CAPITAL WHOLESALE DRUG CO. 267

October 5, 2006

The Honorable Mark McClellan, MD, PhD
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington DC 20201

Re: CMS-1321-P (ASP Issues)

Dear Dr. McClellan:

On behalf of Capital Wholesale Drug Co., I would like to take this opportunity to provide our comments on the Proposed Rule, CMS-1321-P, "*Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B*" (the "Proposed Rule"). This rule was published in the *Federal Register* on August 22, 2006 (71 *Fed. Reg.* 48980).

Capital Wholesale Drug Co. is a first-tier pharmaceutical wholesaler: We only purchase pharmaceuticals directly from manufacturers. These drugs are supplied on a daily basis to Physicians, Community pharmacies, Long-term care facilities, Hospitals, and Government agencies. We maintain pedigree information for our sales, and comply with all manufacturer product withdrawals and recalls.

Capital is an active member of the Healthcare Distribution Management Association (HDMA). Our president, George K. Richards, serves on its Board of Directors and on its committees. We are very involved in all aspects of the pharmaceutical distribution industry and understand our position in the marketplace as well as the effects of low reimbursements on our customer base.

As part of our membership activities, we have reviewed the HDMA written comment letter to the Centers for Medicare and Medicaid Services (CMS), on the proposed rule referenced above. Capital Wholesale Drug Co. fully endorses the HDMA comments, and is, by submission of this letter, incorporating the HDMA comments by reference into our written comments for the record.

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While we fully agree with all of the points raised in the HDMA letter, we wish to place special emphasis on two items addressed in the HDMA comment letter regarding Average Sales Price (ASP) Issues. First, Capital especially encourages CMS to reconsider its opinion that prompt pay discounts should continue as a type of price concession that manufacturers must include in their ASP calculation, and we urge CMS to reverse its position, and inform manufacturers that customary prompt pay discounts should not be applied to wholesalers when they calculate ASP. We strongly believe that manufacturers could continue to deduct any prompt pay discounts extended directly to end customers on sales that do not go through a wholesaler, but those that are not passed along to the customer are not appropriately included in the ASP. This revision is consistent with recent congressional directives that prompt pay discounts should be excluded from the Average Manufacturer's Price (AMP) calculation.

Second, Capital strongly endorses CMS' proposal to codify the definition of bona fide services, to treat fees paid to wholesalers the same as fees paid to third party logistics providers, and not to deduct those bona fide service fees when ASP is determined.

I thank you for this opportunity to provide our comments on Proposed Rule CMS-1321-P, and to endorse the comments of the HDMA as written. We hope these comments are constructive in your deliberation of developing an Average Sales Price calculation that represents an equitable and reasonable approach to reimbursement for the products which we distribute.

Sincerely,

George D. Richards

George D. Richards, RPh

Chairman
Capital Wholesale Drug Co.

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House of Representatives
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COURTS, THE INTERNET AND INTELLECTUAL PROPERTY

COMMITTEE:
SMALL BUSINESS

SUBCOMMITTEE:
TAX, FINANCE, AND EXPORTS

October 10, 2006

Leslie V. Norwalk, Esp.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on Practice Expense Methodology: Five-Year Review of Work Relative to Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology Notice (August 22, 2006)

Dear Acting Administrator Norwalk:

I am writing in response to the recent Centers for Medicare & Medicaid Services (CMS) proposed Notice issued August 22, 2006, specifically in regards to the proposed cuts to certain procedures in the practice expense methodology. Over 120 cardiologists in my district and around central Florida will have to close their doors to Medicare patients if this proposed change in methodology is finalized. Up to eighty percent of the patients in many of these doctor's practices are Medicare patients. I continue to be concerned about the effect that these proposed cuts will have on vital procedures to Medicare patients.

Cardiologists in my district provide a cost-effective alternative to hospital based procedures. The drastic reduction proposed with the practice expense methodology does not accurately represent either the cost of performing the service, or a comparable rate that Medicare pays for the same group of procedures when they are performed in a hospital outpatient center. The proposed changes do not include actual costs of providing catheterization procedures in a non-hospital setting and would result in the closure of freestanding centers.

I fear that the proposed cuts under the CMS physician fee payment schedule as well as the expense methodology could diminish Medicare patient's access to cardiac care. The different proposal for payment rates for outpatient cardiac catheterization services included in this August Notice is not the right solution. Because there is insufficient data to determine the best way to proceed, I continue to request that CMS freeze payments for cardiac catheterization-related procedures for at least one year to allow time for a complete assessment of the cost profile. If this one year freeze is not a possibility, I urge CMS to implement a transition period of at least

four years, to allow these clinics to adjust accordingly and to gather the data needed to make the most informed decision possible.

Finally, I have enclosed a listing of cardiac care centers in central Florida that will be impacted severely by these proposed cuts. I have also enclosed a listing from these centers of direct and indirect costs associated with these centers and the proposed impact of these cuts. Thank you for your consideration.

Sincerely,

Ric Keller
Member of Congress

Cardiology Practice Listing
Central Florida Area

Cardiac Care Specialists
7824 Lake Underhill Road
Suites D & E
Orlando, FL 32822
Phone: 407-273-2378
Fax: 407-273-9699
Dr.'s: Alexander Alperovich M.D., Glenn Harris M.D., Brian Kelly D.O., Chika Okereke M.D.

Cardiac Clinic
311 West Oak Street
Kissimmee, FL 34741
Phone: 407-933-1423
Fax: 407-933-2740
Dr.'s: Sunil Kakkar M.D., Atul Madan M.D., Padma Raju M.D., Dianne Zullow M.D.

Cardiology Care Center
1355 S. International Pkwy
Suite 1481
Lake Mary, FL 32746
Phone: 407-804-9199
Fax: 407-804-9393
Dr.'s: Jacob Agamasu M.D., Jay Bradley Bitar M.D.

Cardiology Consultants
2320 N. Orange Avenue
Orlando, FL 32804
Phone: 407-896-0054
Fax: 407-894-0032
Dr.'s: James Bolen M.D., Robert Boswell M.D., Robert Rothbard M.D., Egerton van den Berg Jr., M.D.

Cardiovascular Associates, Inc.
601 Oak Commons Blvd.
Kissimmee, FL 34741
Phone: 407-846-0626
Fax: 407-846-2524
Dr.'s: Rodolfo Aldir M.D., Roberto Barrett M.D., Alejandro Franceschi M.D., Thomas Kim M.D., Prashanta Laddu M.D., Johnson Massey M.D., Patrick Mathias M.D.

Cardiovascular Care Centers
100 West Gore Street
Suite 403
Orlando, FL 32806
Phone: 407-872-8588
Fax: 407-872-1875
Dr. Caleb Mercado

Cardiology Practice Listing
Central Florida Area

Cardiovascular Heart Center
3802 Oakwater Circle
Suite 2
Orlando, FL 32806
Dr. Zulima Nicoloff M.D.
Phone: 407-855-1520
Fax: 407-855-1590

Cardiovascular Interventions, P.A.
1900 North Mills Avenue
Suite 107
Orlando, FL 32803
Dr. Pradipkumar Jamnadas M.D.
Phone: 407-894-4880
Fax: 407-894-2364

Central Florida Cardiology
1745 North Mills Avenue
Suite 100
Orlando, FL 32803
Dr.'s: J. Craig Barnett M.D., Brian Dublin M.D., Michael Hardee M.D., Anil Kumar M.D. Gregory May M.D., Sharon Nichols M.D., Michael Nocero M.D., Scott Pollak M.D., Arsenio Rodriguez M.D., Nadarajah Srikumar M.D., Bruce Stein M.D., William Story M.D., Andrew Taussig M.D.
Phone: 407-841-7151
Fax: 407-425-2768

Florida Cardiology
483 North Semoran Blvd.
Suite 102
Winter Park, FL 32792
Dr.'s: Abbas Ali M.D., Pradup Baiju M.D., Sandeep Bajaj M.D., Steven Davis M.D., Ashraf A.H.F. El-Shalakany M.D., Darlene Go M.D.,Milan Kothari M.D., Claudio Manubens M.D., Karan Reddy M.D., Louis Scala M.D., Ravlprasad Subraya M.D.
Phone: 407-645-1847
Fax: 407-645-5616

Florida Heart Group
1613 North Mills Avenue
Orlando, FL 32803
Dr.'s: Jose Arias M.D., Puxiao Cen M.D., R. Charles Curry M.D., Francis Fahey M.D., Patricia Guerrero M.D., H.B. Karunaratne M.D., Chin Kim M.D., Salvador Lanza M.D., Mark Milunski M.D., George Monir M.D., Amir Morsi M.D., Carlos Saenz M.D., Kerry Schwartz M.D., Hani Seifein M.D., Curtis Weaver M.D., William Willis M.D.
Phone: 407-894-4474
Fax: 407-894-7136

Cardiology Practice Listing
Central Florida Area

Harold Greenberg M.D.
235 South Maitland Avenue
Suite 101
Maitland, FL 32751
Phone: 407-645-5504
Fax: 407-645-0229

Heart of Florida Cardiology P.A.
808 West Oak Street
Kissimmee, FL 34741
Dr. LeRoi Price
Phone: 407-847-6900
Fax: 407-847-7018

Heart with Rhythm
203 North Park Avenue
Suite 104
Apopka, FL 32703
Dr. S. Kamal Ashraf M.D.
Phone: 407-889-1902
Fax: 407-889-1903

Interventional Cardiovascular and Vascular
615 East Princeton Street
Suite 104
Orlando, FL 32803
Dr. Ashish Pal M.D.
Phone: 407-898-8449
Fax: 407-896-6344

Invasive and Noninvasive
616 East Altamonte Drive
Suite 202
Altamonte Springs, FL 32714
Dr.'s: Joseph Asch M.D., Joel Greenberg M.D., Juan Zarate M.D.
Phone: 407-834-1010
Fax: 407-834-4861

Longwood Cardiology
515 West S.R. 434
Suite 307
Longwood, FL 32750
Dr.'s: Wasim Ahmar M.D., Khalid Yaqood M.D.
Phone: 407-767-8200
Fax: 407-339-1200

Cardiology Practice Listing
Central Florida Area

Mid Florida Cardiology
1717 South Orange Avenue
Suite 105
Orlando, FL 32806
Phone: 407-351-5384
Fax: 407-445-0321
Dr.'s: David Bello M.D., Jorge Cusco M.D., Chandresh Duggal M.D., Arnold Einhorn M.D., Marcos Hazday M.D., Louis Kantounis M.D., Javier Lorenz M.D., Sundeep Mediratta M.D., Enrique Polanco M.D., Mouaz Tawam M.D., Peter Taylor M.D

New Life Heart Center
1460 West Fairbanks Avenue
Winter Park, FL 32789
Phone: 407-862-4151
Fax: 407-862-9323
Dr. Sunil Kapoor

Orlando Heart Center
60 West Gore Street
Orlando, FL 32806
Phone: 407-650-1300
Fax: 407-650-1307
Dr.'s: Louis Alvarez M.D., George Andreae M.D., Enrique Chapman M.D., Robert Dalton M.D., Robert Domascek M.D., Aurelio Duran M.D., Roland Filart M.D., Joel Garcia M.D., Scott Greenwood, M.D., Pavel Guguchev M.D., Melvin Johnson III M.D., Jose LeFran M.D., Parimal Manir M.D., Isreal Juan Mantecon M.D., Mark Steiner M.D., James Tarver M.D., Deepak Vivek M.D., Adam Waldman M.D., Irwin Weinstein M.D., Linus Wodi M.D.

Orlando Heart Specialists
450 West Central Parkway
Suite 2000
Altamonte Springs, FL 32714
Phone: 407-767-8554
Fax: 407-767-9121
Dr.'s: Amish Parikh M.D., Nanakishore Ranadive M.D., Rajesh Shaw M.D., Babak Alex Vakili M.D., Vikas Verma M.D.

Orlando Heart & Vascular LLC.
11317 Lake Underhill Road
Orlando, FL 32836
Phone: 407-446-8686
Fax: 407-363-4851
Dr. Vineel Sompalli M.D.

Nuclear Changes 2007-2010

2006 Physician Fee Schedule

Components	78465	78465	78478	78478	78480	78480	Totals
	TC	TC	TC	TC	TC	TC	
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00	
PE	11.82	$447.95	1.56	$59.12	1.56	$59.12	
MP	0.62	$23.50	0.10	$3.79	0.10	$3.79	
	12.44	$471.44	1.66	$62.91	1.66	$62.91	$597.26
	Global	Global	Global	Global	Global	Global	
Work	1.46	$55.33	0.62	$23.50	0.62	$23.50	
PE	12.34	$467.66	1.78	$67.84	1.78	$67.46	
MP	0.67	$25.39	0.12	$4.55	0.12	$4.55	
	14.47	$548.38	2.53	$95.88	2.52	$95.50	$739.76
	Pro	Pro	Pro	Pro	Pro	Pro	
Work	1.46	$55.33	0.62	$23.50	0.62	$23.50	
PE	0.52	$19.71	0.23	$8.72	0.22	$8.34	
MP	0.05	$1.89	0.02	$0.76	0.02	$0.76	
	2.03	$76.93	0.87	$32.97	0.85	$32.59	$142.49

2007 Proposed Transition PE Changes

Components	78465	78465	78478	78478	78480	78480	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	11.64	$441.13	1.32	$50.02	1.32	$50.02		
MP	0.62	$23.50	0.10	$3.79	0.10	$3.79		TC
	12.26	$464.62	1.42	$53.81	1.42	$53.81	$572.25	-$26.01
								-4.18%
	Global	Global	Global	Global	Global	Global		
Work	1.46	$55.33	0.50	$18.95	0.30	$11.37		
PE	12.21	$462.73	1.56	$58.74	1.52	$57.60		
MP	0.67	$25.39	0.12	$4.55	0.12	$4.55		Global
	14.34	$543.46	2.17	$82.24	1.94	$73.52	$809.21	-$40.55
								-5.48%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	1.46	$55.33	0.50	$18.95	0.30	$11.37		
PE	0.57	$21.60	0.24	$9.10	0.20	$7.58		
MP	0.05	$1.89	0.02	$0.76	0.02	$0.76		Pro
	2.08	$78.83	0.76	$28.80	0.52	$19.71	$127.34	-$15.18
								-10.64%

Fully Implemented Proposed PE Changes

Components	78465	78466	78478	78479	78480	78481	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	11.08	$419.90	0.58	$21.96	0.58	$21.96		
MP	0.62	$23.50	0.10	$3.79	0.10	$3.79		TC
	11.70	$443.40	0.68	$25.77	0.68	$25.77	$494.94	-$102.12
								-17.13%
	Global	Global	Global	Global	Global	Global		
Work	1.46	$55.33	0.50	$18.95	0.30	$11.37		
PE	11.81	$447.57	0.83	$31.45	0.73	$27.67		
MP	0.67	$25.39	0.12	$4.55	0.12	$4.55		Global
	13.94	$528.29	1.45	$54.95	1.15	$43.58	$626.82	-$112.93
								-15.27%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	1.46	$55.33	0.50	$18.95	0.30	$11.37		
PE	0.73	$27.67	0.25	$9.47	0.15	$5.68		
MP	0.05	$1.89	0.02	$0.76	0.02	$0.76		Pro
	2.24	$84.89	0.77	$29.18	0.47	$17.81	$131.88	-$10.01
								-7.46%

LHC Changes 2007-2010

2006 Physician Fee Schedule

Components	93510	93610	93555	93655	93556	93656	Totals
	TC	TC	TC	TC	TC	TC	
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00	
PE	37.05	$1,404.48	6.29	$238.38	9.92	$376.04	
MP	2.31	$87.54	0.34	$12.89	0.51	$19.33	
	39.37	$1,492.02	6.63	$251.26	10.43	$395.37	$2,138.56
	Global	Global	Global	Global	Global	Global	
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45	
PE	39.24	$1,487.10	6.61	$250.50	10.24	$388.07	
MP	2.61	$98.91	0.37	$14.02	0.54	$20.46	
	46.17	$1,749.73	7.79	$295.22	11.61	$439.98	$2,484.94
	Pro	Pro	Pro	Pro	Pro	Pro	
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45	
PE	2.18	$82.62	0.32	$12.13	0.32	$12.13	
MP	0.3	$11.37	0.03	$1.14	0.03	$1.14	
	6.8	$257.70	1.16	$43.96	1.18	$44.72	$346.38

2007 Proposed Transition PE Changes

Components	93510	93610	93555	93655	93556	93656	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	31.93	$1,210.07	4.77	$180.77	7.58	$286.51		
MP	2.31	$82.40	0.34	$12.89	0.51	$20.40		TC
	34.24	$1,302.47	5.11	$193.66	8.07	$306.91	$1,809.03	-$335.53
								-15.65%
	Global	Global	Global	Global	Global	Global		
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45		
PE	34.17	$1,294.96	5.12	$194.04	7.92	$300.15		
MP	2.61	$98.91	0.37	$14.02	0.54	$20.46		Global
	41.10	$1,557.59	6.30	$238.75	9.29	$352.07	$2,148.41	-$336.53
								-13.54%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45		
PE	2.24	$84.89	0.35	$13.26	0.36	$13.64		
MP	0.30	$11.37	0.03	$1.14	0.03	$1.14		Pro
	6.86	$259.98	1.19	$45.10	1.22	$46.23	$351.31	$4.93
								1.42%

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LAW OFFICES
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info@gosfield.com

October 6, 2006

Via Email [David.Walczak@cms.hhs.gov; http:\\www.cms.hhs.gov/eRule] **Followed by Mail**

Mr. David Walczak
Centers for Medicare Medicaid Services
CMS 13-21
P.O. Box 8015
Baltimore, MD 21244 (3 copies)

Re: Proposed Reassignment and Self-Referral Rules

Dear David,

I am writing to provide my comments to the proposed changes to the reassignment and self-referral rules particularly as they relate to diagnostic tests. My primary concerns turn on what appears to be a confounding of the concept of purchased tests and reassignment. Although there has never been a clear definition published with regard to what qualifies as either a purchased technical component or a purchased professional component, in the proposals the primary issue is the definition of a purchased professional component.

From my analysis, a purchased professional component by definition is not a reassignment. As demonstrated in the other reassignment rules which have long been on the books, the purchased professional component that is permissible under the old Carrier's Manual 3060 provisions is specifically not a true reassignment.

The effect of a purchased service billing is relatively limited with regard to the impact on the physician practice. By contrast, reassignment is a different undertaking. In addition to joint and several liability for overpayments in the billing interrelationships that were clarified with the Medicare Modernization Act liberalizations, when a physician of a different specialty reassigns his right to payment to the billing group, the specialty of the practice for utilization profiling purposes converts to "multi-specialty group".

That critical distinction having been stated, the implications of the following statement would vitiate the effect of the Medicare Modernization Act provision.

> "We believe there are current rules on purchased diagnostic tests which generally should be applicable in both situations in which the billing entity is purchasing the test without a formal reassignment as well as situations in which the physician performing the test has reassigned his or her right to Medicare payment to the billing physician or medical group."

By this mechanism, a physician group which leases on a block time basis the use of technology, completely consistent with the shared facilities rules under Stark, would be treated as if they had merely purchased the technical component. Moreover, if they engaged in that activity, but did not themselves perform the professional component, which was read by an independently practicing radiologist, the arrangement would be prohibited. The approach stated in the quotation above would vitiate effectively the shared facility rules as they have been published extensively under Stark if an independent contractor physician either supervised or interpreted the service. This would fly in the face of the very explicit recognition in the Stark Phase I regulations of independent contractors as being "in the group" for Stark purposes.

In addition, the purported desired consistency of the rules with respect to purchased diagnostic tests, by expanding the definition of a professional component to include the reassignment by an independent contractor physician to a billing physician group, would create pragmatic problems as well inasmuch as the independent contractor who may be supervising the test under the Stark and diagnostic testing rules would not be able to interpret the same study that he supervised unless he were an employee, lest the group run afoul of the proposed purchased professional component provisions.

The fundamental problem is that there has never been an articulation of what constitutes a purchased service. Do block time leases under the Stark shared facilities rules create a purchased technical component? I would argue they do not. A purchased technical component is a single per use payment for a study including the use of the equipment and technician. Period. Nothing else is a purchased technical component.

My definition of a purchased professional component would be a per study payment for an interpretation <u>where the physician does not reassign</u> his payment to the group. Any other definition would disenfranchise independent contractor physicians from relationships with practices which include diagnostic testing interpretations.

The only statement that we have with regard to anything pertaining to purchased technical components let alone purchased professional components is that provided in the old Medicare Carrier's Manual provision section 15048 which talked about questionable payment arrangements. That language, in and of itself, is completely outdated since it does not take into account the right of the group to bill for independently contracted technicians.

Taken together, I think that the proposed changes which would turn all independent contractor reassignment in connection with diagnostic testing into purchased professional components is ill advised.

As always, I would welcome the opportunity to talk with you about these issues.

Sincerely yours,

Alice G. Gosfield

(AGG/eaf)

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AMERICAN SOCIETY OF PLASTIC SURGEONS

October 4, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: 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

Dear Ms. Norwalk:

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule for "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B" that was published in the August 22, 2006 *Federal Register*. As requested in the proposed rule, the relevant "issue identifier" that precedes the section we are commenting on is used as a sub-heading throughout this letter to assist the Agency in reviewing these comments.

The American Society of Plastic Surgeons (ASPS) is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. ASPS promotes the highest quality patient care, professional, and ethical standards and supports the education, research and public service activities of plastic surgeons.

ASPS offers the following comments on the Notice of Proposed Rule Making (NPRM).

PROVISIONS
Resource-Based Practice Expense RVU Proposals for CY 2007

Direct Practice Expense (PE)

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W. L. GORE & ASSOCIATES, INC.
3750 WEST KILTIE LANE • P.O. BOX 2400 • FLAGSTAFF, ARIZONA 86003-2400
PHONE: 928/779-2771 • MAIN FAX: 928/779-1456 • MARKETING FAX: 928/774-3525
MEDICAL PRODUCTS DIVISION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. 8015
Baltimore, MD 21244-8015

Re: Physician Fee Schedule Proposed Rule,
August 22, 2006 (CMS-1321-P)
Update for Calendar Year 2007

Your consideration of these comments and recommendations will be appreciated.

Section: "PROVISIONS" A.2. "Payment for Splint and Cast Supplies"

We support the proposed rule to continue the separate billing and payment for casting supplies with the use of Q codes. This will ensure Medicare beneficiaries receive the medically necessary supplies and providers are appropriately reimbursed.

The list of supplies reported with Q codes as published in the Federal Register, Vol. 71, No. 162, page 48987, included a combination of generic and trade names. We request that the GORE PROCEL® Cast Liner, reported with Q4050, also be listed in the Final Rules as was previously published in the Final Rule, Vol. 65, No. 212, page 65396 dated November 1, 2000.

We encourage CMS and recommend the reeducation of providers on the use of Q codes for casting supplies through MedLearn articles and Carrier education initiatives. This will ensure appropriate reporting and payment for these medically necessary supplies.

Section: "DRA PROPOSALS"E.1.(a)."Payment for Multiple Imaging Procedures for 2007"

We support maintaining the current level of multiple imaging reductions at the 25 percent level rather than increasing the reduction percentage. This will provide for further evaluation to prevent inappropriate reductions which may hinder Medicare beneficiary access to radiology services.

Section: "DRA Proposals" E.3. "Section 5112-Proposed Addition of Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)"

We support the implementation of Section 5112 of the DRA of 2005 to provide coverage under Part B for ultrasound screening for AAAs. We commend CMS in adding language to provide for identification of the patient criteria screening benefit through the NCD process for expansion of coverage. We encourage CMS to frequently review medical and scientific data that may expand this AAA screening benefit to identify Medicare beneficiaries that may be appropriate for life-saving treatment.

Please do not hesitate to contact me with questions or need for further information at 928-864-2420 or email, asheen@wlgore.com.

Sincerely,

Antoinette L. Sheen, Associate

2722

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September 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2007 and Other Changes to Payment Under Part B – **"DRA Proposals."**

Dear Dr. McClellan:

As a vascular surgeon who practices in Nevada and as a member of the Society for Vascular Surgery (SVS), I am writing in response to the publication of CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, specifically the section regarding implementation of Section 5102 (b) (1) of the Deficit Reduction Act (DRA) and the list of imaging services that the Centers for Medicare and Medicaid Services (CMS) has included within the scope of "imaging services" defined by the DRA provision.

I am concerned that CMS has proposed to include non-invasive vascular diagnostic studies, CPT codes 93875 – 93990 and G-code 0365, in the list of imaging codes that are defined by Section 5102(b) of the DRA when in fact these studies contain no imaging or are predominately non-imaging in nature. Given the inclusion criteria that CMS has proposed, there are numerous reasons that these studies should not be listed in Addendum F.

The CPT manual is very clear that non-invasive physiologic studies are performed using equipment that is separate and distinct from the duplex scanner. In a vascular surgeon's practice, we perform physiologic studies on Medicare patients where there are signs and symptoms of peripheral arterial disease and we use physiologic vascular studies, CPT codes 93922, 93923 and 93924 to confirm presence of disease, assess the severity, allow accurate delineation of prognosis and provide a measure of effectiveness of treatments including exercise programs, percutaneous intervention and bypass surgery. Because these codes **do not contain imaging**, CMS should remove them from the list of services included under the imaging provisions of the DRA in the Final Rule, just as it has done in the proposed rule for nuclear medicine services that are "non-imaging diagnostic services" and radiation oncology services that are "not imaging services".

CMS should also exclude duplex scans of arteries (CPT codes 93880, 93883, 93925, 93926, 93930, 93931 and 93990) from DRA because the most important component of these procedures is collection of Doppler velocity data, **a non-imaging ultrasound modality**. For example, CPT 93880 is a non-invasive duplex scan of extracranial arteries; a complete bilateral study. B-mode imaging ultrasound is used to find the arteries in the neck, but non-imaging Doppler-based blood flow velocities are the most important data collected during the exam. Non-imaging Doppler-based blood flow velocities are the most important elements on which arterial stenosis measurements are based, and the stenosis determination is the criterion on which clinical treatment decisions are made. In summary, the single main reason for "imaging" in the carotid duplex scan is to find the correct location to obtain Doppler velocity measurements.

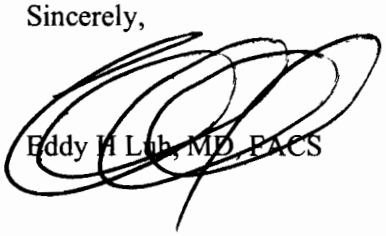
In addition, I believe there is confusion regarding the term "Doppler" and the information that this modality provides to a vascular surgeon for use in diagnosing vascular disease. There are several forms of Doppler ultrasound used in non-invasive vascular diagnosis (continuous-wave Doppler, pulsed-wave Doppler, color-flow Doppler velocity mapping), but all Doppler modalities have one thing in common – they measure blood flow. In the absence of blood flow, the Doppler measures nothing: there is no audible sound, velocity determination or flow mapping. The Doppler does not provide images of body parts. Thus, **Doppler techniques do not meet CMS's definition for inclusion, as these services do not provide "visual" information.** Duplex scans should be excluded from the DRA provisions in the Final Rule because the most important information provided by these tests is based on Doppler.

I recently participated in a survey conducted by the SVS of its members with office-based vascular labs regarding the impact of cuts on non-invasive vascular diagnostic studies, if they are erroneously included under DRA. The dramatic results demonstrate that Medicare beneficiaries' access to these services would be severely affected: 54 percent of vascular surgeons with office-based vascular labs would no longer provide or would reduce vascular laboratory services to Medicare beneficiaries and 24 percent would close the lab entirely or reduce services; 35 percent estimate that Medicare beneficiaries would wait three to four weeks to receive services if they had to go elsewhere and 22 percent estimate that patients would have to travel more than 20 miles to receive suitably high-quality vascular lab studies.

Given this level of impact and the fact that non-invasive vascular diagnostic studies do not meet CMS's proposed criteria for inclusion under DRA and instead meet the criteria CMS is proposing to exclude certain diagnostic services, I respectfully request that CMS remove these codes from Addendum F – Proposed CPT/HCPCS Imaging Codes Defined by Section 5102(b) of the DRA.

I greatly appreciate this opportunity to provide CMS with information and I would be happy to answer any questions. Please do not hesitate to contact me at 702-258-7788.

Sincerely,



Eddy H Luh, MD, FACS

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Bayer HealthCare

October 10, 2006

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

RE: CMS-1321-P: Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Bayer HealthCare LLC

400 Morgan Lane
West Haven, CT 06516

Phone: 203-812-2000

Dear Dr. McClellan:

Bayer Healthcare LLC ("Bayer") submits the following comments in response to the proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (the "Proposed Rule").[1] For more that 100 years, Bayer has produced high-quality drugs and biologics that have helped patients lead healthier lives. We appreciate this opportunity to comment on the Proposed Rule and look forward to working with the Centers for Medicare and Medicaid Services ("CMS") throughout 2007 to improve the health of Medicare beneficiaries.

In summary, Bayer presents the following comments for consideration regarding the Average Sales Price ("ASP") related provisions of the Proposed Rule:

- Treatment of Bona Fide Service Fees: We have concerns about CMS' proposal to expand its prior bona fide service fee guidance beyond wholesalers and distributors, the

[1] 71 Fed. Reg. 48982 (Aug. 22, 2006).

organizations that specifically received that guidance in the CMS letter dated December 9, 2004. Bayer encourages the Agency to look to the Anti-kickback Statute Safe Harbors to inform its development of this price reporting rule affecting other customers in order to ensure that federal policy in this area is consistent and can be practically applied.

- Possible Distinctions Between Types of Services: It appears that CMS may be suggesting that some services wholesalers and distributors provide to manufacturers will qualify for bona fide service fee treatment and some will not so qualify. If this is the case, CMS should abandon this proposal because all bona fide services, regardless of their nature, should be treated as services for price reporting purposes. Any other rule would mischaracterize the services and lead to inaccurate ASPs.

- Determination of Fair Market Value: Bayer believes that the Agency's proposal to provide more guidance in this area would be helpful. However, detailed guidance would necessarily fail to appreciate the dynamic nature of fair market value in the marketplace and the evolution in the nature of the services being provided. Accordingly, CMS should concentrate on providing an explicit, general standard and call upon manufacturers to apply that standard appropriately and reasonably.

- Price Reporting Rules vs. Accounting Rules: Bayer strongly urges CMS to recognize that there is a presumption at work in the accounting rules that is not, and should not, be the premise for how fees are treated as price reporting matters.

- Bundled Price Concessions: We appreciate CMS' proposal to provide additional guidance on how to apportion price concessions across bundled drugs, but we do not believe the Proposed Rule contains enough information about the proposal to provide an opportunity to offer meaningful comments.

- Problem of Beneficiary Access to IVIG: Bayer is troubled by reports that some Medicare beneficiaries are having difficulty obtaining IVIG therapy. We believe this access problem can be

ameliorated if CMS takes two actions – (1) issuing separate HCPCS codes to each IVIG product, and (2) reviewing the administration costs of IVIG.

- Additional Beneficiary Access Concerns: Bayer is also apprehensive about the impact of the proposed cut in the Medicare physician fee schedule conversion factor as well as the dramatic cuts to imaging services that result from the Deficit Reduction Act ("DRA") of 2005.

We thank you in advance for consideration of our comments on these issues, which are discussed in detail below.

I. Fees Not Considered Price Concessions

A. Application of the Bona Fide Service Fee Guidance to GPOs and PBMs

Bayer has noted CMS' discussion of the modified bona fide service fee guidance and the circumstances under which those bona fide service fees shall not constitute price concessions for ASP reporting purposes. We are quite concerned about the guidance and its unintended consequences. Specifically, we are concerned that this proposal is unnecessary, will significantly erode the ASPs of many products, and will impair beneficiary access.

The Proposed Rule provides the following definition of bona fide service fees:

> "fees paid by a manufacturer to an entity, that (1) represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer (2) that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and (3) that are not passed on in whole or in part to a

> client or customer of an entity, whether or not the entity takes title to the drug."[2]

One particular concern is the provision that states that the guidance would apply prospectively "whether or not the entity takes title to the drug." This substantially broadens the scope of prior guidance, which was directed only to wholesaler and distributor arrangements (possession takers), as evidenced by the fact that the guidance was announced in the context of a guidance letter specifically addressed to and designed for a wholesaler and a distributor trade association. Now, CMS is proposing that the guidance also would prospectively apply to entities that do not take title to product such as Pharmacy Benefit Managers ("PBMs") and Group Purchasing Organizations ("GPOs").

Bayer is concerned that this expansion of the guidance to include fees paid to PBMs and GPOs will completely erode the ASPs for many products, resulting in significant threats to access. We urge CMS to continue to apply the guidance to wholesalers and distributors, as per the established industry practice. In Bayer's experience, most GPOs and PBMs will not represent and warrant that they will not make any portion of the fee we pay them available to their clients or customers under any circumstances. The effect, then, of applying this guidance to GPO and PBM administrative fees would be to reduce the reimbursement rate that Congress intended, 106 percent of ASP, to 106 percent of ASP, less the GPO and PBM administrative fees.

Since the GPO Safe Harbor to the Anti-kickback Statute ("AKS") explicitly permits GPO administrative fees of up to 3 percent of the purchase price and even more than that amount, if certain steps are taken, [3] and because the Office of the Inspector General for the Department of Health and Human Services ("OIG") has encouraged

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[2] *Id.* at 49082.

[3] The Safe Harbor provides that payments by a vendor of goods or services to a GPO do not constitute prohibited remuneration under the AKS if (1) the GPO has a written agreement with each entity; (2) the fee paid to the GPO is 3% or less of the purchase price of the goods or services; (3) if the fee paid to the GPO is not fixed at 3% or less of the purchase price, the agreement specifies the maximum amount that will be paid; and (4) the GPO discloses to its members at least once a year the fees its receives. 42 CFR § 1001.952(j).

manufacturers to base their PBM relationships on the GPO safe harbor,[4] the effect of the Proposed Rule would be to reduce reimbursement to an effective rate of 103 percent of ASP, or less. Because ASP is merely an average of all acquisition prices and because a significant number of purchasers are acquiring product at prices above ASP now, CMS' proposed policy will necessarily mean that a significant portion of customers will be asked to acquire product at a price that is below the effective rate of reimbursement.

The situation will be even more dire as some price increases must be taken, at a minimum, to keep pace with the rate of inflation and for increased costs, and, because of the two quarter lag, those price increases must further erode the effective reimbursement rate. We fear that as high as half of all purchasers could be put into a position where they are asked to pay more for a product than they are reimbursed if CMS extends its guidance to PBMs and GPOs. In such circumstances, we believe that an effect on Medicare access is inevitable.

Additionally, we do not believe that this proposed expansion of the bona fide service fee definition is necessary because GPOs and PBMs have been subject to AKS guidance since the GPO Safe Harbor was promulgated in 1991. As indicated above, at least from that time, manufacturers have used the AKS Safe Harbor to inform the scope of permissible activity in the price reporting arena. Many manufacturers, for instance, treat an administrative fee of 3 percent of the purchase price as a bona fide service fee and any administrative fees in excess of that amount, if any, as price concessions. This yields a price reporting rule that is consistent with the AKS Safe Harbor, and we believe that CMS should formally adopt this position as a price reporting rule. One of the dangers of the Proposed Rule is that it would create a disconnect between the AKS Safe Harbor and the price reporting rules, where, in one case, FMV is presumed under certain circumstances (and, with fewer requirements, where the

[4] Specifically, the OIG stated "Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBMs customers' purchases *potentially* implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j)." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736 (May 5, 2003).

administrative fee does not exceed 3 percent) and where, in the other, some as yet undefined "proof" of fair market value must be collected.

We should also note that the government has an interest in both GPOs and PBMs being able to pass along fees because it sponsors some PBMs and because pass through fees reported by the members of GPOs, such as hospitals, that report their costs may have the effect of reducing various Medicare payment obligations. If the government created disincentives for pass-throughs to occur in connection with these non-possession takers, the government will experience negative fiscal effects.

Lastly, to date, CMS' bona fide service fee guidance has only been issued in the ASP reporting context. There has been no discussion of how the guidance may or may not apply to Medicaid or other price reporting contexts. Since the guidance has not been expanded to include other contexts, we will assume the guidance does not apply in any other context other than ASP reporting.

B. Distinction Between Types of Services

CMS received comments in response to the ASP reporting Interim Final Rule stating that bona fide services include handling, storage, inventory reporting, shipping, receiving, patient education, disease management and data. According to CMS, the commenters reportedly did not explain the process for determining whether these activities are bona fide services actually performed on behalf of the manufacturer or otherwise.

We are confused by this portion of the Proposed Rule. It appears that CMS may be trying to draw a distinction between the types of services wholesalers and distributors provide to manufacturers, with some types of services perhaps qualifying for bona fide service fee treatment and others perhaps categorically not permitted to have such status. Thus, CMS has sought comments on the "specific types of services entities perform on behalf of manufacturers that a manufacturer would otherwise perform (or

contract for) and the necessity of those services in the efficient distribution of drugs."[5]

If CMS is suggesting that some services provided to manufacturers cannot be treated as bona fide service fees, this would be very troubling, because there was no suggestion of this in the prior guidance and because we see no principled distinctions to be made based on the type of services wholesalers and distributors provide to manufacturers. Bayer believes that the requirement that all services must be performed "on behalf of" manufacturers for purposes of ASP reporting clearly can apply with respect to all of the types of services that CMS listed in its Proposed Rule.

Of course, manufacturers should be required to ensure that the services they contract for and treat as bona fide services offer a benefit to the manufacturer, meaning that they involve services to the manufacturer or to customers of the manufacturer that the manufacturer would seek from others to support its operations as a manufacturer, in the absence of assistance from the arrangement giving rise to the bona fide service fee that are appropriate for the customer to provide. Given the fact specific nature of the inquiry and the likely evolution in services over time, categorical conclusions offered by regulation about the permissible or impermissible nature of services are unwarranted and unhelpful.

C. Determination of Fair Market Value

CMS also calls for comments on the determination of fair market value. The prior guidance has been widely criticized because of its ambiguous reference to payments that are consistent with what would be made to "third parties" for the applicable services. If, as we believe to be the case, this guidance merely indicates that FMV must be determined without regard to the fact that a wholesaler or distributor is a customer, and that FMV cannot involve any "extra" payment, beyond fair market value because an entity is a customer, then we believe that the current guidance on the determination of fair market value is largely correct and appropriate as written.

[5] 71 Fed. Reg. at 49001.

A minority of analysts, however, have suggested that this standard may mean that there can be no FMV determination where the service is of a kind that only a wholesaler or distributor can provide, because of their unique role in the pharmaceutical sector. Some of these analysts have suggested that this may be so even though the manufacturer is only paying an appropriate amount to the service provider, as determined in arms length negotiations. If this is the intent of the current guidance, it is unrealistic, unworkable, and inconsistent with the long-standing guidance issued under the AKS addressing the very same issue.

In a Special Fraud Alert, the OIG has stated that "'fair market value' must reflect an arms length transaction which has not be adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them."[6] Bayer believes that this well-settled understanding of what constitutes FMV is the standard that CMS should adopt in connection with wholesaler and distributor arrangements.

With respect to the issue as to whether CMS should issue more specific guidance as to the manner in which particular services should be analyzed for FMV purposes, we do not believe that this kind of exercise would prove fruitful. FMV is, of necessity, always a reflection of variable circumstances, and we do not think it would be possible for CMS to anticipate all of the relevant variables or to not anticipate the range of relationships that exist and will come to develop in the marketplace. If CMS were to issue detailed guidance on how to determine FMV for ASP reporting purposes, it would be anomalous because in other contexts the government, particularly the OIG, has declined to give detailed guidance on FMV.

Indeed, the OIG will not opine on FMV issues in advisory opinions.

Virtually every OIG Advisory Opinion that discusses the concept of FMV includes a footnote that reads in part, "We are precluded by statute from opining on whether fair market value shall

[6] Issued October 1994.

be or was paid for goods, services, or property."[7] The statutory basis for this statement is found in the Social Security Act.[8]

Accordingly, Bayer believes that any reasonable approach a manufacturer takes to determine FMV should be sufficient because FMV should be determined on an individualized basis, taking all relevant factors into account.

D. Price Reporting Rules vs. Accounting Rules

Bayer feels strongly that CMS should not look to accounting rules to determine price reporting issues because the two areas are fundamentally different. We understand that accounting guidance promulgated by the Financial Accounting Standards Board ("FSAB") creates a presumption that even bona fide service fees must be treated as a reduction in sales price, when the service is obtained and can only be obtained from a customer. Because this presumption does not attempt to reflect what actually is occurring in any given circumstance, in order to further the publics' interests in conservative recognition of revenues for securities and financial accounting purposes, this presumption is not relevant in the ASP context. The government's stated interest in the ASP reporting context is to ensure the most accurate ASP possible. Indeed, no other intent would be consistent with the Congressional intent, as reflected in the Medicare Modernization Act ("MMA"), to create an accurate price reporting metric for reimbursement purposes through the creation of the ASP system.

Rather than apply the blunt instrument of a presumption in ASP reporting, the existing CMS guidance has established a test designed to determine whether or not, on the facts presented, a particular payment is a bona fide service fee or not. That is the only approach that will ensure accuracy and fairness to all interested parties—the government, providers, patients, and others.

Additionally, Bayer respectfully suggests that CMS should eliminate the "no pass through" requirement even for wholesalers

[7] *See, e.g.*, Adv. Op. No. 03-15 (Dec. 11, 2003).
[8] § 1128D(b)(3)(A).

and distributors. The key inquiry should be did the manufacturer pay FMV for the services? If this is the case, it is irrelevant what the wholesaler or distributor ultimately does with its FMV payment, so long as manufacturers do not direct that payments be passed through to end customers. In such a case, the wholesaler's or distributor's relationship with its customer does not concern or involve the manufacturer.

Further, Bayer does not know how to determine whether or not fees are passed through because only the wholesalers and distributors know what they are doing with the fees they receive. If CMS is determined to maintain the no pass through requirement, it should explicitly state that, if a manufacturer receives a no pass through representation from a wholesaler or distributor, this is sufficient to meet the requirement.

E. Bundled Price Concessions

Bundled price concessions are commonly described as arrangements in which a purchaser's price for one or more drugs is contingent upon the purchase of other drugs or items. In the Proposed Rule, CMS acknowledged that it has not provided prior guidance in the ASP context regarding the proper method to apportion price concessions across drugs that are sold under bundling arrangements, and that manufacturers may make reasonable assumptions in their ASP calculations. We applaud CMS' statement that it is considering providing guidance on the proper method to apportion price concessions among drugs sold under bundling arrangements. We believe this guidance will be most helpful in assisting manufacturers with this difficult price reporting issue.

However, we do not believe that the Proposed Rule contains enough discussion on this issue for us to provide meaningful feedback in these comments. Bayer respectfully suggests that CMS provide some alternative mechanism or forum for manufacturers and other interested parties to have a more in depth dialogue with the agency on this important issue. For any discussion to be helpful, the scenarios at issue must be clearly presented and the proposed treatment or alternative treatment must be specified. With that said, as a general matter, any bundled relationship should have price

reporting treatment that accurately reflects the value of the bundle to the products that are the subject of that bundle, and we support that policy.

F. IVIG Access Problem

We continue to be troubled by the IVIG beneficiary access problem. We understand that some Medicare beneficiaries are having difficulty obtaining their life-saving IVIG therapy because of two coding related reimbursement issues that CMS has the authority to rectify. We urge CMS to (1) issue separate Healthcare Common Procedure Coding System ("HCPCS") codes to each, single source IVIG product, and (2) increase the payment for administration services to reflect adequately the full cost of providing the service.

On the HCPCS coding issue, since IVIG is currently designated as a multiple source product, IVIG ASP reimbursement is based on the weighted average of the ASPs for multiple IVIG products. Thus, some IVIG products will be reimbursed based on a class ASP that is below the product's actual ASP. This leads to the unfortunate consequence of some Medicare providers having to provide IVIG at a reimbursement rate below his or her acquisition cost. Fortunately, CMS has the authority to code and reimburse all IVIG products separately.

On the administration services payment issue, we believe strongly that CMS should undertake a review of the extraordinary costs inherent in the administration of IVIG, and make appropriate adjustments based on the evidence presented. IVIG is a unique product, and its safe and effective administration is quite labor intensive. The MMA contemplated that administration service reimbursement could and should be altered where additional reimbursement was proven necessary. Bayer believes the administration of IVIG is just such a situation.

G. Additional Beneficiary Access Concerns

We would also like to note our concern with two provisions of the Proposed Rule that we fear may significantly hinder beneficiary access to care. Bayer is deeply troubled by the impact of the proposed

cut in the Medicare physician fee schedule conversion factor as well as the dramatic cuts to imaging services that result from the Deficit Reduction Act ("DRA") of 2005.

The adequate reimbursement of physicians is the cornerstone of access to care for Medicare beneficiaries. As practice expenses continue to rise and reimbursement steadily decreases, we are concerned that physicians will no longer provide care to Medicare beneficiaries. We fear that beneficiaries will find it more difficult to locate Medicare providers, travel greater distances for their care, and face longer wait times to schedule appointments. None of these is a desirable outcome, and we urge CMS to take all permissible administrative action to reduce the impact of the statutorily imposed payment reduction.

Similarly, we are concerned that the significant imaging cuts required by section 5102(b)(1) of the DRA will erode beneficiary access to a variety of imaging services. As stated in the Proposed Rule, CMS will cap the PFS payment amount for imaging services furnished on or after January 1, 2007, prior to geographic adjustment, by the CY 2007 outpatient prospective payment system ("OPPS") payment amount, prior to geographic adjustment. Bayer appreciates that CMS must implement this significant cut. In doing so, we urge CMS, acting within the confines of its statutory mandate, to define this cut narrowly. Acting otherwise would subject providers unnecessarily to these sweeping cuts and put further pressure on beneficiary access to imaging services. In this respect, CMS should examine whether all of the services subject to the proposed cuts are, in fact, "imaging" services or whether they involve non-imaging components.

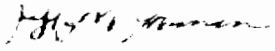
Each of these payment reductions is likely to have a significant impact on beneficiary access. We urge CMS to proceed thoughtfully as it implements both.

II. Conclusion

Thank you again for your consideration of the above comments on the Proposed Rule. We appreciate your thorough review of our concerns regarding the treatment of bona fide service fees. As such,

Bayer would be happy to discuss any or all of the aforementioned issues with you in person. We look forward to continuing to work with you to improve the health of Medicare beneficiaries and thank you in advance for your time.

Sincerely,



Mr. Jeffrey M. Greenman
Bayer HealthCare LLC
General Counsel and Secretary

cc: Tom Lilburn, Bayer
Sandra Oliver, Bayer

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Baxter

October 10, 2006

BY HAND DELIVERY

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

SUBJECT: CMS-1321-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B)

Dear Administrator Norwalk,

Baxter Healthcare Corporation (Baxter) appreciates the opportunity to comment on the above-mentioned proposed rule published in the Federal Register on August 22, 2006 (the "Proposed Rule").[1]

For 75 years, Baxter has assisted healthcare professionals and their patients with the treatment of complex medical conditions, including hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma and other conditions. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives.

Baxter would like to thank you and the Secretary for your willingness to work with patients, providers, manufacturers and suppliers of health care products to arrive at adequate payment for providers who serve Medicare beneficiaries. Appropriate reimbursement continues to be a key factor in ensuring patient access to treatment, especially when patients are prescribed high-value and/or recurring treatment. With these critical patient access issues in mind, we address specific concerns related to the payment policies set forth in the Proposed Rule.

Our comments focus on payment for drug administration services, as well as proposed methods for calculating average sales price (ASP). In addition, we have several specific comments related to reimbursement for

[1] 71 Fed. Reg. 48982

plasma-derived and recombinant analog therapies. These therapies treat rare disorders such as primary immune deficiency, genetic emphysema, and hemophilia.

In recent years, there have been a number of regulatory and legislative initiatives that have the potential to greatly impact reimbursement for drug and biological products and associated administration services. More recently, proposed changes resulting from the Deficit Reduction Act (DRA), the physician fee schedule five-year review, and the planned 5.1 percent reduction in the fee schedule, introduce potential disincentives for adoption of important advances in therapy for patients.

We urge CMS to consider the breadth and cumulative effect of these changes on reimbursement levels for drug and biological therapy. Moreover, we urge the agency to provide mechanisms that provide for equitable payment levels, enable stability in payment rates, and yield transparency in payment determinations.

RECOMMENDATIONS

Baxter recommends that CMS take the following actions:

1. CMS should utilize existing administrative authority to ensure adequate provider reimbursement for the purchase and administration of IVIG administered in the physician office.

    A. Re-instate the IVIG pre-administration fee.
    B. Ensure adequate reimbursement for each IVIG product by establishing unique Healthcare Common Procedure Coding System ("HCPCS") codes for each product.
    C. Use existing authority to increase reimbursement for the purchase of IVIG to a rate that reflects the true provider acquisition costs.
    D. Properly classify IVIG as a biologic response modifier ("BRM") and reimburse it accordingly.

2. Delay implementation of reductions in reimbursement for drug administration services until the full impact of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) reforms on beneficiary access to care can be understood and providers can be assured of adequate and equitable payments.

3. Exempt HCPCS codes containing multiple brands of biological therapies from reimbursement reduction as a result of Widely Available Market Price (WAMP) adjustment.

4. Exclude downstream fees and service agreements from the calculation of ASP and provide additional examples and clarification of methodology.

5. Increase the clotting factor furnishing fee by the percentage increase in the consumer price index ("CPI") for medical care for the 12-month period ending June, 2006 and publish the updated furnishing fee in the final rule.

6. Encourage patient services that slow or prevent renal disease, such as self-management for diabetics.

We would like to discuss these recommendations in depth below:

1. **CMS Should Utilize Existing Administrative Authority to Ensure Adequate Provider Reimbursement for the Purchase of IVIG Administered in the Physician Office**

   During the past 21-months many Medicare beneficiaries have faced serious and sometimes insurmountable barriers to IVIG access. We believe CMS has the authority and flexibility to address the existing Medicare Part B IVIG access concerns. While we appreciate the agency's willingness to study and maintain an ongoing dialog on this issue, we are hopeful that these discussions will quickly translate into the implementation of solutions that will ensure adequate access to IVIG and other life sustaining therapies.

   Since January 2005, Medicare beneficiaries have faced significant barriers to IVIG access[2] in the physician office and home health[3] settings as a result of inadequate reimbursement. We believe that a thorough review and comparison of the ASP information and product reimbursement for the identical quarters will clearly demonstrate that the current reimbursement formula does not provide adequate reimbursement for all brands of IVIG. Although the current formula is intended to provide cost-based reimbursement, there are several

[2] Patient organizations have received numerous calls from patients, physicians, home health care companies and other sites of care concerning treatment problems related to Medicare reimbursement of IVIG. Access concerns were quantified in an Immune Deficiency Foundation (IDF) survey[2] of 287 physicians treating a total of 4189 patients with primary immune deficiency disease and 935 patients with other disorders currently receiving IVIG. The survey found that 31% of physicians who treat primary immune deficient patients with IVIG reported patients experiencing significant problems related to reimbursement of IVIG. Of this group, 43% reported adverse health effects on patients as a result of reimbursement. The impact on patients included: 21% switched to a different site of care, 22% postponed infusions, 13% switched brands, and 8% had the interval between infusions increased.

[3] IVIG is covered under Part B for primary immune deficient patients.

factors that prevent adequate reimbursement of all brands of IVIG. The two primary factors are explained below.

The ASP information used for reimbursement is based on a historical market price and not the current selling price. The two-quarter delay between the sale of the product and the use of the selling prices for reimbursement purposes leads to inadequate reimbursement in a recovering market. IVIG pricing is recovering after a brief, but disruptive period when the selling prices of IVIG decreased to an unsustainable level. The result was severe market disruption that affected the economic health of the plasma industry.

In addition, IVIG is one of a very limited number of biological therapies with mixed HCPCS codes. Both of the codes representing IVIG contain products with differing characteristics and value. As a result, reimbursement is based on the weighted average of all products within the code, not the historical average selling price of each therapy. This results in further under-reimbursement of some higher value therapies.

Baxter believes that CMS has the authority to remove the current barriers to access by providing adequate reimbursement. We are hopeful that the agency will take advantage of the administrative options available to preserve patient access to this vital therapy.

A. Re-instate the IVIG Pre-Administration Fee

In the Proposed Rule, CMS appears to have discontinued the $69 payment for IVIG pre-administration-related services. While not a permanent, or universal solution to the current reimbursement challenges, the additional funds available as a result of the pre-administration fee have been an important resource that restored access to some beneficiaries using a subset of products. It is both surprising and concerning that the Agency would propose to decrease the already inadequate IVIG reimbursement. The result will almost certainly be decreased access to life-saving treatment for Medicare beneficiaries. We are hopeful that CMS will choose to improve, not further limit access to IVIG by continuing and increasing the pre-administration rate in 2007.

B. Establish Unique Codes for All IVIG Products

Baxter believes that the Agency could provide more equitable reimbursement for each IVIG therapy by establishing a unique HCPCS code for each brand. This would allow the Agency to determine reimbursement for each product based on its own ASP information. This will yield rates that are more pertinent to actual cost, thus enhancing access to the IVIG therapy most appropriate for each beneficiary's medical needs.

There are often clinical reasons why physicians order one brand of IVIG over another.

- Some products contain less immunoglobulin A ("IgA"), which may prevent or lessen adverse reactions for patients with IgA deficiencies;
- Some products contain no sugars, which is beneficial for diabetics;
- Some products have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function; and
- Some products have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

CMS' coding and payment for IVIG should recognize the differences between therapies by establishing a unique HCPCS for each product.

C. Increase Reimbursement for IVIG Via an Add-On Payment or Formula Change

We believe that there are many opportunities within the Agency's existing authority to ensure adequate reimbursement for the purchase of IVIG. Three options are discussed below.

Utilize Inherent Reasonableness Authority

The Medicare statute permits CMS to modify Medicare payment rates if it determines that the existing payment amount is grossly excessive or grossly deficient through "inherent reasonableness" authority.[4] Specifically, the agency regulations specify that an adjustment to the payment rate can be made if it is determined that the current rate varies from a realistic and equitable payment amount by more than 15%.[5] Such an adjustment could be used to increase IVIG reimbursement to a rate that will restore beneficiary access to IVIG in the physician office and home health settings

[4] SSA § 1842(b)(8).
[5] 42 C.F.R. § 405.502(g).

Reimburse IVIG as Both a "Drug and Biological" and "Blood and Blood Product"

We believe that IVIG, a plasma derived, biological therapy, could be appropriately interpreted as both a blood product as well as a biological when administered in the physician office. As a result, we are hopeful that CMS will acknowledge the dual nature of this therapy and carefully investigate opportunities to establish reimbursement from a blend of the formula for "drugs and biologicals" and "blood and blood products".

CMS may have the authority to interpret section 1842(o)(1)(F) to include IVIG as a "blood and blood product" because the statute does not define the phrase "blood and blood products" except to state that the phrase does not include blood clotting factors.[6] Furthermore, the inclusion of IVIG within "blood and blood products" is consistent with the Secretary's treatment of IVIG under Food and Drug Administration ("FDA") regulations. Such regulations define "blood and blood product" as a "drug which consists of human whole blood, plasma, or serum, or any product derived from human whole blood, plasma or serum. . . ." [7] Since IVIG is a drug derived from plasma, it falls squarely within the FDA definition of "blood and blood product."

Similarly, CMS has called IVIG a blood product in a national coverage determination regarding IVIG. In that determination, CMS stated that "Intravenous immunoglobulin is a blood product prepared from the pooled plasma of donors." [8] Thus, in addition to CMS possessing discretion to define IVIG as a blood product, there is precedent for CMS doing so.

We acknowledge the provision in SSA § 1842(o)(1) which addresses the payment rate for IVIG administered in the home health setting. This provision indicates that payment for intravenous immune globulin products provided in this setting in 2005, and thereafter, is determined under SSA § 1847A (the ASP statute).[9] To the extent CMS exercises its discretion to define "blood and blood products" to include IVIG, sections 1842(o)(1)(E) and 1842(o)(1)(F) could be

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[6] Social Security Act ("SSA") § 1842(o)(1)(F).

[7] 21 C.F.R. § 607.3(b).

[8] "Decision Memo for Intravenous Immune Globulin for Autoimmune Mucocutaneous Blistering Diseases," available at http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=43 (emphasis added).

[9] SSA § 1842(o)(1)(E).

perceived to be in conflict. In such circumstances, the agency implementing the statutes has the authority to attempt to resolve the potential conflict.[10] Accordingly, CMS may be within its authority in reading these two provisions to allow it to establish a blended payment rate consisting of the formulas for "blood and blood products" and "drugs and biologicals" for IVIG administered in the physician office.

Establish a Demonstration Project

CMS may conduct demonstration projects to provide incentives for economy while maintaining or improving quality of care.[11] In the past, the Agency has exercised this authority to create a demonstration project that provides additional payments for physicians that provide certain information to CMS.[12] The agency has the authority to establish a similar demonstration project for IVIG that would provide necessary information on the physician acquisition cost and use of IVIG while also providing additional payments to compensate physicians for the inadequate reimbursement, relative to their acquisition cost.

D. Classify IVIG As A Biologic Response Modifier

Baxter urges CMS to clarify that IVIG is considered a "biologic response modifier" for purposes of the code to be billed for administering the product.

Under these codes, chemotherapy administration codes apply to parenteral administration of biologic response modifiers, according to the language of the code. As a result, any product that is a "biologic response modifier" should be billed under such codes. IVIG is such a product. According to the U.S National Library of Medicine, biologic response modifier therapy is defined by reference to "immunotherapy," which is defined as "Treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases."[13] IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki's disease, chronic lymphocytic leukemia, primary immune deficiency disease, and secondary immune deficiency diseases. Thus, there can be no doubt that IVIG is a biologic response modifier, and CMS must state clearly in the final

[10] Citizens to Save Spencer County v. U.S. Environmental Protection Agency, 600 F.2d 844, 871 (D.C. Cir. 1979).
[11] 42 U.S.C. § 1395b-1(a)(1)(A).
[12] 69 Fed. Reg. at 66308-09.
[13] *See* http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy.

rule that hospitals should bill for administering the product using the CPT codes applicable to biologic response modifiers.

2. Delay implementation of reductions in reimbursement for drug administration services.

CMS proposes significant changes to the payment levels for drug administration services. These changes are a direct result of proposed revisions to the work and practice expense relative value units (RVUs) for these services proposed under the five-year review, and will be exacerbated by a proposed 5.1 percent reduction to the conversion factor for CY 2007. Combined with recent and ongoing reforms in Medicare's payment method for drugs based on ASP, the cumulative effect of these changes will create a high degree of instability with respect to reimbursement levels for drug administration services. Baxter is concerned that this environment threatens beneficiary access to medically necessary treatments.

As proposed, the RVUs for the majority of drug administration services would decline in CY 2007. As practice expense RVU changes become fully implemented by 2010, the RVUs for many drug administration services are projected to decline by 4 to 33 percent. Combined with the expected reductions in the conversion factor for CY 2007, many physicians will experience substantial declines in Medicare payments for drug administration services.

Baxter is concerned that the proposed revisions to payment levels for drug administration services will undermine the protections that CMS has implemented in the past two years to protect these payment levels, as mandated by Congress in the MMA. Specifically, when Congress created reimbursement for physician-administered drugs and biological products based on ASP in MMA, it also recognized that payments for drug administration services would require special treatment to ensure that physicians provide continued access to critical therapies for Medicare beneficiaries. As a result, MMA included a number of provisions to address the special circumstances surrounding reimbursement for these services. The result was an increase in payments for drug administration services by 32 percent in 2004 and by 3 percent in 2005.

We believe that adequate and equitable physician payments for drug administration services are critical to protecting Medicare beneficiary access to care. **Baxter urges CMS to delay the implementation of reductions in reimbursement for drug administration services until such time as the full impact of the MMA reforms on beneficiary access to care can be understood and providers can be assured of adequate and equitable payments.** Specifically, we recommend a delay in payment rate changes until the results of Medicare Payment Advisory Commission's January 2007 report outlining the effect of current payments

on access to care can be fully understood. Moreover, we believe that the full impact of MMA reforms will not be known until such time as complete claims data for 2006 are available.

3. Exempt HCPCS Codes Containing Multiple Brands of Biological Therapies from Reimbursement Reduction as a Result of Widely Available Market Price (WAMP) Adjustment Authority.

Under the ASP statute, if the Office of the Inspector General ("OIG") finds that the ASP for a product exceeds the widely available market price ("WAMP") by a percentage threshold, the OIG informs CMS and the agency then adjusts the ASP rate in the next quarter[14]. In the Proposed Rule, CMS requests comment on operational issues related to WAMP.[15]

Baxter requests that CMS exclude biological therapies that are bundled in HCPCS codes with more than one brand. As you are aware, biological therapies are neither generic nor exactly equivalent. There are important differences related to the processing, purity and tolerability of these therapies. While we believe that the lack of equivalence should preclude CMS from bundling unique therapies within mixed codes, many biological therapies produced by Baxter have been bundled. A payment adjustment predicated on the WAMP of one therapy within a code, may not reflect the market price of all products within the code. The result would be a barrier to access to all but the lowest value therapy within the category. This therapy may not be appropriate for all beneficiaries.

Examples of codes that include multiple therapies with differing characteristics are below.

- IVIG: While IVIG therapies are bundled into mixed codes, the products differ in IgA, sugar content, osmolality, volume and pH.
- Hemophilia Clotting Factor: Several brands of recombinant factor viii with differing value, cell cultures and storage requirements are included in the same code.
- Alpha One Proteinase Inhibitor: Three products of varying value are included in the same code. While the product with the lowest value is the most widely distributed, all therapies are needed to ensure an adequate supply is available to treat the current population.

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[14] SSA § 1847A(d)(3)(C)

[15] 71 Fed. Reg. at 49004.

If a WAMP adjustment is implemented based on a lower value therapy within a code, beneficiaries may face a barrier to the therapy that is most appropriate for their medical needs. Therefore, we respectfully request that CMS preserve access to all appropriate therapies by exempting HCPCS codes with more than one brand of biological therapy from potential WAMP adjustments.

4. Exclude Downstream Fees and Service Agreements From The Calculation of ASP and Provide Additional Clarification

A. Bona Fide Service Fees

Baxter appreciates efforts by CMS to-date to resolve questions and provide clarification on manufacturer ASP reporting obligations. The calculation of ASP is highly complex and has significant implications on provider reimbursement and, in turn, patient access to important therapies. The proposed rule raises a number of issues with respect to ASP reporting which we address below.

Baxter generally supports the treatment of *bona fide* services fees in the ASP calculation as proposed by CMS. We concur that these fees, which represent fair market value for selected services performed on behalf of the manufacturer, should be exempt from consideration as price concessions. We are concerned, however, with the CMS application of the *bona fide* service fee standard to group purchasing organizations (GPOs) that do not take title to the product. **Specifically, Baxter recommends that CMS clarify its policy to specify that fees paid to GPOs are not subject to the ASP calculation.**

Baxter is concerned that CMS has defined bona fide service fees as fees that cannot "be passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug". Despite the possibility that such fees as those paid to GPOs or any other entity may be passed on in whole or in part to their provider members, they do not constitute a price concession and should not be reflected in the ASP calculation.

GPOs are non-purchaser entities and do not take title of the drugs; they merely negotiate with manufacturers on behalf of their members. Any fees distributed to members are in accordance with contractual terms established between the GPO and their members and do not represent a discount, particularly as provider members make their own purchases from manufacturers based on the contract terms previously negotiated by the GPO.

Furthermore, tracking these fees would be difficult for manufacturers as they do not have visibility to how those earned

fees are being discharged by the entity. We would submit that legitimate fees that meet the definition of *bona fide* service fees be exempt from the calculation of ASP.

Baxter also urges CMS to maintain that services such as handling, storage, inventory reporting, shipping, receiving, patient education, disease management, and data collection continue to be viewed as *bona fide* services. **Baxter urges CMS to provide additional details from CMS regarding guidance on what type of services may qualify as bona fide services for purposes of the ASP calculation.** Moreover, this information also should indicate any revisions to the methodology manufacturers must use to determine fair market value of bona fide services performed on their behalf.

B. Methods to Estimate Lagged Exempt Sales

Manufacturers are required to exclude from the ASP calculation those sales that are exempt from the Medicaid best price calculation. CMS recognizes that data on these sales may not be available at the time the ASP is calculated, however. In the proposed rule, CMS outlines a standard methodology to calculate lagged sales. The method requires all manufacturers to use a 12-month (or less, if applicable) rolling average ratio to estimate exempted sales known on a lagged basis (through charge backs or rebates). The agency asserts that this method would more accurately exclude these sales from the ASP calculation.

Baxter agrees with the limited details provided by CMS regarding the proposed lagged exempted sales methodology related to chargebacks, rebates, and discounts. We would note that while over time, this may help to reduce potential errors in manufacturers' ASP calculation, there might be variations in the ASP from quarter to quarter initially for products or NDCs with less than 12 months of sales. We are hopeful that a consistent methodology will be implemented across all types of lagged discounts. However, we would like specific examples and an estimation methodology for such sales.

C. Nominal Sales

Manufacturers are required to exclude from the ASP calculation sales that are merely nominal in amount. Currently, a nominal sale is a sale at a price less than 10 percent of the average manufacturing price (AMP) in the same quarter for which the AMP is calculated. The DRA made several significant changes in the definition of a nominal sale, which may apply to the ASP calculation. In light of the DRA provisions, CMS proposes that manufacturers continue to use the existing definition of nominal

sales for purpose of the ASP calculation. **Baxter agrees with the CMS proposal on nominal sales for purposes of the ASP calculation.** We believe that the proposed approach provides for continuity in reporting and minimizes reporting burdens.

D. Other Price Concession Issues

In the proposed rule, CMS provides additional guidance on proper methods to estimate lagged price concessions when a product has less than 12 months of sales data. **Baxter agrees with CMS's proposal to specify that the period used to estimate lagged price concessions is the total number of months the NDC has been sold.** We would note that this may cause ASP figures to vary or fluctuate in the initial period because the number of price concessions may be significantly fewer given the limited number of months the NDC(s) was available on the market. Baxter would like additional clarification and examples of the proposed methodology for determining lagged price concessions for NDCs with less than 12 months of sales.

In the proposed rule, CMS also addresses instances when an NDC is changed and lagged price concessions offered for the prior NDC remain in effect. In this case, CMS provides guidance that twelve months of sales and price concession data from the prior and re-designated/redesigned NDC should be used, unless the product is repackaged or relabeled by a different manufacturer or re-labeler, or is privately labeled. **Baxter agrees with CMS's proposal regarding estimation of lagged price concessions for re-designated NDCs.** We also agree that if less than 12 months of sales is available that manufacturers may use the total number of months of sales of the prior and re-designated NDCs. Again, there may be quarter-to-quarter variation to the ASP in the initial period if less than 12 months of sales data was available.

Finally, the proposed rule also provides discussion on the possibility of providing future guidance on price concessions that should be applied when drugs are sold under bundling arrangements (e.g., purchaser's price for one or more drugs is contingent upon the purchase of other drugs or items). CMS requests comments on the range of issues to be considered in its guidance regarding bundling.

Baxter believes that ASP should represent as accurately as possible the average price of a drug in the market. Clear guidance and predictability in the reporting of ASP data by manufacturers is essential. However, given the uniqueness and complexity of bundling agreements, it is challenging to quantify the impact of such agreements on ASP calculations for our products. **We urge**

CMS to provide more specifics of its proposed bundling policy, as well as an opportunity for public comment, before finalizing the approach in regulation or in guidance document(s).

5. **Increase hemophilia clotting factor furnishing fee by the percentage increase in the consumer price index ("CPI")**

In the Proposed Rule, CMS explains that it will increase the clotting factor furnishing fee by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending June 2006. This proposal is consistent with the statute[16] and should help to protect beneficiary access to these life-saving treatments. Baxter asks CMS to publish the updated furnishing fee in the Final Rule.

6. **Encourage patient services that slow or prevent renal disease, such as self-management for diabetics.**

Baxter encourages CMS to continue efforts to provide coverage for services like diabetes self-management and other services to slow the progression of kidney disease as well as help patients who have kidney failure obtain a high quality of life. Patient education and training is a critical tool in the prevention of diabetes-related conditions, including kidney failure. Baxter encourages CMS to continue to explore additional services such as a pre-end stage renal disease education benefit that can slow the progression of chronic kidney disease and renal failure.

CONCLUSION

Baxter appreciates the opportunity to comment on this Proposed Rule. We remain deeply concerned however about the impact the Proposed Rule could have on the lives of patients who suffer from serious and life threatening conditions which require treatment with IVIG, alpha one proteinase inhibitor, and hemophilia clotting factor. We urge CMS to carefully review the concerns and potential strategies outlined above and to implement a system that will not impede access to care.

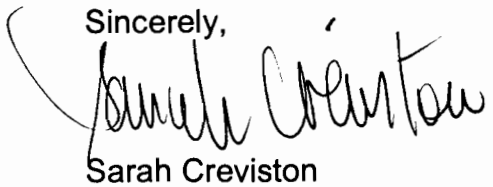
Baxter also believes that the revisions we have recommended to physician fee schedule payment for drug administration services will provide for more appropriate, equitable and predictable payment for these providers while ensuring beneficiary access to important therapies. In addition, our comments on methods for reporting ASP information will provide for consistency and accuracy of these data.

We urge you to take full advantage of the expertise in the patient, supplier and manufacturer communities and draw on their knowledge and

[16] SSA § 1842(o)(5)(C).

experience to establish payment rates that are equitable, reasonable and adequate. We look forward to working with you and the staff at CMS toward that goal. Should you have any questions or wish to discuss our comments further, please contact me at (847) 948-4278.

Sincerely,



Sarah Creviston
Vice President, Government Affairs and Public Policy
Baxter Healthcare

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September 29, 2006

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

I am writing to express my concern as an anesthesiologist over upcoming changes to the physician fee schedule. I've been advised that the proposed practice expense methodology and changes in work values will result in a 10 percent cut in payments to anesthesiologists over the next 4 years. This only compounds the problems with the standard growth rate formula, adversely affecting all Medicare Part B physicians. Experts are projecting an alarming 34 percent reduction in reimbursement over the next 10 years based on the proposed 4.6 percent reduction to the fee schedule in 2007.

These cuts stand to have a dire impact on access to vital medical care for America's seniors. Medicare's failure to keep pace with the cost of delivering patient care is disturbing. Costs continue to increase while reimbursements decrease at an alarming rate. This is particularly troubling because the proposed practice expense methodology changes stand to adversely affect anesthesiologists more than any other specialty.

I am urging both CMS and Congress to address this issue immediately and make significant changes to the current methodology used to reimburse providers. I feel it would be in CMS' best interest to take advantage of the American Society of Anesthesiologists and other physician organizations' offer to financially support a comprehensive, multi-specialty practice expense survey. By collecting and using new practice expense data, CMS can take major steps towards improving the basis and accuracy of practice expense payments for all providers. Likewise, Congress needs to take action by supporting legislation that eliminates the unrealistic sustainable growth rate formula and replaces it with a more market-sensitive system based on positive changes to the Medicare Economic Index.

The ever-increasing gap between physician reimbursement and the costs incurred to provide care cannot be allowed to continue. My concern is that our nation's most vulnerable populations face a shortage of anesthesia care in operating rooms, pain clinics and critical care facilities throughout the country, unless action is taken. I greatly appreciate your time and consideration in this matter.

Sincerely,

Victor T. Nicolas, M.D.

Victor T. Nicolas, M.D.

Cc: Senator Mike DeWine
Senator George Voinovich
Congressman Michael G. Oxley

As you are aware Cardiovascular Disease accounts for the largest number of deaths in the United States. The physicians of Central Florida Cardiology Group feel that the unreasonable decrease in Medicare reimbursement will have two fold effect.
We pride ourselves on providing excellent care to our patients, and you will make the decision for us on how to continue to provide that care with a reimbursement of 40%-62% less than the prevailing years.
First, with hard work and dedication we have tried to maintain not only patient satisfaction but employee as well, and with these cuts you require us to lay off a substantial percentage of our staff in order to keep our doors open to the community.
Second, you will begin to see that understaffed facilities will not be able to accommodate the patient load if you continue to cut the reimbursement for our office based procedures.
We are asking that you freeze the current cut, and develop a fair and informed solution that works for everyone.

Thank you for taking the time to realize the importance of your decision.

Sincerely,

Scott Pollak, M.D.

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I overestimated - only 11 pages!
Thanks,
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Comments of the
Michigan Society of Pathologists
on the Revisions to Payment Policies Under the
Physician Fee Schedule for Calendar Year 2007
[CMS–1321–P]

The Michigan Society of Pathologists (MSP) is pleased to have the opportunity to comment on the proposed revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule"). 71 Fed. Reg. 48982 (Aug. 22, 2006). MSP is a professional society of pathologists practicing in the state of Michigan. Our members perform a variety of services that are reimbursed under the physician fee schedule. Thus, most members will be significantly affected by the changes in the Proposed Rule. The MSP comments on the Proposed Rule focus on the revisions to the reassignment and physician self-referral rules, and changes to the rules governing how anatomic pathology services are billed.

PROVISIONS

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

MSP supports action to curb the growth of so-called "pod" or condo laboratories. *Id.* at 49054. These arrangements give referring physicians the opportunity to earn revenues based on their own referrals for services performed by others. The Medicare program has always expressed concern about such arrangements and has numerous provisions in place to curb such abuses. CMS is taking an important step by revising the reassignment rules and the Stark self-referral laws as a way of curbing these abusive arrangements. However, MSP believes that in order to be effective in addressing the pod laboratory issue, CMS must implement not only the independent contractor reassignment revisions that pertain to the technical and professional components of anatomic pathology, but also implement measures that would limit the use of part-time employee pathologists in such arrangements.

As CMS recognizes, there are two different, but related, methods for curbing these practices: (1) First, clarify the prohibition on reassignment, which is designed specifically to prevent Medicare from paying physicians for work performed by others, (except in limited situations0 and (2) Second, modify the Stark self-referral law, which is designed to prevent physicians from profiting by referring business to entities with which they have a financial relationship. As CMS notes, many pod arrangements are established either in contravention of these requirements or by taking advantage of ambiguities that exist. Generally, MSP is supportive of the changes that CMS is making, but we are aware of additional measures that should be applied to prevent abusive practices through part time employment of physician by pod laboratories.

Changes to the Reassignment Rule

In the area of the changes to the prohibition on reassignment, CMS makes the following proposals:

> Clarify that physicians acting pursuant to the contractual arrangement exception must still meet the requirements applicable to the purchase of diagnostic testing, with regard to the professional component.

MSP position: **supports** applying current purchased-service limitations in situations of reassignment and clarifying that they apply in the contracted reassignment setting.

Stark Self Referral Provisions

As CMS recognizes, in order to limit these types of practices in all areas, it is also necessary to further clarify specific provisions in the Stark self-referral law. MSP agrees that this clarification is imperative. We are especially concerned that in response to changes in the reassignment rules, discussed above, many pod arrangements will simply restructure and hire pathologists as part-time employees, which could circumvent the purpose of many of these changes. MSP believes that the Stark law may provide the most direct way of curbing these new abuses.

MSP is concerned that in response to the provisions in the Proposed Rule, pod lab oratory arrangements may be restructured so that pathologists will be retained as part-time employees rather than independent contractors. For example, a pathologist could become a part-time employee of several different groups under arrangements that potentially satisfy both the reassignment rules and the physician service or in-office ancillary services exceptions to the Stark self-referral provisions. From the standpoint of the group practice and the retained pathologist, the arrangement need not differ significantly from an independent contractor relationship. Thus, MSP considers it to be essential that CMS address both structures in its rulemaking.

MSP recognizes that some groups may decide to hire their own pathologist, but they should be required to make the same investment in salaries and capital that any other business would have to make in that endeavor and undertake the same type of business risk. They should not be able to avoid that requirement by re-characterizing an "independent contractor" pathologist as a "part-time employee" pathologist, without incurring the additional costs and risk attendant to hiring that person. Without some limitation on this practice, groups will simply restructure without any risk and continue to profit from their own referrals. MSP believes that the part-time employee concern could be addressed through modifications in the "group practice" requirements under the Stark self-referral rules or, potentially, through changes in the employee reassignment provision.

MSP is aware of and **support** suggested alternative regulatory proposals that would address this issue through the "substantially all" requirements for group practices under Stark. In essence, these proposals would require that, in addition to the group practice as a whole having to perform at least 75% of its patient care services through the group, each individual member would need to perform at least one-half of its patient care services through the group. Such a provision could be limited to pathology services or written more boradly. Alternatively, CMS

could, in the same provision of Stark establish a maximum number of group practices to which any one pathologist could belong. MSP would strongly support this approach. These are more fully described in the comments of the American Clinical Laboratory Association, so they need not be repeated in detail here. Basically, if a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

INDEPENDENT LAB BILLING

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

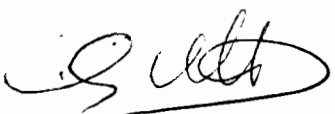
MSP believes that the proposed rule misstates the intention of the proposal to discontinue the Grandfather provision, where it states "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe the intent was to state that "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." We urge CMS to correct this language if this concept is to appear in the final rule.

Given this major change to these historical billing rules, we strongly urge CMS to help hospitals understand their new obligations and move forward to address them to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testing services.

CONCLUSION

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Respectfully submitted,



Emily E. Volk, MD
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October 9, 2006

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October 10, 2006

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

Re: CMS-1321-P—Comments on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B—ASP Issues.

Dear Administrator McClellan:

The Johnson & Johnson family of companies, the world's most comprehensive and broadly based manufacturer of health care products for the consumer, pharmaceutical, medical device and diagnostics markets appreciate the opportunity to submit these comments on behalf of its pharmaceutical Operating Companies who manufacture products reimbursed under Medicare Part B. These comments are in response to the proposed rule published by the Center for Medicare and Medicaid Services' ("CMS") on August 8, 2006, regarding Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B ("Proposed Rule").[1] In particular, these comments focus on the ASP calculation and reporting issues raised in the Proposed Rule.

We generally support the comments submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO"), but we believe it is important to augment their comments in the areas of bundling, bona fide service fees, the use of an estimating methodology for excluding lagged sales, and other issues to reflect our experience and some additional observations and comments. The specific comments we provide in the corresponding sections below are as follows:

[1] 71 Fed. Reg. 48982 (August 22, 2006).

1. *Fees Not Considered Price Concessions*

- CMS needs to clearly define the term "Purchaser," so that it will be clear to all manufacturers whether ASP is to be determined net of price concessions, regardless of whether those price concessions are paid to possession-takers or non-possession-takers.
- CMS' proposed definition of *bona fide* service needs to be more specific. In our comments below we make recommendations that provide certainty to manufacturers as to what types of services qualify for such treatment, i.e., "core" and "non-core" services, and simultaneously provides sufficient flexibility to accommodate evolution in the marketplace.
- CMS should provide guidance on appropriate methods for establishing and documenting fair market value ("FMV"). FMV should be established in an arms length negotiation and the value of the service should be determined independent of the sale or purchase of any product exchanged between the parties.
- CMS needs to either delete the "no pass through" requirement or provide practical guidance on how manufacturers can satisfy this requirement.
- The proposed criteria for *bona fide* service fees *should not* be applied to administrative fees and service fees otherwise protected under the anti-kickback safe harbors. Fees protected under the safe harbor should not be treated as price concessions for purposes of the ASP calculation.
- The treatment of service fees paid to wholesalers and distributors under accounting standards should not determine whether they may be excludable under the ASP calculation

2. *Estimation Methodology for Lagged Exempted Sales*

- Although at first glance CMS's proposed methodology for estimating lagged exempted sales appears reasonable, our comments show that it is flawed and could result in distortions to the ASP. We recommend CMS apply a methodology that ignores the sales units for excludable payer transactions, e.g., SPAPs and Part D transactions, as is done for Medicaid rebates. This would be consistent with the methodology for treating all excludable payers in the Medicaid AMP calculation.

3. *Nominal Sales*

- We support CMS's proposal

4. *Price Concessions for NDCs with Less than 12 Months of Sale and Redesignated NDCs*

- We support CMS's proposal.

5. Intracompany Sales and Transfers

- CMS should issue clear guidance that sales between wholly-owned affiliates should not be included when calculating and reporting ASP.

Our comments on bundling were submitted under separate cover by Ortho Biotech Products, L.P., a Johnson & Johnson company, on September 29, 2006.

Background on ASP Issues

Section 303(c) of the Medicare Modernization Act ("MMA") amended Title XVIII of the Social Security Act by adding new section 1847A which established a new payment methodology for most Part B covered drugs and biologicals furnished on or after January 1, 2005. Section 1927(b) of the Act set forth the requirements for calculation and reporting of manufacturers' ASPs on a quarterly basis. On April 6, 2004, CMS published an interim final rule with comment period ("IFC") (69 Fed. Reg. 17935) to implement the ASP calculation and reporting requirements and on September 16, 2004, CMS published a final rule addressing only those comments relating to the methodology for estimating lagged price concessions. CMS has addressed other narrow issues related to ASP calculation and reporting requirements in rulemaking implementing the Competitive Acquisition Program. (70 Fed. Reg. 39069; 70 Fed. Reg. 45842; 70 Fed. Reg.70215, and 70 Fed. Reg. 70477).

In addition, CMS has issued certain guidance letters, such as the one addressed to HDMA and SBDA dated December 9, 2004, and numerous questions and answers to manufacturers available on its website in an effort to address calculation and reporting issues. This guidance was not issued with notice and an opportunity for comment.

It is also relevant that the Office of Inspector General for the Department of Health and Human Services ("OIG") has been auditing manufacturers' ASPs for compliance during this interim period. The OIG does not appear to fully understand how CMS intends that manufacturers apply the service fee guidance. Manufacturers have also indicated that they are uncertain as to how to interpret and apply much of the guidance. J&J has repeatedly sought additional guidance from CMS. We are very grateful, indeed, that CMS has issued the Proposed Rule and is seeking comment on a range of important ASP issues. CMS is to be congratulated for taking this step.

Despite the current need for greater clarity in ASP reporting, it is significant that a manufacturers' CEO, CFO or an authorized, direct report to one of these two executives must certify a manufacturer's quarterly ASP submission, subject to penalties of $10,000 per day for each incorrectly calculated ASP or for ASP not timely submitted. The need for clarity is underscored by this fact and the burden that it creates.

A. Fees Not Considered Price Concessions

CMS has proposed to prospectively change its bona fide service fee guidance "beginning with the ASP reporting for sales during the first calendar quarter of 2007. The prospective changes would affect bona fide service fees that are paid by a manufacturer to an entity, whether or not the entity takes title to the drug. Bona fide service fees are not considered price concessions under § 414.804(a)(2) insofar as, and to the extent that, they satisfy the definition of a bona fide service fee that is now proposed at § 414.802. It is important that the changes would only have a prospective impact as they are substantive in nature.

The proposed definition at § 414.802 states that bona fide service fees are:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Accordingly, CMS proposes that fees paid to group purchasing organizations ("GPOs") or pharmacy benefit managers ("PBMs"), including service fees, administrative fees, and other fees, will not be categorized as price concessions for purposes of § 414.802(a)(2) only "insofar as, and to the extent that" they satisfy this proposed definition. 71 Fed. Reg. 49001. This represents a departure from the guidance previously released in the form of the HDMA and SBDA letter, which was specifically addressed only to wholesaler and distributor trade associations.

CMS requests comments on and is considering providing further guidance regarding:

(1) the types of services that may qualify as bona fide services (which could vary by drug category);

(2) the methodology manufacturers must use to determine the fair market value of a bona fide service (and seeks comments specifically on whether fees "tied to performance of a service, fixed fee, revenue generated by product sales, or other basis" may represent fair market prices);

(3) "appropriate methods for determining whether a fee is passed on in whole or in part"; and

(4) any implications that the treatment of service fees for ASP calculation purposes differently from the treatment of such fees for financial accounting or other purposes may have for manufacturers.

1. CMS Should Define the term "Purchaser"

In the preamble to the proposed rule, CMS proposes that its rule on *bona fide* service fees apply to entities "whether or not the entity takes title to the drug." This text begs the question of whether CMS intends for this criteria to apply for purposes of determining who is a "purchaser" under the ASP statute. We urge CMS to define the term "purchaser" so as to specifically address the relevance of whether an entity takes title in determining the effect of discounts, rebates and other price concessions. This critical term and it interpretation have fundamental effect on whether discounts, rebates and other price concessions must be included in the ASP calculation when paid to GPOs, PBMs, and other non-possession-takers. Given the potential for different interpretations of this fundamental question t create an uneven playing field, we believe that this term should be clearly defined so as to ensure that manufacturers calculate ASP in a consistent and compliant manner.

2. CMS Should Establish a Definition of *Bona Fide* Services that Provides Manufacturers with Sufficient Certainty as to what Types of Services Qualify for Treatment as *Bona Fide* Services and Simultaneously Retains Sufficient Flexibility to Accommodate the Inevitable Evolution of Services in the Marketplace.

While J&J supports CMS' confirmation of the general principle that "bona fide service fees" do not constitute price concessions, we are deeply concerned with several aspects of CMS' proposed standards for identifying "bona fide service fees".[2] The definition being proposed by CMS is similar in some respects to the guidance previously issued on this question, but there are many components of the proposal that are problematic.

We are particularly concerned about the statement that the itemized service must relate to a service "the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement." This quoted language raises practical issues for manufacturers because some services that a manufacturer may seek to procure from a wholesaler, for example, cannot be performed by the manufacturer itself or by a third-party who is not also purchasing and reselling the product. Examples of this would be fees paid for inventory management or data related to the end customers for manufacturer's products. The fact that these services are provided by entities that are customers as well as service providers does not in any way change the fact that the services are, in fact, services, and not price concessions.

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[2] CMS proposed to define a bona fide service fee as fees paid by a manufacturer to an entity (i) that represent fair market value, (ii) for a bona fide, itemized service actually performed on behalf of a manufacturer, (iii) that the manufacturer would otherwise perform (or contract for) in the absence of the service agreement, and (iv) that are not passed on, in whole or in part, to a client or customer of the entity.

We recommend that the standard be amended to require that a service be "reasonably necessary to accomplish [a] commercially reasonable business purpose of the manufacturer." This standard is already used in the personal services safe harbor at 42 C.F.R. § 1001.952(d)(7) and has been given meaning by interpretations under that regulation. This standard allows manufacturers the necessary flexibility to enter into appropriate substantive service relationships without focusing on the "form" by which they do so. It also has the value of aligning the relevant fraud and abuse and the price reporting guidance.
CMS also stated that the Agency is considering issuance of a list of services for which fees can be paid to wholesalers, distributors, Specialty Distributors and Specialty Pharmacy Providers ("SPPs"). CMS identified handling, storage, inventory reporting, shipping, receiving, patient education, disease management and data as appropriate services. CMS further stated that it is seeking comments regarding (1) activities that should not be considered bona fide services, (2) bona fide services that relate to unique types of products and circumstances, and to all or specific types of products, and (3) the costs and relative costs of such services.

First, we agree that the specific services identified by CMS can be treated as *bona fide* service fees. Indeed, we believe that this fact is well-established within the industry and self-evident, given the robust and important nature of these services.

In addition, however, we believe that these particular services should be characterized as examples only, as there are many other services that a manufacturer may seek. In light of this, CMS should issue guidance in the form of principles or a standard that can be applied to identify other services not specifically identified by CMS or not yet developed in this rapidly evolving industry.

Given the uncertainty created by CMS' call for comments on the nature of the services that may be subject to the guidance, it is especially critical that CMS be clear on the point of whether it is permitting fees to be paid on "core" and "non-core" services, as the wholesaler and distributor industry is rapidly moving to a fee-for-service model for both "core" and "non-core" services. "Core" services are those that are typically provided by a wholesaler or distributor, such as shipping and delivery services, and "non-core" services are those that are less regularly provided by a wholesaler or distributor, such as data fees (since a manufacturer may or may not elect to receive that service from its wholesalers and distributors). Therefore, we urge CMS to state plainly in the guidance it issues that it is appropriate to pay those entities subject to the guidance for their core and non-core services. We note that the prior guidance issued by CMS made no distinction between core and non-core services, and we believe that CMS should make no distinction between these services. What matters in both situations, is that the services, whether core or non-core in nature, are, in fact, services and not price concessions.

We believe that guidance expressed in this manner will provide sufficient elasticity for the rule to accommodate the rapid evolution in these markets. We do not believe that guidance issued by CMS should be more granular in detail than this, aside from some

relevant examples to explain what is meant by "core" and "non-core," as we believe that such an approach would unnecessarily restrict the market and inhibit the development of new services.

3. CMS Should Provide Guidance on Appropriate Methods for Establishing and Documenting Fair Market Value

CMS' "current guidance provides that bona fide service fees means expenses that would have generally been paid for by the manufacturer at the same rate had these services been performed by other entities." 71 Fed. Reg. 49001. This limited guidance is insufficient to reasonably apprise manufacturers of the methods that may be used to establish the fair market value ("FMV") of *bona fide* services.

The proposal, with its reference to compensation that is the same as what would be paid to "other entities," is ambiguous. It may be read or misread to create the impression that fair market value cannot be determined where the services can only be provided by the type of entity from which they were secured, as in the case of inventory management and wholesaler and distributor data fees. Fair market value can be determined and paid in such circumstances, and ASP reporting will not be accurate, as intended by Congress, unless the true nature of these fees are reflected in price reporting.

Accordingly, we propose that FMV be defined as:

> that price at which items or services would be exchanged between a willing buyer and seller, neither being under any compulsion to buy or sell and both having reasonable knowledge of the relevant facts, and without consideration of either party's position to make or influence orders or utilization, to furnish items or services to, or otherwise generate business for the other party at the time of the agreement.

This proposed definition, which is consistent with the relevant fraud and abuse guidance, captures the central concept that the value be established in an arms length negotiation. Further, it captures the important element that the value of the service be determined independent of the sale or purchase of any product exchanged between the parties.

In developing guidance on what manufacturers must do to establish FMV, CMS must acknowledge that FMV is not a precise value, but a range of values. Therefore, CMS should explicitly acknowledge that FMV exists in a range, rather than a single price point. (In other words, any price *within this range* and meeting the other criteria, should not be considered a price concession.)

We further request that CMS issue guidance that any reasonable method of determining FMV is acceptable for purposes of this proposed rule. To clarify, we consider the following approaches, based on consultation with valuation experts, to be appropriate methods for manufacturers to use to establish FMV:

- A Cost Build-up Method (a form of Cost Approach)
    - This is an activity-based approach derived from determining the cost to perform the required service.
- A Similar Transaction Method (a form of Market Approach)
    - Manufacturer looks at comparable transactions in the market place.
- An Income Approach
    - Manufacturer looks at the present worth of a future economic benefit.
    - The value is dependent on the amount and timing of cash flows generated by the service.

We ask that, without indicating that these are the only methods that may be employed, these are among the methods that can, in fact, be used in full compliance with the guidance and the reporting obligations.

We caution CMS on the risks of establishing thresholds for fees that it considers to be FMV for a particular service. The reality is that such an approach would undermine manufacturers as they negotiate with wholesalers, distributors and SPPs to negotiate lower prices for specific services. To the extent that CMS establishes a presumption that a certain dollar or percentage is FMV for those services, the market will move to that point and the lowest cost will not be realized. We believe that this threat is particularly significant to the extent that CMS establishes a safe harbor for certain fees as a percentage of sales.

We wish to note that the form of a payment, whether it is fixed, in the form of a percentage of sales, or expressed in any other manner, is not determinative of fair market value. Regardless of the form of the payment, a given payment may be or may not be fair market value. CMS should explicitly acknowledge that the form of the payment is not determinative in its final rule.

We urge CMS to require that the analysis and assumptions used to establish the FMV of a service should be documented, retained, and made available in the event of an audit. We do not believe, however, that this analysis should be included with a manufacturer's assumptions that are part of their quarterly ASP submissions. A requirement like that, given the range of service agreements that a manufacturer may have, would be burdensome on both manufacturers and CMS. If CMS is unwilling to rely upon the audit process to obtain this information, CMS should permit manufacturers to provide transparency to excluded *bona fide* service fees by disclosing the types of services provided and the range of fees paid in a summarized form with their quarterly ASP submission. (This would be similar to what has been considered for prompt pay discounts paid to wholesalers that will be excludable from Medicaid AMP calculations pursuant to the Deficit Reduction Act.)

4. CMS Should Delete the "No Pass Through Requirement" from the Definition of *Bona Fide* Service Fee, or in the Alternative, Provide Clear Guidance on what efforts on the part of the manufacturer will Satisfy this Requirement.

We disagree with the fourth proposed requirement in CMS' proposed criteria for *bona fide* service fees. This is the requirement that fees not be passed on to a client or customer of the recipient.

In this context, the central question in evaluating whether amounts from a payor constitute a discount offered by the payor or a fee paid for a service is whether the payor intends it to be passed on to a downstream entity, not whether a service provider actually chooses, for its own reasons and based on its own independent decisions, to pass some portion of the fees to a downstream entity.

As a practical matter, manufacturers generally are not in a position to know whether, when, or how such a pass-through may occur. For example, if a wholesaler or distributor entity makes a profit on a service performed for a manufacturer (which is entirely consistent with the requirement that any payment be fair market value), the entity might use that profit to subsidize a lower price to its customers, but the manufacturer would have no way of knowing or monitoring the degree to which its payment subsidized those lower prices. Nor should the wholesaler's or distributor's independent decision be attributed to the manufacturer under these circumstances.

By the same token, of course, where the wholesaler or the distributor and a manufacturer agree that some portion of a fee will be passed on to a downstream customer, the affected portion of the fee would represent a discount, and not a service fee.

To the extent that CMS does maintain its no pass through requirement, it must implement it in a manner that is as practical as possible. Accordingly, if CMS makes the decision to continue with this requirement, it should explicitly state that a service provider's contractual representation that it will not pass on a fee provides a sufficient basis for a manufacturer to comply with this requirement.

5. CMS Should Not Apply the Proposed Rule to Administrative Fees Protected under the Anti-Kickback Safe Harbor for Group Purchasing Organizations.

CMS is proposing to apply the same criteria that apply to bona fide service fees to administrative fees for group purchasing organizations as a condition for such fees to be excludable from the ASP calculation. CMS proposes that this requirement apply prospectively, starting with the first Quarter 2007. This proposal raises questions about the relationship of this proposed rule with the anti-kickback safe harbor on GPO administrative fees, at 42 C.F.R. § 1001.952, which applies more broadly than just to drugs reimbursed under Medicare Part B.

We strongly disagree with CMS' proposal to extend its criteria for "bona fide service fees" to GPO administrative fees. The anti-kickback safe harbor at 42 C.F.R. § 1001.952(j) specifically protects administrative fees paid to GPOs, and contains no requirement that such fees meet standards such as those that CMS is proposing here. For example, CMS proposes that bona fide service fees must be "itemized." No such requirement exists in the anti-kickback safe harbor, nor can such a requirement be easily applied in the context of GPO fees.

While such fees account for some relatively definable "services," such as group contract negotiation, contract marketing and contract administration, they also reflect that Congress made a public policy decision that the costs of group purchasing may be allocated to vendors in light of the efficiencies associated with group purchasing. This latter factor is not easily subject to "itemization."

Likewise, there is no requirement in the GPO safe harbor specifying that group purchasing services must be of a type that would otherwise be performed by a manufacturer or limiting a GPO's ability to pass such excess administrative fees through to their members, and again, both of these proposals pose practical difficulties. For example, some GPOs are owned in part by their members, and the members may be entitled to investment returns based on their ownership interests if the GPO is profitable. Not only do we not believe that such returns should not be viewed as price concessions, but also manufacturers are not in the position to access or demand information concerning GPOs' internal distributions to their members.

In short, the proposed "actual pass-through" test is both misplaced and unworkable in our view in the context of GPOs, and will only create greater uncertainty for manufacturers who seek to comply with applicable anti-kickback safe harbors.

Further, while CMS' proposed criteria would apply to manufacturers of Part B drugs, without simultaneously amending the GPO safe harbor, the same fees could be treated differently by the two parties to an arrangement—a manufacturer may be required to characterize such fees as price concessions for reporting purposes and yet GPO members may characterize such fees differently in their cost reports in order to attempt to lay claim to the safe harbor.

Manufacturers have structured their GPO and PBM relationships for more than a decade on the GPO safe harbor, and have been encouraged to do so by the OIG's model compliance guidance document for pharmaceutical manufacturers. Indeed, manufacturers came to rely on the fraud and abuse standards created by the GPO safe harbor for price reporting purposes precisely because no price reporting guidance was available. Given that manufacturer reliance has been so strong on the safe harbor, the importance of consistency in anti-kickback and price reporting guidance, and the safeguards present in the GPO safe harbor, CMS should formally adopt the position that administrative fees that comply with the safe harbor are not price concessions for price reporting purposes.

6. The Treatment of Service Fees Paid to Wholesalers and Distributors Fees for Financial Accounting Purposes Should Not Impact their Recognition as Excludable *Bona Fide* Service Fees for Purposes of the ASP Calculation

CMS has proposed that *bona fide* service fees, meeting the criteria outlined above, may be excluded from price calculations based on the view that when they meet such criteria they do not act as a reduction to the price realized by the manufacturer. Separately, the Financial Accounting Standards Board ("FASB") has issued guidance that some might interpret to require that such fees must be treated as a price concession, to the extent that the services must be or are typically secured from a customer. Although we do not believe that FASB's rule *requires* that such fees be treated as price concessions, we believe that the financial accounting rules should not have any bearing on the price reporting rules, in any event.

FASB's Emerging Issues Task Force ("EITF") issued guidance addressing the appropriate accounting by a vendor, such as a manufacturer, for service fees and for sales incentives or consideration that are paid to a reseller, such as a wholesaler or specialty distributor. This guidance establishes a presumption that cash consideration given by a vendor to a customer is a reduction of the selling prices of the vendor's products or services, and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement. EITF Issue No. 01-09, "Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products," November 2001. The presumption is not intended to and does not purport to yield an accurate outcome in any particular circumstance or situation.

Significantly, EITF goes on to state that the presumption that such fees are discounts or price concessions is overcome, if the following conditions are met:

a. The vendor received, or will receive, an identifiable benefit (goods or services) in exchange for the consideration. In order to meet this condition, the identified benefit must be *sufficiently separable* from the recipient's purchase of the vendor's products such that the vendor could have entered into an exchange transaction with a party other than a purchaser of its products or services in order to receive that benefit.

b. The vendor can reasonably estimate the fair value of the benefit identified under condition (a). If the amount of consideration paid by the vendor exceeds the estimated fair value of the benefit received, that excess amount should be characterized as a reduction of revenue when recognized in the vendor's income statement.

(Emphasis added.)

The FASB rule contemplates that "consideration," even though it may be in exchange for a service, should nevertheless be treated as a "reduction in revenue" for accounting purposes, because of the public interest in conservatively determining the amount of corporate revenues. Accordingly, treatment of an item under the FASB standard as a "reduction in revenue" is not necessarily inconsistent with its treatment as a bona fide service fee for price reporting purposes, precisely because the criteria for determining that a fee is a *bona fide* service fee are different than the criteria in EITF 01-09, which, of course, address fundamentally different issues and concerns.

The FASB rule requires a service to "be sufficiently separable from the recipient's purchase of the vendor's products such that the vendor could have entered into an exchange transaction with a party other than a purchaser of its products or services in order to receive that benefit." By contrast, CMS' proposed criteria is that the "itemized service actually [be] performed on behalf of the manufacturer [and] the manufacturer would otherwise perform (or contract for) [these services] in the absence of the service arrangement."

Accordingly, some items which CMS has, in our view, recognized as *bona fide* services, such as data, inventory management functions, and shipping and handling, may not be "sufficiently separable" from the products themselves to meet the FASB requirement to be treated as expenses. Nevertheless, these services must not be treated as price concessions for price reporting services, if ASPs are to be an accurate reflection of net prices on pharmaceutical products, as required by the MMA and intended by Congress.

In short, the criteria laid out by CMS and FASB for their respective and quite different reporting requirements are entirely distinct and reflect their quite separate purposes. In light of the different purposes of the reporting regimes, CMS should not consider the accounting rules in defining the price reporting requirements, and CMS should specifically acknowledge that a manufacturer's treatment of such fees for financial accounting purposes is not determinative of their treatment for ASP calculation purposes.

B. Estimation Methodology For Lagged Exempted Sales

Section 1847A(c) (2) of the Act requires manufacturers to exclude from the calculation of ASP those sales that are exempt from Medicaid best price ("BP") calculations, such as Medicare Part D sales, State pharmacy assistance programs ("SPAPs") and Federal sales. CMS seeks to establish a uniform methodology for excluding exempt sales that are known on a lagged basis. 71 Fed. Reg. 49002. CMS lays out a proposed methodology for excluding lagged exempt sales and characterizes the proposed methodology as "similar to the methodology manufacturers are required to use to estimate price concessions known on a lagged basis." CMS expresses that it believes this approach, which it considers to be similar to the approach used for estimating lagged price concessions, "is reasonable and reduces potential errors in the manufacturers' ASP calculations, while assuring that exempted sales are appropriately removed from the ASP

calculation." CMS disclosed that some manufacturers recommended the proposed methodology.

1. CMS' Proposed Methodology Distorts the ASP in Practical Application

We support CMS in its quest to establish a reasonable and consistent method for estimating lagged exempted sales that may be excluded from manufacturers' ASP calculation. At first glance, the proposed methodology appears reasonable. *We contend that in actuality it is seriously flawed and will produce unanticipated and unreasonable results, in the nature of negative units, negative ASPs, and increased quarterly fluctuations.* We believe that CMS' proposal generally will move the ASP further away from representing the true average price to purchasers. The following paragraphs explain why.

To understand the following explanation, it is important to first recognize that the ASP methodology counts only a single unit in the denominator for each manufacturer "sale," yet accumulates the discounts and price concessions associated with multiple "price" transactions throughout the supply chain in the numerator, such as to a distributor, a provider and a payer (who never actually purchases the product). CMS' proposed methodology assumes that excluding (subtracting) certain transactions from the calculation will reflect a net zero impact on the ASP, as if that "sale" did not occur. It doesn't accomplish this objective because, as explained above, there may be multiple price-related transactions in the supply chain related to one unit. To exclude an excludable sale from the ASP calculation in the manner proposed by CMS, one must be able to identify *all* price concessions associated with an excludable transaction, including those given upstream in the supply chain. For example, it would not be sufficient to exclude only the price concessions given to an SPAP itself; a corresponding reduction would need to be made in the price concessions, if any, given to providers and distributors, for those same units. Otherwise, those price concessions would remain in the calculation while the corresponding unit is excluded from the calculation. This would distort the ASP calculation.

2. Two Significant Conceptual Issues Are Overlooked by CMS' Proposed Methodology for Estimating Lagged Excludable Units

- *Multiple price concessions may be associated with a single excludable unit.* As a result, if units to an excludable customer were excluded (subtracted), the includable discounts on that sale would remain in the calculation with no related units. This is best illustrated through example. Assume a sale of 1 unit is made at $100 through a distributor who receives a $2 discount to a provider who is under contract for a $3 discount and that the sale is then reimbursed by a PDP (Part D). The CMS proposed methodology would exclude the Part D sale (1 unit, $100) but the $2 discount to the distributor and the $3 discount to the provider would remain

in the ASP calculation. This would clearly distort ASP. *See Appendix A, Scenario 1, CMS Proposed Calculation.*

- *Multiple exclusions may be applicable to single unit.* Some sales may be excludable under more than one government program. If these units are excluded more than once, as is possible under CMS' proposed methodology, the adjustment for excluded sales and units would be overstated. This would tend to inflate ASP. Assume, for example, that a sale of 2 units is made at $100 each through a distributor who receives a $2 discount per unit. Assume that one of these units is sold to 340B eligible provider who receives a $3 discount and that this unit is then reimbursed by a PDP (Part D). CMS' proposed methodology would exclude 2 units and $200 in sales—one for the sale to the 340b eligible provider and one for the Part D sale—even though both discounts and units relate to the same physical unit sold by the manufacturer. It would leave the initial discount to the distributor for the units, in the calculation. This would clearly distort ASP. *See Appendix A, Scenario 2.*

The other reason for the distortion that will be caused by CMS' proposed methodology, is that an actual "sale" only occurs with certain customer types that physically purchase product, namely distributors and providers. The inclusion of payers (SPAP, Part D Plans, etc) in the definition of purchasers and the treatment of them as though they were like purchases causes distortion. In fact, payers typically do not purchase product and the exclusion of their "sales" by subtracting them creates a number of issues such as those noted above. Our recommended methodology described below not only simplifies the methodology but also better reflects the Average Sales Price to purchasers.

There are practical problems raised by the proposed methodology as well. First and foremost, for products with significant excludable sales that have been handled differently in the past, the new methodology may result in a significant change in ASP. Similarly, by using a 12-month rate that may be skewed because of increasing or decreasing sales, the proposed methodology may produce an ASP that is not reflective of current quarter pricing. Additionally, since 12 months of sales may not be available for all excludable sales programs (specifically 12 months of Part D data will not be available until mid-2007), the 12-month rate will be skewed. It would not be practical to evaluate excludable sales on a program-by-program basis. While the use of a 12-month rate tends to smooth quarter-to-quarter fluctuations, it also raises timing issues.

The complexities associated with CMS' proposed methodology are evident. Ensuring accuracy becomes more challenging as the calculations become more complex and new data types are introduced to the calculation. If CMS elects to proceed with the proposed methodology, further clarification regarding the data to be used will be required. For instance, should the payer data (utilization based transactions) be applied to a quarter based on period earned or paid? Also, utilization data received from payers typically only include units. The original purchase price often cannot be established. To apply

CMS' proposed methodology, a dollar value would need to be assigned to these units. This assignment can be subjective and use of terms in a contract may not be appropriate.

2. CMS Seeks Suggestions On Alternative Methodologies That May Be Less Complex.

We recommend applying current exclusion methodologies to the new excludable customer types (SPAP, Part D) and any future programs. Specifically, for purchasers (Federal purchasers, CAP, etc) this means subtracting the sales units, from the included distributor sale, resulting in a net zero impact. For payers (those customers who do not purchase product and thus their transactions represent utilization, not a purchase or sale, e.g., SPAPs and Part D plans) this means ignoring the sales units, just as is done for Medicaid utilization. Ignoring payer transactions would effectively exclude the discounts to those entities in a way that does not distort the ASP units or the end calculation. This would eliminate the conceptual issues raised above, as well as the practical issues identified above. This would be consistent with the current requirement for handling State Medicaid rebates within the ASP calculation methodology.

C. Nominal Sales

Section 1847A of the Act requires manufacturers to exclude from the ASP calculation sales that are merely nominal in amount, making reference to the Medicaid rebate agreement. Now that the Deficit Reduction Act ("DRA") has narrowed the Best Price exemption for "nominal" sales after January 1, 2007 to apply only to nominal sales (sales below 10% of AMP for that period) that are made to certain entities (340B covered entities, intermediate care facilities for the mentally retarded, State-owned for operated nursing facilities, and other safety-net providers identified by CMS), CMS has proposed that § 414.804(a)(4) be clarified to state that manufacturers must continue to use the Medicaid threshold (less than 10% of that quarter's AMP) to determine nominal sales, subject to the additional limitations imposed in section 1927(c)(1)(D) of the Act.

We support CMS' proposal to continue to use Medicaid AMP as the basis for determining nominal sales, with the addition of the new limitations on nominal imposed by the DRA. The ASP calculation is sufficiently complex as is without imposing yet another definition of nominal for purposes of this calculation. We advocate that CMS continue to identify opportunities, such as this, to simplify the ASP calculation, particularly when that objective can be achieved with little or no financial impact to the resulting ASPs, as is the situation here.

D. Price Concessions For NDCs With Less Than 12 Months Of Sales And Redesignated NDCs

In response to manufacturer's requests for guidance on how to determine estimated price concessions when an NDC has been sold for less than 12 months, CMS proposes to

revise § 414.804(a)(3) to specify that the period used to estimate lagged price concessions is the total number of months the NDC has been sold (except in situations when the manufacturer has redesignated the product's NDC).

We support this proposal. We also support CMS' proposal that when an NDC is changed (except when a product is repackaged or relabeled by a different manufacturer or relabeler or is privately labeled) and lagged price concessions remain in effect, the manufacturer must use 12 months of sales and price concession data from the prior and the redesignated NDCs to estimate lagged price concessions applicable to the redesignated NDC.

E. Intracompany Sales And Transfers

CMS recognizes that stakeholders have more experience with the ASP calculation now than they did at the time that the IFC was issued and express that they are seeking input on the ASP calculation that reflect this greater experience. 71 Fed. Reg. 49000. In this regard, we have identified that neither the text of the ASP provisions nor any of the implementing regulations specifically address the treatment of intracompany sales, such as those between wholly-owned affiliates. We request CMS clarify in regulation that intracompany sales between wholly-owned affiliates should not be included when calculating and reporting ASP. This interpretation is supported by analysis of the statute and legislative history.

The amended Social Security Act provides that "a manufacturer's 'average sales price' means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

> (A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by
> (B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

42 U.S.C. § 1395w-3a.

Therefore, it is established that the Medicare ASP provisions were designed to ensure that prices paid for drugs under Medicare Part B more closely mirror the actual acquisition cost for those drugs. The statute and accompanying legislative history make clear that Congress instituted the ASP methodology out of a perceived concern that the previous payment methodology for Medicare Part B drugs, which was based on average wholesale price ("AWP"), did not reflect market reality. *E.g.* Conference Report No. 108-391, 108th Cong. 1st Sess. at 582 (November 21, 2003) ("There is substantial evidence that indicates that AWPs for many Medicare-covered products far exceed the acquisition cost paid by suppliers and physicians.").

Congress, therefore, instituted the ASP methodology to ensure that payment for Part B drugs will be consistent with actual acquisition costs. Including intracompany sales when calculating ASP would be inconsistent with these principles. Prices set for sales between subsidiaries may not be comparable to the prices available to third-party purchasers in the marketplace for prescription drugs. Instead, intra-company prices may reflect various internal considerations. Therefore, the prices may not reflect the actual acquisition cost for commercial purchasers and may not provide a logical basis for establishing prices to be paid under Medicare Part B. Indeed, including intracompany sales when calculating ASP could result in inaccurate price data being reported to CMS.

For these reasons, we urge CMS to clarify in regulation that intracompany sales between wholly-owned subsidiaries should be excluded from the ASP calculation.

Conclusion

We thank you for the opportunity to comment on these important regulations. The Johnson & Johnson family of companies strongly supports CMS' efforts to develop robust and meaningful guidance for manufacturers to follow in the development and submission of ASP data. We believe that only through this process of close collaboration with industry can the objectives of Congress be achieved by establishing meaningful ASP reporting requirements and reasonable reimbursement levels for providers that will generate access to drugs and biologics for Medicare Part B beneficiaries as Congress intended.

Respectfully,

Stephanie P. Gilson

Assistant General Counsel

APPENDIX A

Scenario 1		A	B	C		
J&J Proposed	*Customer*	*Distributor*	*Provider - Eligible*	*Payer - Excludable*	*Calculation*	*Calculation -formula*
	Sale $	$ 100.00	$ 100.00	$ 100.00	$ 100.00	A
(Ignores Payer transaction)	Units	1	1	1	1	A
	Discount	$ 2.00	$ 3.00	$ 15.00	$ 5.00	A+B
	Net Price	$ 98.00	$ 97.00	$ 85.00	$ 95.00	(Sales$-Disc)/Units
	Methodology reflects cumulative eligible discounts applied to the one unit of sale					
CMS Proposed	*Customer*	*Distributor*	*Provider - Eligible*	*Payer - Excludable*	*Calculation*	*Calculation -formula*
	Sale $	$ 100.00	$ 100.00	$ 100.00	$ 0.00	A-C
(Subtracts Payer transaction)	Units	1	1	1	0	A-C
	Discount	$ 2.00	$ 3.00	$ 15.00	$ 5.00	A+B
	Net Price	$ 98.00	$ 97.00	$ 85.00	$ No Result (a)	(Sales$-Disc)/Units
	Methodology reflects cumulative eligible discounts applied to original sale less excludable sale					

Scenario 2		A	B	C		
J&J Proposed	*Customer*	*Distributor*	*Provider - Excludable*	*Payer - Excludable*	*Calculation*	*Calculation -formula*
	Sale $	$ 200.00	$ 100.00	$ 100.00	$ 100.00	A-B
(Subtracts Provider transaction; Ignores Payer transaction)	Units	2	1	1	1	A-B
	Discount	$ 4.00	$ 3.00	$ 15.00	$ 4.00	A
	Net Price	$ 98.00	$ 97.00	$ 85.00	$ 96.00	(Sales$-Disc)/Units
	Methodology reflects cumulative eligible discounts applied to the one unit of sale					
CMS Proposed	*Customer*	*Distributor*	*Provider - Excludable*	*Payer - Excludable*	*Calculation*	*Calculation -formula*
	Sale $	$ 200.00	$ 100.00	$ 100.00	$ 0.00	A-B-C
(Subtracts Provider transaction; Subtracts Payer transaction)	Units	2	1	1	0	A-B-C
	Discount	$ 4.00	$ 3.00	$ 15.00	$ 4.00	A
	Net Price	$ 98.00	$ 97.00	$ 85.00	$ No Result (a)	(Sales$-Disc)/Units
	Methodology reflects cumulative eligible discounts applied to original sale less excludable sales					

Note:

a) ASP eligible units calculation results in 0 units therefore Net Price per unit can not be calculated.

AAWC

October 10, 2006

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http://www.cms.hhs.gov/eRulemaking

CMS-1321- P, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

PROVISIONS Section Comments:

The Association for the Advancement of Wound Care (AAWC) is a multi-disciplinary wound care specialty organization of physicians, physical therapists, nurse practitioners, clinical nurse specialist, researchers and certified wound care nurse experts. As the largest professional organization dedicated to the advancement of wound care, the AAWC respectfully submits our comments regarding changes to the method of payment for casting and strapping supplies proposed for the 2007 Physician Fee Schedule.

PROVISION SECTION

2. Payment for Splint and Cast Supplies (beginning page 31)

In the Physician Fee Schedule (PFS) final rule published November 1999 (64 FR 59380) and November 2000 (65 FR 65376), CMS removed splint and cast supplies from the practice expense (PE) database for the CPT codes for fracture management and cast/strapping application procedures. Because splint and cast supplies could be separately billed using Healthcare Common Procedure Coding System (HCPCS) codes (Q4001-Q4051) that were established for payment of these supplies under section 1861(s)(5) of the Act, CMS did not want to make duplicate payment under the PFS for these items.

In the CY 2006 PFS proposed rule (70 FR 70116), CMS proposed to reinstate payment for all splints and cast supplies through the PE component of the PFS because they believed they may have **unintentionally prohibited remuneration for these supplies when they are not used for reduction of a fracture or dislocation (covered under section 1861(s)(5) of the Act),** but rather are provided (and

covered) as "incident to" a physician service under section 1861(s)(2)(A) of the Act. This proposal was not finalized in the final rule. However, CMS asked the medical specialties and the PERC to determine the typical supplies for splints and casts necessary for each of the fracture management codes and the cast/strapping application codes to be certain that the supply inputs were correct before we proceeded with rulemaking for the CY 2007 PFS.

At its February 2006 meeting, the PERC reviewed and approved the supply inputs submitted by the American Association of Orthopedic Surgeons for each CPT code for fracture management and cast/strapping application and these were forwarded to us as PERC recommendations. During this interim period, CMS also reassessed the options for payment of materials for splints and casts.

CMS believes that the majority of the splint and cast supplies that are currently paid through the Q-codes are furnished in relationship to cast/strapping procedures for the management of fractures and dislocations. However, CMS did not intend for the medically necessary splint and cast supplies used for other reasons (for example, serial casting, wound care, or protection) not to be paid. Because it may be difficult for the contractors to identify the purpose for the cast/strapping application procedure on a claim form, CMS believes that contractors may have been paying for the splint and cast supply Q-codes when the service is performed for other purposes than treatment of fractures and dislocations.

Since these splint and cast supplies can be covered under both sections 1861(s)(5) and 1861(s)(2)(A) of the Act, CMS is proposing to include payment for both statutory benefits using the separate HCPCS Q-codes. This would allow for payment for these medically necessary supplies whether based on sections 1861(s)(5) or 1861(s)(2)(A) of the Act, while ensuring that no duplicate payments are made.

Physicians would continue to bill the HCPCS Q-codes, in addition to the cast/strapping application procedure codes, to be paid for these materials. The following supplies would continue to be paid separately using the HCPCS Q-codes and would not be included in the PE database upon adoption of this proposal:

- Fiberglass roll
- Cast padding
- Cast shoe
- Stockingnet/stockinette
- Plaster bandage
- Denver splint
- Dome paste bandage
- Cast sole

- Elastoplast roll
- Fiberglass splint
- Ace wrap
- Kerlix
- Webril
- Malleable arch bars and elastics

The splint and cast supplies would not be included in the PEs for the following CPT codes:

- 24500 through 24685
- 25500 through 25695
- 26600 through 26785
- 27500 through 27566
- 27750 through 27848
- 28400 through 28675
- 29000 through 29750. (29580 Unna Boot application often used for compression application and 29445 used for contact cast application)

Descriptions for Current Q-Codes

Q4001	00100	CASTING SUPPLIES, BODY CAST ADULT, WITH OR WITHOUT HEAD, PLASTER
Q4002	00100	CAST SUPPLIES, BODY CAST ADULT, WITH OR WITHOUT HEAD, FIBERGLASS
Q4003	00100	CAST SUPPLIES, SHOULDER CAST, ADULT (11 YEARS +), PLASTER
Q4004	00100	CAST SUPPLIES, SHOULDER CAST, ADULT (11 YEARS +), FIBERGLASS
Q4005	00100	CAST SUPPLIES, LONG ARM CAST, ADULT (11 YEARS +), PLASTER
Q4006	00100	CAST SUPPLIES, LONG ARM CAST, ADULT (11 YEARS +), FIBERGLASS
Q4007	00100	CAST SUPPLIES, LONG ARM CAST, PEDIATRIC (0-10 YEARS), PLASTER
Q4008	00100	CAST SUPPLIES, LONG ARM CAST, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4009	00100	CAST SUPPLIES, SHORT ARM CAST, ADULT (11 YEARS +), PLASTER
Q4010	00100	CAST SUPPLIES, SHORT ARM CAST, ADULT (11 YEARS +), FIBERGLASS
Q4011	00100	CAST SUPPLIES, SHORT ARM CAST, PEDIATRIC (0-10 YEARS), PLASTER
Q4012	00100	CAST SUPPLIES, SHORT ARM CAST, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4013	00100	CAST SUPPLIES, GAUNTLET CAST (INCLUDES LOWER FOREARM AND HAND), ADULT (11 YEARS
Q4013	00200	+), PLASTER
Q4014	00100	CAST SUPPLIES, GAUNTLET CAST (INCLUDES LOWER FOREARM AND HAND), ADULT (11 YEARS
Q4014	00200	+), FIBERGLASS
Q4015	00100	CAST SUPPLIES, GAUNTLET CAST (INCLUDES LOWER FOREARM AND HAND), PEDIATRIC (0-10
Q4015	00200	YEARS), PLASTER
Q4016	00100	CAST SUPPLIES, GAUNTLET CAST (INCLUDES LOWER FOREARM AND HAND), PEDIATRIC (0-10

Q4016	00200	YEARS), FIBERGLASS
Q4017	00100	CAST SUPPLIES, LONG ARM SPLINT, ADULT (11 YEARS +), PLASTER
Q4018	00100	CAST SUPPLIES, LONG ARM SPLINT, ADULT (11 YEARS +), FIBERGLASS
Q4019	00100	CAST SUPPLIES, LONG ARM SPLINT, PEDIATRIC (0-10 YEARS), PLASTER
Q4020	00100	CAST SUPPLIES, LONG ARM SPLINT, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4021	00100	CAST SUPPLIES, SHORT ARM SPLINT, ADULT (11 YEARS +), PLASTER
Q4022	00100	CAST SUPPLIES, SHORT ARM SPLINT, ADULT (11 YEARS +), FIBERGLASS
Q4023	00100	CAST SUPPLIES, SHORT ARM SPLINT, PEDIATRIC (0-10 YEARS), PLASTER
Q4024	00100	CAST SUPPLIES, SHORT ARM SPLINT, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4025	00100	CAST SUPPLIES, HIP SPICA (ONE OR BOTH LEGS), ADULT (11 YEARS +), PLASTER
Q4026	00100	CAST SUPPLIES, HIP SPICA (ONE OR BOTH LEGS), ADULT (11 YEARS +), FIBERGLASS
Q4027	00100	CAST SUPPLIES, HIP SPICA (ONE OR BOTH LEGS), PEDIATRIC (0-10 YEARS), PLASTER
Q4028	00100	CAST SUPPLIES, HIP SPICA (ONE OR BOTH LEGS), PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4029	00100	CAST SUPPLIES, LONG LEG CAST, ADULT (11 YEARS +), PLASTER
Q4030	00100	CAST SUPPLIES, LONG LEG CAST, ADULT (11 YEARS +), FIBERGLASS
Q4031	00100	CAST SUPPLIES, LONG LEG CAST, PEDIATRIC (0-10 YEARS), PLASTER
Q4032	00100	CAST SUPPLIES, LONG LEG CAST, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4033	00100	CAST SUPPLIES, LONG LEG CYLINDER CAST, ADULT (11 YEARS +), PLASTER
Q4034	00100	CAST SUPPLIES, LONG LEG CYLINDER CAST, ADULT (11 YEARS +), FIBERGLASS
Q4035	00100	CAST SUPPLIES, LONG LEG CYLINDER CAST, PEDIATRIC (0-10 YEARS), PLASTER
Q4036	00100	CAST SUPPLIES, LONG LEG CYLINDER CAST, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4037	00100	CAST SUPPLIES, SHORT LEG CAST, ADULT (11 YEARS +), PLASTER
Q4038	00100	CAST SUPPLIES, SHORT LEG CAST, ADULT (11 YEARS +), FIBERGLASS
Q4039	00100	CAST SUPPLIES, SHORT LEG CAST, PEDIATRIC (0-10 YEARS), PLASTER
Q4040	00100	CAST SUPPLIES, SHORT LEG CAST, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4041	00100	CAST SUPPLIES, LONG LEG SPLINT, ADULT (11 YEARS +), PLASTER
Q4042	00100	CAST SUPPLIES, LONG LEG SPLINT, ADULT (11 YEARS +), FIBERGLASS
Q4043	00100	CAST SUPPLIES, LONG LEG SPLINT, PEDIATRIC (0-10 YEARS), PLASTER
Q4044	00100	CAST SUPPLIES, LONG LEG SPLINT, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4045	00100	CAST SUPPLIES, SHORT LEG SPLINT, ADULT (11 YEARS +), PLASTER
Q4046	00100	CAST SUPPLIES, SHORT LEG SPLINT, ADULT (11 YEARS +), FIBERGLASS
Q4047	00100	CAST SUPPLIES, SHORT LEG SPLINT, PEDIATRIC (0-10 YEARS), PLASTER
Q4048	00100	CAST SUPPLIES, SHORT LEG SPLINT, PEDIATRIC (0-10 YEARS), FIBERGLASS
Q4049	00100	FINGER SPLINT, STATIC
Q4050	00100	CAST SUPPLIES, FOR UNLISTED TYPES AND MATERIALS OF CASTS
		SPLINT SUPPLIES, MISCELLANEOUS (INCLUDES THERMOPLASTICS, STRAPPING,
Q4051	00100	FASTENERS,
Q4051	00200	PADDING AND OTHER SUPPLIES)

These Q codes would be billable with the CPT codes: 24500 through 24685; 25500 through 25695; 26600 through 26785; 27500 through 27566; 27750 through 27848; 28400 through 28675 and 29000 through 29750.

AAWC Recommendation:

The AAWC agrees with the CMS proposal to allow the use of the Q-HCPCS codes for casting. splinting and strapping supplies for all medical uses. AAWC understands that the CMS intents to allow payment for casting, splinting and strapping supplies to physicians when these supplies are provided "incident to" physicians' services, and therefore not reimbursed through the practice expense component assigned to the CPT for the related service.

The inclusion of Q-codes makes sense for dislocations and fractures, however, this still limits and penalizes clinicians when casting and strapping CPT codes are used for some wound care, protection and spiral casting applications. The current Q-codes are not an all-inclusive list of the supplies required for these clinical conditions. The materials needed for management of venous ulcers for example, through the application of an Unna boot or Duke boot, are only partially listed in the Q-codes and a majority of the supplies needed for 'standard-of-care' graduated, sustained, compression for venous ulcers are <u>not</u> included. Instead these supplies are assigned HCPCS A-codes, which are included in the Surgical Dressing Policy.

Under direction in the Chronic Wound Care Policy, L16448 (Adminastar Federal) which was revised January 1, 2006, clinicians are instructed to use CPT 29580 for the application of multi-layer, graduated, sustained, moderate-to-high compression systems for venous ulcers until such time as a separate CPT code or HCPCS code is assigned.

AAWC requests that CMS temporarily include the A- HCPCS codes listed below as billable HCPCS codes in conjunction with the Strapping and Casting CPT procedure codes included in this proposal. This will provide appropriate compensation to physicians for the full range of supplies needed for wound care, spiral casting and protection and to comply with the intent of this proposed rule. This approach should remain in place until a CPT code is established for wound care applications. The below list of A-code identifies the materials required for wound care applications covered in the Strapping and Casting CPT codes.

A6441 Padding bandage w >=3" <5"/yd
A6442 Conforming bandage n/s w<3"/yd
A6443 Conforming bandage n/s w>=3"<5"/yd
A6444 Conforming bandage n/s w>=5"/yd
A6445 Conforming bandage s/ w <3"/yd
A6446 Conforming bandage s/ w>=3" <5"/yd
A6447 Conforming bandage s/ w >=5"/yd

A6448 Light compression bandage <3"/yd

A6449 Light compression bandage >=3" <5"/yd

A6450 Light compression bandage >=5"/yd

A6451 Moderate compression bandage w>=3"<5"/yd

A6452 High compression bandage w>=3"<5"yd

A6453 Self-adherent bandage w <3"/yd

A6454 Self-adherent bandage w>=3" <5"/yd

A6455 Self-adherent bandage >=5"/yd

A6456 Zinc paste bandage w >=3"<5"/yd

A6457 Tubular dressing

We believe this approach is in line with the CMS's intent to rectify the unintentional prohibited remuneration for these supplies when they are not used for reduction of a fracture or dislocation.

On behalf of the patients with wounds that we serve, we appreciate the opportunity to submit these comments and provide input concerning appropriate billing for wound care procedures and supplies under the Strapping and Casting CPT codes.

Respectfully,

Peggy Dotson
Government and Regulatory Task Force
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AMERICAN COLLEGE OF GASTROENTEROLOGY

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October 4, 2006

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Re: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007, and Other Changes to Payment Under Part B

To Whom It May Concern:

The American College of Gastroenterology is pleased to provide these comments with respect to CMS' proposed rule, published in the ***Federal Register*** on August 22, 2006, on revisions to the payment policies under the Physician Fee Schedule and Other Changes to Payment under Part B for the (Calendar Year 2007).

INTRODUCTION

The American College of Gastroenterology (ACG) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers more than 9,000 physicians among its membership. While the majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology--the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be educational.

In addition to the College's comments, which follow, we also wish to endorse specifically the comments submitted jointly by the American College of Gastroenterology, the American Society for Gastrointestinal Endoscopy, and the American Gastroenterological Association.

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Budget Neutrality and the Sustainable Growth Rate

The sustainable growth rate (SGR) formula continues to be a major impediment to fairness and quality in health care, despite Congressional intervention in the nature of a short-term fix to provide a two-year increase in overall physician reimbursements. Congress made it very clear in the Medicare Prescription Drug, Improvement and Modernization Act of 2004 (MMA) that the SGR policy is a failure, the result of its implementation is detrimental to the public health, and that it must be replaced. It confines physician payments within a budget baseline along with other non-physician health services, such as drugs and biologicals. Therefore, increases in non-physician payment Part B services prompt automatic reductions in the SGR. Tying the SGR baseline to the gross domestic product (GDP) produces similar problems.

We are very concerned about the proposed 5.1% payment cut for 2007. CMS knows that this is not an isolated cut—if the SGR formula is not fixed, these negative updates to the Medicare Physician Fee Schedule can be expected to continue a downward spiral in payment of 5% per year, more or less, each year through at least 2012. CMS argues in this proposal and elsewhere that: (1) the SGR will automatically cut the reimbursement for all Medicare services by somewhere around 5% next year; (2) the budget neutrality under the 5-year review necessitates an additional 10% across-the-board cut in the work RVUs for all Medicare services, including life-saving colorectal cancer screening colonoscopies; and (3) that precipitous cut to the facilty fees paid for cases performed in ambulatory surgery centers should be undertaken. This cumulatively would result in cuts of at least 15%. When the new ASC payment reform policy is factored in, the effective rate of the one-year cuts, including CMS's outrageous proposal to cut the average GI facility fee in the ASC setting by 27%, could be 30-40% or more. Basic economics demonstrates that no business/sector in the economy can endure the type of budget neutrality driven proposal being pursued by CMS, i.e., to cut all work RVUs by an additional 10% and still continue to function anywhere close to normally. The cumulative effect of these three CMS proposals, and specifically the 10% budget neutrality adjustment, would be to force physicians to limit access to Medicare beneficiaries or force them out of business altogether. This 10% across-the-board cut is wrong and must not stand. The alternative suggested by CMS of a roughly 5% cut to the conversion factor is equally unacceptable. At this point, CMS and the government have simply extracted too much money out of the system already; further cuts of the magnitude suggested will cause the system to collapse.

Separating Physician and Non-Physician Services

There is growing sentiment among physician organizations and in Congress that there are a few steps that can be taken by the agency right now to make the current formula more equitable with respect to physician payments. One would be to delink spending on physician payments from non-physician services. Annual spending growth on drugs and physical therapy far outstrip that of physician services. Despite CMS' prior statements

that it has no ability to avert the next fee schedule fiasco in 2007, the agency has direction from Congress to do so, and could exercise its role in administering the Medicare program to modify or amend the tenets of the SGR in this way. Creating completely separate funding pools under the global Medicare budget for physician services and non-physician services, each with its own respective target, would have an immediate and significant impact on alleviating the projected "negative adjustment" expected for physician services payments in the 2006 physician fee schedule. Such a modification would achieve a result that would be appropriate, reasonable and beneficial for physicians and beneficiaries.

So, we reiterate our plea that CMS announce its support for replacing the SGR policy, creating separate accounts for physician and non-physician services, and working with Congress on the development of an equitable and forward-looking successor to the SGR that can be implemented in time for the 2007 physician fee schedule

Payment for Physician Office Visit in Advance of a Medicare Screening Colonoscopy

There is an inconsistency and inequity in the Medicare Physician Fee Schedule as it applies to the provision of clinical gastroenterology services, particularly colorectal cancer screening for Medicare patients. Specifically, this concerns the need to secure payment for services provided when a beneficiary comes in for a pre-operative clearance visit prior to having a screening colonoscopy. The correct policy should be that the pre-operative clearance visit conducted in advance of (and not on the same day as) a screening colonoscopy should be reimbursed by all Medicare carriers.

Since the vast majority of patients undergoing colonoscopy receive sedating medications, which increase potential risks for a procedure, these risks should be discussed and certain medications discontinued before a patient takes off time from work and undergoes the colon preparation. For example, the physician needs to determine that the patient is an appropriate candidate for the test, as the Medicare population is, by definition, at greater risk for complications (e.g., if the patient is taking anticoagulants they might be excluded from the colonoscopy). Sound medical practice requires clarifying in advance certain key information that can only be determined through a thorough evaluation of the patient by a physician.

In fact, JCAHO, AAAHC and many state governments REQUIRE that the patient be seen by the physician before being sedated to determine medical history, their appropriateness for the procedure, and preparation instructions. The necessity for this pre-procedure office visit cannot be overstated. Patients are sent to the gastroenterologist or come on their own not only to discuss colonoscopy but also to review the options that the Medicare CRC screening benefit has provided. Colonoscopy may or may not be the most suitable screening option, depending on the patient's underlying medical condition. Whether the patient has a cardiac or pulmonary condition, hemophilia, diabetes or any other coexisting medical conditions or medication intake (and, commonly, more than one of these conditions), the gastroenterologist should

be able to consider the unique circumstances of the patient before ordering the preparation for the procedure and before performing the colonoscopy.

Some Medicare carriers, e.g., Trailblazer, have adopted the policy concerning this visit correctly. Unfortunately, there are carriers who deny payment for the pre-operative clearance visit held before the screening colonoscopy, even though the same carrier will pay for a similar pre-operative clearance office visit when it is provided before a diagnostic colonoscopy (i.e., the identical procedure, except that in a diagnostic colonoscopy there is an identified indication). This is one of the current incongruities which would be remedied if CMS adopts the consistent policy we are advocating for all colonoscopies, whether diagnostic or screening in origin. Before sedation is received, patients should have the option to visit the physician who will perform the procedure, and CMS should clarify that Medicare will pay for this visit (for most beneficiaries, colonoscopy is limited to once every ten years).

The history of the physician fee schedule demonstrates convincingly that HCFA: (1) did not bundle the pre-procedure service into the RVUs for the procedure itself; (2) anticipated that most Medicare patients would require a pre-operative clearance visit in advance of any colonoscopy; and (3) that all endoscopic procedures have always had a "0" global days, so all pre- and post- visits are separately billable. On page 25832 of the June 1991 proposed rule to establish the resource based relative value scale (RBRVS) fee schedule, HCFA stated:

> *"On the other hand, if documented evaluative services are performed in addition to the surgical procedure or 'scopy,' payment could be made for the visit. For example, a new patient is referred to a gastroenterologist for a possible scopy. The gastroenterologist conducts a thorough examination to first determine if the patient is a candidate for a scopy, and immediately proceeds to do the scopy. In this case, both the visit and a scopy could be billed if the visit is clearly documented."*

In summary, there are two major inconsistencies: (1) distinctly different policies for the pre-operative clearance visit for a screening colonoscopy depending on the Medicare carrier, and (2) different policies for screening colonoscopy versus diagnostic colonoscopy, though they are identical procedures. The inconsistencies would be remedied if CMS clarifies that the pre-screening/pre-operative clearance visits are reimbursable. To reiterate, currently, if a beneficiary is to have a *diagnostic* colonoscopy, all carriers recognize the need for the beneficiary to receive a pre-operative clearance visit in advance of the procedure. If, however, the beneficiary is having the identical procedure for *colorectal cancer screening*, the preoperative visit is equally important and should be covered. As CMS has not clarified these inconsistencies and recognized that this is an appropriate, medically necessary service, some carriers refuse to pay for the pre-screening/pre-operative clearance visit.

In conclusion, ACG requests CMS to rectify the inconsistencies in its current policy in order to reduce ambiguity and establish a universal policy that the pre-operative

clearance visit conducted in advance of (not the same day of procedure) a diagnostic or screening colonoscopy be fully covered.

Site of Service Policy for GI Endoscopies

The proposed fee schedule perpetuates a misguided CMS payment policy wherein essential GI procedures are reimbursed at higher rates when performed in an office setting than when performed in an ASC or HOPD. This site of service differential grossly distorts payment for physician services depending on where the procedure is performed without regard to which setting is more beneficial to patient outcomes. In its proposed rule for the 2005 Fee Schedule, CMS would reimburse a physician more than twice as much ($336.17 to $162.59) for an upper GI endoscopy with biopsy (43239) done in an office than for the same procedure performed in an HOPD or ASC. Yet both federal and state governments heavily regulate HOPDs and ASCs in order to receive Medicare and Medicaid certification; this is also the setting where 95% of most endoscopic procedures are still performed.

Ever since it was implemented, ACG has strongly opposed this policy because it is detrimental to patients and their ability to choose the appropriate location for the procedure with their physician. Much to the credit of gastroenterologists, they have refrained from "taking the bait" of the higher reimbursement level to shift to the office setting. Percentage volume for each respective site has not shifted, as the rate for performing a diagnostic colonoscopy in an office setting still hovers at less than five percent. CMS maintains this site of service bifurcated fee schedule even though these endoscopic procedures fail to meet the Agency's own criteria for such classification, namely, the presence of at least 10% office volume as stated in the June 1997 proposed rule.

The American Medical Association's *Archives of Surgery* released a study in September 2003 (Vol. 138, No. 9, September 2003), which identified data on whether patient safety is similar in ASCs and unregulated physician offices in Florida. Of thirteen deaths in a physician's office that occurred during the study period, two were related to endoscopy. In fact, this study concluded that there was a ten-fold increased risk of adverse incidents and death associated with surgical procedures provided in an unregulated physician's office (these are not "ASC look-alikes" which would meet Medicare ASC qualifications but for certificate of need problems; rather, these are essentially unregulated office settings with no controls on training, equipment or the like) versus the ASC. The study concluded that 43 injuries and 6 deaths per year in Florida could have been prevented if all procedures had been provided in facilities that met ASC criteria. This study completely debunks, with U.S. data, the false conclusion from the 2002 GAO report, which stated that there was little or no difference between the unregulated office setting and the ASC. The GAO report, from 2002, failed to find any United States surgical data and cited data from a study done in France, where circumstances, standards, training and care are decidedly different than in the U.S.

Some private payers are inclined to follow CMS' lead on this policy. As is noted on page 3, however, and in previous comments to the Agency, we have used the example of Blue Cross/Blue Shield of Massachusetts. Initially, the company instituted a CMS-like site-of-service policy for GI endoscopic procedures in 2002. Upon further review, however, BC/BS of Massachusetts set 37 endoscopic procedures with a single fee and total RVU so that prospectively all GI endoscopies are reimbursed at the higher office rate. This summer, Anthem BC/BS of Connecticut notified gastroenterologists in its network that it would follow CMS' lead and create a bifurcated fee schedule for endoscopic procedures. Once again, however, after reviewing the compelling patient safety evidence – as well as the precedent set by BC/BS of Massachusetts – the company decided not to pursue the site of service/bifurcated fee schedule.

ACG would appreciate the opportunity to work with the agency in framing and adopting an appropriate remedy for this problem. Ideally, the remedy would (1) shift these GI procedures out of the site-of-service policy (because they are below the 10% office volume threshold established by CMS); and (2) set these procedures with a single fee and total RVU at the **higher** office rate.

Conclusion

As we have noted above, despite our concurrence in retaining the work RVUs for the key GI services at their current level as recommended by RUC and CMS, we are deeply concerned that the cumulative cuts from this rule, the SGR, and the pending reform to the ambulatory surgery payment system will drive many practices (and ASCs) out of the Medicare system and/or out of business. These proposals may be the final straw in terms of breaking the American health care system, which has been the victim of an unprecedented cost-cutting siege, largely at the hands of the federal government, CMS, and the Medicare program over the past dozen years. This downward spiral must stop.

We appreciate the opportunity to submit our comments on this proposal and we would be pleased to answer questions or otherwise engage in dialogue with the agency about how to improve/remedy the deficiencies in the current proposal.

Very truly yours,

Jack DiPalma, M.D., FACG
President

Edward Cattau, M.D., FACG
Chair, ACG National Affairs Committee

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October 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Re: File code CMS-1321-P Criteria for National Certifying Bodies- Advanced Practice Nurses

Dear Sirs:

The undersigned represent national advanced practice nursing organizations whose missions support the educational preparation and certification of nurse practitioners (NPs). Through the collective activities of our organizations, we share a common goal of promoting high quality, safe and cost-efficient health care services delivered by NPs. It is in the interest of this goal that we are responding to the proposed rule "Medicare Revisions to Payment Policies Under the physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B;" (42CFR Parts 405, 410, et al) as announced in the Federal Register on August 22, 2006.

In the discussion of proposed changes to CFR 410.76 as noted on page 49066, CMS noted its intent to establish standards to guide recognition of certification organizations eligible for participation in CMS programs. We wish to inform CMS that standards for recognition have already been established by the profession that should be used by CMS to make such determinations. To inform your work, we would like to summarize several key points that reflect out collective declarations about certification for NP specialties:

* NP education and certification of specialty practice remains the standard for credentialing and regulation of NP practice. Board certification in the specialties of Adult NP, Adult Acute Care NP, Family NP, Gerontology NP , Neonatal NP, Pediatric NP, Pediatric Acute Care NP, Women's Health NP and Psych/Mental Health NP has been already recognized for licensure and credentialing.

*Sub-specialty NP certification provides added value to NP specialty board certification. Sub-specialty NP practice builds on the NP specialty preparation and promotes an increased depth of knowledge to provide focused high quality care for specific diseases, systems and settings. Examples would include an Adult NP who sub-specializes in Diabetes management or Forensics.

National accreditation of educational and certification programs assures that appropriate quality standards are addressed. Eligibility to sit for board certification is determined by graduation from educational programs preparing NPs that are nationally accredited by a nursing accrediting organization recognized by the Department of Education. Both specialty and sub-specialty certification examinations should be nationally accredited through NCCA or ABNS.

We request that the already established standards such as those printed in the NCSBN Criteria for Advanced Practice Regulation be used by CMS. We hope that this information is helpful as you consider developing standards for recognizing NP certification organizations.

American Academy of Nurse Practitioners Certification Program
Jan Towers 202-966-6414

American Association of Critical Care Nurses Certification Corporation
Carol Hartigan 949-268-7507

National Certification Corporation
Betty Burns 312-951-0207

National Organization of Nurse Practitioner Faculties
Kitty Werner 202-289-8044

Pediatric Nursing Certification Board
Janet Wyatt 301-330-2921

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RIC KELLER
8TH DISTRICT, FLORIDA

419 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-0908
(202) 225-2176
FAX: (202) 225-0999

DISTRICT OFFICE:
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SUITE 650
ORLANDO, FL 32801
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FAX: (407) 872-1944

www.house.gov/keller

Congress of the United States
House of Representatives
Washington, DC 20515-0908

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COURTS, THE INTERNET AND INTELLECTUAL PROPERTY

COMMITTEE:
SMALL BUSINESS

SUBCOMMITTEE:
TAX, FINANCE, AND EXPORTS

October 10, 2006

Leslie V. Norwalk, Esp.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on Practice Expense Methodology: Five-Year Review of Work Relative to Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology Notice (August 22, 2006)

Dear Acting Administrator Norwalk:

I am writing in response to the recent Centers for Medicare & Medicaid Services (CMS) proposed Notice issued August 22, 2006, specifically in regards to the proposed cuts to certain procedures in the practice expense methodology. Over 120 cardiologists in my district and around central Florida will have to close their doors to Medicare patients if this proposed change in methodology is finalized. Up to eighty percent of the patients in many of these doctor's practices are Medicare patients. I continue to be concerned about the effect that these proposed cuts will have on vital procedures to Medicare patients.

Cardiologists in my district provide a cost-effective alternative to hospital based procedures. The drastic reduction proposed with the practice expense methodology does not accurately represent either the cost of performing the service, or a comparable rate that Medicare pays for the same group of procedures when they are performed in a hospital outpatient center. The proposed changes do not include actual costs of providing catheterization procedures in a non-hospital setting and would result in the closure of freestanding centers.

I fear that the proposed cuts under the CMS physician fee payment schedule as well as the expense methodology could diminish Medicare patient's access to cardiac care. The different proposal for payment rates for outpatient cardiac catheterization services included in this August Notice is not the right solution. Because there is insufficient data to determine the best way to proceed, I continue to request that CMS freeze payments for cardiac catheterization-related procedures for at least one year to allow time for a complete assessment of the cost profile. If this one year freeze is not a possibility, I urge CMS to implement a transition period of at least

four years, to allow these clinics to adjust accordingly and to gather the data needed to make the most informed decision possible.

Finally, I have enclosed a listing of cardiac care centers in central Florida that will be impacted severely by these proposed cuts. I have also enclosed a listing from these centers of direct and indirect costs associated with these centers and the proposed impact of these cuts. Thank you for your consideration.

Sincerely,

Ric Keller
Member of Congress

Cardiology Practice Listing
Central Florida Area

Cardiac Care Specialists
7824 Lake Underhill Road
Suites D & E
Orlando, FL 32822
Phone: 407-273-2378
Fax: 407-273-9699
Dr.'s: Alexander Alperovich M.D., Glenn Harris M.D., Brian Kelly D.O., Chika Okereke M.D.

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Cardiac Clinic
311 West Oak Street
Kissimmee, FL 34741
Phone: 407-933-1423
Fax: 407-933-2740
Dr.'s: Sunil Kakkar M.D., Atul Madan M.D., Padma Raju M.D., Dianne Zullow M.D.

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Cardiology Care Center
1355 S. International Pkwy
Suite 1481
Lake Mary, FL 32746
Phone: 407-804-9199
Fax: 407-804-9393
Dr.'s: Jacob Agamasu M.D., Jay Bradley Bitar M.D.

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Cardiology Consultants
2320 N. Orange Avenue
Orlando, FL 32804
Phone: 407-896-0054
Fax: 407-894-0032
Dr.'s: James Bolen M.D., Robert Boswell M.D., Robert Rothbard M.D., Egerton van den Berg Jr., M.D.

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Cardiovascular Associates, Inc.
601 Oak Commons Blvd.
Kissimmee, FL 34741
Phone: 407-846-0626
Fax: 407-846-2524
Dr.'s: Rodolfo Aldir M.D., Roberto Barrett M.D., Alejandro Franceschi M.D., Thomas Kim M.D., Prashanta Laddu M.D., Johnson Massey M.D., Patrick Mathias M.D.

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Cardiovascular Care Centers
100 West Gore Street
Suite 403
Orlando, FL 32806
Phone: 407-872-8588
Fax: 407-872-1875
Dr. Caleb Mercado

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Cardiology Practice Listing
Central Florida Area

Cardiovascular Heart Center
3802 Oakwater Circle
Suite 2
Orlando, FL 32806
Phone: 407-855-1520
Fax: 407-855-1590
Dr. Zulima Nicoloff M.D.

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Cardiovascular Interventions, P.A.
1900 North Mills Avenue
Suite 107
Orlando, FL 32803
Phone: 407-894-4880
Fax: 407-894-2364
Dr. Pradipkumar Jamnadas M.D.

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Central Florida Cardiology
1745 North Mills Avenue
Suite 100
Orlando, FL 32803
Phone: 407-841-7151
Fax: 407-425-2768
Dr.'s: J. Craig Barnett M.D., Brian Dublin M.D., Michael Hardee M.D., Anil Kumar M.D. Gregory May M.D., Sharon Nichols M.D., Michael Nocero M.D., Scott Pollak M.D., Arsenio Rodriguez M.D., Nadarajah Srikumar M.D., Bruce Stein M.D., William Story M.D., Andrew Taussig M.D.

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Florida Cardiology
483 North Semoran Blvd.
Suite 102
Winter Park, FL 32792
Phone: 407-645-1847
Fax: 407-645-5616
Dr.'s: Abbas Ali M.D., Pradup Baiju M.D., Sandeep Bajaj M.D., Steven Davis M.D., Ashraf A.H.F. El-Shalakany M.D., Darlene Go M.D.,Milan Kothari M.D., Claudio Manubens M.D., Karan Reddy M.D., Louis Scala M.D., Raviprasad Subraya M.D.

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Florida Heart Group
1613 North Mills Avenue
Orlando, FL 32803
Phone: 407-894-4474
Fax: 407-894-7136
Dr.'s: Jose Arias M.D., Puxiao Cen M.D., R. Charles Curry M.D., Francis Fahey M.D., Patricia Guerrero M.D., H.B. Karunaratne M.D., Chin Kim M.D., Salvador Lanza M.D., Mark Milunski M.D., George Monir M.D., Amir Morsi M.D., Carlos Saenz M.D., Kerry Schwartz M.D., Hani Seifein M.D., Curtis Weaver M.D., William Willis M.D.

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Cardiology Practice Listing
Central Florida Area

Harold Greenberg M.D.
235 South Maitland Avenue
Suite 101
Maitland, FL 32751
Phone: 407-645-5504
Fax: 407-645-0229

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Heart of Florida Cardiology P.A.
808 West Oak Street
Kissimmee, FL 34741
Dr. LeRoi Price
Phone: 407-847-6900
Fax: 407-847-7018

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Heart with Rhythm
203 North Park Avenue
Suite 104
Apopka, FL 32703
Dr. S. Kamal Ashraf M.D.
Phone: 407-889-1902
Fax: 407-889-1903

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Interventional Cardiovascular and Vascular
615 East Princeton Street
Suite 104
Orlando, FL 32803
Dr. Ashish Pal M.D.
Phone: 407-898-8449
Fax: 407-896-6344

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Invasive and Noninvasive
616 East Altamonte Drive
Suite 202
Altamonte Springs, FL 32714
Dr.'s: Joseph Asch M.D., Joel Greenberg M.D., Juan Zarate M.D.
Phone: 407-834-1010
Fax: 407-834-4861

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Longwood Cardiology
515 West S.R. 434
Suite 307
Longwood, FL 32750
Dr.'s: Wasim Ahmar M.D., Khalid Yaqood M.D.
Phone: 407-767-8200
Fax: 407-339-1200

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Cardiology Practice Listing
Central Florida Area

Mid Florida Cardiology — Phone: 407-351-5384
1717 South Orange Avenue — Fax: 407-445-0321
Suite 105
Orlando, FL 32806
Dr.'s: David Bello M.D., Jorge Cusco M.D., Chandresh Duggal M.D., Arnold Einhorn M.D., Marcos Hazday M.D., Louis Kantounis M.D., Javier Lorenz M.D., Sundeep Mediratta M.D., Enrique Polanco M.D., Mouaz Tawam M.D., Peter Taylor M.D

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New Life Heart Center — Phone: 407-862-4151
1460 West Fairbanks Avenue — Fax: 407-862-9323
Winter Park, FL 32789
Dr. Sunil Kapoor

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Orlando Heart Center — Phone: 407-650-1300
60 West Gore Street — Fax: 407-650-1307
Orlando, FL 32806
Dr.'s: Louis Alvarez M.D., George Andreae M.D., Enrique Chapman M.D., Robert Dalton M.D., Robert Domascek M.D., Aurelio Duran M.D., Roland Filart M.D., Joel Garcia M.D., Scott Greenwood, M.D., Pavel Guguchev M.D., Melvin Johnson III M.D., Jose LeFran M.D., Parimal Manir M.D., Isreal Juan Mantecon M.D., Mark Steiner M.D., James Tarver M.D., Deepak Vivek M.D., Adam Waldman M.D., Irwin Weinstein M.D., Linus Wodi M.D.

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Orlando Heart Specialists — Phone: 407-767-8554
450 West Central Parkway — Fax: 407-767-9121
Suite 2000
Altamonte Springs, FL 32714
Dr.'s: Amish Parikh M.D., Nanakishore Ranadive M.D., Rajesh Shaw M.D., Babak Alex Vakili M.D., Vikas Verma M.D.

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Orlando Heart & Vascular LLC. — Phone: 407-446-8686
11317 Lake Underhill Road — Fax: 407-363-4851
Orlando, FL 32836
Dr. Vineel Sompalli M.D.

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Nuclear Changes 2007-2010

2006 Physician Fee Schedule

Components	78465	78465	78478	78478	78480	78480	Totals
	TC	TC	TC	TC	TC	TC	
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00	
PE	11.82	$447.95	1.56	$59.12	1.56	$59.12	
MP	0.62	$23.50	0.10	$3.79	0.10	$3.79	
	12.44	$471.44	1.66	$62.91	1.66	$62.91	$597.26
	Global	Global	Global	Global	Global	Global	
Work	1.46	$55.33	0.62	$23.50	0.62	$23.50	
PE	12.34	$467.66	1.79	$67.84	1.78	$67.46	
MP	0.67	$25.39	0.12	$4.55	0.12	$4.55	
	14.47	$548.38	2.53	$95.88	2.52	$95.50	$739.76
	Pro	Pro	Pro	Pro	Pro	Pro	
Work	1.46	$55.33	0.62	$23.50	0.62	$23.50	
PE	0.52	$19.71	0.23	$8.72	0.22	$8.34	
MP	0.05	$1.89	0.02	$0.76	0.02	$0.76	
	2.03	$76.93	0.87	$32.97	0.86	$32.59	$142.49

2007 Proposed Transition PE Changes

Components	78465	78465	78478	78478	78480	78480	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	11.64	$441.13	1.32	$50.02	1.32	$50.02		
MP	0.62	$23.50	0.10	$3.79	0.10	$3.79		TC
	12.26	$464.62	1.42	$53.81	1.42	$53.81	$572.25	-$25.01
								-4.19%
	Global	Global	Global	Global	Global	Global		
Work	1.46	$55.33	0.50	$18.95	0.30	$11.37		
PE	12.21	$462.73	1.55	$58.74	1.52	$57.60		
MP	0.67	$25.39	0.12	$4.55	0.12	$4.55		Global
	14.34	$543.45	2.17	$82.24	1.94	$73.52	$699.21	-$40.55
								-5.48%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	1.46	$55.33	0.50	$18.95	0.30	$11.37		
PE	0.57	$21.60	0.24	$9.10	0.20	$7.58		
MP	0.05	$1.89	0.02	$0.76	0.02	$0.76		Pro
	2.08	$78.83	0.76	$28.80	0.52	$19.71	$127.34	-$15.16
								-10.64%

Fully Implemented Proposed PE Changes

Components	78465	78465	78478	78478	78480	78480	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	11.08	$419.90	0.58	$21.98	0.58	$21.98		
MP	0.62	$23.50	0.10	$3.79	0.10	$3.79		TC
	11.70	$443.40	0.68	$25.77	0.68	$25.77	$494.94	-$102.32
								-17.13%
	Global	Global	Global	Global	Global	Global		
Work	1.46	$55.33	0.50	$18.95	0.30	$11.37		
PE	11.81	$447.57	0.83	$31.45	0.73	$27.67		
MP	0.67	$25.39	0.12	$4.55	0.12	$4.55		Global
	13.94	$528.29	1.45	$54.95	1.15	$43.58	$626.82	-$112.93
								-15.27%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	1.46	$55.33	0.50	$18.95	0.30	$11.37		
PE	0.73	$27.67	0.25	$9.47	0.15	$5.68		
MP	0.05	$1.89	0.02	$0.76	0.02	$0.76		Pro
	2.24	$84.89	0.77	$29.18	0.47	$17.81	$131.88	-$10.61
								-7.45%

LHC Changes 2007-2010

2006 Physician Fee Schedule

Components	93510	93510	93555	93555	93556	93556	Totals
	TC	TC	TC	TC	TC	TC	
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00	
PE	37.06	$1,404.48	6.29	$238.38	9.92	$375.94	
MP	2.31	$87.54	0.34	$12.89	0.51	$19.33	
	39.37	$1,492.02	6.63	$251.26	10.43	$395.27	$2,138.56
	Global	Global	Global	Global	Global	Global	
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45	
PE	39.24	$1,487.10	6.61	$250.50	10.24	$388.07	
MP	2.61	$98.91	0.37	$14.02	0.54	$20.46	
	46.17	$1,749.73	7.79	$295.22	11.61	$439.99	$2,484.94
	Pro	Pro	Pro	Pro	Pro	Pro	
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45	
PE	2.18	$82.62	0.32	$12.13	0.32	$12.13	
MP	0.3	$11.37	0.03	$1.14	0.03	$1.14	
	6.8	$257.70	1.16	$43.96	1.18	$44.72	$346.38

2007 Proposed Transition PE Changes

Components	93510	93510	93555	93555	93556	93556	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	31.93	$1,210.07	4.77	$180.77	7.56	$286.51		
MP	2.31	$92.40	0.34	$12.89	0.51	$20.40		TC
	34.24	$1,302.47	5.11	$193.66	8.07	$306.91	$1,803.03	-$335.53
								-15.69%
	Global	Global	Global	Global	Global	Global		
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45		
PE	34.17	$1,294.96	5.12	$194.04	7.92	$300.15		
MP	2.61	$98.91	0.37	$14.02	0.54	$20.46		Global
	41.10	$1,557.59	6.30	$238.75	9.29	$352.07	$2,148.41	-$336.53
								-13.54%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45		
PE	2.24	$84.89	0.35	$13.26	0.36	$13.64		
MP	0.30	$11.37	0.03	$1.14	0.03	$1.14		Pro
	6.86	$259.98	1.19	$45.10	1.22	$46.23	$351.31	$4.93
								1.42%

Fully Implemented Proposed PE Changes

Components	93510	93510	93555	93555	93556	93556	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	16.55	$627.20	0.21	$7.96	0.49	$18.57		
MP	2.31	$92.40	0.34	$12.89	0.51	$20.40		TC
	18.86	$719.60	0.55	$20.84	1.00	$38.97	$779.42	-$1,359.14
								-63.55%
	Global	Global	Global	Global	Global	Global		
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45		
PE	18.95	$718.16	0.66	$25.01	0.95	$36.00		
MP	2.61	$98.91	0.37	$14.02	0.54	$20.48		Global
	25.88	$980.79	1.84	$69.73	2.32	$87.92	$1,138.44	-$1,346.50
								-54.19%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	4.32	$163.72	0.81	$30.70	0.83	$31.45		
PE	2.40	$90.95	0.45	$17.05	0.46	$17.43		
MP	0.30	$11.37	0.03	$1.14	0.03	$1.14		Pro
	7.02	$266.04	1.29	$48.89	1.32	$50.02	$364.95	$18.57
								5.36%

2007 PE RVU Changes
Echo
(93307, 93320, 93325)

2006 Physician Fee Schedule

Components	93307	93307	93320	93320	93325	93325	Totals
	TC	TC	TC	TC	TC	TC	
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00	
PE	3.87	$146.66	1.71	$64.80	2.91	$110.28	
MP	0.23	$8.72	0.12	$4.55	0.21	$7.96	
	4.1	$155.38	1.83	$69.35	3.12	$118.24	$342.97
	Global	Global	Global	Global	Global	Global	
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65	
PE	4.22	$159.93	1.86	$70.49	2.94	$111.42	
MP	0.26	$9.85	0.13	$4.93	0.22	$8.34	
	5.4	$204.65	2.37	$89.82	3.23	$122.41	$416.87
	Pro	Pro	Pro	Pro	Pro	Pro	
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65	
PE	0.35	$13.26	0.15	$5.68	0.03	$1.14	
MP	0.03	$1.14	0.01	$0.38	0.01	$0.38	
	1.3	$49.27	0.54	$20.46	0.11	$4.17	$73.90

2007 Proposed Transisiton PE Changes

Components	93307	93307	93320	93320	93325	93325	Totals	Net Change
	TC	TC	TC	TC	TC	TC		
Work	0.00	$0.00	0.00	$0.00	0.00	$0.00		
PE	[illegible]	$141.74	[illegible]	$63.29	[illegible]	$89.06		
MP	0.23	$8.72	0.12	$4.55	0.21	$7.96		TC
	3.97	$150.45	1.79	$67.84	2.56	$97.02	$315.31	-$27.67
								-8.07%
	Global	Global	Global	Global	Global	Global		
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65		
PE	[illegible]	$156.52	[illegible]	$69.35	[illegible]	$90.20		
MP	0.26	$9.85	0.13	$4.93	0.22	$8.34		Global
	5.31	$201.24	2.34	$88.68	2.67	$101.19	$391.10	-$25.77
								-6.18%
	Pro	Pro	Pro	Pro	Pro	Pro		
Work	0.92	$34.87	0.38	$14.40	0.07	$2.65		
PE	[illegible]	$14.40	[illegible]	$6.06	[illegible]	$1.14		
MP	0.03	$1.14	0.01	$0.38	0.01	$0.38		Pro
	1.33	$50.40	0.55	$20.84	0.11	$4.17	$75.42	$1.52
								2.05%

400.60

25% Cut for Echo

Cancer Centers
of North Carolina

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September 29, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule (CMS-1321-P), published in the Federal Register on August 22, 2006.

Our radiation oncology center is deeply concerned with the proposed cuts for the RVUs associated with the delivery of breast brachytherapy. Breast brachytherapy is an important alternative to whole breast external radiation therapy (WBXRT) for a number of reasons. Breast brachytherapy delivers radiation to the tissue at greatest risk for recurrence, decreases time and inconvenience of WBXRT (shorter therapy duration: 4-5 days), reduces acute

and chronic toxicity, and eliminates scheduling problems with chemotherapy. Breast brachytherapy is well established, having greater than five year follow-up, with recurrence rates equivalent to WBXRT. The alternative is women having to endure 6 weeks of radiation when receiving WBXRT.

Radiation therapy after breast conservation surgery is considered the standard of care in the industry. Yet, in the last fifteen years, there has been a 250% increase of patients who receive breast conservation surgery without radiation therapy. As published in the *Journal of the National Cancer Institute* and *Lancet*, **omission of radiotherapy is associated with a threefold increase of ipsilateral breast tumor recurrence. The use of radiotherapy is associated with a 5 - 8% breast cancer mortality reduction. No subset of patients has been identified that can forgo radiation following lumpectomy, yet 46% of patients with DCIS, who are potential BCT candidates, receive lumpectomy alone. At five years, use of radiotherapy following lumpectomy for DCIS reduces the risk of recurrence from 16% to 8%.** The inconvenience of a six week regimen of radiation therapy associated with WBXRT is a major factor in the decision making process for these patients. In the November 2005 edition of *Cancer*, Voti et al found that the odds of a patient completing a course of WBXRT dropped by 3% with every 5-mile increase in distance to a radiation facility.

The RVUs for WBXRT are proposed to increase by 55% or $6,000 during the transition period and will be reimbursed at a proposed rate of more than $9,000 higher than HDR Breast Brachytherapy. HDR treatment is extremely beneficial for the patient because it irradiates considerably less healthy tissue and allows the patient to return back to their life activities in just five days. However, HDR breast brachytherapy does require more time for the radiation oncologist to plan and calculate the patient's treatment. The proposed cuts in RVUs are insufficient to cover the cost and time required to administer HDR breast brachytherapy and will result in limited access to this radiation treatment for women who are Medicare beneficiaries.

Specifically, CMS has proposed drastic cuts in the RVUs assigned to the global fee schedule for HDR breast brachytherapy. The RVUs are proposed to be reduced by more than 50% by 2010 for breast brachytherapy treatment.

THESE PROPOSED REDUCTIONS WILL NEGATIVELY IMPACT THE ABILITY OF MEDICARE ELIGIBLE WOMEN TO BE TREATED WITH HDR BREAST BRACHYTHERAPY. These proposed cuts are illustrated in the table below.

TABLE 1

CPT Code	Description	Units	2006 RVU	2006 Average Rate	2010 RVU	Variance 2010 to 2006	Variance 2010 to 2006
99245	office consult, comprehensive	1	5.91	$224	6.25	$1	0%
77263	physician treatment planning, complex	1	4.41	$167	4.16	($18)	-10%
77470	special treatment procedure	1	14.64	$555	4.55	($391)	-71%
76370	CT for planning	1	4.29	$163	5.48	$35	21%
77370	special medical physics consult	1	3.68	$139	2.51	($49)	-35%
77290	simulation, complex (contour volumes)	1	9.02	$342	15.22	$206	60%
77326	Brachytherapy isodose plan	1	3.78	$143	3.89	($3)	-2%
77300	dose calc	10	2.26	$856	1.80	($209)	-24%
77336	weekly medical physics consult	1	3.15	$119	1.08	($81)	-67%
77280	simulation, simple	5	4.62	$875	5.27	$72	8%
77781	Afterloading HDR brachy (1-4 source positions)	10	23.69	$8,978	6.58	($6,611)	-74%
TOTALS				$12,562		***($7,049)***	***-56%***

NOTE: 2006 CF is $37.8975 with assumption for 2010 using proposed CF of $35.9647; applicable to Physician Fees

In summary, there are several RVUs that are decreasing by more than 5%. I recommend that CMS implement a maximum of no more than 5% reduction and this maximum should remain in effect during the time necessary for CMS and the RUC to re-evaluate the data applicable to these RVUs, specifically, HDR breast brachytherapy. I am willing to provide data to my professional society so that they may provide the necessary data to CMS and the RUC in order to make a more informed proposal in the readjustment of these RVUs applicable to HDR breast brachytherapy.

Texas Oncology/US Oncology is the nation's largest provider of cancer care and radiation services. Our cutting-edge technologies, treatments and research are offered in welcoming and comfortable environments. We maintain comprehensive quality oversight and responsible financial management. The

proposed reductions to reimbursement will significantly limit our ability to treat Medicare beneficiaries with HDR breast brachytherapy.

Sincerely,

Victor C. Archie, MD

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