Fee Schedule (PFS) for CY 2007 published on December 1, 2006 in the Federal Register (the "Final Rule"). Philips Medical is one of the largest manufacturers of medical systems in the world. Philips' product line includes technologies in general imaging and cardiac ultrasound, X-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), nuclear medicine (including Positron Emission Tomography (PET), radiation therapy planning, patient monitoring and resuscitation, as well as information technology solutions.

Philips remains extremely concerned about the potential impact of the Final Rule on access to high quality medical imaging services in non-hospital settings. We continue to strongly object to CMS's decision to impose the hospital outpatient "cap" that was enacted by the Deficit Reduction Act (DRA) on services, such as cardiac CT and CTA, which are new technologies that have not yet been assigned a CPT Category I code. These services, which are currently reportable using Category III codes, do not even have separately identifiable "technical" components: Rather, to the extent that these services are covered by local carriers in non-hospital settings, they are generally paid on a global basis. CPT III codes are "temporary codes for emerging technology services, and procedures" that are assigned for the purposes of data collection. Subjecting these new and emerging technologies to the draconian limits imposed by the DRA will unnecessarily and prematurely limit the ability of physicians to gain the kind of experience with these services that is necessary for Category I codes to be assigned.

Likewise, we strongly believe that PET/CT and other services that are not assigned relative value units on a national basis should be exempt from the DRA cap. Section 5102(b)(1) of the DRA, the statutory provision directing CMS to establish the cap, provides that the cap is to apply only where the "**technical component** (including the technical component portion of a global fee) of the service **established** for a year **under the fee schedule**" exceeds the amount payable for the same service under the hospital outpatient prospective payment system. (Emphasis added.) For services such as PET/CT, whose allowances are determined by local carriers, there simply is no "technical component" that is "established under the fee schedule". Therefore, we continue to believe that CMS exceeded its statutory authority by including this service among those subject to the DRA cap.

Moreover, we continue to believe that services that include both physiological and imaging components, such as duplex studies, should be exempted from the DRA cap.

Finally, we also strongly support the comments of the Remote Cardiac Services Provider Group (the "Provider Group"). We are extremely concerned that, while some of the reductions that had been proposed have been ameliorated by the agency's acceptance of the Provider Group's direct cost data, Medicare payment for remote cardiac monitoring services will be reduced substantially once the practice expense revisions are fully phased in: In fact, reductions for holter monitoring services will be in range of 50%. In this regard, we urge CMS to continue to examine alternatives for the allocation of indirect practice expenses—alternatives that do not disadvantage technical component services by allocating indirect expenses based on physician work.

We concur with the Provider Group's request that holter device equipment costs be allocated to the holter monitoring technical component codes (CPT Codes 93226 and 93232), rather than to the hook-up codes (93225 and 93231). In fact, the purchasers of Philips' holter devices are the providers of the monitoring services, who may or may not be the physicians who hook up the equipment. We therefore support the reallocation of holter monitors to the monitoring codes.

In addition, we support the Provider Group's suggested changes to the Independent Diagnostic Testing Facility requirements. We urge CMS to make the requested modifications and clarifications to the requirements pertaining to the availability of home monitors for on-site inspection; the insurance requirements pertaining to these devices; and the role of the supervising physician.

We appreciate your consideration of these comments, and look forward to continued dialogue with you on these and other issues.

Sincerely yours,

Laurel Sweeney

Submitter : Mr. Matthew Schulze **Date:** 01/02/2007

Organization : American Society for Clinical Pathology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Diane Millman** **Date: 01/02/2007**

Organization : **Diane Millman**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-FC-43-Attach-1.DOC

CMS-1321-FC-43-Attach-2.DOC

AFROC
ASSOCIATION OF FREESTANDING RADIATION ONCOLOGY CENTERS
Our Voice in Washington

December 21, 2006

Leslie V. Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington DC 20201

Re: CMS-1321-FC; Revisions to Physician Fee Schedule for CY 2007

Dear Ms. Norwalk:

On behalf of the Association for Freestanding Radiation Oncology Centers (AFROC), I am writing to you regarding the final Physician Fee Schedule for CY 2007 (the "2007 PFS").

Preliminarily, we wish to thank CMS for its comprehensive analysis of AFROC's comments regarding the practice expense/hour (PE/hr) for radiation oncology, and its decision to increase the radiation oncology PE/hr based on the study conducted by Direct Research and submitted with AFROC's comments. We very much appreciate the work performed by CMS and by its contractor, the Lewin Group, on this issue.

We would appreciate clarification of one issue raised by the 2007 PFS, relating to Medicare payment and coding for stereotactic radiosurgery and radiotherapy. It is our understanding that there are three new CPT codes for stereotactic radiosurgery/radiotherapy that will become effective in January, 2007:

- CPT Code 77371 – Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of one session; multi-source Cobalt 60-based.

- CPT Code 77372 – Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of one session; linear accelerator based.

- CPT Code 77373 – Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed five fractions.

In addition, the CY 2007 PFS includes a number of "G" codes for robotic, image guided radiosurgery (G0339 and G0340), which are listed as carrier priced (Status Indicator "C").

We are concerned that the allowances for the new CPT codes established for use in CY 2007 (CPT codes 77371, 77372 and 77373), which will range from approximately $800 to approximately $1500 in CY 2007, are entirely inadequate to cover the costs of the services involved. For example, we are aware of one facility that provides cobalt-based SRS which cost over $5 million to construct and equip.

We are not aware of a significant number of facilities that provide stereotactic radiosurgery (either cobalt or linear accelerator-based) or stereotactic body radiation therapy on a freestanding basis. Because there have been no CPT codes available to report the enormous technical component costs involved, it is our understanding that most of the facilities that provide these services are hospital-based, and we believe it unlikely that there are a sufficient number of freestanding facilities in operation to ensure that the direct cost data underlying the interim final RVUs set forth in the Final Rule are accurate. Nor does that data appear to be available on the CMS website.

In addition, we believe that the cost of these services is quite dependent on circumstances that are particular to each facility. While the capital costs involved are substantially higher than the costs involved in the provision of conventional radiation therapy, the appropriate patient population is relatively small. Therefore, the cost per service is very dependent on relatively small variations in volume.

In light of the relative dearth of freestanding facilities that provide these services and the relative infrequency of the provision of these services at this time, we recommend that these services be carrier-priced, at least until a more robust data base can be established. Maintaining carrier-based status for these services would be consistent with the decision to allow carrier pricing of robotic, image-guided stereotactic radiotherapy and the well-reasoned decision to continue the carrier-priced status of proton beam radiotherapy, another radiation oncology service involving extraordinary facility costs and relatively few patients.

We appreciate your consideration of these comments and look forward to working with CMS in further refining the Medicare payment for radiation therapy technical component services over the coming years.

Sincerely yours,

Association of Freestanding Radiation Oncology Centers

David Rice, MD
President

cc: AFROC Board
Sheila Gell

Submitter : **Diane Millman** **Date:** **01/02/2007**

Organization : **Diane Millman**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-FC-44-Attach-1.DOC

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS 1321-FC
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS File Code: CMS-1321-FC; Comments on 2007 Medicare Physician Fee Schedule

Dear Ms. Norwalk:

On behalf of Philips Medical ("Philips" or "Philips Medical"), I am delighted to have this opportunity to provide these comments regarding the final Physician Fee Schedule (PFS) for CY 2007 published on December 1, 2006 in the Federal Register (the "Final Rule"). Philips Medical is one of the largest manufacturers of medical systems in the world. Philips' product line includes technologies in general imaging and cardiac ultrasound, X-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), nuclear medicine (including Positron Emission Tomography (PET), radiation therapy planning, patient monitoring and resuscitation, as well as information technology solutions.

Philips remains extremely concerned about the potential impact of the Final Rule on access to high quality medical imaging services in non-hospital settings. We continue to strongly object to CMS's decision to impose the hospital outpatient "cap" that was enacted by the Deficit Reduction Act (DRA) on services, such as cardiac CT and CTA, which are new technologies that have not yet been assigned a CPT Category I code. These services, which are currently reportable using Category III codes, do not even have separately identifiable "technical" components: Rather, to the extent that these services are covered by local carriers in non-hospital settings, they are generally paid on a global basis. CPT III codes are "temporary codes for emerging technology services, and procedures" that are assigned for the purposes of data collection. Subjecting these new and emerging technologies to the draconian limits imposed by the DRA will unnecessarily and prematurely limit the ability of physicians to gain the kind of experience with these services that is necessary for Category I codes to be assigned.

Likewise, we strongly believe that PET/CT and other services that are not assigned relative value units on a national basis should be exempt from the DRA cap. Section 5102(b)(1) of the DRA, the statutory provision directing CMS to establish the cap, provides that the cap is to apply only where the "**technical component** (including the technical component portion of a global fee) of the service **established** for a year **under the fee schedule**" exceeds the amount payable for the same service under the hospital outpatient prospective payment system. (Emphasis added.) For services such as PET/CT, whose allowances are determined by local carriers, there simply is no "technical component" that is "established under the fee schedule". Therefore, we continue to believe that CMS exceeded its statutory authority by including this service among those subject to the DRA cap.

Moreover, we continue to believe that services that include both physiological and imaging components, such as duplex studies, should be exempted from the DRA cap.

Finally, we also strongly support the comments of the Remote Cardiac Services Provider Group (the "Provider Group"). We are extremely concerned that, while some of the reductions that had been proposed have been ameliorated by the agency's acceptance of the Provider Group's direct cost data, Medicare payment for remote cardiac monitoring services will be reduced substantially once the practice expense revisions are fully phased in: In fact, reductions for holter monitoring services will be in range of 50%. In this regard, we urge CMS to continue to examine alternatives for the allocation of indirect practice expenses—alternatives that do not disadvantage technical component services by allocating indirect expenses based on physician work.

We concur with the Provider Group's request that holter device equipment costs be allocated to the holter monitoring technical component codes (CPT Codes 93226 and 93232), rather than to the hook-up codes (93225 and 93231). In fact, the purchasers of Philips' holter devices are the providers of the monitoring services, who may or may not be the physicians who hook up the equipment. We therefore support the reallocation of holter monitors to the monitoring codes.

In addition, we support the Provider Group's suggested changes to the Independent Diagnostic Testing Facility requirements. We urge CMS to make the requested modifications and clarifications to the requirements pertaining to the availability of home monitors for on-site inspection; the insurance requirements pertaining to these devices; and the role of the supervising physician.

We appreciate your consideration of these comments, and look forward to continued dialogue with you on these and other issues.

Sincerely yours,

Laurel Sweeney

Submitter : Mr. Matthew Schulze **Date:** 01/02/2007

Organization : American Society for Clinical Pathology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment for comments related to reassignment of benefits issues

CMS-1321-FC-45-Attach-1.PDF

American Society
Clinical Pathology®
Washington Office

1225 New York Avenue NW
Suite 250
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www.ascp.org

January 2, 2007

Leslie Norwalk, JD
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
7500 Security Boulevard
Baltimore, MD 21244-8015

Dear Ms. Norwalk:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide comment on the Centers' for Medicare and Medicaid Services (CMS) final physician fee schedule. Our comments focus on the issue of "pod" or "condo" labs (reassignment of billing privileges).

ASCP is disappointed in CMS' decision not to implement the proposals it outlined in its August 2006 proposed physician fee schedule. We urge CMS to issue final regulations on this issue as soon as possible.

Pod laboratories exploit a loophole in Medicare's in-office ancillary services and assignment of benefit regulations, enabling the referring provider to capture the payments intended for the performance of the pathology services. These enterprises rely on contractual arrangements to reassign billing rights from the pathologist performing the anatomic pathology services to the *referring* provider. These laboratories typically charge rates far below fair market value, creating an economic incentive for clinicians to profit from the performance of laboratory services. Indeed, the margin between what these labs charge and what providers can bill is how these businesses are marketed.

This financial incentive distorts rational medical decisions and leads to over-utilization of health care services. These enterprises inflate the cost of laboratory services and undermine patient trust in the medical profession, but more importantly *these operations adversely affect the quality of patient care*. Pod labs encourage referring providers to refer testing to those labs offering the greatest margin between what providers can bill for the service and what the provider pays. This dynamic undermines the importance of

quality in the selection of clinical laboratories--and increases the risk of injury to the patient. CMS should keep in mind that most patient diagnoses are based, in large part, on the information obtained from laboratory testing.

Besides causing economic harm to other clinical laboratories, these entities can adversely affect the quality of testing industry-wide. Clinical laboratories losing business to pod labs often are increasingly forced to cut costs and increase personnel workloads to, or beyond, the point at which quality suffers. The result is that patients are increasingly exposed to unnecessary, potentially poor quality, invasive testing, and higher health care costs.

Not surprisingly, the practices in which "pod" laboratories engage have been declared unethical by the American Medical Association. AMA's Council on Ethics and Judicial Affairs (CEJA) has outlined AMA's strong opposition to fee splitting and markups. Opinion E-6.02 states that "[payment] by or to a physician for the referral of a patient is fee splitting and is unethical." CEJA has also opined that if anatomic pathology services are provided at a discount, the purchasing physician should not charge a mark-up.

In Opinion E-8.02 AMA expresses its deep concern with physicians selecting laboratories not on the basis of quality, but on cost. This Opinion states that a "physician who disregards quality as the primary criterion or who chooses a laboratory solely because it provides low-cost laboratory services on which the patient is charged a profit, is not acting in the best interests of the patient."

To rein in the abusive practices pod laboratories engage in ASCP strongly urges CMS to issue final regulations to stop these enterprises and others that engage in similar abusive billing practices. With regard to the proposals outlined by CMS in its August 2006 proposed rule, ASCP supports the agency's following proposals:

- clarify that reassignment of benefits rules pertaining to contractual arrangements are subject to program integrity safeguards relating to the right of payment for diagnostic testing.

- amend the regulations for payment of the technical component so that when a reassignment involves a contractual arrangement with a physician or other supplier who performs the test, payment does not exceed the lowest of the physician or other supplier's net charge to the billing physician or medical group, the billing physician's or medical group's actual charge, or the fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.

- require that when billing for the technical component, the billing entity must perform the interpretation.

- require these laboratories to contain, on a permanent basis, the necessary equipment to perform the designated health services that are performed in the space.

- require these laboratory arrangements to be staffed by an on-site full-time employee or independent contractor.

While ASCP supports the intent of CMS's proposal to change the definition of a centralized building to restrict the types of space ownership or leasing arrangements that would qualify for purposes of the physician self-referral in-office ancillary services exception and physician services exception as well as the minimum square footage requirement, it is not clear to us this would be appropriately effective.

I am attaching a copy of ASCP's policy statement on fee-splitting and markups, which provides additional information on the problems that can be traced to the contractual arrangements in which pod laboratories engage. I am also attaching a copy of a recent Wall Street Journal article highlighting some of the billing abuses engaged in by these laboratories. Though the article isn't directly focused on Medicare, it focuses on the abusive practices engaged in by pod labs.

ASCP's comments regarding abusive contractual arrangements relate only to the laboratory industry. ASCP has no position on whether these sorts of restrictions should apply to other physicians and specialties. Our comments are intended solely to reflect on the abuses that have occurred in laboratory medicine and pathology.

ASCP appreciates this opportunity to provide comments. If you have any questions or need additional information, please contact me or Matthew Schulze, ASCP's senior manager for federal and state affairs, at (202) 347-4450.

Sincerely,

John S.J. Brooks, MD, FASCP
President, ASCP

Submitter : Ms. Kathy Lester **Date:** 01/02/2007

Organization : Patton Boggs LLP on behalf of Biosphere Inc.

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Interim Relative Value Units

Interim Relative Value Units

See Attachment

CMS-1321-FC-46-Attach-1.PDF

PATTON BOGGS LLP
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January 2, 2007

The Honorable Leslie Norwalk
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1321-FC:** Revisions to Payment Policies, Five Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule and Other Changes to Payment Under Part B for CY 2007

Dear Ms. Norwalk:

I am writing on behalf of BioSphere Medical, Inc., to provide you with comments about the new CPT code and reimbursement rates for Uterine Fibroid Embolization (UFE), which appear in the Revisions to Payment Policies, Five Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule and Other Changes to Payment Under Part B for CY 2007 (Final Rule).[1] Specifically, I am concerned that CMS has adopted the value recommended by the RVS Update Committee (RUC) of the American Medical Association (AMA), which is based upon a zero global days. Even though it may be possible in the future to routinely perform UFE without a required overnight hospital stay, current clinical practice indicates that an overnight stay for observation and pain management is customary. Thus, we urge CMS to revisit its decision and adopt a ten-day global with the appropriate and corresponding RVUs. As an alternative, we suggest phasing-in the change over a four-year period to avoid the nearly 60 percent cut in reimbursement from hitting physicians in a single year.

BioSphere specializes in the development of embolotherapy technology, including the use of microsphere embolization for the treatment of benign uterine fibroid tumors. We work

[1] 71 *Fed. Reg.* 69623 (Dec. 1, 2006).

with physicians, patients, and patient advocates to raise awareness about UFE as a safe and effective alternative to surgical options, such as myomectomy and hysterectomy.

I. CMS Policies Should Encourage, Not Threaten, Access to UFE.

UFE provides women with a uterine-sparing, non-surgical option for the treatment of benign uterine fibroid tumors, one of the most prevalent women's health problems in the United States today. Uterine fibroids grow on the muscle tissue of the uterus. These tumors cause pelvic pressure, abdominal bloating, heavy menstrual bleeding, anemia, urinary pressure or incontinence, and possible infertility. Twenty to forty percent of women of childbearing age experience fibroids; more than five million women are symptomatic. African-American women are three times as likely to be affected by the condition.

Traditionally, women suffering from fibroids have had to have a hysterectomy (removal of the entire uterus) or a myomectomy (removal of the affected portion of the uterus). Researchers estimate that more than one-third of the 600,000 hysterectomies performed in the United States each year is undertaken to treat uterine fibroids. Both of these surgical procedures are invasive, painful, and require a lengthy recovery period. In addition, they can result in complete infertility and health complications during and after surgery.

UFE is a newly developed procedure that provides women with an FDA market-cleared, non-surgical alternative treatment for uterine fibroid tumors. Controlled clinical studies demonstrate that UFE is minimally invasive, clinically effective, and cost-efficient. In addition, it allows women to retain their uterus and fertility. UFE is performed by inserting two small catheters to inject tiny particles into the uterine blood stream that block the blood supply to the tumor. Clinical data demonstrate that one year after UFE 90 percent of women are symptom free; five years after the procedure 73 percent of patients remain symptom free.[2] The cost associated with UFE is generally lower than surgical treatment. A recent study found that 96 percent of women who undergo UFE are satisfied with the treatment 12 months following the procedure. All of these evidence-based attributes are remarkable for a procedure that has emerged in such a short time period.

Many women prefer UFE. First, it shortens the hospitalization period. The procedure generally includes an overnight hospital stay, rather than the two-to-four day hospitalization associated with surgical treatments. Second, it provides for a quicker recovery. Patients can

[2] James B. Spies, *et al*, "Uterine Artery Embolization for Leiomyomata," *Obstetrics & Gynecology* (March 2001), 98, 29-34; James B. Spies, *et al*, .Long-Term Outcome of Uterine Artery Embolization of Leiomyomata," *Obstetrics & Gynecology* (November 2005), 106, 933-939.

usually return to their activities of daily living and work in 7-10 days, as opposed to the several weeks of recovery following surgical treatment. Third, it preserves fertility. Because the uterus is not removed, a high percentage of patients may still have children, if desired.

In addition to its clinical benefits and patient-friendly attributes, UFE has also been shown to be more cost-effective than traditional surgical treatments for fibroid tumors. The procedure generally allows a patient to go home the next morning rather than staying in the hospital for three-to-four days, as would be the case with a hysterectomy. This difference alone significantly reduces the costs of treating fibroid tumors. Furthermore, because a patient is typically able to return to work and normal activity within 10-11 days instead of waiting the four-to-six weeks required for recovery after a hysterectomy, there is also less expense associated with recovery costs of the procedure. Given the significant population of women who experience fibroid tumors and the number of procedures undertaken each year to treat this condition, the development of UFE as a clinically effective and cost efficient treatment method holds tremendous promise for patient benefit and savings.

II. The Final Rule Threatens Access to UFE for Women Because It Assigns Zero Global Days, which Does Not Accurately Reflect Clinical Practice

The Final Rule's assignment of zero global days threatens the ability of women to have access to UFE. This decision does not reflect the current clinical standard of care and, therefore, establishes an inappropriate reimbursement rate. Although the RUC establishes the RVUs, CMS must assign the correct global day period. Therefore, we strongly urge CMS to establish a ten-day global period for the new UFE code and to adjust the RVUs accordingly. If not done, the reimbursement rates for UFE will be cut approximately 60 percent. Such a dramatic cut may make it impossible for physicians to continuing to offer the procedure to their patients. Given that UFE is more efficient and cost-effective overall than surgical options, CMS should encourage its use through appropriate reimbursement policy. Furthermore, because UFE is a relatively new treatment option that is still gaining support among patients and clinicians, a flawed reimbursement policy is even more likely to have a negative impact on the availability of this procedure, thus stifling the growth of an important treatment alternative for women.

BioSphere Medical appreciates the importance of establishing codes that properly capture the cost of providing medical services and CMS's role as a responsible fiduciary for the federal government. As part of this responsibility, it is especially important that CMS exercise its resources to ensure that the value inputs assigned to individual service codes reflect the true costs of furnishing the service. We also understand the difficulty in assigning a global day period that is different than the period assumed by the RUC in developing its value recommendations.

However, the critically important task of determining an appropriate value and reimbursement level that will not impede patient access to a procedure warrants the extra time and consideration necessary to assess the proper global day period and associated value for the UFE code.

Currently, interventional radiologists bill for the service using a combination of existing office visit, radiology, and transcatheter placement CPT codes to capture all of the components of the UFE procedure. Given the difficulties multiple codes create in the billing and auditing process, we appreciate the need to establish a single code. Nonetheless, it is important that this single code incorporate all of the physician time that is associated with the procedure.

First and foremost, we are concerned that the physician survey data used by the RUC in its development of a recommended code value for UFE contained a critical error in the number of global days that it assumed CMS should assign to the procedure. As Dr. James Spies (Professor of Radiology, Chairman and Chief of Service, Department of Radiology at Georgetown University Hospital) discussed at our August meeting with CMS staff, the clinical literature on UFE focuses on only a small time segment of the actual UFE procedure. These studies describe the process from the time the catheter is inserted in the patient to the time it is removed. As an author of many of these studies, Dr. Spies stresses that they do not account for the preparation time or the follow-up care. Clinicians who actually perform these services (and many of whom were not surveyed during the SIR process) suggest that while the procedure is performed on an outpatient basis, most UFE patients spend the night following the procedure at an inpatient facility for pain management and observation purposes. In fact, in one of the leading peer-reviewed clinical studies on the UFE procedure involving more than 3000 patients. Ninety-four percent of the patients were kept in the hospital overnight and discharged the next day.[3] They also typically receive several follow-up calls with their physician during the week following the procedure and a follow-up office visit. Thus, while some patients may go home the day of the procedure, the vast majority of patients have one night of inpatient care as standard practice. When these factors are taken into account, the ten-day global is most appropriate for the new code.

We appreciate that it may be difficult for CMS to assign a ten-day global period when the RUC value fails to incorporate the additional period of care in its recommended value. However, CMS has the authority to adopt the global day period and the RVUs for new CPT codes. When additional consideration is needed to reconcile differences between the global period assumed by the RUC and the global period most appropriate based upon the clinical

3 Robert Worthington Kirsch, et al., "The Fibroid Registry for Outcomes Data for Uterine Embolization," 106 Obstetrics & Gynecology (July 2005).

requirements of a procedure, CMS should exercise its authority to undertake this extra effort to ensure proper reimbursement for the service at issue.

III. To Ensure Access to UFE for All Women, CMS Should Delay Adoption of the UFE CPT Code.

To ensure that all women have access to UFE, any new code must appropriately account for the time, skill, and intensity it takes to provide UFE. The proposed code likely to be adopted is based upon an incorrect number of global days and, thus, will undervalue the work involved. Therefore, we urge CMS to refrain from adopting a new CPT code for UFE until appropriate data that is based on an accurate understanding of the procedure can be gathered. Until that time, CMS should allow physicians to use the set of codes that are currently used to process claims.

CMS has the authority not to adopt all of the CPT codes proposed by the AMA. We understand that the code will remain in the AMA CPT code book even if CMS does not immediately adopt the new code. However, under the HIPAA transactions and code set regulations, all health insurers must use codes that have been adopted by the agency for electronic claims transactions.[4] If CMS does not adopt this particular code, it will not become part of the HIPAA code set and, therefore, cannot be used to process claims transactions. We understand that applying the HIPAA rule in this manner should be a rare occurrence. However, given the potential harm that the new CPT code and its possibly inappropriate global period could create, we believe this measure should be exercised in order to provide additional time to gather and assess accurate data on the UFE procedure.

If CMS does not adopt the code, the specialists who perform this procedure will have the additional time they need to resolve the outstanding questions and concerns. Although Medicare beneficiaries do not frequently suffer from fibroid tumors, it is nonetheless important that the procedure is properly valued given the impact of Medicare values on reimbursement in other sectors, including Medicaid and the private insurance market. To assist with the appropriate valuation of the codes, we encourage CMS to acknowledge that it agrees that a ten-day global period would be appropriate to assign to the code. In addition, CMS should encourage the interested parties to resolve the issue in a transparent, thoughtful, and deliberative manner that demonstrates a comprehensive understanding of the procedure and the needs of patients.

IV. As an Alternative, CMS Should Phase-In the Implementation of the New Code and Value.

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[4] 45 C.F.R. 162.925.

Alternatively, if CMS chooses to move forward with the code values as proposed, it should be willing to address the drastic nature of this payment cut by providing a phase-in period for the new code values. As noted earlier, the adoption of the new code and value for UFE will ultimately result in an estimated payment cut of nearly 60 percent for physicians performing this procedure. A payment reduction that is so significant could certainly have a chilling effect on the uptake of this new technology in the marketplace, ultimately limiting patient access to an extremely promising treatment option for uterine fibroids.

Historically, CMS has phased-in the reimbursement changes to allow physicians to adjust to the payment changes and avoid an interruption or reduction in availability of services. For example, in its recent implementation of reimbursement changes related to the geographic wage index, CMS recognized the potential impact on Medicare providers that would experience significant payment reductions under the new policy and provided for a phase-in period of four years in order to allow those physicians to prepare for the new reimbursement rates. A phase-in period is especially critical for new technologies and services, such as UFE, that are still developing a patient and physician following in the market and thus are more likely to be directly impacted by shifts in reimbursement.

V. Conclusion

BioSphere Medical appreciates the opportunity to comment on this important issue for women. It is imperative that CMS ensure that its coding decisions do not threaten access to UFE and thwart the desire of many Members of Congress who are working to educate more women, especially those in the African-American community, about this important and effective new alternative to surgery. We also understand the role of the RUC in assisting CMS with the valuation of codes; however, there are times when it is appropriate for the Agency to address issues that may have been overlooked in the RUC process, such as the appropriate assignment of global days. Thus, to remain consistent with Agency's overall objective to assign appropriate values to codes and to ensure patient access to promising, new technologies, CMS should not adopt the UFE CPT code in the Final Rule or, at the very least, provide a phase-in period for the new code to allow physicians to adjust to the drastic reduction in reimbursement.

We would welcome the opportunity work with CMS to ensure the code is appropriately values and available for adoption next year. Please do not hesitate to contact me at 202-457-6562.

Sincerely,

Kathleen J. Lester
Partner

Submitter : **Date: 01/02/2007**

Organization : **Remote Cardiac Serivces Provider Group**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments.

Interim Relative Value Units

Interim Relative Value Units

Please see attached comments.

CMS-1321-FC-47-Attach-1.DOC

Remote Cardiac Services Provider Group

January 2, 2006

Sent Electronically to: www.cms.hhs.gov/eRulemaking

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS 1321-FC
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS File Code: CMS-1321-FC;
Comments on 2007 Medicare Physician Fee Schedule and Revisions to Independent Diagnostic Testing Facility (IDTF) Regulation

Ladies and Gentlemen:

The Remote Cardiac Services Provider Group (the Provider Group) appreciates this opportunity to submit comments on the Physician Fee Schedule, as published in the Federal Register for December 1, 2006. The Provider Group consists of 9 companies which furnish the majority of remote cardiac monitoring services in this country including cardiac event monitoring, pacemaker monitoring, holter monitoring and INR monitoring. The Provider Group members are all enrolled in Medicare as independent diagnostic testing facilities (IDTFs). They all operate on a 24-hour, 7-day per week basis because the services that they provide require round-the-clock service.

Comments on the Physician Fee Schedule Values

The Remote Cardiac Services Provider Group appreciates the opportunity to comment and wishes to thank CMS for consideration and acceptance of many of its recommendations for the development of practice expense RVUs for remote cardiac services. We also appreciate the Agency's characterization of the 2007 PE RVUs as "interim" and its willingness to work with the Provider Group to develop more accurate cost information for our services. We look forward to meeting with agency staff early in 2007 on these issues.

In the meantime, however, we would like to make you aware of several concerns we have with the final 2007 rule. First, we note that even though many of our recommendations and direct cost data were accepted, most of our codes will still undergo significant cuts as reflected in the table below:

Code	Description	Percent change by 2010
93012	Cardiac Event Monitoring	-30.27%

	(30 days): Post Symptom Only	
93271	Cardiac Event Monitoring (30 days): Pre- and Post Symptom	-12.72%
93226	Holter Monitoring: With Superimposition	-51.93%
93232	Holter Monitoring: Without Superimposition	-51.72%
G0248	INR Demonstration of Home Use	-49.25%
G0249	INR Monitoring and provision of test materials	-39.20%

While we are concerned about all of the significant reductions, we are especially concerned about the cuts to the Holter Monitoring and INR services. Reductions of this magnitude, if not corrected, will result in many IDTFs ceasing to provide this service.

We are also concerned that, despite the agency's use of the cardiology practice expense data and IPCI in calculating indirect PE RVUs for remote cardiac services, the methodology used to assign indirect costs still undervalues these services. Members of the Provider Group typically have indirect costs of approximately 60%. The methodology used to allocate indirects, which relies in large part on physician work RVUs, means that these codes will not get their fair share of indirect costs relative to codes that do have physician work. We appreciate the agency's decision to use clinical labor RVUs to assign indirect costs for codes that do not have work RVUs. However, the methodology still creates serious inequities with respect to indirect costs.

Another issue of concern to the Provider Group is the need to include, in practice expenses, the very high technology costs associated with providing remote cardiac services. We were pleased that CMS accepted our recommendations for higher equipment costs. However, there are additional costs that should be, but are not, included. These consist of customized computer hardware and software, software licenses, servers including built-in back up or redundancy, web access, and telephone systems for handling trans-telephonic transmissions. In addition, many companies must pay high annual licensing fees to vendors to be able to use the equipment. Not all of these costs are reflected in the equipment costs recognized by the fee schedule methodology and we recommend that CMS include them.

Holter Services

With respect to holter services, we believe part of the solution lies in assigning the holter device equipment costs to CPT Codes 93226 and 93232. Currently, they are assigned only to the hook-up codes (93225 and 93231). We have already discussed this issue with CMS staff and it

is our understanding that it may be resolved through a technical correction. Nevertheless, we are including it in our written comments.

Typically, the hook-up service is done in the physician's office, by physician staff using the holter device owned by the IDTF and provided to the physician's office by the IDTF for this purpose. The cost of the device is incurred entirely by the IDTF which performs the analysis and report billed under CPT Codes 93226 or 93232. Further, IDTFs perform this service well over 50 percent of the time.[1] Therefore, the holter device should be assigned to CPT Codes 93226 and 93232 and not the hook-up codes.

INR Services

The Provider Group is puzzled by the final PE RVUs for INR services (G0248 and G0249). We are pleased to see that the agency accepted some of our recommendations by increasing equipment costs and changing the clinical labor type to registered nurse. Overall, the direct cost inputs for both codes increased significantly. However, the final PE RVUs are virtually the same as those in the proposed rule. We understand that CMS used a larger budget neutrality or scaling factor adjustment in the final rule than in the proposed rule; however, we question whether this entirely explains the problem. We urge that CMS review the methodology as applied to these services to make sure that no error has occurred.

Independent Diagnostic Testing Facility (IDTF) Changes

The Provider Group is very concerned about the applicability of the "2-day rule" in section 410.33(g)(4) which requires that an IDTF have all portable equipment available for inspection within two days of a request by CMS. As we have discussed with CMS staff, it would be impossible for providers of remote cardiac monitoring services to comply with this requirement with respect to monitoring devices that are provided to patients for use in the home or are housed in physicians' offices for hook-up by physician office staff, and, as such, are not within the IDTF's direct control. We understand from our discussions with CMS staff that it is not CMS' intent that this requirement apply to remote cardiac devices provided to patients for use in the home and we are hopeful that the agency will at least provide clarifying guidance in the short term and consider modifying the rule in the longer term to eliminate the requirement to produce these devices if they are in use by the physician or patient. As an alternative, the Provider Group would be happy to provide other evidence of ownership such as device serial numbers and invoices, if necessary.

Section 410.33(g)(6) requires that an IDTF list on its comprehensive liability insurance policy the serial numbers of all equipment. As we have explained to CMS staff, this provision seems to require that each monitoring device be individually insured, presumably for property damage, although it is not altogether clear to us the purpose of this provision. In many cases, IDTFs that provide remote cardiac monitoring have thousands of these devices in use at any one

[1] Based on current Medicare utilization data.

time and purchase new devices and replace old ones regularly. The insurance policy would have to be updated constantly to list the new devices and remove the old ones. This is not done now and would be an additional unnecessary burden and expense. As we discussed with CMS staff, if the concern is that the device in fact exists, we recommend elimination of this requirement and permit the IDTF to keep and make available to the Carrier an inventory of the devices (with serial numbers), as is otherwise required under the rule. If the concern is that diagnostic equipment is specifically insured in order make sure that it can be replaced if it is damaged, then the Provider Group recommends that CMS modify the rule and/or provide guidance clarifying that monitoring devices such as those provided to patients to monitor cardiac function are not required to be specifically listed in the IDTF's insurance policy.

Finally, as we have discussed with CMS staff, the revisions to Section 410.33(b) substantially expand the responsibility of the supervising physician. The prior rule emphasized that the supervising physician was responsible for the clinical aspects of the IDTF. This made sense. However, Section 410.33(b) states that "The IDTF supervising physician is responsible for the overall operation and administration of the IDTFs." This makes the physician responsible for the non-clinical aspects of the IDTF and makes the physician more like a CEO than a supervising physician. The services provided by IDTFs that furnish remote cardiac monitoring services require only "general supervision" and thus, for coverage purposes, the physician does not need to be on-site at the facility. To now require the physician to be in charge of the "overall operation and administration" of the facility requires the physician to be on-site on a substantially regular basis. This changes the very nature of the general supervision requirement. The Provider Group recommends modification of this provision to limit the responsibility of the supervising physician to the clinical aspects of the facility as under the prior rule. Alternatively, we recommend that the rule be modified to limit a supervising physician's responsibility to the clinical aspects of the IDTF if that IDTF provides services under the general supervision of a physician.

****

If you have any questions about these comments, please contact our Washington representatives Jim Jorling, Esq. or Rebecca Burke, Esq. at 202-466-6550.

Sincerely,

David Bondietti, Senior Vice President
Biomedical Systems
St. Louis, MO

Phillip Leone
Vice-President
Cardionet
Conshohocken, PA

John Nasuti, President and CEO
ECG Scanning & Medical Services, Inc.
Dayton, OH

Richard Edwards, Owner & CEO
Life Support Systems, Inc.
Clearwater, FL

Leigh Ann Kelly, Vice President
LifeWatch, Inc.
Buffalo Grove, IL

Dan Balda, MD, President
Medicomp, Inc.
Melbourne, FL

Frank Movizzo, CEO
Mednet Healthcare Technologies, Inc.
Ewing, NJ

Greg Marsh, COO and CFO
PDSHeart
West Palm Beach, FL

Robert Sass, General Manager
Raytel Cardiac Services, Inc.
Windsor, CT

Submitter : **Kent Thiry** **Date: 01/02/2007**

Organization : **Kidney Care Partners**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-FC-48-Attach-1.PDF

KIDNEY CARE
PARTNERS

January 2, 2007

Leslie Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-FC and CMS-1317-F
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Part B (CMS-1321-FC and CMS-1317-F) Final Rule

Dear Ms. Norwalk:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology Final Rule (Final Rule).[1] KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[2]

KCP would like to express its support for the recommendations offered by the Renal Physicians Association regarding revisions to the RVUs associated with evaluation and management (E&M) service codes, as well as our previous recommendation for the

[1] 71 *Fed. Reg.* 69623 (Dec. 1, 2006).

[2] A list of Kidney Care Partners coalition members is included in Attachment A.

potential use of these revised values to determine RVU levels for nephrologist services provided to dialysis patients.

As noted in our comments on the proposed rule on the Five-Year Review and the Revised Practice Expense Methodology, KCP supports the RPA recommendation that outpatient and inpatient dialysis services that use E&M codes as "building blocks", or components of their valuation, should have the full increases for the E&M codes incorporated into their values as well. We noted that the monthly dialysis codes should be revised to correspond to the sum of their E&M building blocks based on the mid-level adult G-code (G-0318) and extrapolated proportionately to other codes in the family, and that the inpatient dialysis code should be revised upward to reflect the increases of their E&M elements. These services are surrogates for the E&M care that would be provided to dialysis patients in the absence of these services. These changes are necessary because they are consistent with the intent and spirit of the RUC recommendations and the CMS notice to apply the E&M code increases to both the outpatient and inpatient dialysis codes.

As a result, we share RPA's concern that the Agency's response in the Final Rule did not address these issues. It is highly inequitable that the E&M increases would apply to all of the bundled code families except for the dialysis families of codes. Further, the changes will have a profound impact on the relativity of the dialysis code families to both E&M codes and other codes in the fee schedule. However, CMS's discussion in the Final Rule only notes that because the descriptors are markedly different than the previously valued codes, CMS is unable to make the recommended changes. The final rule does not provide a rationale for making these decisions. In light of these significant changes and their likely negatively impact, KCP urges CMS to revise the 2007 work RVUs for the dialysis families of codes so that they reflect the increases provided to their E&M coding elements.

KCP members appreciate your review of our concerns and look forward to working with the Agency on issues affecting the care provided to the nation's kidney patient population. Please do not hesitate to contact Kathy Lester at 202-457-6562 if you have questions regarding these comments.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

Attachment A

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Roche
Satellite Healthcare
Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

Submitter : Dr. Myron Gerson **Date:** 01/02/2007

Organization : American Society of Nuclear Cardiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-FC-49-Attach-1.DOC

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

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December 22, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8018

Dear Ms. Norwalk:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to provide comments on the Final Rule entitled **Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007** published in the *Federal Register* on December 1, 2006 (71 Fed. Reg. 69623).

As you know, ASNC is a greater than 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

Deficit Reduction Act (DRA)

ASNC remains adamantly opposed to the Centers for Medicare & Medicaid Services (CMS) decision to extend the scope of the Deficit Reduction Act payment ceiling on imaging services to carrier-priced services. The agency's belief that the DRA applies to all imaging procedures paid under the physician fee schedule and that carrier pricing is just an alternative pricing methodology is indefensible.

In addition, ASNC finds it troubling that CMS believes that it lacks statutory authority to exclude Category III codes from the DRA payment ceiling. Clearly, the agency must recognize that these codes are not priced on the national fee schedule and that the ability to make a legitimate comparison between the fee schedule payment and the APC rate under the Hospital Outpatient Prospective Payment System (HOPPS) is impossible. By definition, Category III codes represent emerging technology and are traditionally placed in new technology APCs under the HOPPS. And, in those cases where CMS bypasses utilization of the new technology APCs for category III codes in favor of an arbitrary APC placement, the result is usually not ideal.

For example, CMS assigned the Category III CPT codes for cardiac computed tomography (CCTA) to the APC for nuclear cardiology procedures. This assignment reflects only CMS staff's assessment that this was the appropriate assignment for cardiac imaging services. The APC placement for the CCTA codes reflects no data on hospital costs and charges because these category III codes were implemented in January 2006. Hospital claims data from the last nine months of 2005 – the time period cited by CMS as its evidentiary basis for establishing 2007 HOPPS payment rates – do not reflect **any** true cost data for providing CCTA.

ASNC is deeply concerned that hospitals do not report their costs in a consistent and accurate way. In addition, hospitals do not regularly update their charges to appropriately reflect relative costs among procedures. Application of the DRA to Category III new technology codes will, therefore, provide wholly inadequate reimbursement for emerging technology services performed in the physician office setting.

We have also found this problem with hospital data regarding myocardial PET studies as evidenced by CMS's decision to lump both single and multiple PET myocardial studies into one APC. ASNC believes that the CMS data has considerably low single frequency claims data for single and multiple studies -- signifying that the cost conclusions are not indicative of real costs and only statistical in nature. With so few single claims used for cost setting in the universe of a relatively small absolute number of total studies performed, data likely represents statistical noise at best.

The CMS proposition that a rest and stress myocardial perfusion PET study can be equated in cost to a single rest study lacks both face-validity, and an understanding of the respective procedures. And while ASNC recognizes that we are highlighting Category I codes, myocardial PET studies remain carrier-priced and therefore will also undergo the same chilling effect that will certainly befall CCTA under the DRA payment ceiling.

ASNC strongly urges CMS to remove all Category III CPT codes from Addendum F and instead allow Medicare carriers to determine appropriate pricing in 2007.

CMS must realize that Medicare payments to nuclear cardiologists will fall by an average of 15 percent in 2007 due to the new practice expense methodology and the DRA imaging provisions -- despite recent congressional action to avert the five percent cut in the conversion factor. Practices that have invested heavily in the growing areas of CCTA and myocardial PET studies will experience an even larger negative impact.

The membership of ASNC is committed to improving the quality of nuclear cardiology care provided to Medicare beneficiaries. Cuts of this magnitude, however, threaten the ability of practicing nuclear cardiologists to implement the kinds of quality improvement measures that we know will benefit patients.

Again, ASNC appreciates the opportunity to comment on the Final Rule. Should you have questions or need additional information, please contact Christopher Gallagher, Director of Health Policy, at 301-215-7575 or via email at Gallagher@asnc.org.

Sincerely,

Myron Gerson, MD
President

Submitter : **Date: 01/02/2007**

Organization : **Medical Group Management Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-FC-50-Attach-1.PDF

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

January 2, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC and CMS-1325-F
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Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B

Dear Ms. Norwalk:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the final rule entitled the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B," as published in the Dec. 1, 2006 *Federal Register*. We appreciate the Centers for Medicare & Medicaid Services' (CMS) outreach to the provider community and their willingness to participate in constructive dialogue to improve the Medicare program. We look forward to continuing our collaborative work on this and other administrative simplification issues. For these reasons, MGMA offers the following critiques and recommendations related to this rule, as outlined below.

MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA's 20,000 members manage and lead more than 12,000 organizations in which more than 242,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently, so physician time and resources can be focused on patient care.

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Sustainable growth rate (SGR)

For the past five years, providers have anticipated cuts to Medicare payments. In fact, without congressional action, physicians would have been cut over 20 percent since 2001. The Medicare Payment Advisory Commission estimates that payment will be cut every year for the foreseeable future, a trend that will have grave consequences on the health care system as a whole. If the current trend continues, providers will face difficult decisions as they evaluate the economic practicability of caring for Medicare beneficiaries. The economic viability of practices is further undermined by the widespread use of the Medicare physician fee schedule as a benchmark for private insurance reimbursement rates.

MGMA has conducted extensive surveys of medical practice costs for more than 50 years. MGMA-collected data indicate that the cost of operating a group practice rose by an average 4.5 percent per year over the last 10 years. In fact, between 2000 and 2005, MGMA data show that operating costs have risen more than 26.1 percent. Medicare reimbursement rates for physician services have fallen far short of the increased cost of delivering quality services to Medicare patients. Agency-initiated administrative modifications can help mitigate the anticipated cuts for CY2007 and beyond.

Definition of "physician services"
The statutory language of the Social Security Act that defines the payment update formula requires CMS to assess the allowed and actual expenditures of the Medicare program. MGMA maintains that the definition used by CMS for "physician services" in the sustainable growth rate (SGR) formula is inappropriate. MGMA believes this definition is incorrect due to the inclusion of the cost of physician administered outpatient prescription drugs.

A significant factor in the growth in Medicare expenditures has been the introduction of the program's coverage of costly new prescription drugs administered in the physician's office. Since the SGR base year, SGR spending for physician-administered drugs has more than doubled. These expenses reflect the acquisition of products rather than services rendered by a medical professional and therefore are different than "physician services." The inclusion of drugs in the definition of physician services is inaccurate and runs counter to CMS' stated goal of paying appropriately for drugs and physician services. MGMA asserts that the definition of "physician services," as required by the statute, does not include the cost of prescription drugs.

A separate definition of physician services clearly distinguishes physician administered outpatient prescription drugs from services rendered by physicians. CMS adopted this definition in the Dec. 12, 2002 "Inherent Reasonableness" rule (67 FR 76684). Plainly, the definition of physician services must be applied consistently for fair and equitable administration of the Medicare program. Furthermore, the recent proposed rule to reform the payment system for physician administered prescription drugs establishes a separate venue to address the utilization and cost of drugs. MGMA strongly urges CMS to remove prescription drug expenditures from the definition of "physician services" used to calculate the physician payment update factor.

MGMA understands that CMS explored the legal ramifications of removing physician administered outpatient prescription drugs from the definition of physician services and appreciates CMS' willingness to do so. MGMA realizes that CMS continues to have concerns about the removal of these drugs from the formula on a retrospective basis; however, MGMA urges CMS to remove these drugs from the definition of "physician services" used in the calculation of the physician payment update factor.

Full impact of law and regulation

The current SGR calculation fails to adequately capture the impact of changes to laws and regulations as required by law. For example, although Medicare has added new screening benefits, the formula fails to account for the downstream services that will result when the screenings reveal health problems. The same is true of the Medicare prescription drug benefit, which will unquestionably lead to more medical visits, and in turn will generate additional tests and care. The SGR does not account for this inevitable program spending.

Additionally, the impact of administrative coverage decisions is excluded from the SGR entirely even though those decisions may have as great an impact on patient demand for services as a statutory change. In last year's rule, for example, CMS administratively extended screening glaucoma coverage to Hispanic patients over age 65. Such changes are likely to be highly beneficial for patients, but may contribute to negative reimbursement updates through the SGR calculation. MGMA believes CMS has the administrative authority to better account for the full impact of such changes to law and regulation, and vigorously urges CMS to assert this authority.

MEI calculation

Another component of the Medicare physician reimbursement formula that requires improvement is the Medicare Economic Index (MEI). The MEI was established in 1973 to reflect the rising cost of practicing medicine. However, the current MEI calculation is showing its age, and fails to incorporate all of the costs a physician group practice bears to care for patients. MGMA agrees with a recommendation by the Practicing Physicians Advisory Council made to CMS in 2004 that the MEI be expanded to reflect costs such as compliance with extensive new billing regulations, including hiring new staff and increased training for current staff to comply with expanding regulations. The MEI also should reflect steps taken to improve patient safety and include those additional costs not included in the MEI in 1973, but which clearly must be a part of the calculation today.

Additionally, the MEI must reflect the modern level of support staff. A particular concern to MGMA is that employee wages used in the MEI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. MGMA recommends that CMS work with other government agencies such as the Bureau of Labor Statistics and private organizations to identify other nationally collected data sources or to collaborate the development of survey methodology and data collection if no such source currently exists.

MGMA urges CMS to work with Congress to eliminate the SGR and develop a methodology that will accurately reflect the increase in the cost of practicing medicine.

The Tax Relief and Health Care Act of 2006

After the release of the 2007 Medicare physician fee schedule, Congress acted to mitigate the anticipated reduction in physician payment rates. MGMA appreciates the efforts of Congress and the Administration that resulted in the mitigation of anticipated cuts in Medicare physician payment resulting from the flawed SGR formula. However, the provisions of H.R. 6111, the Tax Relief and Health Care Act of 2006, also affect a number of other program policies. MGMA urges CMS to promulgate any necessary regulations as quickly as possible in consultation with providers. Specifically, MGMA requests that the Medicare physician fee schedule be reissued to incorporate the changes resulting from H.R. 6111, as well as the two correction notices published after the publication of the final fee schedule. There is a great deal of confusion among providers regarding which values should be used to determine payment, especially given the recent changes to the law, the improper values contained within the Dec. 1 rule and the incorrect amounts contained within the documents disseminated by the carriers containing the payments for Medicare-covered services. Additionally, ample and timely provider materials, written in easy-to-understand language, must be available at the same time to decrease provider uncertainty and

misunderstandings during this transition. MGMA looks forward to partnering with CMS during this and other conversions.

Physician Voluntary Reporting Program (PVRP)

MGMA supports quality improvement activities that focus on improving patient care, outcomes, satisfaction and the cost-effective use of resources. The 1.5 percent bonus incentive payment to physicians who report on quality measures through the Medicare PVRP is a step in the right direction; however, many issues and questions remain. These include:

- Is the 1.5 percent bonus only calculated on the claim that is submitted with the codes or the practice's entire Medicare book of business?
- How will the legislatively-mandated cap be calculated?
- When will the bonuses be paid on a quarterly basis or held until 2008 and paid in one lump sum? If this is a capped bonus pool, is it possible that CMS will run out of funds, even though providers have met all of the requirements for participation?
- Will bonus monies count as new monies against the SGR baseline?
- Can practices that are participating in the other CMS demos also choose to participate in the PVRP program?
- Can non-physician providers report under the PVRP?
- How will scope be defined under the PVRP? Would self-selection of applicable measures based on the practice's definition of their scope be allowed under the 2007 PVRP?
- What are CMS's plans for meeting the validation requirement contained within the new law?
- What are CMS' plans for analyzing the cost burden to various specialty practices and practice settings? For example, a large percentage of practices do not yet have EMRs available to them.
- What plans are being made by the Medicare contractors for receiving this data?
- Is reporting the data enough - will there be certain thresholds that need to be met for each measure? Will the bonus be 1.5 percent, no matter what the outcome is?

Additionally, MGMA is concerned that groups will have to make the decision to participate with little information about the return on their investment, since bonuses will be calculated and paid out in 2008. MGMA urges CMS to issue guidance on the PVRP as early as April, so that organizations, such as MGMA, have adequate time to disseminate information and educate practice managers who will lead quality reporting efforts in their groups.

Resource-based practice expense RVUs

MGMA brings a particularly valuable perspective to this issue. As a research oriented organization, MGMA has collected practice expense data since 1955. Our data collection involves group practices which range in size from two to several hundred physicians. As such, we understand the magnitude and complexity of CMS' task. In addition, MGMA represents an equal proportion of primary and specialty care practices that are in the primary care and specialty care sectors. Consequently, we are able to detach ourselves from the "outcome" and focus primarily on the "methodology" applied.

Methodology

MGMA supports CMS' decision to implement a *bottom-up* methodology as opposed to the previous *top-down* approach. While the results of both approaches depend on the quality of the medical practice expense data collected, MGMA believes the *bottom-up* approach has a greater likelihood of providing accurate values. History has shown that calculating practice expenses using a data based methodology is more accurate when compared to a method that uses estimates of actual inputs.

In previous years, CMS has provided a significant amount of specificity regarding the process for developing the practice expense methodology. This year CMS did not include in the final rule a thorough explanation of the calculations to allow specialties to determine their individual impact level of the practice expense changes to their specialty. CMS did not present sufficient examples to the provider community to make the change in methodology transparent. MGMA recommends that CMS provide explicit examples for selected specialties to demonstrate to the provider community how the methodology is calculated. In addition, CMS provides data on the first and fourth year of the transition period; however, there is no data provided on the impact of the changes to the methodology for years two and three. MGMA recommends that CMS provide that information to the provider community in an interim final rule with comment period.

Data Source

As in previous comments, MGMA maintains its concern that the practice expenses methodology is based on the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) data, which is dated, and the Clinical Practice Expert Panel's (CPEP) data, which is extremely subjective. The SMS data used to calculate practice expenses for CY2007 is from 1995-1999. MGMA recommends CMS conduct a new SMS survey in order to develop more accurate data that would result in equality for all specialties. The entity or organization contracted to conduct this new survey needs to be one that has proven its reliability in this area previously.

MGMA agrees with CMS that while the AMA SMS survey data is dated, a survey of this nature is the most appropriate and only primary data set in existence to determine specialty specific cost pools. We believe that not only does a new survey need to be conducted, but the methodology for conducting the survey needs to be enhanced as described below.

It is critical that the unit of observation used in a new survey reflect the organization rather than individual physicians who are owners or part-owners of their practices. The primary responsibility of the particular respondents is often the practice of medicine rather than the business operations of the practice. There are several reasons why the organization is preferable. First, the respondent must have both adequate knowledge about the business of medical practices and a comprehensive understanding about the information being sought. Second, the respondent must have the ability to access such information for the entire practice.

While AMA's survey response rate has been strong historically at about 60 percent, not all respondents answered the practice expense portion of the survey. Specifically, the 1996 SMS report based on 1995 data indicates that 4004 overall respondents to the survey, 2352 were self-employed physicians and therefore eligible to report data on practice expenses. Of the 2352, 1552 provided total professional expenses, 1595 payroll, 1504 medical equipment, 1538 medical supply optimal resources, and 1573 office expenses. The overall response rate to the practice expense portion was 39.9 percent. While we understand that it is difficult for physicians who are owners or part-time owners of practices to respond to the practice expense portion, MGMA is

hopeful that the response rate and thus the quality of responses will improve when the practice becomes the unit of observation.

Presently, AMA is collecting data on clinical labor, supplies, equipment and other practice costs. MGMA recommends that the entity chosen to conduct a new survey refine the expense categories to identify ancillary service expenses and activity data. Our experience has shown that medical groups with radiology or laboratory ancillary services have different expense experience than medical groups that do not have these services. Future refinements of the practice expense Relative Value Unit (RVU) component should isolate the effect of ancillary services from the total expense profile of the practice. This can only be accomplished if ancillary service expense data is separately collected.

When conducting a new survey, there must to be a mechanism to validate data. The benefit of collecting data from profit and loss statements is that the practice expense responses cannot be exaggerated.

MGMA remains concerned about the quality of the data gathered by the CPEPs but is pleased that it plays less of a role in the *bottom-up* methodology. As CMS, or an entity in its place, considers the practice expense issue, it must seek input from practice managers, especially since the information sought focuses largely on clinical and administrative staff time and not on physician time. Assuming the make-up of the panels is appropriate, they have the potential to refine the CPEP's data. However, to the extent that the panels will not have access to any actual practice expense data gathered from physician practices, they will have limited effectiveness. Nevertheless, convening panels could help identify egregious errors and/or highly anomalous results. MGMA recommends that panels be convened subsequent to the accumulation of actual practice expense data to allow them to complete their work based on more accurate information.

MGMA is concerned about the process that CMS used to determine practice expenses. The *bottom-up* methodology loses an element of the data that provides for the significant differences between practices of the same specialty. To create a resource-based approach that conforms to real-world practice costs, CMS must collect actual service-level practice expense data directly from physician practices and base both direct and indirect PE RVUs on that data. Such data would give CMS a far more accurate database for direct costs than the current estimates developed by the CPEPs' process. Recognizing time constraints established by Congress and limited resources, at the very least, CMS should undertake a limited study on a cross-section of practice settings nationwide to obtain actual practice expense data from physicians' offices. The agency could use this data, however limited, to validate or refine the existing data obtained through the panels' process.

Four-year transition

MGMA supports a transition period and applauds CMS for the development of a transition period. We appreciate CMS' consideration of the other upcoming regulatory and legislative changes for CY 2007; however, we believe that the implementation timeline is not ideal because of the level of uncertainty surrounding the cumulative impact of the reductions in reimbursements on medical practices. MGMA recommends that CMS delay the implementation of practice expenses until all of the provisions within the Medicare Modernization Act have been implemented. This would allow all specialties sufficient time to implement provisions regulated prior to the practice expense changes.

Work RVU budget neutrality adjustor

MGMA believes that CMS should reconsider applying the budget neutrality adjustment factor to work RVUs. CMS does not provide an adequate rationale for shifting the budget neutrality adjustor to the work RVUs. In the past, CMS has suggested the same proposal and the provider community responded negatively. By placing the budget neutrality factor on the work RVUs, the effect to specialties is varied because of the different levels of work involved. Constant variation in the work RVUs due to budget neutrality adjustments hinders the process of establishing work RVUs for new and revised services. MGMA recommends that CMS apply the budget neutrality adjustor to the conversion factor in order to make the calculations more equitable and understandable to the provider community. MGMA believes that applying the budget neutrality to the conversion factor will have less impact on other payers who use the Medicare resourced-based relative value scale and be consistent with the notion that budget neutrality.

CMS is moving towards making pricing information for physicians, hospitals and other providers more transparent. MGMA recommends that CMS apply the principles of transparency to the Medicare policy that govern these prices. By applying the budget neutrality adjustment to the conversation factor, pricing information to the provider community will be more transparent. Transparency of the financial effect of these changes will apply physicians and policymakers to more easily understand the impact of the cuts. In order to achieve CMS' goal of transparency of pricing information, the budget neutrality adjustments should be made to the conversion factor.

Geographic practice cost indices (GPCIs)

As noted in our previous comments, MGMA remains opposed to CMS using inappropriate data sources to calculate the GPCIs. This includes the use of census data to calculate GPCI values. The very nature of the data render the values outdated by the time CMS is able to utilize the information. Additionally, although the statute mandates updating the GPCI values every three years, they are in essence updated every 10 years since the census is collected once every decade. MGMA maintains that this is unacceptable. A separate source with more timely data must be identified to adhere to the three year update schedule that Congress intended. MGMA recommends that CMS work with other government agencies, including the Bureau of Labor Statistics and private organizations, to identify alternative data sources. Alternatively, CMS should work with these groups to identify an appropriately indexed data source to meet the statutory requirements.

Of particular concern to MGMA is that employee wages used in the GPCI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. While it remains true that the 2000 census definitions of certain medical professionals are more expansive than the 1990 definitions, limited improvements result for the updated GPCI values. The wages of several prominent professions continue to be excluded, including physician assistants, occupational and physical therapists, certified practice managers, IT professionals, transcriptionists and certified coders. MGMA recommends that CMS revise the GPCIs to include these employees to ensure that the occupations used in the formula reflect the numerous categories of medical workers found in modern practices.

As in years past, the office rental indices used to calculate the practice expense GPCIs are based on the Department of Housing and Urban Development's (HUD) residential apartment rent data. While MGMA is sympathetic to the difficulty CMS has in identifying alternative sources for pricing medical office space, MGMA remains opposed to the use of residential and not

commercial data for this purpose. Such use is inconsistent with the core objective of the Balanced Budget Act of 1997 to make Medicare payments resource based.

As noted in previous comments, MGMA also highlights the findings of the General Accountability Office (GAO) in their March 2005 report on HUD estimates of fair market rents (GAO-05-342). The report identified major concerns raised by the HUD estimates, substantiating the level of inaccuracy reported by many MGMA members. The report also explains that HUD will soon use a new data source, the American Community Survey (ACS). It is important to note that ACS processes rates differently than HUD has in the past. With this impending data shift, MGMA urges CMS to work with HUD and the Bureau of Labor Statistics to determine whether the values populating the GPCI calculations for medical practice rent are accurate and will meet the agency's needs once ACS data is adopted by HUD.

Deficit Reduction Act (DRA) provisions

Imaging

MGMA appreciates CMS' decision to limit the reduction of the technical component for multiple imaging services performed on contiguous body parts to 25 percent, rather than the proposed 50 percent, for calendar year 2007. MGMA remains concerned that the 25 percent reduction is arbitrary. While CMS claims to have based this figure on data relating to costs, it still has not released its actual calculations used to justify the 25 percent reduction. MGMA maintains that the proposed cuts do not cover costs and would limit patient access to imaging services. We urge CMS to share the data used to make this policy change, severely impacting certain specialties. While MGMA appreciates CMS' decision to calculate the multiple services reduction before applying the statutorily-mandated cap (the OPPS amount), we urge further consideration and evaluation of the multiple services reduction before it is implemented.

Furthermore, MGMA reiterates its request that CMS educate providers of diagnostic imaging services and Medicare contractors regarding their continued ability to bill globally for diagnostic imaging services subject to the reduction. As previously experienced with physician scarcity and health professional shortage area payments, global payments for services with technical components that are treated differently caused major system errors and necessitated that these codes be unbundled for several months. MGMA seeks clarification and assurances that these services may continue to be billed globally.

Therapy Cap

CMS implemented two annual therapy caps, one for speech-language pathology and outpatient physical therapy and another for outpatient occupational therapy, on Jan. 1, 2006. In Section 5107(a) of the Deficit Reduction Act of 2005, which was enacted on Feb. 8, 2006, Congress mandated that the Secretary of the Department of Health and Human Services create an exceptions process for the therapy caps.

At the time of publication, the exceptions process was scheduled to expire on Dec. 31, 2006. However, since that time, Congress has extended the exceptions process for another year. To date, CMS has yet to inform providers how the therapy exceptions process will work for 2007. MGMA requests that CMS continue to utilize the exceptions process implemented in 2006 and urges CMS to make this information available to providers quickly. MGMA believes that the continuity of a process would lessen possible administrative burdens and is willing to assist in the education of providers regarding this process.

Abdominal aortic aneurism screening

Effective Jan. 1, 2007, CMS will reimburse physicians for the provision of abdominal aortic aneurism (AAA) screening. MGMA is pleased to learn that CMS has already promulgated the carrier transmittal and provider education materials to ensure that both Medicare carriers and providers are alerted to this new service available to Medicare beneficiaries. MGMA urges CMS to promulgate additional provider education materials when additional risk factors are identified as part of the national coverage determination process. Furthermore, MGMA recommends that this information be included in the functionality for the standardized electronic eligibility transaction (X12 4010 A1 270/271) implemented by Medicare. The eligibility status reported to the provider should contain information generated by all Medicare carriers, so providers can determine in advance whether a Medicare beneficiary is eligible for an AAA screening. While beneficiaries will receive most of their health care services within one carrier's jurisdiction, it is foreseeable that a beneficiary may receive services in multiple jurisdictions. Providers should receive complete information as a result of the electronic eligibility transaction.

End-Stage Renal Disease (ESRD) Provisions

Hospital data used

MGMA remains concerned about the appropriateness of using acute care hospital wage index data in the calculation of the ESRD-Composite Payment Wage Rate Index. This index is used to determine payment to both hospital-based and independent ESRD facilities. The use of only hospital data in this calculation would indicate that wages in hospital-based and ambulatory facilities are the same or similar in nature; however, no such determination has been made. In fact, the costs for hospital-based facilities and ambulatory centers vary greatly. The ESRD-Composite Payment Wage Rate Index needs to take into consideration wages paid in independent facilities, in addition to those paid in acute care hospital inpatient settings. MGMA urges CMS to locate an alternative data source that reflects information directly tied to ESRD facilities.

Use of Floor/Ceiling Values

CMS has again reduced the wage index floor for the ESRD-Composite Payment Wage Rate Index in the face of cuts to physician reimbursement. This decrease will penalize ESRD facilities that have already faced cuts from the transition to the average sales price drug reimbursement methodology. These cuts to facilities' reimbursement will make it even more difficult to recruit and retain qualified personnel in areas affected by the removal of this floor.

Reassignment and Physician Self-Referral

MGMA is pleased that CMS decided not to finalize its proposals relating to reassignment and the physician self-referral law. As indicated in MGMA's comments to the proposed rule, MGMA believes that the proposed restrictions were overly broad and premature. CMS' proposals would have precluded many legitimate business arrangements between healthcare providers and inhibited flexibility for group practices.

MGMA would welcome the opportunity to meet with CMS to discuss these provisions further. If CMS decides to move forward with major changes of general applicability to the reassignment and Stark rules, MGMA urges CMS to publish any changes in a new proposed rule, especially

considering that CMS has yet to publish an actual proposal with respect to new restrictions on the reassignment of the professional component of services.

Employee Access to Claims Billed on Reassignment

While MGMA shares CMS' interest in program integrity, MGMA continues to oppose the new requirements on employee access to billing records. Congress authorized CMS to develop additional protections related to reassignment by contractors. It evidenced no intent to change the reassignment rules, which have applied to owners and employees of physician practices for decades. Nor is there any evidence of which MGMA is aware to suggest that this is a current program integrity issue.

While employed providers generally have some access to records in the practice, they do not necessarily have unfettered access to all billing records. This is a matter generally left to the terms of a provider's employment contract with the practice, record retention and storage policies and common sense as billing or audit issues arise. Overlaying new regulatory requirements on this aspect of the employer-employee relationship is fraught with potential issues not addressed by this proposal. For example:

1. Does the requirement extend to employees? For how long?
2. Can it be used to harass a former employer in a manner unrelated to any legitimate concern about prior Medicare billings?
3. What about standard contract provisions that prevent a former employee from taking group records as part of a non-compete or non-solicitation provision in the employment contract?
4. What does "unrestricted" mean? Who decides?
5. Does it mean access to original records or only copies? Who pays for copying costs, retrieval from storage and/or separation of one provider's records from those of the others, of Medicare records from those related to other payers?
6. How much time does the group have to produce the records?
7. What if the records are no longer available?
8. How does the group prevent unauthorized disclosure of HIPAA-protected patient information now in the hands of a former employee?

Not only does CMS fail to adequately address these questions, but many are simply not answerable in a "one size fits all" manner. Were CMS to try to answer them all, this perhaps well-intended change would become a major new regulatory burden at a time when both government and physician practices are seeking ways to simplify the administration of healthcare.

Instead, CMS denies the need to even address these questions, leaving them up to "common sense." MGMA does not oppose applying common sense solutions, rather than government intrusion into group practice management; however, this is a situation where CMS is leaving practices with too many unanswered questions, which will only lead to increased confusion. Here, it is the government interfering with the common sense solution: leaving this question to negotiations between employers and employees.

One of the many benefits of group practice is the use of centralized administrative staff to perform billing and records functions, leaving providers the time and opportunity to focus on clinical care. While both the group and the employed providers generally share liability to Medicare if billing problems exist, it is generally the group's obligation to have systems in place to prevent them to the extent possible and to resolve them if and when they arise. Most groups

have billing compliance programs. It is those programs that set the framework for involvement of individual providers in order to ensure integrity. MGMA believes that is the better approach to protecting program integrity, not the addition of yet another regulatory requirement.

Independent Diagnostic Testing Facility (IDTF) Issues

CMS' proposal to adopt performance standards for independent diagnostic testing facilities (IDTFs) raises several concerns. MGMA believes that requiring federal certification of IDTFs will not control the growth in utilization or cost of IDTF services and will not ensure that medical imaging studies are being performed in a high quality, clinically appropriate manner. Rather, compliance with and implementation of these standards will further increase costs to individual medical practices and will yield little information for policy makers or health care consumers.

IDTF certification imposes a new layer of federal regulation on physicians providing diagnostic imaging services. CMS has not given any explanation of how the new standards will result in substantial savings. Before imposing additional administrative hurdles for IDTFs, CMS should evaluate the effectiveness of current requirements in order to ensure that additional regulations will not merely impose more costly burdens without achieving CMS' stated goals.

In addition, the medical community is working to ensure the quality and safety of medical imaging performed by developing residency training standards and CMS programs for ultrasound, MR, CT, and PET. They are also developing appropriateness criteria and practice guidelines for reasonable incorporation of these technologies into patient care. Performance measures and other quality-improvement tools are also being considered. CMS should recognize and not duplicate or override efforts being made by the medical community to ensure quality and safety. IDTFs are already subject to specialty-specific requirements, as well as state laws and regulations currently in place that stipulate equipment quality controls and technologist training requirements. CMS should support the efforts of the medical community to develop specialty-neutral standards for IDTFs.

MGMA appreciates CMS' elimination of the requirement that comprehensive liability insurance coverage be at least 20 percent of an IDTF's average annual Medicare billings. This requirement was overly burdensome and would have required complex and ongoing calculations by IDTFs to ensure compliance. MGMA remains concerned, however, about the proposed prohibition on solicitation of patients. Though CMS' commentary regarding this proposal indicates that IDTFs will be allowed to use public advertising as a method of providing information to patients, CMS did not clarify the language of the standard to make this clear. Instead, it maintained the requirement that IDTFs only accept patients referred by an attending physician. This standard limits the ability of Medicare beneficiaries to be informed about and to select their health care providers and requires the beneficiary to rely on the referral arrangements developed by his or her attending physician. MGMA supports a beneficiary's ability to be fully informed about health care providers and to be allowed to direct his or her care.

Finally, MGMA asks CMS to delay the effective date of this regulation to give existing IDTFs time to comply with its requirements. These standards were only made final on November 1, 2006 and only published in the Federal Register on December 1, 2006, IDTFs will have had, at most, 2 months to comply with these requirements. Given that IDTFs are currently bracing themselves for huge cuts in reimbursement rates, CMS should provide more time to comply with the IDTF standards.

MGMA appreciates your consideration of these comments and looks forward to collaborating to educate medical group practices on the numerous Medicare program changes. If you have any questions, please contact Lisa P. Goldstein in the Government Affairs Department at (202) 293-3450.

Sincerely,

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