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January 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-FC
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Comments on CMS-1427-FC; Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates for High-Energy Extracorporeal Shock Wave

Dear Administrator McClellan:

HealthTronics, Inc., formerly HealthTronics Surgical Services, Inc., ("HealthTronics") appreciates this opportunity to comment on the classification of High-Energy Extracorporeal Shock Wave ("ESW") in the 2005 Hospital Outpatient Prospective Payment System ("HOPPS") final rule with comment period published at 69 *Fed. Reg.* 65682 (Nov. 15, 2004) (the "Final Rule"). These comments are directed toward the Centers for Medicare and Medicaid's ("CMS's") placement of High-Energy ESW in new technology ambulatory payment classification ("APC") code 1547. APC code 1547 has a reimbursement rate of \$850.00, plus a minimum unadjusted co-payment rate of \$170.00. HealthTronics respectfully requests revision of the rule to assign High-Energy ESW to new technology level XXII (\$2,000-\$2,500) APC code 1559, as discussed herein.

CMS initially published a proposed rule regarding the 2005 HOPPS in the Federal Register on August 16, 2004. This proposed rule did not identify the classification of High-Energy ESW. The Final Rule, which places High-Energy ESW in new technology APC code 1547, provides the opportunity to comment on APC assignments of HCPCS codes identified in Addendum B of the rule with new interim comment codes. The High-Energy ESW procedures, at HCPCS/CPT codes C9720 and C9721, are identified with a new interim comment code and are, thus, open to further comments.

I. Background

HealthTronics, headquartered in Atlanta, Georgia, is the leading source in North America of equipment for the provision of High-Energy ESW. The company was founded in 1995 for the purpose of providing state-of-the art non-invasive treatment solutions for certain urologic and orthopedic conditions. HealthTronics' product is the OssaTron® for treatment of plantar fasciitis and chronic lateral epicondylitis ("tennis elbow").

A. High Energy Extracorporeal Shock Wave Procedure

The OssaTron® uses "high energy" shock waves to effectuate treatment. It was the first medical device approved for the provision of High-Energy ESW to treat plantar fasciitis (October 12, 2000) and was later approved for the provision of High-Energy ESW for the treatment of tennis elbow (March 14, 2003). OssaTron® High-Energy ESW is non-invasive in that it does not require an incision. High-Energy ESW with the OssaTron® is a surgical procedure that is only furnished to patients under anesthesia, by a physician and in a hospital outpatient or ambulatory surgical setting. OssaTron High-Energy ESW applies the high-dose shock pulse to the identified affected tissue in order to create a healing response. The technique and service is similar to how lithotripsy targets high-dose shock pulses to disrupt the kidney stone.

1. *Plantar Fasciitis*

Chronic proximal plantar fasciitis is defined as pain in the area of the insertion of the plantar fascia on the inferomedial calcaneal tuberosity that has persisted for six months or more. It is a common problem occurring most frequently in adults 40 years and older, especially women. Athletes, particularly runners and joggers are often affected; however, people from all walks of life suffer from this disorder. Obesity, standing on hard surfaces, walking on uneven surfaces, and activities that increase dorsiflexion of the toes increases the risk of proximal plantar fasciitis. Repetitive microtrauma at the origin of the plantar fascia is thought to cause degenerative change resulting in pain near the medial calcaneal tubercle.

Although the exact etiology is unknown, causative factors suggested are plantar fascia inflammation, avulsion of the fascia, and avascular degeneration. Histological examination shows tissue degeneration, disruption of collagenous fiber patterns, fibrotic thickening and chondroid metaplasia with calcifications. Radiographic findings indicate that 60-75 % of patients with heel pain will have a heel spur present at the origin of the flexor digitorum brevis. Although initially associated with subcalcaneal pain, the spur has never been established as the etiological cause of pain and does not routinely disappear after successful treatment with High-Energy ESW. High-Energy ESW has been found to be an effective treatment for many patients with chronic plantar fasciitis.

2. *Tennis Elbow*

Chronic lateral epicondylitis ("tennis elbow") is defined as symptoms of moderate to severe pain at the point of tenderness in the affected lateral epicondyle that has persisted for at least six months or more. Tennis elbow is a condition in which there is inflammation or degeneration of the tendons attached to the outside, lateral side of the elbow. This disease process is generally characterized as an abrupt or subtle tearing of the tendonous area around the lateral aspect of the elbow, and normally affects people between the ages of 30 and 50. Although many tennis players suffer with tennis elbow, the majority of people affected are not involved in sports. Because pain occurs from injured or damaged tendons near the elbow, people

in occupational settings that require repetitive wrist and forearm movements such as painters, mechanics, and clerical workers are also likely to suffer from lateral epicondylitis. Like plantar fasciitis, tennis elbow can be effectively treated in many patients with High Energy ESW.

3. *High-Energy ESW Procedure*

High-Energy ESW is performed in a surgical setting, *e.g.* a hospital outpatient setting or an ambulatory surgical center in order to treat plantar fasciitis or tennis elbow.¹ Prior to the procedure, anesthesia is administered to the patient because the high energy shock waves are very painful. The types of anesthesia used vary but all are of the levels that dictate the services of an anesthesiologist in a facility setting. The procedure requires that a physician, certified in the use of the High Energy ESW device and protocol, administer the shock waves to the patient's affected area. In addition, a technologist trained on the High-Energy ESW device and protocol manages the OssaTron® during a procedure.

B. **Standards for Establishing an APC**

Under the HOPPS, outpatient procedures classified in the same ambulatory payment classification ("APC") group must be clinically comparable and use comparable resources. 42 U.S.C. § 1395l(t)(2)(B); 42 C.F.R. § 419.31. These outpatient services are paid on a rate-per-service basis that varies according to the APC group to which the service is assigned² and each APC is assigned a relative weight that reflects the APC's use of resources as compared to other APCs. 42 C.F.R. § 419.31. The APC payment rates are calculated on a national basis and then adjusted by geographic area. The payment rate for services and procedures in a given APC is the product of the conversion factor and the relative weight for the year. 42 U.S.C. § 1395 l(t)(3)(C); 42 C.F.R. § 419.32(c).

¹ This contrasts with "low-energy" ESW therapy, which is non-surgical, can be provided by a technician, and can be performed in an office setting. Further, low-energy ESW therapy does not require anesthesia. Low energy ESW therapies uses 100-200 percent less energy per shock pulse than High-Energy ESW and the overall clinical results for low energy therapies are less promising.

² See 69 Fed. Reg. 50448, 50450, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates (Aug. 16, 2004).

New technology APCs are intended by CMS to address appropriate payment for services that cannot be accurately described by existing codes and are not similar, either clinically or in terms of resource use, to an existing APC group. CMS determines the payment rate for each new technology APC based on the midpoint of a range of costs. Medicare Guide ¶ 4312, New Technology APCs. Until CMS has adequate data to assign a new service to an appropriate APC, the service is retained within the new technology APC. *Id.*; 69 Fed. Reg. 50448, 50451 (Aug. 16, 2004). *Id.*; 69 Fed. Reg. 50448, 50451 (Aug. 16, 2004).

C. American Medical Association Coding

In the Final Rule, CMS placed High-Energy ESW into HCPCS/CPT codes C9720 and C9721, replacing the former codes of 0020T and 0019T. Recently, however, the American Medical Association (the "AMA") has indicated its intention to grant our request for different CPT classifications for High-Energy ESW. Although the new CPT classifications are not currently effective and new codes will not be officially assigned until publication of the AMA's CPT Volume, it is the AMA's intention to issue the new codes this year. Specifically, we have been informed that the AMA intends to establish a Category I CPT Code (2825X) for High-Energy ESW for plantar fasciitis and that a separate Category III Code (now described as "00XXT") will be established for High-Energy ESW for the lateral epicondyle (tennis elbow). The new Category III Code for High-Energy ESW will properly differentiate it from low energy extracorporeal shock wave therapy, which will remain under code 0019T. We fully support the AMA's decision to distinguish between High-Energy ESW procedures and low energy ESW therapies. When these new CPT codes become effective, however, providers and carriers will be faced with two different codes for High-Energy ESW - the CPT codes and the HCPCS codes. This will cause difficulties with provider billing and reimbursement of the procedure. Although this impending double coding will need to be addressed further in separate discussions, it is an issue that we would like CMS to be aware of in its reconsideration of the classification of High-Energy ESW.

III. Analysis

A. The Assigned APC Code's Reimbursement will Not Cover the Costs and Resources Associated with High-Energy ESW

The classification of High-Energy ESW into new technology APC 1547 at a total payment rate of \$1,070 does not cover the basic costs of performing the treatment. In our application for a new technology we submitted estimated costs of the procedure to CMS. Those costs were based on 4,800 procedures performed over an eight-month period. It appears that CMS did not accept those submitted costs. Following publication of the Final Rule, our counsel had several discussions with CMS regarding the cost calculations for High-Energy ESW. As far as perceived from its conversations, the following table demonstrates a comparison of the costs submitted by HealthTronics based on actual procedures performed and the costs CMS used in its placement determination:

Costs	HealthTronics Cost Data	CMS Cost Data ³
Capital Costs	<ul style="list-style-type: none"> • \$500,000 - cost of device • \$48,0000 - cost of specialized van • 7 year life span of device/van • 20 procedures per month Per Procedure Total: \$326.19	<ul style="list-style-type: none"> • \$500,000 – cost of device • \$48,0000 - cost of specialized van • 7 year life span of device/van • 20 procedures per month Per Procedure Total: \$281.55 ⁴
Resources	<ul style="list-style-type: none"> • \$400 - surgery room rate • \$342 - ESW technician fee • \$40 - recovery room rate • \$43 - oxygen and supplies • \$75 - IV supplies and solutions • \$85 - cost of electrode • \$15 - other supplies • \$116 - cardiac monitor • \$200 - anesthesia drugs (plus \$203 if general anesthesia is used) • \$207 - service and maintenance • \$6 - malpractice expense • \$25 - liability insurance • \$84 - technician travel/mileage • \$191 - administrative costs • \$20 - miscellaneous expenses Per Procedure Total: \$1,849.00	<ul style="list-style-type: none"> • \$478.15 - median cost data; resource cost for diagnostic colonoscopy • \$85 - cost of electrode Per Procedure Total: \$563.15
Staff Work	<ul style="list-style-type: none"> • \$25 - nursing, pre-operational • \$32 - nursing, procedure • \$50 - nursing, post-operational Per Procedure Total: \$107.00	Per Procedure Total: not included
TOTAL	\$2,282.19	\$844.70⁵

As outlined above, the assignment of High-Energy ESW in the Final Rule to APC 1547 does not cover the actual costs of performing the surgery. Hospitals and other providers will not furnish High-Energy ESW at a loss. The effect of the classification of High-Energy ESW in APC 1547 will be the denial of patient access to a safe and effective treatment for plantar

³ This information was gathered during discussions with CMS after the publication of the final rule.

⁴ Discussions with CMS revealed that it accepted HealthTronics \$548,000 capital costs, device life of 7 years, and estimate of 20 procedures per month, yielding a per procedure cost of \$326.19. CMS, however, calculated these per procedure costs at \$281.55. We cannot account for this difference.

⁵ The total amount of reimbursement, including the minimum unadjusted copayment, is \$1,020.

fasciitis and tennis elbow. This could force patients to undergo more expensive, riskier, or less effective treatments, harming the patient and the Medicare fisc.

B. CMS' Assignment of APC Code 1547 Violates the Administrative Procedure Act

1. The Final Rule Violates Notice and Comment Procedure

The Administrative Procedure Act requires agencies to publish notice of proposed rulemakings and provide interested parties with an opportunity to comment. These comments must be properly considered and significant points must be discussed in subsequent publications of the rule. *See St. James Hospital v. Heckler*, 760 F.2d 1460 (7th Cir. 1985). Here, the Proposed HOPPS Rule published in 69 *Fed. Reg.* 50448 (August 16, 2004) failed to mention High-Energy ESW or its APC placement entirely. The Final Rule, while identifying the APC classification of High-Energy ESW failed to discuss the methods CMS used to make the placement and failed to discuss High-Energy ESW at all in the Preamble. These failures make proper comments addressing CMS' actions extremely difficult if not impossible. Moreover, finalizing a rule without explanation is unlawful.

2. The Assignment of APC Code 1547 is Arbitrary, Capricious, and in Excess of Statutory Authority

a. Administrative Procedure Act Provisions

The placement of High-Energy ESW in APC code 1547 was arbitrary, capricious, and in excess of statutory authority in violation of the Administrative Procedure Act. *See* 5 U.S.C. § 706. The Administrative Procedure Act provides that an agency may not take an action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* at § 706(2)(A). Further, agency rules must be rational and within the scope of the authority delegated to the agency by statute. *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983). Agency rulemakings must be consistent with the mandates of the legislature and not "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C). The Supreme Court has stated that "[n]ormally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 43. CMS must consider all alternatives and provide a rational basis for its decisions regarding procedure placement in its outpatient hospital reimbursement rates. All such changes must also be based on factual predicates and be in accordance with the mandates of Congress. *See* 5 U.S.C. § 706; *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance*

Co., 463 U.S. 29, 43 (1983) (stating that an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made'").

b. CMS Assigned the APC Code Based on Improper Data for New Technology Payments

CMS has granted High-Energy ESW new technology status. In this regard, HealthTronics submitted cost data to permit CMS to assign High-Energy ESW into an appropriate new technology level. It appears that CMS, however, has ignored HealthTronics' data regarding resource use and, instead, compared the resource costs for High-Energy ESW with an entirely different procedure - a diagnostic colonoscopy. Not only does this defeat the purpose of assigning procedures to a new technology APC code, this comparison is also inaccurate with regard to High-Energy ESW.

As CMS has stated, new technology payments are designed to address appropriate payment for services that cannot be accurately described by existing codes and that are not similar, either clinically or in terms of resource use, to an existing APC group. Medicare Guide ¶ 4312, New Technology APCs. New technology APCs are "defined on the basis of costs and not the clinical characteristics of a service." Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002; Final Rule, 66 Fed. Reg. 59856, 59897 (November 30, 2001). Then, once sufficient cost data is collected for a service, the service is moved to a clinically appropriate APC group. By comparing High-Energy ESW with diagnostic colonoscopies, CMS is ignoring its duty to define the new technology APC on the basis of the actual costs of the procedure itself.

Further, CMS has not established that the resources for a diagnostic colonoscopy are comparable to those for High-Energy ESW. Diagnostic colonoscopies are performed by inserting a long tube-shaped camera through the length of the colon to look for abnormalities including colorectal cancer or other diseases. This procedure is not comparable to High-Energy ESW, which uses a device, necessarily managed by a technician, to administer high energy shock waves to the elbow or foot of patients to relieve plantar fasciitis or tennis elbow. As our table above demonstrates, the resource costs associated with High-Energy ESW exceed those of diagnostic colonoscopies. According to CMS, the resource costs for a diagnostic colonoscopy are \$478.15.⁶

⁶ Diagnostic colonoscopies (CPT code 45378) are reimbursed under the Final Rule at a payment rate of \$490.01.

January 12, 2005

Administrator McClellan

Re: Comments on CMS-1427-FC

Page 8 of 9

Since CMS has failed to provide an analysis of the data used to calculate the resource costs for diagnostic colonoscopies, we are unable to provide a formal comparison of the costs of the two procedures. Based on informal data, however, the labor and consumables costs of colonoscopies are only approximately \$76.⁷ This is significantly less than the resource costs for High-Energy ESW. Our informal data calculates a cost per colonoscopy of \$96.16 without facility fees. The current reimbursement rate of a diagnostic colonoscopy, which includes facility fees, is \$490.01. We have demonstrated that the cost per High-Energy ESW is approximately \$1,516.19 without facility fees and such miscellaneous, but necessary, costs as liability insurance, malpractice expense, and administrative costs.⁸ Thus, the comparison between the two procedures is improper.

HealthTronics has demonstrated that the total resource costs for High-Energy ESW are at least \$1,950.⁹ This cost data, and not the cost data for a non-similar procedure, should be considered by CMS in determining the appropriate new technology APC. Accordingly, it is unacceptable to assign the resource costs for a diagnostic colonoscopy to High-Energy ESW. New technology payments are, under CMS' own language, based on costs and are intended to address appropriate payment for services that cannot be accurately described by existing codes and are not similar, either clinically or in terms of resource use, to an existing APC group. Thus, the comparison of High-Energy ESW to diagnostic colonoscopies is arbitrary, capricious, and in excess of statutory authority.

Additionally, CMS has improperly classified High-Energy ESW into the same APC code as endoscopic epidural lysis.¹⁰ This violates the Social Security Act requirements for grouping procedures for cost data based on clinical and resource comparability.¹¹ Basing APC groups for outpatient services on costs and not clinical and resource comparability is not authorized by the Social Security Act. 41 U.S.C. § 1395(l)(t).

⁷ The MD Buyline, an independent, non-profit healthcare intelligence firm based in Dallas, Texas, published the cost data for diagnostic colonoscopies. *Molecular FingerPrinting will Revolutionize Cancer Testing*, MD Buyline Leading Edge Report, October 12, 2004. Capital costs are stated to be \$80,000 with a five-year life cycle. The data is based on a consideration of 1,000 procedures per year.

⁸ Since it is unclear whether administrative costs, malpractice expenses, and liability insurance costs were included in MD Buyline's pre procedure cost analysis, we have not included them for our comparison.

⁹ This number is equal to the costs of the resources and staff, including the technician who is required to manage the OssaTron® device. As indicated in our table, the resource costs plus the capital costs total \$2,282.19, which is appropriate for our requested classification of High-Energy ESW to APC code 1559.

¹⁰ Endoscopic epidural lysis has a HCPCS/CPT code of 0027T.

¹¹ 42 U.S.C. § 1395l(t)(2).

January 12, 2005

Administrator McClellan

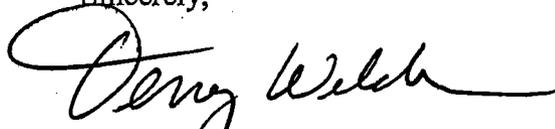
Re: Comments on CMS-1427-FC

Page 9 of 9

IV. Conclusion

The placement of High-Energy ESW into APC code 1547 at a total reimbursement rate of \$1,020 is improper in that it does not cover the costs of performing the procedure. We have demonstrated that the actual costs of the procedure are \$2,282.19. Since providers will not perform procedures at such a loss, patients may be forced into more expensive, riskier, or less effective treatment for their chronic disorders. This could harm both patients and the Medicare fisc. Instead, the treatment should be assigned, immediately and retroactively, to new technology APC code 1559. This reimbursement rate more appropriately compensates providers for the actual costs of the procedure.

Sincerely,



Terry Welch
Asst. VP, Medical Policy and
Reimbursement

Cc: Tom Mills.
Winston and Strawn
1400 L Street, NW
Washington DC 20005



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Imaging

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Burlay

September 12, 2005

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

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and
Calendar Year 2006 Payment Rates. CMS-1501-P

Dear Dr. McClellan:

SonoSite, Inc., appreciates the opportunity to comment on the Proposed Rule for the 2006 Hospital Outpatient Prospective Payment System (HOPPS) (CMS-1501-P). SonoSite is a manufacturer of high quality portable ultrasound systems located in Bothell, Washington. SonoSite manufactures and markets ultrasound systems that provide full diagnostic ultrasound studies and are optimized for use at the point of care. SonoSite's products are used throughout the hospital outpatient setting to provide a wide variety of diagnostic and guidance imaging services.

Status Indicators/Bundled Codes

I. Issue

In the proposed HOPPS rule, the Centers for Medicare and Medicaid Services (CMS) states that for 2006, CPT code 76937 -- *Ultrasonic guidance for vascular access* shall continue to be assigned a status-indicator of N, thus bundling the payment for this separate ultrasound study. This proposal is in direct conflict with a decision made by CMS in the 2003 Final HOPPS rule. In the 2003 Final Rule, CMS proposed to accept the recommendations of the APC Panel and provide separate payment in 2003 for all radiology guidance codes designated as "N" in 2002. CMS' deviation from its current policy in regard to assigning a status indicator of "N" to CPT code +76937 creates a provider incentive not to perform this service when it is medically indicated.¹ Thus, the adoption of this important patient safety practice is curtailed by existing payment policy.

¹ Federal Register, Vol. 67, No. 212, Friday, November 1, 2002, pg. 66724

II. Recommendation

To ensure that Medicare beneficiaries have access to safe, high quality care, SonoSite recommends that the Status Indicator assigned to CPT code +76937 be changed to an "S" allowing for separate payment of this service when provided in the hospital outpatient setting and that CPT code +76937 be assigned to APC 0268 - Ultrasound Guidance Procedures.

III. Supporting Information

Analysis of 2004 OPSS Data Reveals Low Level of Utilization

In August of 2005, the APC Advisory Panel considered a request for separate payment of +76937 and deferred a decision pending analysis of 2004 OPSS data to determine current utilization of the code. The Panel also sought to learn the median cost associated with +76937 to ensure that its placement in 0268 – Ultrasound Guidance Procedures would be appropriate, given the median cost of the other procedures assigned to APC 0268.

To answer the above questions SonoSite, Inc. analyzed the claims file that CMS released with the 2006 OPSS Proposed Rule to determine the level of utilization of +76937 under OPSS in 2004, modeled the median cost of +76937 if it were assigned a status indicator of "S," and compared that median cost with that of the other codes in APC 0268. Specific activities undertaken to complete this analysis included:

- Identifying and creating single-procedure claims, following the CMS rules. This includes "natural singles" that have only one payable procedure APC on the claim, and other types created from the claims by splitting the claim by date, bypassing certain payable HCPCS codes, and looking for claims with no packaged services on the claim.
- Packaging all costs into the major payable APC on the claim, while excluding costs for separately paid OPSS items and items paid under other methods, such as fee schedules.
- Adjusting the costs for each hospital's wage index, calculating statistical trim points, and trimming outliers.
- Determining median costs for the remaining single-procedure claims, by APC, ignoring HCPCS codes for ill-defined "not elsewhere classified" services when they occur in an APC.
- Changing the CMS rules to make HCPC code +76937 a payable code, changing the status to "S", placing it in APC 0268, and re-running the entire rate calibration process to produce a new set of median costs.

The results of this data analysis show for those vascular access procedures that +76937 can be used with, CPT codes 36555 to 36585, CPT code +76937 was reported an average of 14% of the time with the greatest utilization rate no more than 25%. The data confirms that it is currently not the "typical" practice to use ultrasound to guide vascular access procedures.

HCPCS	Label	APC for this HCPCS	Count of claims lines for this HCPCS	Percent of vasc. access claims with +76937	Number of claims with +76937	
36555	Insert non-tunnel cv cath	0621	234	6%	14	
36556	Insert non-tunnel cv cath	0621	19,589	15%	2,954	
36557	Insert tunneled cv cath	0622	216	18%	39	
36558	Insert tunneled cv cath	0622	26,230	23%	6,111	
36560	Insert tunneled cv cath	0623	93	17%	16	
36561	Insert tunneled cv cath	0623	48,814	10%	4,747	
36563	Insert tunneled cv cath	0623	558	4%	24	
36565	Insert tunneled cv cath	0623	3,205	6%	190	
36566	Insert tunneled cv cath	1564	606	7%	40	
36568	Insert tunneled cv cath	0621	246	18%	44	
36569	Insert tunneled cv cath	0621	30,561	25%	7,516	
36570	Insert tunneled cv cath	0622	37	8%	3	
36571	Insert tunneled cv cath	0622	14,395	6%	836	
36575	Repair tunneled cv cath	0621	1,218	0%	3	
36576	Repair tunneled cv cath	0621	563	0%	2	
36578	Replace tunneled cv cath	0622	924	1%	9	
36580	Replace tunneled cv cath	0621	2,265	2%	49	
36581	Replace tunneled cv cath	0622	9,075	2%	200	
36582	Replace tunneled cv cath	0623	1,265	2%	27	
36583	Replace tunneled cv cath	0623	122	1%	1	
36584	Replace tunneled cv cath	0621	2,065	4%	80	
36585	Replace tunneled cv cath	0622	341	2%	8	
		Total	162,622		22,913	14%

Furthermore, our modeling of the median cost for +76937 indicates that it is similar to the median cost for other HCPCS codes assigned to APC 0268.

HCPCS in APC 0268	Label	Total Number of claims lines	Estimated Number of Single- Procedure Claims	Estimated Median Cost
76490	Us for tissue ablation	98	2	\$ 67
76930	Echo guide, cardiocentesis	100	34	\$ 70
76932	Echo guide for heart biopsy	498	55	\$ 225
76936	Echo guide for artery repair	1,091	718	\$ 137
76937	Us guide, vascular access	27,429	1,640	\$ 112
76940	Us guide, tissue ablation	376	32	\$ 76
76941	Echo guide for transfusion	7	5	\$ 110
76942	Echo guide for biopsy	189,248	64,629	\$ 99
76945	Echo guide, villus sampling	20	19	\$ 103
76946	Echo guide for amniocentesis	182	179	\$ 71
76948	Echo guide, ova aspiration	10	10	\$ 151
76950	Echo guidance radiotherapy	138,714	137,868	\$ 52
76965	Echo guidance radiotherapy	12,104	1,852	\$ 57

In fact, the modeling indicates that if there had been separate payment for +76937 in 2004, the payment rate for APC 0268 would have changed by less than \$1.00 from \$62.96 to \$63.25.

This data indicates that this important safety practice is by no means routine and lends credence to the concern expressed by AHRQ in their review of this practice (discussed in further detail below) that lack of additional payment for capital equipment investment is the principal hurdle to adoption of this procedure.

AHRQ Recommends Ultrasound Guidance of Central Venous Catheter Placement

AHRQ's June 2001 report entitled "Making Health Care Safer: A Critical Analysis of Patient Safety Practices"² cites the use of real-time ultrasound guidance of central venous catheter insertion to be one of the top 11 practices needed to improve patient safety.

AHRQ indicates in its report that "The majority of CVC insertions are placed using the landmark method" – meaning that no ultrasound guidance is used—resulting in unsuccessful insertion in up to 20% of cases. So-called "blind insertions" have significantly higher rates of serious complications such as arterial puncture, hematoma, pneumothorax, and brachial plexus injury.

AHRQ concluded that when ultrasound is used to guide CVC insertions there is a reduction in the relative risk of 78%.

² Shojania KG, Duncan BW, McDonald KM, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43. (Prepared by the University of California at San Francisco–Stanford Evidence-based Practice Center under Contract No. 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

Assigning a status indicator of "S" to CPT code +76937 and crosswalking it to APC 0268 would ensure that Medicare beneficiaries who need CVC placements would have access to ultrasound guidance and thus suffer fewer multiple insertion attempts and complications.

Inappropriate Packaging

CMS' rationale for packaging services is that the performance of one service necessitates performance of the second service, i.e., the services are "directly related and integral."³ Yet when CPT code +76937 was created it was for the purpose of billing ultrasound guidance "in conjunction with another procedure for which ultrasound is not inherent."⁴

Previously CMS has acknowledged that payment affects provider behavior and that therefore, medically important, yet discretionary services must be afforded "separate payment so as not to discourage their use where appropriate."⁵ We applaud the reasoning expressed in that earlier judgment and contend that the same logic applies in this instance.

Multiple Diagnostic Imaging Procedures

I. Issue

In the 2006 Proposed HOPPS Rule, CMS states that it believes that a policy similar to its longstanding policy of reducing payment for multiple surgical procedures performed on the same patient in the same operative procedure should be implemented for diagnostic imaging services. CMS believes that efficiencies may be gained when multiple studies using the same imaging modality on contiguous body areas are performed during the same session. Using an analysis of the direct expense inputs used to calculate the practice expense relative value units under the Medicare Physician Fee Schedule, CMS is proposing to make a 50 percent reduction in OPSS payments for second and subsequent imaging procedures within eleven designated families when performed during the same session.

Current methods used under the OPSS system to bundle the reported hospital costs into a single procedure claim ensure that payments under the APC system already incorporate any available efficiencies that result when multiple services are performed. Nonetheless, using the rationale CMS has articulated based upon practice expense inputs from the Medicare physician fee schedule, the logical arguments stated in this proposed rule may not apply to all the imaging Families identified for reduction.

In the case of the ultrasound codes included in Family 1, while there may be some small efficiencies in pre- and post service clinical staff activities identified by CMS as the source of savings and the supplies used to complete the procedures, most of the costs associated with providing the services are incurred in intra service activities that are fully

³ Federal Register, Vol. 69, No. 157, Monday, 8/16/04, pg. 50453.

⁴ CPT Changes 2004, An Insider's View, American Medical Association, 2003.

⁵ Federal Register, Vol. 67, No. 212, Friday, November 1, 2002, page 66768.

duplicated when multiple studies are performed. Further, because in the ultrasound codes at issue, the equipment minutes are either associated with intra-service time or documentation, which CMS indicates is not a source of efficiencies, there are no available efficiencies in equipment time and indirect costs. Thus, the available savings from multiple ultrasound procedures being performed in a single session are significantly less than the proposed 50% reduction in the payment under OPPS that would result from the proposed new policy and the rationale for reduced payment does not apply to Family 1 Ultrasound Services. In fact, our calculations indicate that the savings would only justify a 5% reduction in the payment.

II. Recommendation

To ensure that Medicare beneficiaries continue to have access to safe, high quality care that is appropriate given their clinical indications, SonoSite recommends that CMS maintain its current payment policy for Family 1 Ultrasound services rather than applying the proposed 50% reduction.

III. Supporting Information:

Clinical staff time for Family 1 – Ultrasound Codes:

Below is a table that presents the clinical staff inputs from the Medicare Physician Fee Schedule (MPFS) Direct Practice Expense Inputs used in calculating the practice expenses for the Final 2005 MPFS for the ultrasound CPT codes listed in Family 1. It is important to note that the great majority of the clinical staff minutes incorporated into the RVU calculation for the ultrasound CPT codes are intra service minutes -- minutes spent acquiring the images necessary to complete the study. This is because the process of acquiring ultrasound images is a manual one -- each image is individually created and acquired by the sonographer. Indeed, none of these codes is assigned any post service clinical staff minutes. As a result, there are no savings available to account for any duplication for cleaning the room, post-service patient education, etc.

The clinical staff activities that may not be duplicated with a second procedure – i.e. greeting, escorting and positioning the patient; providing education and obtaining consent – and are thus identified by CMS as a potential source of efficiencies when multiple studies are performed in the same session are all pre-service and post-service activities. According to the time allocation for these activities under the physician's fee schedule, the actual savings that could be realized vary between \$1.50 - \$2.50 depending on which procedure is subsequent or second. Indeed, some pre-service activities identified by CMS as potential sources of efficiencies when multiple studies are performed in the same session are either not used at all during ultrasound procedures, such as setting up the IV, or take very little time at all, as in the case of positioning the patient. We list in the table below, the time allocated under the physician's fee schedule for pre-service and post service activities for all the CPT codes in Family 1, Ultrasound codes.

Clinical Labor Allocation -- Family 1 Ultrasound Codes

HCPCS	Source	Rate	Description	Pre-Time NF	Intra-Time NF	Post-Time NF	Available Savings from multiple services (Per CPT)
76604	PEAC	0.5	Diagnostic Medical Sonographer	5	24	0	\$2.50
76645	PEAC	0.5	Diagnostic Medical Sonographer	5	29	0	\$2.50
76700	PEAC	0.5	Diagnostic Medical Sonographer	5	37	0	\$2.50
76705	PEAC	0.5	Diagnostic Medical Sonographer	5	31	0	\$2.50
76770	PEAC	0.51	RN/Diagnost ic Medical Sonographer	3	37	0	\$1.53
76775	PEAC	0.5	Diagnostic Medical Sonographer	5	31	0	\$2.50
76778	PEAC	0.5	Diagnostic Medical Sonographer	3	45	0	\$1.50
76830	PEAC	0.51	RN/Diagnost ic Medical Sonographer	3	37	0	\$1.53
76831	PEAC	0.51	RN/Diagnost ic Medical Sonographer	3	36	0	\$1.53
76856	PEAC	0.5	Diagnostic Medical Sonographer	3	37	0	\$1.50
76857	PEAC	0.51	RN/Diagnost ic Medical Sonographer	3	29	0	\$1.50

Supplies for Family 1 – Ultrasound Codes:

Each CPT code listed in Family 1 – Ultrasound codes has the same set of supplies, not including the tapes or films needed to meet the documentation requirements of each study. The total cost of these supplies is \$2.31. The table below lists the supplies used in performing these procedures that could be duplicative and their costs.

HCPCS	SOURCE	Description	Price	Quantity-NF	Quantity-F	Cost-NF
76604	PEAC	drape, non-sterile, sheet 40in x 60in	0.222	1	0	0.222
76604	PEAC	gloves, non-sterile	0.084	2	0	0.168
76604	PEAC	gown, patient	0.533	1	0	0.533
76604	PEAC	paper, exam table	0.014	7	0	0.098
76604	PEAC	underpad 2ft x 3ft (Chux)	0.23	1	0	0.23
76604	PEAC	disinfectant, surface (Envirocide, Sanizide)	0.163	0.33	0	0.05379
76604	PEAC	sanitizing cloth-wipe (patient)	0.037	2	0	0.074
76604	PEAC	x-ray envelope	0.153	1	0	0.153
76604	PEAC	ultrasound transmission gel	0.013	60	0	0.78
Total Available Savings						\$2.31

Minutes of Use for Equipment Listed for Family 1 – Ultrasound Codes:

In the proposed rule CMS states that since equipment costs are allocated based on the clinical labor time, the minutes the equipment is in use should be reduced by the same number of pre and post-service minutes that clinical staff time is reduced. While we agree with CMS that equipment would not be set-up and taken down twice, the minutes in use that are assigned in the MPFS Direct Expense Inputs for the ultrasound equipment in this series of ultrasound codes, equal the minutes assigned to the clinical staff for intra-service work. The minutes assigned to the film processors and the film alternator are the amount of time required to process and document the image for the patient's medical

record. There would not be a reduction in the minutes for these two types of equipment as the images acquired during the second study will also have to be processed and documented in the patient's medical record. Therefore, there are no reductions that can be taken to account for duplicative pre-service minutes or post-service minutes of equipment use, as minutes were only assigned for when the equipment is being used to acquire or process the images. The chart below illustrates this point.

HCPCS	SOURCE	Time NF	Equipment Type
76604	PEAC	2	Film processor, dry, laser
76604	PEAC	24	room, ultrasound, general
76604	PEAC	2	Film alternator (motorized film viewbox)
76645	PEAC	2	Film processor, dry, laser
76645	PEAC	29	room, ultrasound, general
76645	PEAC	2	Film alternator (motorized film viewbox)
76700	PEAC	10	Film processor, dry, laser
76700	PEAC	37	table, exam
76700	PEAC	37	room, ultrasound, general
76700	PEAC	37	Film alternator (motorized film viewbox)

76705	PEAC	4	film processor, dry, laser
76705	PEAC	31	room, ultrasound, general
76705	PEAC	4	film alternator (motorized film viewbox)
76770	PEAC	10	film alternator (motorized film viewbox)
76770	PEAC	5	film processor, dry, laser
76770	CPEP	47	room, ultrasound, general
76770	PEAC	37	room, ultrasound, general
76775	PEAC	4	film alternator (motorized film viewbox)
76775	PEAC	4	film processor, dry, laser
76775	PEAC	31	room, ultrasound, general
76778	PEAC	5	Film processor, dry, laser
76778	PEAC	45	room, ultrasound, general

76778	PEAC	10	Film alternator (motorized film viewbox)
76830	PEAC	10	Film alternator (motorized film viewbox)
76830	PEAC	5	Film processor, dry, laser
76830	PEAC	37	room, ultrasound, general
76831	PEAC	5	film processor, dry, laser
76831	PEAC	36	room, ultrasound, general
76831	PEAC	10	film alternator (motorized film viewbox)
76856	PEAC	10	film alternator (motorized film viewbox)
76856	PEAC	37	room, ultrasound, general
76856	PEAC	5	film processor, dry, laser
76857	PEAC	29	room, ultrasound, general
76857	PEAC	5	film processor, dry, laser
76857	PEAC	10	film alternator (motorized film viewbox)

Appropriate Percentage Reduction to Account for Duplication

From the calculations performed above, it appears that the total savings that result from more than one imaging study being performed in the same patient session can be no more than \$4.81 for those procedures listed in Family 1.

The following table shows the reduction in payment that hospitals would receive if the proposed new policy were to be applied to Family 1 – Ultrasound codes.

	2006 APC Assignment	2006 Payment	Proposed Payment Reduction
76604	0266	\$96.85	\$48.43
76645	0265	\$60.34	\$30.17
76700	0266	\$96.85	\$48.43
76705	0266	\$96.85	\$48.43
76770	0266	\$96.85	\$48.43
76775	0266	\$96.85	\$48.43
76778	0266	\$96.85	\$48.43
76830	0266	\$96.85	\$48.43
76831	0267	\$155.54	
76856	0266	\$96.85	\$48.43
76857	0265	\$60.34	\$30.17

Depending upon which combination of codes was submitted, the reduction from the new policy could range from \$30.17 to as much as \$48.43. Both of these amounts greatly exceed the economies that can be truly realized when more than one of these services is provided in combination with another. The true economies would indeed only justify a 5% reduction in the payment amount, based upon CMS' rationale.

SonoSite, Inc. appreciates the opportunity to provide comments on this proposed rule. If SonoSite can provide CMS with additional information regarding this matter, please do not hesitate to contact me at 425-951-1205 or Irene.Plenefisch@sonosite.com.

Sincerely,



Irene Plenefisch

Director, Payer and External Relations

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COLORADO HEALTH & HOSPITAL ASSOCIATION

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September 13, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, CMS-1501-P, 70 Fed. Reg. 42,674 et seq. (July 25, 2005).

Dear Sir or Madam:

On behalf of the affected hospitals in the state of Colorado, the Colorado Health and Hospital Association (CHA) would like to submit the following comments regarding proposed changes to the hospital Outpatient Prospective Payment System (OPPS) and calendar year 2006 payment rates, specifically the Rural Hospital Adjustment.

CHA would like to strongly recommend that the Centers for Medicare & Medicaid Services (CMS) adjust OPPS payment rates for all Sole Community Hospitals (SCHs) regardless of geographic location.

There are two non-rural SCHs in Colorado; North Colorado Medical Center in Greeley and St. Mary's Hospital & Medical Center in Grand Junction. According to US Census Bureau data for 2000, the population of Greeley was 76,930 and the population of Grand Junction was 41,986. In each case, the hospital is located in a very large, mostly rural county, despite its urban designation. Each hospital serves a large rural population and would not be characterized as urban by any other agency, except CMS.

The qualification criteria for SCH status is the same regardless of the location of the hospital. Urban SHCs actually face more stringent qualification criteria than rural SCHs due to the fact that they have only one way to qualify for SCH status.

(more)

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Washington, DC 20201
September 13, 2005
Page Two

Rural Adj

Given that Congress did not distinguish between urban and rural hospitals in the SCH qualification criteria, and that the urban SCHs in Colorado serve large rural areas and populations like the rural SCHs, it is our position that urban SCHs should receive the same protections under the prospective payment system as rural SCHs. Therefore, CHA recommends that CMS consider adjusting the OPPS payment rates for all SCHs regardless of geographic location.

Thank you for your consideration in this matter. If you have any questions, please feel free to contact me at 720-489-1630.

Sincerely,



Larry H. Wall
President

Rec'd 9/15/05
J.N.W.

143



September 14, 2005

The Honorable Mark McClellan, 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

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Ahmed
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Susan Slaton
Director, Reimbursement
6 West Belt
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Telephone: (973) 305-5374
Fax: (973) 305-4440

RE: CMS-1501-P, Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Administrator McClellan:

Berlex Laboratories appreciates the opportunity to comment on CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates as published in the Federal Register on July 25, 2005.¹

Berlex Laboratories, the U.S. affiliate of Schering AG Germany, is a pharmaceutical company producing, developing, and marketing specialized medicines in the areas of female healthcare, oncology, central nervous system disorders and diagnostic imaging. For the past twenty-five years, Berlex has worked to make important treatments available to Medicare beneficiaries.

We commend CMS for proposing many of the new provisions regarding payment for drugs and biologics as outlined in the Proposed Rule. Specifically, we appreciate CMS's implementation of the following outlined revisions to help ensure that Medicare beneficiaries continue to access important therapies:

- Continuation of separate payment using the ASP methodology for drugs, biologics and radiopharmaceuticals whose median costs per day exceed \$50.²
- Continuation of separate payment for LOCM in 2006.³

¹ 70 Federal Register 42673. July 25, 2005.

² Id. at 42726.



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September 16, 2005

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Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1501-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-1501-P; Medicare Program; Proposed Changes to the Hospital
Outpatient Prospective Payment System and Calendar Year 2006 Payment
Rates; Proposed Rule**

Dear Administrator McClellan:

On behalf of Centocor, Inc., I am writing to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates." See 70 Fed. Reg. 42,674 (July 25, 2005) (the "Proposed Rule"). Centocor appreciates this opportunity to comment on important aspects of the Proposed Rule, and looks forward to working with CMS to ensure that the Rule is implemented in a manner that reflects our concerns.

I. BACKGROUND

As a leading biopharmaceutical company that discovers, acquires and markets innovative medicines and treatments that improve the quality of life of people around the world, Centocor is deeply committed to ensuring equitable and fair access to all necessary medicines for all patients. Among other life-improving medicines,¹ Centocor manufactures Remicade®, a product used by patients who suffer from the debilitating effects of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, and psoriatic arthritis, enabling these individuals to enjoy longer, more productive lives. Rheumatoid arthritis is a chronic disease that attacks the body's joints, causing inflammation, tissue destruction, and joint erosion. It affects over two million Americans, many of whom are Medicare beneficiaries. Each year, an additional 50,000 Americans are diagnosed with rheumatoid arthritis. Crohn's disease is a relatively rare condition, causing inflammatory disease of the intestine with symptoms that include diarrhea, severe abdominal pain, fever, chills, nausea and fistulae.² Ankylosing spondylitis is a painful and progressive form of spinal arthritis

¹ Centocor also manufactures ReoPro®, for acute coronary care.

² Fistulae are painful, draining, abnormal passages between the bowel and surrounding skin.

that can also affect internal organs, peripheral joints, and vision. Psoriatic arthritis is characterized by the complex symptoms of joint inflammation and skin lesions. Without proper treatment, the pain associated with these conditions can severely impact the quality of life of afflicted individuals.

Although rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, and psoriatic arthritis are chronic and debilitating conditions, Remicade[®] is a highly effective treatment that can slow the progression of these diseases and significantly enhance the quality of patients' lives by reducing their pain and other incapacitating conditions. Thousands of Medicare beneficiaries afflicted with these illnesses rely on Remicade[®] and other medicines to manage their conditions and improve the quality of their lives.

II. THE PROPOSED RULE

A. CMS Should Clarify its Reporting and Payment Policies Under the New CPT Codes

Centocor commends CMS for its proposal to continue requiring hospitals to report drug administration services using CPT codes that reflect the full resource utilization associated with these services. We continue to believe that using CPT codes for this purpose will provide CMS with more accurate data regarding drug administration services and enable the agency to establish more accurate payment rates. However, as described below, we urge CMS to clarify several issues regarding the new CPT coding reporting requirements in the Final Rule.

1. CMS Should Clarify that It Is Adopting the Same CPT Coding Classifications for the OPSS that It Adopted for the Physician Fee Schedule

As you know, in the 2005 Physician Fee Schedule Final Rule, the agency adopted temporary G-codes that reclassified drug administration services into new codes. *See* 69 Fed. Reg. 66,236, 66,303-07 (Nov. 15, 2004). Since January 1, 2005, physicians have had three sets of codes – hydration, non-chemotherapy (other than hydration), and chemotherapy – to use for reporting drug administration services. Additionally, pursuant to the recommendation of the American Medical Association CPT Editorial Panel, CMS expanded the definition of chemotherapy for drug administration purposes to include monoclonal antibodies and other biologic response modifiers. *See id.* at 66,303. Consequently, physicians administering these drugs in office settings have been able to report the administration of complex biologics using codes that more accurately reflect the resources used in providing these therapies.

While CMS did not adopt these new G-codes or classification policies for hospital outpatient departments in 2005, in the Proposed Rule, the agency states that it will adopt the new CPT codes that are scheduled to replace the G-codes on January 1, 2006. *See* 70 Fed. Reg. at 42,737-38. However, the Proposed Rule does not clearly indicate that the underlying reclassification of the administration of complex biologics into the chemotherapy administration codes will also be adopted. Under the classification system in place for physician offices, the administration of complex biologics, historically reported with CPT codes 90780 and 90781, are reported using the chemotherapy drug administration codes. However, the crosswalk provided in

the Proposed Rule indicates that CPT codes 90780 and 90781 will only be mapped to the therapeutic and diagnostic drug administration codes and does not reflect that some drug administrations reported using these codes should be mapped to the chemotherapy administration codes. See id. at 42,738. While we believe that the agency intends to apply the same CPT coding system to both physician offices and hospital outpatient departments – a belief reinforced by the statement in the recently released excerpts from the 2006 CPT codes that the administration of certain complex biologics are to be reported using chemotherapy administration codes (see www.ama-assn.org/ama/pub/category/3113.html), we strongly urge CMS to clearly state in the Final Rule that hospitals are to report the administration of monoclonal antibodies using the chemotherapy administration codes. We have attached a modified version of Table 27 that we believe reflects the intended policy.³

2. CMS Should Clarify that Hospitals May Receive Payment for Multiple Drug Administration Services Provided During a Single Encounter

Under the reporting system currently used in physician offices for drug administration services, physicians report multiple drug administrations provided during a single patient encounter by using one “initial” code for the first hour of administering the “key” drug and by reporting the administration of additional drugs using the sequential administration codes. See 69 Fed. Reg. at 66,305-07. Physicians are thus able to be reimbursed not only for each drug they administer, but also for each administration service that is provided. Under the reporting methodology announced in the Proposed Rule, hospitals will be reimbursed for each separately payable drug administered but not for each administration service provided in a multiple administration encounter. This anomaly occurs because, in the proposed crosswalk, the codes for sequential administrations have status indicator “N,” indicating that the code is not a payable code. See 70 Fed. Reg. at 42,738. We do not believe that CMS intended to prevent hospitals from obtaining reimbursement for all of the services they provide. We urge the agency to address this issue by creating a separate payment rate for sequential administrations and establishing a modifier that would direct the fiscal intermediary to disregard the “N” status indicator and provide payment for multiple administrations when appropriate.

B. CMS Should Reconsider Its Proposed Pharmacy Overhead Data Collection and Payment Methodologies

As discussed in the Proposed Rule, in the Medicare Modernization Act of 2003, Congress directed the Medicare Payment Advisory Commission (MedPAC) to study the overhead costs associated with the administration of separately payable drugs in hospital outpatient departments. See id. at 42,728. In June, MedPAC issued its report, finding that the handling costs associated with such drugs are “nontrivial,” and recommending that Medicare make an adjustment to the outpatient payment rates to reflect these costs. See Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program 149 (June 2005) (hereinafter “MedPAC Report”). Specifically, MedPAC recommended that CMS classify separately payable drugs into seven categories, reflecting the relative handling costs for each drug, and then collect

³ See Tab A.

hospital charge data for each of the categories to establish a budget neutral payment adjustment for drug handling costs under the outpatient Prospective Payment System. See id. at 42,729. In response, CMS proposed creating three drug handling categories with corresponding C codes and APCs. See id. at 42,729-30. Under the Proposed Rule, hospitals will charge for overhead costs and report these charges using the appropriate C code. See id. at 42,730. CMS will then collect the charge data for two years and develop payment rates for the APCs. See id. In the interim, CMS proposes to provide an add-on payment for pharmacy overhead costs equal to two percent of a drug's average sales price (ASP). See id.

1. CMS Should Increase the Number of Proposed Drug Handling Categories to Allow for Greater Accuracy in Data Collection

In the Proposed Rule, CMS proposes to conflate the six non-radiopharmaceutical drug handling cost categories recommended by MedPAC into three. See id. at 42,729. Centocor has two concerns about this proposal. First, we are concerned that limiting the number of categories for which hospitals report their drug handling costs will not provide accurate cost data. Hospitals administer a wide variety of drugs through their outpatient departments. As MedPAC recognized in creating its categories, the handling requirements for these drugs vary widely. See MedPAC Report at 145. Not all injections and IV preparations have the same or even similar handling costs. Reducing the number of categories into which drugs are classified as CMS proposes will require hospitals to report drugs with disparate handling costs under a single category, thereby limiting the ability of the reported charge data to accurately reflect the underlying overhead costs associated with handling and mixing the drugs.

Second, if, despite this lack of accuracy, CMS retains its proposed three categories of drug handling costs, we are concerned that the agency's descriptions of these categories do not provide sufficient clarity for hospitals to appropriately classify all of their drugs. Specifically, certain drugs may arguably fit within both Category 2 (injections and IV preparations) and Category 3 (cytotoxic agents and "[s]pecialty IV or [a]gents requiring special handling in order to preserve their therapeutic value . . ."). We assume, for example, that drugs such as Remicade[®] should be included in Category 3 because their "special handling" requirements, including cold chain storage and limited life after reconstitution, are clearly necessary to preserve their therapeutic value. Additionally, these handling requirements generally mandate that the preparation process be conducted on demand, which is itself another special handling requirement. We request that CMS clarify that Category 3 encompasses such drugs and biologics.

2. CMS Should Increase the Pharmacy Overhead Payment Adjustment

We also believe that the proposed pharmacy overhead payment rate of two percent of a drug's ASP does not adequately reflect the actual overhead costs incurred by hospitals in administering separately payable drugs. In its June report, MedPAC found that pharmacy overhead costs represented between 25 and 29 percent of hospital pharmacy department costs. See MedPAC Report at 140. Testimony presented at the APC Advisory Panel meeting in August clearly demonstrated that the proposed two percent add-on will not adequately reimburse hospitals for these costs. Moreover, as you may be aware, a 1999 study of cost report data prepared by Kathpal Technologies entitled "High Cost Drugs Under the Outpatient Prospective

Payment System” estimated that overhead costs represent 35.9 percent of hospital pharmacy department costs. Recently, Centocor and Scios, Inc. jointly engaged two consulting firms, the Moran Company and the Resource Group, to replicate this study. Using more recent data, the Moran Company and the Resource Group calculated that overhead costs account for 38.8 percent of hospital pharmacy costs.⁴ Based on these calculations, to provide adequate reimbursement for these costs, CMS would have to provide a payment adjustment reflecting a 50 to 60 percent markup of drug costs, which is significantly higher than the proposed two percent of ASP. Consequently, we recommend that the agency consider the APC Panel testimony as well as the data presented by commenters and increase the add-on for pharmacy overhead costs to more closely approximate the findings reported by MedPAC (as supported by the findings of the Moran Company and the Resource Group).

III. RECOMMENDATIONS

As described above, the Proposed Rule raises important policy issues that could significantly affect reimbursement for innovative therapies furnished by hospitals to Medicare beneficiaries. To address these issues, Centocor strongly encourages CMS to adopt the following recommendations in implementing the Final Rule:

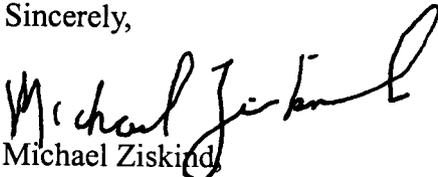
- CMS should clarify that, upon release of the new CPT codes, the administration of certain complex biologics should be reported using the chemotherapy administration codes.
- CMS should establish a methodology that will ensure hospitals are reimbursed for all drug administration services provided within a single patient encounter.
- CMS should reconsider consolidating MedPAC’s recommended drug handling categories into the three listed in the Proposed Rule and should provide clearer direction to enable hospitals to properly classify drugs into the appropriate category.
- CMS should increase the pharmacy overhead payment adjustment to more closely approximate the findings reported by MedPAC.

⁴ See Tab B.

IV. CONCLUSION

We appreciate the opportunity to comment on these important issues raised by CMS's Proposed Rule. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Ziskind". The signature is fluid and cursive, with a large loop at the end of the last name.

Michael Ziskind
Senior Director, Public Payor Policy, Strategy, and Marketing
Strategic Customer Franchise
Centocor, Inc.

--DRAFT 08/10/05--

Estimating Overhead Costs of Hospital Pharmacy Services Hospital Using Cost Reports

Prepared for:
Scios, Inc.

Mary Jo Braid-Forbes
Judith J. Baker, The Resource
Group

August, 2005

THE MORAN COMPANY

Estimating Overhead Costs of Hospital Pharmacy Services Hospital Using Cost Reports

I. Introduction

The Moran Company and The Resource Group have conducted this study of hospital overhead costs for Scios, Inc. We were requested to study how much it costs hospitals to operate their pharmacy departments over and above the acquisition costs of the pharmaceuticals and biologics they dispense. Building on prior analysis, we found that between 36.5% and 38.8% of hospital pharmacy costs were attributable to overhead.

This work is timely, as the Centers for Medicare and Medicaid Service (CMS) has recently published a rule proposing to set reimbursement rates for separately payable pharmaceuticals and biologics using a more direct measure of acquisition cost and an estimate of overhead costs starting January 1, 2006.¹ Section 621(a)(1) of The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003,² requires that payment for these drugs in the outpatient hospital setting be equal to the average acquisition cost for the drug for that year, as determined by the Secretary with reference to a study by the Government Accountability Office (GAO), but subject to adjustment for overhead costs. In this proposed rule, CMS has estimated acquisition costs for separately payable drugs and biologics as the Average Sales Price (ASP) plus 6 percent. CMS estimated the overhead costs for separately payable drugs as the residual of the amount left when subtracting the acquisition cost from what would have been the budget neutral pool of dollars for these separately payable drugs using the standard methodology of charges reduced to costs. CMS estimated this residual as 2 percent of ASP.³ Consequently, hospitals will receive a total payment rate of ASP plus 8 percent to cover both acquisition and handling costs for separately payable drugs and biologics.

In this study, we look at calculating pharmacy overhead costs directly using hospital cost reports, replicating and building on a prior study. The prior study of the relationship between product acquisition costs and total pharmacy costs in the hospital setting was conducted in 1999 for CMS (formerly the Health Care Financing Administration) done by Myers and Stauffer LC as a subcontractor to Kathpal Technologies.⁴ In Chapter 5 of that report, "Hospital Purchasing and Billing Practices for Drugs," they report the results of an analysis of 55 hospital cost reports for 1996, from which they concluded that costs other than product acquisition costs accounted for about one-third of the costs captured in the pharmacy cost center. This translated into a 50 percent mark-up over product acquisition cost. The Medicare Payment Advisory Commission (MedPAC) also conducted an analysis of over 3,000 hospital cost reports, as well as Maryland hospital

¹ *Federal Register*, Vol. 70 No. 141, July 25, 2005, p. 42725.

² Pub. L. 108-173, codified at Section 1833(t)(14)(A)(iii) of the Social Security Act

³ *Federal Register*, p. 42730.

⁴ Kathpal Technologies, *High cost drugs under the Outpatient Prospective Payment System*. Prepared for the Health Care Financing Administration. Fairfax, VA 1999.

cost reports⁵ and found that overhead costs accounted for between 25 and 28 percent of pharmacy costs.⁶ Both these studies estimate overhead costs that are significantly greater than the estimate of two percent over acquisition cost that CMS is proposing for payment rates in 2006.

In this study, we replicated the Myers and Stauffer methodology using over 3,000 hospital cost reports with fiscal years ending in 2003. We found very consistent findings regarding the percent of total costs accounted for by overhead when using the same methodology. Specifically, we found the charge-weighted mean value for overhead costs for the drugs charged to patients cost center to be 36.5%.

We then refined the methodology to ameliorate some of its limitations. The Myers and Stauffer study had a very small sample size and used a breakdown of “salaries” versus “other” as reported for the pharmacy cost center on a hospital cost report as an estimate of overhead versus product costs. True pharmacy overhead costs would include more than just salaries in the pharmacy cost center. We refined this methodology to better approximate the split between true overhead and product costs. Specifically, we added fringe benefit allocations to the pharmacy department from another section of the cost report to salary.

In summary we found:

- Using the Myers and Stauffer methodology, 36.5 percent of pharmacy costs were attributable to overhead.
- As would be expected the overhead proportion was inversely proportional to hospital size; smaller hospitals with pharmacy departments had a higher proportion of costs related to overhead than larger hospitals.
- For-profit hospitals also seemed to have a higher proportion of costs related to overhead relative to not-for-profit or government hospitals. Major teaching hospitals appeared to have a lower proportion of costs related to overhead relative to non-teaching hospitals, though this may be more related to hospital size since major teaching hospitals tend to be larger hospitals.
- Adding the pharmacy departments’ fringe benefit allocation to salaries and re-estimating the proportion of pharmacy department costs that relate to overhead produced a higher estimate of 38.8 percent overall. The pattern of differences among hospital types is similar to the initial methodology.

An important limitation of both the original Myers and Stauffer methodology and our refinements is that neither can capture product-specific differences in storage and handling costs. There can be significant difference in these costs for different products. MedPAC studied these differences and found that using an injection as the reference, relative costs for handling different types of compounds ranged from 0.36 for orals to

⁵ Cost reports submitted by hospitals in Maryland are more detailed to accommodate that state’s hospital rate setting system.

⁶ MedPAC, “Payment for pharmacy handling costs in hospital outpatient departments”, *Report to Congress: Issues in a Modernized Medicare Program*, June 2005, p.140.

5.33 for cytotoxic agents.⁷ It is still useful to know the total overhead proportion so that the pool of dollars that is available to allocate to individual products accounts for the true total.

II. Policy Background

How much it costs hospitals to operate pharmacy departments over and above the acquisition cost of the pharmaceuticals and biologics they dispense is an important question as the reimbursement methodology employed by CMS for pharmaceuticals and biologics changes to more directly measure acquisition cost. The MMA requires CMS to use an estimate of hospital acquisition costs, taking into account the GAO survey, to pay for “specified covered outpatient drugs.” As discussed in the introduction, in the current proposed rule for payments in 2006, CMS has estimated acquisition costs for all separately payable drugs and biologics as ASP plus 6 percent.

The MMA also required MedPAC to report on handling costs for pharmacies in hospital outpatient departments. MedPAC presented its findings in its June 2005 report to Congress.⁸ The Commission concluded that “handling costs are nontrivial and an adjustment is warranted.”⁹ However, MedPAC went on to recommend that any adjustment be budget neutral. It is MedPAC’s position that hospital charges reflect handling costs. Citing the MedPAC report, CMS estimated the overhead costs for separately payable drugs as the residual of the amount left when subtracting the acquisition cost (ASP plus 6 percent) from what would have been for the budget neutral pool of dollars for these drugs using the standard methodology of charges reduced to costs. This CMS calculation results in total payments for acquisition and handling costs of ASP plus 8 percent.

It is important to note that the separately payable drugs are a subset of the drugs charged from the pharmacy department and generally represent only higher cost drugs. To the extent that higher cost drug charges do not receive a proportional allocation of mark-up for overhead, the CMS methodology for calculating the pool of dollars will not reflect the true overhead for pharmacy departments. In fact, research has shown that the charges for higher cost drugs have systematically lower mark-ups than lower cost drugs—which would bias CMS’s estimate of total pharmacy costs, and therefore residual overhead, downward.¹⁰

An additional potential source of bias in the CMS calculation of overhead costs is that the cost-to-charge ratios used to reduce charges to costs are determined for the hospital pharmacy department as a whole, including inpatient and outpatient services. The cost reports do not break out outpatient costs. In interviews that MedPAC conducted, hospital pharmacy directors indicated that the types of medications that are administered more

⁷ MedPAC, p.145.

⁸ MedPAC, chapter 6, p137-155.

⁹ MedPAC, p.137.

¹⁰ Braid, Mary Jo, Forbes, Kevin F and Moran, Donald W. “Pharmaceutical ‘Charge compression’ under the Medicare Outpatient Prospective Payment System” *Journal of Health Care Finance*, 2004;30(3):21-33.

frequently in outpatient departments generally require more pharmacy preparation time than do those for inpatients.¹¹

Before the implementation of the Hospital Outpatient Prospective Payment System (HOPPS) in 2000, outpatient hospital reimbursement for most pharmacy services was based on "reasonable cost." In response to concerns that a prospective payment system for pharmacy services would not adequately compensate hospitals for administering new technologies, Congress created a system of transitional pass-through payments for certain drugs and biologics, as well as new medical devices. Payments for eligible drugs and biologicals were based on Average Wholesale Price (AWP). This system, described in §1833(t)(6) of the Social Security Act, restricted the period of pass-through payments for eligible products to no less than two years but no more than three years. Since payments under HOPPS are set on a calendar year basis, pass-through payment eligibility for many products expired at the end of 2002.

Beginning January 1, 2003, CMS began calculating payment rates for drugs previously eligible for passthrough payments in a similar manner as other services under the Ambulatory Payment Classification (APC) system used for other HOPPS services were calculated. CMS used the hospital charges multiplied by each hospital's specific pharmacy department cost-to-charge ratio to estimate costs. As noted above, it is this cost finding methodology that CMS used to calculate the pool of total payments for separately payable drugs and biologics that it used to determine the appropriate adjustment for overhead.

Because of concern over the charges reduced to cost methodology, Congress in the MMA required that separately covered outpatient drugs be paid based on Average Wholesale Price (AWP) in 2004 and 2005, until a method based on acquisition cost with adjustments for overhead could be determined. As discussed, CMS has proposed such a methodology beginning January 1, 2006.

III. Findings

We were able to replicate the Myers and Stauffer methodology, which was done with a small number of cost reports from 1996, using the universe of hospital cost reports with fiscal years ending in 2003. We found very similar results—36.5%— for the percentage of the total pharmacy costs that were attributable to overhead compared to the Myers and Stauffer finding of 35.9%. This was true even though a comparison of the cost-to-charge ratios that are the components of this calculation indicate a trend of hospitals increasing charges faster than increasing costs. Our findings indicate the mark-up ratio for product costs necessary to account for acquisition cost is 1.576.

Table 1 below summarizes these findings.

¹¹ MedPAC, p.140.

Table 1: Replication of Myers and Stauffer Methodology

	Myers & Stauffer (n=52)	Replication this Study (n=3,120)
Pharmacy Overall Cost-to-Charge Ratio (CCR)	0.334	0.234
Overhead CCR	0.120	0.085
Overhead/Pharmacy Overall CCR	35.9%	36.5%
Implied Markup Ratio	1.560	1.576

We also examined the ratio of overhead to total pharmacy costs for different types of hospitals. As would be expected the overhead proportion was inversely proportional to hospital size; smaller hospitals with pharmacy departments had a higher proportion of costs related to overhead than larger hospitals. The findings did not vary for hospitals in urban versus rural areas. However, major teaching hospitals did have a lower proportion of costs for overhead, though this might be due to the fact that major teaching hospitals are larger hospitals and the effect observed actually is related to the size of the hospital. For-profit hospitals also seemed to have a higher proportion of costs related to overhead relative to not-for-profit or government hospitals. Table 2 summarizes these findings.

Table 2: Replication of Myers and Stauffer Methodology by Hospital Type

	Providers	Ratio of OH CCR to overall		
		Overall CCR	OH CCR	CCR to overall
By Bed Size				
unknown	13	0.3286	0.1193	0.3630
1-99	1,172	0.2708	0.1102	0.4068
100-199	999	0.2229	0.0862	0.3865
200-299	459	0.2120	0.0772	0.3641
300-499	369	0.2303	0.0843	0.3662
500+	108	0.2756	0.0865	0.3140
By Teaching Status				
unknown	13	0.3286	0.1193	0.3630
non teaching	2,185	0.2089	0.0815	0.3900
minor teaching	699	0.2260	0.0826	0.3655
major teaching	223	0.3073	0.1002	0.3260
By Geographic Location				
unknown	13	0.3286	0.1193	0.3630
Large Urban	1,157	0.2184	0.0800	0.3661
Other Urban	955	0.2483	0.0897	0.3611
Rural	995	0.2770	0.1042	0.3761
By ownership Type				
Not-for-Profit	1,949	0.2519	0.0910	0.3615
For-Profit	621	0.1433	0.0596	0.4159
Government	550	0.2934	0.1003	0.3420

This methodology used only salary as an estimate of overhead. Fringe Benefits are recorded in a separate area of hospital cost reports. Adding the pharmacy departments' fringe benefit allocations to salaries and re-estimating the proportion of pharmacy department costs that relate to overhead, we found a slightly higher estimate of 38.8 percent overall compared to 36.5 percent. The pattern of differences among hospital types was similar to the initial methodology. Table 3 below shows our findings overall for all hospitals and broken out by type of hospital.

Table 3: Methodology Refinement #1: Adding Fringe Benefits to Overhead

	Providers	New Other % of Total Pharmacy Department	New OH CCR	Ratio of New OH CCR to overall
All Hospitals	3,120	77%	0.0908	0.3883
By Bed Size				
unknown	13	81%	0.1266	0.3851
1-99	1,172	75%	0.1167	0.4310
100-199	999	76%	0.0915	0.4107
200-299	459	77%	0.0823	0.3881
300-499	369	77%	0.0892	0.3874
500+	108	77%	0.0925	0.3357
By Teaching Status				
unknown	13	81%	0.1266	0.3851
non teaching	2,185	76%	0.0865	0.4140
minor teaching	699	76%	0.0879	0.3890
major teaching	223	78%	0.1063	0.3460
By Geographic Location				
unknown	13	81%	0.1266	0.3851
Large Urban	1,157	77%	0.0847	0.3879
Other Urban	955	77%	0.0955	0.3844
Rural	995	77%	0.1115	0.4026
By ownership Type				
Not-for-Profit	1,949	76%	0.0974	0.3865
For-Profit	621	79%	0.0619	0.4317
Government	550	78%	0.1059	0.3608

IV. Methodology

We first replicated the Myers and Stauffer methodology; we then enhanced the methodology to account for the limitation that the Myers and Stauffer methodology used only salary as a proxy for overhead, not accounting for other legitimate overhead expenses. In this section, we first describe the Myers and Stauffer methodology. We then describe our refinements of this methodology that ameliorate some of its limitations.

A hospital cost report is a series of accounting worksheets that starts with costs from the hospital's general ledger by department and then through a step-by-step process allocates overhead departmental costs to charge or revenue producing departments. In additional worksheets, Medicare rules regarding limitations on costs, e.g. therapy limits or compensation limits and separate payments for specific costs, e.g. direct medical education are also applied. The final worksheet is a settlement accounting. The worksheets are lettered starting with A, with each worksheet letter representing a different step in the process. Line item numbering remains the same on all major worksheets for purposes of carry-forwards and cross-referencing.

Hospitals report the detail underlying calculation of departmental cost-to-charge ratios (CCRs) in Worksheet C, Part I. The pharmacy department report falls under "drugs charged to patients" (line 56). The data used to develop these "fully allocated" CCRs do not, however, permit disaggregation of the allocated costs into product- and non-product costs.

A. The Myers and Stauffer Methodology

The Myers and Stauffer report estimated the amount of costs in the "drugs charged to patients" line of hospital Medicare cost reports that are related to non-product costs. Myers and Stauffer estimated this split by examining the "salary" versus "other" split in costs recorded in Worksheet A, columns 1 and 2, of the cost reports. Worksheet A reflects departmental costs for all departments prior to allocation of costs from overhead departments to charge producing departments. Using the salary and other split on Worksheet A, they estimated the portion of departmental costs attributable to products to be "other".¹² Using fully allocated costs from Worksheet B, they estimated the amount of overhead costs as a residual after taking out product or "other" costs. Using charges (Worksheet C, Part I, column 6 and 7) for "drugs charged to patients," they calculated an average overhead CCR for pharmacy of 0.120, with a median amount of 0.117. These amounts are relative to their average departmental CCR of 0.334 and median CCR of

¹² Note that hospitals can record the costs for pharmacy in more than one place on Worksheet A (line 16 and line 56). As did Myers and Stauffer, our methodology captures cost of goods information reported in either field. Most hospitals chose either line 16 or 56. There were 74 hospitals out of our total of 3,120 that reported cost information in both pharmacy lines; in these cases we added the values.

0.304.¹³ From these findings, Myers and Stauffer concluded that the share of pharmacy charges attributable to non-product costs represented approximately one third of the total.

The Myers and Stauffer analysis and methodology has a number of limitations. We have discussed the limited sample of 55 hospitals that was used. In addition, because the cost reports are not granular enough to parse fine distinctions in types of costs, the Myers and Stauffer analysis was forced to consider as product costs essentially all non-labor costs. By potentially overstating product costs, the methodology therefore understates pharmacy department overhead costs. Finally, the analysis assumes that the cost relationships imbedded in pre-allocated cost-to-charge ratios are proportional to these cost relationships after allocation.

This report addresses the sample size limitation by applying the Myers and Stauffer methodology to all available hospital cost reports. The report also refines that methodology to reduce the overstatement of product costs.

B. Selection of Cost Reports for this Analysis

We pulled cost reports from the December 2004 quarterly HCRIS update. Our selection criteria for cost reports were:

- Fiscal Year Ending in 2003
- Short term acute care hospitals only
- Eliminate cost reports if cost report covers less than 12 months
- Eliminate the following types of hospitals not subject to prospective payment
 - Located in Maryland
 - Critical Access Hospitals
 - Comprehensive Cancer Hospitals

We used the 2005 Impact file to determine whether a hospital was a Critical Access Hospital or a Comprehensive Cancer Hospital.

Of cost reports in the original data set we eliminated a number of reports with missing or problematic data. This included:

- 66 reports that recorded no charges for pharmacy;
- 103 reports that had total allocated costs less than “other” costs for pharmacy;

¹³ In the report Myers and Stauffer did not provide this much detail on the exact calculation of their estimate. In previous work, The Moran Company drew data from the 1996 HCRIS cost report files, and attempted to match the data presented in Exhibit 5.03 of their draft report. A substantial number of values matched exactly; in most other cases, we saw minor variations (+/-5%) that would be consistent with movement in the numbers from the earlier to later versions of the cost report itself. From this analysis, we concluded that we understood which data Myers and Stauffer had drawn, and the calculations they had made to produce the analysis in Exhibit 5.03.

- 13 reports where cost-to charge ratios were greater than 90 (mostly Kaiser hospitals);
- 1 report that did not record any information on salary or other for pharmacy on Worksheet A;
- 192 reports that did not record "salary" and "other" costs separately on Worksheet A; and
- 19 reports that had a CCR for pharmacy outside three standard deviations of the geometric mean.

There were 3,120 hospitals remaining in our file to which we applied the Meyers and Stauffer methodology as described above.

C. Refinement to the Myers and Stauffer Methodology

We then applied a refinement to this methodology. The Myers and Stauffer methodology considered departmental salaries as overhead and designated all other expenses as product cost.

Our refinement to the methodology increases salaries by adding related employee benefits. Employee benefits (payroll taxes, etc.) are a necessary corollary to net salary expense. In the cost report, employee benefits typically appear separately and are allocated to each department on Worksheet B-1 Part I (column 5). This refinement adds employee benefits to salaries. Thus, the proportion of assumed product cost (other expense) is reduced as the proportion of salary plus employee benefits is increased. It should be noted that this variation does not address the issue of whether all other expenses are product costs.

Specifically we:

- Calculated the percentage of total pharmacy costs on worksheet A that can be attributed to "other" when fringe benefits from Worksheet B-1 Part I (column 5) is added to salary.
- Applied this percentage to the original total of salary and other (column 1 and 2 of worksheet A) to get a new "other costs".
- Calculated the same ratio of overhead CCR to total CCR for pharmacy as in the original methodology.

V. Conclusions

Calculating pharmacy overhead costs directly using hospital cost reports results in an estimate of overhead costs representing 36.5 to 38.8 percent of pharmacy costs. This translates into overhead mark-ups of 50 to 60 percent over product acquisition costs, much higher than the two percent mark-up over acquisition cost that CMS is proposing to

use in setting payment rates for 2006 for separately covered outpatient drugs.¹⁴ This study adds to the prior research on pharmacy overhead costs using cost reports.

The first study was conducted in 1999 for CMS (formerly the Health Care Financing Administration) done by Myers and Stauffer LC as a subcontractor to Kathpal Technologies on a limited number of cost reports. It concluded that costs other than product acquisition costs account for about one-third of the costs captured in the pharmacy cost center. MedPAC also recently conducted an analysis of over 3,000 hospital cost reports and separately Maryland cost reports and found that overhead costs accounted for between 25 and 28 percent of pharmacy costs.

In this study, we replicated the Myers and Stauffer methodology using over 3,000 hospital cost reports with the most recently available cost reports. We found very consistent findings regarding the percentage of total costs accounted for by overhead when using the same methodology as the Myers and Stauffer report. Specifically, we found that the charge-weighted mean value for overhead costs for the drugs charged to patients cost center to be 36.5 percent. The Myers and Stauffer methodology used all other expenses other than salary as a proxy for product costs, which would understate overhead. We refined the methodology to account for this limitation by including employee benefits in salary and calculated that overhead accounted for at least 38.8 percent of pharmacy costs. This refinement still under estimates overhead costs, since hospital cost reports of "other" costs in the pharmacy department likely include a variety of costs beyond drug and biological costs

An important limitation of both the original Myers and Stauffer methodology and our refinements is that neither can capture product-specific differences in storage and handling costs. There can be significant difference in these costs for different products. Further, estimates based on the pharmacy department as a whole, inpatient and outpatient, would underestimate the overhead costs associated with outpatient drugs. The types of medications that are administered more frequently in outpatient departments generally require more pharmacy preparation time than do those for inpatients.

Despite limitations, hospital cost reports remain a rich source of information on hospital costs. Further research on the cost reports that takes a more detailed approach to the different ways hospitals allocate expenses could yield even more precise estimates of overhead versus product costs.

This research highlights a potentially important issue for Medicare reimbursement for drugs and biologicals beginning January 1, 2006. While the CMS methodology is designed to cover the variable cost of acquiring drugs and biologics in the hospital outpatient setting, it makes only limited provision for non-ingredient pharmacy costs, which the research described and cited above shows are substantially larger than the 2%

¹⁴ Hospitals that are able to purchase separately payable drugs and biologicals at "average" prices will receive an 8 percent markup under the methodology of ASP plus 6 percent. However, the 6 percent add-on has been designated as acquisition cost by CMS, to protect those providers who must purchase at above average prices.

to 8% range implied in the CMS methodology. Using the residual after taking charges reduced to cost for the limited subset of separately payable drugs and subtracting acquisition costs may significantly understate the actual handling costs for those therapies.



2005 SEP 12 PM 7: 51

Particle Therapy

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314 G
Washington, DC 20201

Hunter
Kane

POT

September 2nd 2005

Re: Proton Beam Therapy Payment Classification

Dear Dr. McClellan,

In the Proposed Calendar Year (CY) 2006 Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY'06 Payment Rates (CMS-1501-P), CMS proposed rule we note the following as it relates to proton therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.

The proposed rates more accurately reflect the significant capital demands associated with developing and high operating costs of running a proton therapy center.

Also, it should be noted that this technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully, as it is expected to be modest for the next 2-3 years, with an outlook to supporting patient access to proton beam therapy.



Particle Therapy

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPSS rule. We urge CMS to make the proposed rule its final rule for CY 2006.

This will ensure that the Nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires between \$70-\$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPSS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of construction and development.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chris Chandler', written in a cursive style.

Chris Chandler
VP and General Manager
IBA Proton Therapy

SEP 16 2005



146

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September 15, 2005

Mark McClellan, 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

Honorary President

Mary Ann Donovan
(1995-2005)

RE: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Directors Emeriti

Lovejoy Duryea
John P. Warwick

Dear Administrator McClellan:

Executive Director

Donald G. Jacob, Ed.D

On behalf of The Neuropathy Association, (TNA) a national, nonprofit organization providing service to the upwards of 20 million Americans who have peripheral neuropathy, I want to take this opportunity to comment on the proposed Rule #CMS-1501-P regarding changes to payment policies under the hospital outpatient prospective payment system (HOPPS) for calendar year 2006, and request that CMS take special consideration in its reimbursement of intravenous immune globulin (IVIG) due to the current access problems facing patients that rely on this lifesaving and life-enhancing therapy.

Chief Financial Officer

Catherine Law

The Neuropathy Association's mission is to increase public awareness of the nature and extent of neuropathy, facilitate information exchanges about the disease, advocate the need for early intervention and support research into the causes and treatment of neuropathies. Established in 1995. The Neuropathy Association (TNA) has more than 94,000 members, who are dues payers and contributors, and more than 250 support groups in North America and several European and Latin American countries. TNA has recently established a national network of neuropathy centers affiliated with some of the country's most prestigious teaching hospitals. The goal of these centers, five of which are now operating, is to better inform medical professionals, policymakers and the general public about neuropathy by providing resources for education, advocacy and assistance.

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IVIg is an effective treatment for two types of neuropathy: CIDP (*Chronic Inflammatory Demyelinating Polyneuropathy*) and Guillain-Barre Syndrome or AIDP (*Acute Inflammatory Demyelinating Polyneuropathy*). It is believed that 4,000 to 6,000 Americans have GBS.

Approximately 50,000 Americans have been diagnosed with CIDP and 20% of these, or 10,000, are treated with IVIg at any one time. Some patients do not respond to IVIg, some are in remission at any one time, and some are treated with steroids, plasmapheresis, or chemotherapy.

Patient access to care is essential as IVIG is life saving, as well as life sustaining. Earlier this year, CMS implemented the new average sales price (ASP) payment methodology (ASP + 6 percent) under Medicare Part B. This revision in the payment methodology has not been adequate for health care providers under Medicare Part B to continue to purchase and administer IVIG in physicians' offices and infusion suites.

TNA has seen the invoices from the physicians' offices showing that cost for IVIG exceeds the reimbursement payment from CMS. This has caused hundreds of patients to be moved out of their optimal site of care to a new site of care, the hospital, *when available*. Additionally, due to the shift in patients to new sites of care, the hospitals have been overburdened by the increase in demand for IVIG, which has not been easily accessible. Therefore, patients are facing a reduction in product or in frequency of infusions and higher exposure to infections, which has led to an increase in adverse health impacts of up to forty percent of these patients. Our national office has received numerous calls and emails from patients regarding their difficulty getting IVIg treatment – some having to wait several months!

TNA supports comparable and adequate reimbursement at all sites of care and opposes differential rates that have the effect of restricting patient access. Currently, most sites of care under Medicare Part B have been eliminated and we are concerned that if the reimbursement for the hospitals mirrors the reimbursement under Medicare Part B, neuropathy patients will have no place to

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receive their lifesaving therapy. We urge CMS to avert a regretful and avoidable outcome such as hospitals discontinuing service to neuropathy patients requiring IVIG.

Additionally, a letter was sent to Secretary Leavitt on September 6, 2005 by nearly thirty Members of Congress requesting that the Secretary act upon the recommendations made by the HHS Advisory Committee on Blood Safety and Availability (ACBSA) on May 16, 2005 to declare a public health emergency to enable CMS to apply alternative mechanisms for determination of the reimbursement schedule of IVIG products. ACBSA recognized the "worsening crisis" of IVIG access and how the crisis places "patients' lives at risk." We ask that you work with the Secretary to help increase access to IVIG in all sites of care.

Most recently, TNA participated in an IVIG summit on September 7, 2005, where a diverse group representing patients, physicians, group purchasing organizations, distributors and manufacturers of IVIG discussed the current access to care problems facing the IVIG community. From this meeting, the following recommendations were proposed to prevent patients from losing access to IVIG in the hospital outpatient setting:

RECOMMENDATIONS:

TNA requests that CMS use any and all authority and flexibility to address the existing reimbursement problems that will arise if the proposed HOPPS rates are implemented, as we are currently witnessing under Medicare Part B. Most recently, CMS has worked with the dialysis and chemotherapy communities in order to assure that reimbursement does not deter patient access and care. We request that CMS use this same flexibility so that those Medicare beneficiaries reliant on IVIG are not endangered by a further deterioration in their access to this life sustaining therapy.

For reasons discussed in detail below, TNA recommends that CMS take the following actions, with the recommendations listed in order of priority:

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1. Establish the 2006 HOPPS rate for IVIG based upon a recommendation from the Lewin Group to put in place a "proxy" add-on payment rate until the more comprehensive PPTA-commissioned Lewin study is completed.
2. In the absence of a proxy add-on, CMS should apply the 15% dampening provision to the HOPPS IVIG payment methodology for determining the 2006 payment rate.
3. Enhance the representativeness of the payment rate for each IVIG product by establishing unique HCPCS codes for each product.
4. Properly classify IVIG as a biologic response modifier (BRM) and reimburse its administration in a high complexity category.
5. ASP calculation should not include prompt pay discounts and the lag time should be equal with the lag utilized in calculating the Part B payment rate.

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I. Provide an Add-on Payment

The Lewin Group is studying the complex issue of IVIG reimbursement. The data they collect will demonstrate the actual, market-based pricing of IVIG, which is the price at which broadly based, national samples of hospitals are routinely able to procure it. The first stage of this comprehensive study is scheduled to be completed by December 2005 and will identify, catalogue, and estimate the cost of the full range of services that are related to the provision of IVIG to ensure that reimbursement covers these costs as well as the prices providers must actually pay for the therapy itself. These cost estimates will help policymakers better understand the issues related to supply, pricing policy, and payment. The study will also determine the magnitude of an appropriate "add-on" payment for IVIG, as well as the relative distribution of costs across product acquisition, handling, and administration.

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In the interim, beginning **January 1, 2006** we urge the agency to adopt a short-term solution to ensure that hospitals are adequately reimbursed. Payment rates should not only encompass hospitals' acquisition costs, but also pharmacy services, storage, and handling costs.

1. Based on a pilot study of hospital outpatient departments, Lewin will develop a "proxy figure" that could serve as a reimbursement rate until a more in-depth analysis is complete.

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II. Implement a Dampening Provision in the Absence of an Add-On

CMS could apply a modified version of the "dampening provision" proposed in the 2003 rulemaking process to lessen the impact of dramatic reductions in payment rates for IVIG. CMS stated that the dampening option "mitigate[s] the potential for underpayment" in cases where "costs show significant fluctuations."¹ As mentioned above, the IVIG rates based on ASP+ 6%+ 2% for pharmacy overhead costs in the 2006 proposed rule raise concerns. The present reimbursement environment under Medicare Part B is lead to a situation where in certain cases health care providers can no longer purchase IVIG because the cost of the therapy is exceeding its reimbursement. This has resulted in patients being shifted to the hospital outpatient site of service for treatment. With Medicare now proposing to implement the same model for the outpatient site of service, plus an additional 2% of ASP for hospital pharmacy overhead, we are concerned that a similar situation may develop in hospital outpatient care thus leaving those reliant on IVIG without recourse. As you are aware, the June 2005 Medicare Physician Advisory Commission report found that in the hospital outpatient system, hospital overhead is estimated to be 25-33% of ASP, as this site typically requires greater pharmacy preparation time than do those provided to inpatients. Further, CMS' own Ambulatory Payment Code Advisory Committee recommended that CMS reconsider the 2% add-on for pharmacy overhead costs in addition to reviewing industry data regarding such costs. We request that you to take this into account, specifically as it relates to IVIG, when formulating the final OPPTS rule. A 15% dampening effect applied to

¹ 68 Fed. Reg. 4798, 48003 (Aug. 12, 2003).

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current rates would keep payment rates more in line with actual hospital acquisition costs.

III. Classify IVIG as A Biologic Response Modifier (BRM)

IVIG has been proven to modify the course of several diseases for which there are no other viable therapeutic options. Unfortunately, however, administering IVIG to these patients is a complex undertaking, taking between three to eight hours, and requiring careful monitoring by a trained infusion nurse. In part this relates to the role that IVIG serves as a **biological response modifier (BRM)** in these diseases. A BRM is defined by the National Library of Medicine as: "a treatment intended to stimulate or restore the ability of the immune system to fight infection and disease". **IVIG is a BRM because it enhances the defective components of immunity to fight and protect against infection and complications of infection.** As the administration of IVIG is complex, like other BRMs, the process of administering the product should be reimbursed using higher complexity codes. This will allow for the effective and most importantly safe administration of IVIG to patients dependent upon it.

Given the gravity and acuity of risks in administering IVIG special precautions are required. These include careful monitoring of the entire infusion process which can be as short as three to four hours, but as long as eight hours. Expert nursing care by registered nurses skilled in the administration and risks of IVIG is essential. Nurse to patient ratios of 1:1 and never less than 1:2 are essential to allow frequent clinical assessment (including neurological checks), measurement of vital signs every 15 minutes (including temperature, respirations, heart rate and blood pressure) and comprehensive documentation. Physician and nurse assessment of a patient to determine suitability for the infusion is also necessary as certain comorbidities of the primary diagnoses can preclude, or alter the administration of IVIG. The immediate availability of the physician to evaluate the patient at any point during the infusion for assessment of potential complications is also critical. Finally, preparedness for a number of interventions to manage common infusion-related complications, including adjustment of the infusion rate, supplementation with physiological

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fluids, and provision of analgesics, non-steroidal anti-inflammatory, bronchodilators, antihistamines, steroidal anti-

inflammatories, or occasionally systemic sympathomimetics is also required. Clearly, the safe and effective prescription and administration of IVIG requires a highly skilled and coordinated effort from both nurse and physician.

Currently, administration of IVIG under the non-chemotherapy codes G0347 for the first hour and G0348 for subsequent hours provides \$77.29 and \$25.76, respectively. Given the aforementioned concerns and standard of care this rate fails to meet even nursing labor expense. Reimbursement using the chemotherapy codes G0359 for the first hour and G0360 for subsequent hours would provide \$173.54 and \$39.40, respectively. Clearly these differences are not enormous, but will allow continued access to the standard of care required by the IVIG patient receiving treatment in the HOPPS setting. Most importantly they will allow patients to receive IVIG safely and will allow practitioners to minimize the significant risks incurred by patients who depend upon therapy for their sustenance.

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IV. Establish Unique HCPCS Codes for Each Brand of IVIG

To the extent that CMS finalizes its proposal to pay for all separately payable drugs under OPSS based on ASP information, we believe that CMS could enhance the representativeness of the payment rate for each IVIG product by establishing unique HCPCS codes for each product. That would allow CMS to determine an ASP for each product based on its own ASP information, yielding rates that are pertinent to each product and thus may enhance access to IVIG products.

Unfortunately, there has been an assumption among many policymakers that all eight licensed IVIG products in the United States are exactly the same and the manufacturers' processes have no significant impact on patient care. It is absolutely critical that they understand that IVIG therapies are not interchangeable. Therapies differ in terms of donor pools, manufacturing and final formulation. Indeed, a number of these differences can, and do,

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affect individuals' tolerability, risk of adverse events, infusion rate, and potential efficacy.

However, Congress understood the uniqueness of IVIG by exempting it from the competitive acquisition program (CAP). There are currently eight licensed IVIG products in the United States, but each of the formulations of these products are different, and more importantly patients react differently to each brand of IVIG.

Although this class of therapeutics may be equivalent in some aspect, the U.S. Food and Drug Administration (FDA) recognizes each IVIG brand as unique, and actually makes each drug go through individual clinical trial protocol to receive licensure, even if it is from the same manufacturer. This is because of the differences in basic fractionation and the addition of various modifications for further purification, stabilization and virus inactivation/removal that have yielded products clearly different from one to the other. In addition, there are well-established differences in chemical structure, antibody content, subclass distribution and electrophoretic profile. Clearly, the composition of the final product differs widely.

Additionally, IVIG is a blood product, and goes through the same donation and fractionation process as albumin, clotting factor, and alpha-one prohibitase. When treating neuropathy patients, many factors need to be taken into consideration when deciding which IVIG product should be used. For example:

- Patients with congestive heart failure or compromised renal function may be better off receiving a product with a low osmolality and low volume;
- Patients who are diabetic are better off with a product containing no sugars;
- Patients receiving products with sucrose may be at a higher risk for renal failure;
- Patients with immunoglobulin A (IgA) deficiencies should only receive products with the lowest amount of IgA or they could have anaphylactic reactions; and
- Patients with small peripheral vascular access or a tendency toward phlebitis may want to avoid preparations with a low pH.

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These are just a few examples of some of the adverse effects that physicians are trying to avoid. Physicians often have to prescribe two or more brands of IVIG for infusion at different times in order to monitor for side effects. Having access to all brands of IVIG is vital

to treat a patient without incurring unacceptable serious and often life threatening side effects.

IVIG therapy is prepared from plasma pooled from thousands of donors. Most production processes begin with sequential precipitation and fractionation with ethanol to isolate IgG from other plasma proteins. The IgG concentrates from initial fractionation are subjected to additional processing to produce material suitable for intravenous administration. This is where major differences exist among products and where biologic function is most susceptible to alteration.

The major differences, which lead to the product characteristics are as follows:

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- **Liquid vs. Lyophilized**
The manufacturing process impacts whether the final product is in liquid or lyophilized (freeze-dried powder) form. Liquid preparations are potentially easier to use and may be associated with fewer adverse events. In ready-to-use form, the liquid preparations shorten preparation time and delays for patients. However, lyophilized preparations may have a longer shelf life without the need of refrigeration and are often less costly.
- **Product Concentration**
The manufacturing process also affects product concentration. Products that can be given at higher concentrations decrease volume load, an important aspect in certain patient populations. Concentrating certain products by reconstitution in a smaller volume will increase the osmolality of the final solution and may contribute to significant adverse events such as renal complications or thromboembolic episodes. However, patients that can tolerate rapid infusions can receive higher concentrations of IgG, which would result in shorter infusion times.

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- **Product Composition**

The variety of manufacturing processes, as well as starting materials, leads to differences among preparations that may be clinically important. Choosing the preparation of IVIG must take into account specific differences that can significantly impact the outcome in recipients.

- **Fluid Volumes**

The ability to deliver higher amounts of IgG in lower volumes has a major impact on recipients who may be intolerant of large fluid volumes, such as infants or patients with congestive heart failure or renal insufficiency.

- **Sugar Content**

Various sugars, such as: sorbitol, glucose, and sucrose have been added to some preparations as a stabilizer and preservative in order to prevent aggregate formation. Some products contain no sugar. A major concern associated with sugar content is the incidence of significant adverse events, particularly acute renal failure or insufficiency. Although rare, the CDC reported that 90% of the IVIG-associated renal adverse events in the United States occurred with sucrose-containing IVIG preparations.

- **Sodium Content**

In IVIG solutions, the major contributors to osmolality include sodium, sugars, and other excipient proteins. Solutions of IVIG range from physiologic osmolality to solutions that far exceed these levels. Some sugar-stabilized products have higher osmolalities than other sugar stabilized and sugar-free preparations. In reconstituting lyophilized preparations, careful attention to osmolality is required as adverse events may occur with solutions exceeding the physiologic range. With some lyophilized preparations, reconstitution to higher concentrated solutions results in hyperosmolar solutions.

- **pH**

The pH optimum for IVIG to prevent aggregation is 4.0-4.5. As a consequence, for preparations at higher pH, agents are added to maintain stability and prevent aggregation. There are various reports that low pH may be associated with phlebitis.

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- **IgA Content**
Patients with selective IgA deficiency and the ability to produce antibodies may be at risk for developing IgE or IgG anti-IgA antibodies resulting in reactions, possibly anaphylaxis.
- **Antibody Titers**
There are marked differences in the levels of some antibodies among correctly licensed products, which could significantly determine efficacy of intervention with IVIG.

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Patients affected by certain neuropathies depend on IVIG as a life saving therapy for the rest of their lives. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and does not pose serious and potentially life threatening complications. I want to reemphasize the adverse events that can occur while being treated with IVIG: renal dysfunction or failure (kidney problems), thromboembolic events (excessive blood clotting), hypertension (elevated blood pressure), phlebitis (irritation of veins used for infusions), and anaphylaxis (life threatening allergy). While a patient may experience an adverse event with a particular product, (s)he may tolerate other products quite well. This situation is addressed by prescribing two or more brands of IVIG for infusion at different times and monitoring for side effects. With the current changes in reimbursement under Medicare Part B, patients are not receiving the optimal brand of IVIG and in many incidences are having their brands switched every time the patient is infused. This is leading to devastating results.

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V. Revise Aspects of the ASP Calculation

Currently, the ASP calculation includes both "prompt pay" and "cash discounts" that manufacturers offer to distributors of IVIG. We believe prompt pay discounts are not direct reductions of the cost of the product and should not be included in the ASP price calculations. While we understand that literal exclusion from the price calculation would require a statutory change, we ask that this explanation of what a prompt pay discount encompasses be considered when evaluating the reimbursement adjustment options proposed in this document.

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As a specialty pharmaceutical and plasma-derived blood product, IVIG requires specialized handling. Monies realized through prompt pay discounts are frequently utilized to compensate the distributor for a host of services provided throughout the supply chain which include: managing the storage and delivery of products which often have to be refrigerated; expenses incurred associated with setting up, monitoring and collecting payments; associated credit risk, processing costs; risk of loss due to damage, spillage or other causes; insurance and security expenses; restocking and handling costs involved in processing returns from providers and the direct costs of sales; and technology costs associated with required reporting to the manufacturer to ensure product pedigree integrity. Bona fide prompt pay discounts also represent the time value of money and are not traditionally passed on to the provider customer by the distributor.

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The current ASP + 6% reimbursement in the Part B physician's office setting does not adequately cover the actual costs of acquiring and safely administering IVIG across all classes of trade. We feel the inclusion of prompt pay discounts in the formula for calculation of ASP has the unintended consequence of reducing the actual manufacturer's average selling price of IVIG and request that CMS allow the proposed reimbursement modifiers to negate this effect on the reimbursement rate.

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Furthermore, the nine month lag time applied to HOPPS should at a minimum be balanced with the six month lag time used in the Part B calculation. The six month lag time applied to Part B is not ideal; however, the methodologies between the two sites of service should be equalized.

IMPACT OF MEDICARE PAYMENT REDUCTIONS:

Since January 1, 2005, TNA has received a high volume of calls and letters from patients and physicians regarding access problems related to Medicare reimbursement for IVIG treatment. In order to obtain a fair and unbiased assessment of the current impact of changes in Medicare reimbursement since January 2005 on patients with neuropathy. The experience of problems obtaining IVIG is adversely affecting patient confidence in whether they are

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currently getting optimal treatment, but much more dramatically their confidence in their ability to get appropriate treatment in the future.

CONCLUSION:

Since the implementation of the Medicare Modernization Act, access to IVIG for patients with certain neuropathies and primary immune deficiency diseases has decreased dramatically, putting patients' lives at risk. We are extremely concerned when the hospitals switch over to the ASP reimbursement methodology, patients will lose access to IVIG in all sites of care.

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We look forward to continuing to work closely with your staff and would welcome the opportunity to discuss the access problems our community is having in receiving their lifesaving therapy in the hospital setting, as well as the physicians' office and home care setting. I am available at any time to answer any questions that you or your staff may have in regards to reimbursement issues affecting neuropathy patients' access to care. I can be reached at (212) 692-0379.

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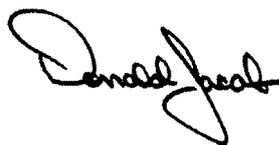
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Thank you for your attention to these very important issues.

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Respectfully submitted,



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147



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September 15, 2005

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1501-P

**Re: Medicare Program; Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006
Payment Rates**

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the proposed rule, CMS-1501-P, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, published in the Federal Register on July 25, 2005. The AMI is comprised of academicians, researchers and nuclear medicine physicians utilizing Positron Emission Tomography (PET) technology, and serves as the focal point for PET education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI also speaks for thousands of physicians, scientists and patients with regard to this lifesaving technology. The AMI greatly appreciates the time and attention that you and your staff have devoted to making PET and PET/CT technology accessible to Medicare beneficiaries.

Summary

PET/CT is one of the leading imaging technologies used for the management of cancer patients. This new imaging technology was first introduced in 2000, and thus had limited hospital utilization in 2001 and 2002. PET/CT is now more widely used in hospitals, and because it provides to physicians numerous clinical benefits beyond conventional PET, and provides to patients more precise treatment planning, it will eventually replace the use of PET-only scanners in the United States.

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Hospitals incur more capital and maintenance costs with a PET/CT scanner than with a conventional PET scanner.

In the 2006 Proposed Hospital Outpatient payment rule, CMS proposed to assign the PET/CT New Technology classification payment rate to New Technology APC 1514 (\$1250). This payment rate is far below the true cost of PET/CT, and it significantly underpays hospitals. This rate also does not recognize the additional diagnostic benefits provided by PET/CT over traditional diagnostic PET and computed tomography (CT) scans.

AMI recommends that in the final hospital outpatient rule, CMS reimburse PET/CT in a New Technology Ambulatory Payment Classification (APC) and, because there is no available claims data for PET/CT, that it base the payment rate on external data. For the reasons set forth below, we respectfully recommend that CMS assign CPT codes 78814¹, 78815², and 78816³ to APC 1519, with a payment rate of \$1,750.

This recommendation is consistent with the New Technology payment policy for new products where no claims data exist, and will make PET/CT available to Medicare beneficiaries in hospitals. This payment rate also reflects the clinical and cost differences between PET and PET/CT.

Clinical Differences Between PET and PET/CT

PET is a highly sensitive technique that detects the metabolic signal from actively growing cancer cells in the body. PET employs two scans to accurately identify the location of this signal. The first detects the metabolic signal; the second detects a radioactive source circulating throughout the body, and is used to correct the metabolic scan for radioactivity that is absorbed or attenuated by the body. The PET scan provides accurate metabolic information, but it does not determine the exact anatomic location of the signal in the body.

The key to PET's effectiveness is that it provides physicians with information about the body's chemistry, cell function, and metabolism that anatomic imaging modalities, such as CT and MRI, do not. Certain diseases cause abnormalities of blood flow or metabolism before anatomic changes become apparent. These abnormalities can be detected by PET at a stage when the anatomic imaging scans appear normal. Moreover, whereas anatomic imaging depends on the size and growth rate of lesions to determine the likelihood of malignancy, PET physicians can determine the presence or absence of malignancy through the evaluation of tissue metabolism.

¹ CPT code 78814 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (e.g. chest, head/neck).

² CPT code 78815 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh.

³ CPT code 78816 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body.

CT is a standard imaging method that provides high-resolution anatomic information by detecting differences in the density of various tissues. The combination of PET and CT into a single device, known as a PET/CT, is a breakthrough in imaging because the images from a PET scan and a CT scan can be seamlessly merged into an image that more accurately identifies and localizes tumors in the body.

When the results of the scans are fused together, they provide the most complete non-invasive information available on cancer location and metabolism. In addition, PET/CT allows both tests to be performed without moving the patient, and the resulting images leave less room for error in interpretation due to the more accurate picture of the cancer provided by the scan.

The benefits to the patient are tremendous: **earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy.** A PET/CT image separates malignant from benign processes and reveals tumors that may otherwise be obscured by the scars and swelling that result from therapies such as surgery, radiation, and drug administration. PET/CT images often reduce the number of invasive procedures required during follow-up care, including biopsies, and may reduce the number of anatomical scans needed to assess therapeutic response. In some cases, the images are so precise that they can locate an otherwise undetectable tumor.

Background on FY 2005 and FY 2006 Hospital Outpatient Payment for PET/CT

During the 2005 rulemaking process for the Hospital Outpatient Prospective Payment System (HOPPS), PET/CT was a new technology with no identifiable Medicare claims data. Because PET/CT did not yet have an established CPT code when HOPPS rates were set, CMS did not set a payment rate for PET/CT when it published the final hospital outpatient rule on November 15, 2004.

The American Medical Association (AMA) granted three new CPT codes (78814, 78815, and 78816), which were implemented in January 2005, to describe PET with concurrent CT when CT is used solely for attenuation correction and anatomical localization (rather than for diagnostic purposes).

In March 2005, with no discussion and without soliciting public comment, CMS assigned these three new codes to New Technology APC 1514, in the Hospital Outpatient Quarterly Update Transmittal 514. CMS established the payment rate of \$1,250, which is \$100 higher than the payment rate for PET scans in APC 1513. CMS correctly assigned PET/CT to a different APC from PET. This is consistent with the Food and Drug Administration's (FDA) conclusion in both its premarket approvals and regulations that PET/CT is a different medical device from PET. For example, PET/CT devices are specifically cleared by the FDA for marketing under the 510(k) process on the basis of marketed (or predicate) PET/CT devices, not PET devices.

However, it is unclear how CMS arrived at the payment rate established in the Quarterly Update. CMS provided no rationale for the rate, and because no code for PET/CT then existed (codes for

PET/CT were first implemented in January 2005), there was no identifiable claims data for PET/CT.

In the 2006 Proposed Hospital Outpatient payment rule, CMS proposed to continue its assignment of PET/CT codes to New Technology APC 1514 with a payment rate of \$1,250.⁴ Although AMI agrees with CMS that PET/CT should remain in the New Technology classification for 2006, we believe the current and proposed payment rates are too low and, due to the lack of claims data, should be modified on the basis of external data.

Recommendation for the Final Hospital Outpatient Rule for PET/CT

AMI greatly appreciates the hard work and careful consideration CMS put into developing the proposed rule. We are concerned, however, that the proposed payment rate for PET/CT does not adequately cover hospitals' costs for providing PET/CT services. The costs and resource use involved in a PET/CT scan are more substantial than those involved in a PET-only scan. For example, hospitals incur more capital and maintenance costs with PET/CT than with conventional PET. A new PET/CT scanner costs approximately \$1.8 million dollars, compared to \$1.2 million for a conventional PET scanner. Further, a PET/CT scanner carries twice the operating cost of a conventional PET scanner, with an annual maintenance contract of approximately \$240,000, compared to \$120,000 for a PET-only scanner.

AMI is also concerned that the proposed payment rate for PET/CT does not reflect that the CT scan performed during a PET/CT is not limited to one part of the body but includes the entire area imaged by the PET scan. When a physician orders a PET/CT and a diagnostic CT the nuclear medicine physician can in some cases perform both a CT scan for attenuation correction and a diagnostic CT scan with contrast with a single PET/CT scan. For example, CPT code 78815 could include a CT scan from the skull base to the mid-thigh, which is equivalent in area to a CT scan of the neck, chest, abdomen, pelvis, and part of the lower extremity. The CT portion of a PET/CT may be equivalent to multiple diagnostic CT scans and is performed with or without contrast. This is more efficient than performing one PET scan plus several separate CT scans for different regions of the body. An individual regional CT scan with contrasts is reimbursed by Medicare at approximately \$300.

In some instances a nuclear medicine physician needs to order both a PET/CT and a diagnostic CT scan. For example, the clinical protocol for diagnosing a small lung nodule calls for the patient to hold their breath during the scan. Because PET/CT requires a longer period of time for image acquisition, it is not possible to perform the PET/CT scan and diagnostic CT scan simultaneously. In that case, the physician must perform a separate diagnostic CT scan.

Because the PET/CT CPT codes and payment rate were first implemented in April 2005, there is no available Medicare claims data for PET/CT. Therefore, for the final hospital outpatient rule

⁴ We appreciate that CMS corrected its technical error with respect to the PET/CT rate, published in the proposed rule as \$1150.

for FY 2006, CMS should base the New Technology payment rate for PET/CT on external data and economic analysis. The attached paper shows the hospital cost of providing a PET/CT scan, based on the extrapolation of a published economic cost model. According to its authors, the model is based on average national utilization rates in the hospital outpatient department, and is adjusted for PET/CT equipment and operational requirements. Based on this economic analysis, the costs for a PET/CT scan are approximately \$1,717. The present PET/CT payment rate is therefore far below the true costs of providing the service in hospital outpatient departments. CMS should use this published economic model cost analysis to set the New Technology rate for 2006.

Based on this external analysis, we recommend that CMS assign CPT codes 78814, 78815, and 78816 to APC 1519 with a payment rate of \$1,750. This recommendation is consistent with the attached data, with the clinical use of PET/CT, and with the greater relative resource use associated with PET/CT than with conventional PET.

AMI Supports the Proposed Payment Classification for PET Scans

We strongly support the proposal in the rule to maintain covered FDG PET procedures in New Technology APC 1513. This decision reflects the fact that the hospital outpatient claims data used to set the 2006 proposed payment rates do not accurately reflect the costs of providing these services. Adequate payment for these services is essential to ensure patient access to this important technology. AMI will continue to work with CMS and providers on issues relating to PET claims data.

Payment for Radiopharmaceutical Fluorodeoxyglucose (FDG)

The proposed rule makes significant changes to hospital outpatient payments for radiopharmaceuticals in 2006 and subsequent years. The rule proposes to pay for FDG and other radiopharmaceuticals based on hospital charges reduced to costs by the hospital cost to charge ratio (CCR). AMI supports this proposal but has concerns about its implementation. AMI is committed to working with CMS and other stakeholders on payment issues for nuclear medicine therapies and isotopes, including how to implement CMS's proposed payment methodology appropriately in FY 2006.

AMI recommends that the hospital-wide CCR be used, as this is the appropriate hospital cost center for FDG. Hospitals have a wide variety of mark-up policies for drugs and radionuclides. It will be critical that hospitals charge appropriately and that CMS and contractors apply the correct CCR. AMI will work with providers to educate them regarding the proposed new payment methodology for FDG.

AMI is interested in working with CMS on establishing appropriate payments for FDG and other radiopharmaceuticals in subsequent years. In the proposed rule CMS asks for comments on whether radiopharmaceuticals should be paid based on average sales price (ASP) starting in 2007. Due to the difficulties with reporting ASP for FDG and other radiopharmaceuticals, AMI believes that CMS should study this issue further in the context of a public process that allows

The Honorable Mark McClellan
September 15, 2005
Page 6 of 6

for significant stakeholder input. AMI stands ready to work with CMS and other stakeholders on payment for FDG in 2007 and subsequent years.

AMI appreciates the opportunity to submit these comments, and looks forward to an ongoing dialogue with CMS on these important issues.

Sincerely,

R Edward Coleman

Dr. R. Edward Coleman
Immediate Past President
Academy of Molecular Imaging

Cost Analysis of PET Modification for the practice of PET in 2005

Jennifer S. Keppler

In 2001, a paper was published describing the results of a multi-year evaluation of the costs of providing PET services (*A Cost Analysis of Positron Emission Tomography, American Journal of Radiology: 177, July 2001* (Keppler JS and Conti PS), "Cost Model"). The publication was the result of a 3-year study funded under a *Cost-Effective Health Care Technologies* award by the National Science Foundation/Whitaker Foundation. The purpose of the study was to identify the cost of PET to providers using several different operating models. In the Cost Model, a one-way sensitivity analysis found that throughput, the number of scans/day, was found to be the most significant success factor. In 2002, we adapted the model to reflect the operating assumptions of PET in the US under the Medicare payment system. First, an adjustment was made to separate the *technical* and *professional* components of the procedure. Second, *throughput* was changed to 2.9/day to reflect the average number of patients performed by PET centers around the country at that time.

Since the Cost Model was published and this first adaptation made, the practice of PET has continued to evolve. Commercial providers for the primary PET imaging agent, F-18 FDG have penetrated nearly all of the major population centers in the US, obviating the need for a cyclotron-based PET center to provide clinical services. Through these commercial entities, accurate data are now available that show the average number of scans performed per day on the devices, based on FDG sales. Furthermore, the introduction of the PET-CT scanner in 2000 provided a significant advancement in imaging capabilities. More than 90% of the PET scanners sold over the last two years are comprised of this new technology. Therefore, the authors of this paper have modified the original model to address the evolving practice of PET. Outlined below are the key assumptions that were changed, as well as the results of the addendum to the cost analysis.

Revised Assumptions:

Parameter	Original Value	Revised Value	Notes
Scanner price	\$1,000,000	\$1,800,000	PET-CT technology
Down days/year	18.0	6.0	No longer need to incorporate cyclotron down days in the analysis
Number of procedures/day		3.8	Data from the Institute for Molecular Technologies (IMT)
Professional Component	Included in total	(\$80)	Average PC
Average price/dose of FDG	\$700	\$300	Market change
Technologist salary rate	\$45,000	\$80,000	Specialized training in both PET and CT required
Hospital based FDG distribution	Included	Deleted	Reflecting status of the market

Results and Discussion:

Based on the changes outlined above, the average scan cost for a Medicare patient in a scanner-only site has changed from the analysis submitted in 2002. Notably, however, the average number of scans performed by a site per day is increasing as this market matures. Overall average cost per scan is going down as well, but are still higher than current and proposed OPPS values.

The table shows the average cost per scan with and without professional component. Radiopharmaceutical costs are not bundled into the total reflecting current reimbursement practices.

Site Configuration:						
		Cyclotron & Scanner			Scanner Only	
		Without PC	With PC	Without PC	With PC	
Scan Fee	\$	3,797	\$ 3,877	\$ 1,717	\$ 1,797	
Isotope	\$	1,893	\$ 1,893	\$ 300	\$ 300	
Total	\$	5,690	\$ 5,770	\$ 2,017	\$ 2,097	

This adjunct analysis demonstrates increased utilization of existing PET scanners. Increasing clinical indication and clinician adoption has led to this, despite the growing numbers of PET-CT scanner sites. This has resulted in a reduction in the average cost per scan as compared with the 2001 analysis. Technical component scan cost has been reduced to \$1,717 from \$1,970, over this time period, but remains significantly higher than the proposed 2006 HOPPS payment levels.



149

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

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September 14, 2005

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
200 Independence Avenue, NW
Room 314-G
Washington, DC 20201

Dear Dr. McClellan:

I am pleased to forward a reprint from the September/October issue of *Health Affairs*, titled "Medical Groups' Adoption of Electronic Health Records and Information Systems." This study outlines current, comprehensive government-funded analysis of health information technology implementation in ambulatory medical settings. The Medical Group Management Association (MGMA), in conjunction with the University of Minnesota School of Public Health, surveyed a representative sample of U.S. medical group practices and produced this analysis with funding from the Federal Agency for Healthcare Research and Quality.

As federal policymakers design a national health information infrastructure, begin collecting pharmaceutical information related to the new Medicare Part D benefit and plan for the collection of clinical performance measures, it is critical that all parties involved understand the latest information concerning the current use of health information technology. Among the noteworthy findings of this study are:

- **Health information technology (HIT) implementation rates** – Survey data reveal that less than 15 percent of medical group practices have implemented electronic health records (EHRs).
- **Larger practices quicker to adopt** – As expected, larger practices have implemented EHR at a higher rate than smaller practices.
- **HIT costs** – Respondents identified the cost of purchasing and maintaining HIT technology as being the single most important barrier to adoption. Initial capital costs are approximately \$33,000 per physician (even higher for smaller practices), while maintenance costs are approximately \$1,500/physician/month. For the average primary care physician, purchasing an EHR could translate to a 10 percent reduction in take-home pay every year for five years.

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- **Return on investment** – There is significant uncertainty regarding the return on HIT investment for medical practices. HIT systems represent a substantial capital investment, and practices are reluctant to commit their resources when the consequences of technologies are unknown. There is great concern that financial incentives are “misaligned” since medical practices incur the expense of purchasing, implementing, and maintaining HIT systems, while many of the initial benefits accrue to health plans.
- **Complicated implementation = reduced productivity** – Survey respondents indicated that medical practices found it significantly more difficult to implement HIT than they had anticipated. In addition to the high initial purchase cost and cost overruns averaging 25 percent more than initial vendor estimates, respondents experienced a significant reduction in productivity, at least through the implementation and acclimation period. Medical practices reported decreases in physician productivity of up to 15 percent, usually lasting a year or more.

Our survey confirms the significant barriers to technology adoption that exist for medical practices, especially smaller offices and those specializing in primary care. As a consequence of this information, we believe that federal policymakers will want offer incentives to small practices, especially primary care practices, since these practices may otherwise be unable to participate in the anticipated transformation of medical practice promised by widespread EHR use.

We also hope that policymakers carefully consider that any pay-for-performance programs based on an assumption of easily collected performance measures through the use EHRs are still premature. Additionally, we hope that policymakers carefully consider the impact of new regulatory and administrative burdens unintentionally created by a rush to reap the benefits of technology dissemination before such technology is widely available. Medical group practices that have not yet adopted EHRs have legitimate reasons for not doing so. We hope that federal policymakers take this into account as we work together to lower the roadblocks to EHR adoption.

We believe that this information will provide a useful resource and we look forward to working with you on methods to encourage the rapid adoption of health information technology.

Sincerely,



William F. Jessee, M.D., FACMPE
President and CEO



PRESS RELEASE

EMBARGOED UNTIL SEPT. 14, 2005, 10a.m. EST

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Research finds low EHR adoption rates for physician groups

ENGLEWOOD, Colo., Sept. 8, 2005 – A comprehensive study by the Medical Group Management Association (MGMA) Center for Research and the University of Minnesota School of Public Health has captured the current state of adoption of electronic health records (EHR) by U.S. medical group practices. More than 3,300 medical group practices participated in the *Assessing Adoption of Health Information Technology* project, which was funded by the federal Agency for Healthcare Research and Quality (AHRQ). The study reports current rates of EHR adoption, which EHR features are more frequently used, barriers to adopting an EHR and how users rated the benefits of having adopted an EHR.

Smaller practices report lower adoption rates

The research shows that just 14.1 percent of all medical group practices use an EHR, and just 11.5 percent indicated that an EHR was fully implemented for all physicians and at all practice locations. More significantly, the research shows that only 12.5 percent of medical group practices with five or fewer full-time-equivalent physicians (FTE) have adopted an EHR. The adoption rate increased with the size of practice; groups with six to 10 FTE physicians reported a 15.2 percent adoption rate, groups with 11-20 FTE physicians reported an 18.9 percent adoption rate, and groups of 20 or more FTE physicians had a 19.5 percent adoption rate.

Other data reveals that 12.7 percent of groups were in the process of implementing an EHR; 14.2 percent said implementation is planned in the next year; and 19.8 percent said implementation was planned in 13-24 months. The remaining 41.8 percent have no immediate plans for EHR adoption. Among those with no immediate plans for implementation, the difference between large and small groups is striking – 47.8 percent of practices with five or fewer FTE physicians compared with only 20.7 percent of practices with 21 or more physicians.

“Obviously, rates are low across the spectrum of all group sizes, but smaller groups face more challenges in adopting these technologies and progress more slowly than their larger counterparts,” said Terry Hammons, MD, senior vice president, research and information, MGMA Center for Research, and co-author of the study. “For widespread adoption of EHRs to be successful, more work needs to be done, and small to medium size medical group practices will need more help than they are getting now.”

Contributing researchers from the University of Minnesota School of Public Health Bryan E. Dowd, PhD, professor and director of Graduate Studies, Division of Health Services Research, Policy, and John E. Kralewski, PhD, professor, Division of Health Services Research and Policy, note that while some practices report important efficiency gains from their EHRs, there is widespread dissatisfaction with the design and performance of these technologies.

Nationally representative sample surveyed

With funding from the Agency for Healthcare Research and Quality (AHRQ), MGMA Practice Management Resources Director David N. Gans, FACMPE, Kralewski, Hammons and Dowd surveyed a nationally representative sample of medical group practices to assess their current use of information technology. They conducted the survey in January and February 2005. MGMA members made up 25 percent of the sample.

“This survey provides a guidepost for where we should focus our efforts to move the adoption of state-of-the-art electronic health record systems,” said AHRQ Director Carolyn M. Clancy, M.D. “Adoption of these EHR systems is an important means to an end in our efforts to improve the quality of health care in America.”

Findings of the research are also highlighted in the September/October edition of *Health Affairs* in “Medical Groups’ Adoption of Electronic Health Records and Information Systems” written by Gans, Kralewski, Hammons and Dowd. (Please contact MGMA Press Relations for a copy of the article)

EHR capabilities vary

The report provides insight into which EHR capabilities are actually used, as not every EHR has all functions and not every medical group fully uses the capabilities of its EHR system. More than 97 percent of the respondents with an EHR reported that their system had functions for patient medications, prescriptions, patient demographic and visit/encounter notes. Less than 65 percent reported the EHR provided drug formulary information or clinical guidelines and protocols. Equally important was that only 83.1 percent of respondents said their EHR was integrated with their practice billing system.

“System integration is a highly important function of the EHR,” Gans said. “Integration with the practice billing system facilitates cost savings by eliminating the manual entry of billing information, improving charge capture and improving documentation in the medical record of billed services.”

Cost a barrier to adoption

Despite state and federal efforts to encourage adoption of these technologies, group practices cited “lack of capital resources to invest in EHR” as the top barrier to adoption. Also, University of Minnesota researchers noted, an important barrier to adoption is that practices are not convinced EHRs will improve their performance. The return on investment in terms of cost and quality are not yet evident, according to Kralewski.

The research indicates that the average purchase and implementation cost of an EHR was \$32,606 per FTE physician. Maintenance costs were an additional \$1,500 per physician per month. Not surprising was the finding that smaller practices had the highest per-physician implementation cost at \$37,204. The study also found that the average cost for EHR implementation was about 25 percent more than initial vendor estimates.

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About AHRQ

The Agency for Healthcare Research and Quality is a component of the U.S. Department of Health and Human Services. The Agency’s mission is to improve the quality, safety, efficiency and effectiveness of health care for all Americans.

Medical Groups' Adoption Of Electronic Health Records And Information Systems

Practices are encountering greater-than-expected barriers to adopting an EHR system, but the adoption rate continues to rise.

by David Gans, John Krlewski, Terry Hammons, and Bryan Dowd

ABSTRACT: We surveyed a nationally representative sample of medical group practices to assess their current use of information technology (IT). Our results suggest that adoption of electronic health records (EHRs) is progressing slowly, at least in smaller practices, although a number of group practices plan to implement an EHR within the next two years. Moreover, the process of choosing and implementing an EHR appears to be more complex and varied than we expected. This suggests a need for greater support for practices, particularly smaller ones, in this quest if the benefits expected from EHRs are to be realized.

MOST MEDICAL GROUP PRACTICES have computer-based billing systems and patient scheduling systems, but the expansion into clinical support functions has been slow.¹ Physician practices are experiencing downward price pressures from managed care plans and from Medicare and Medicaid, as well as pressure to document and improve the quality of care; pay-for-performance programs will but strengthen these forces.

Although the empirical evidence documenting consistent cost or quality improvements resulting from implementing electronic health records (EHRs) in group practices is still limited, there is widespread political support for implementation. The American Academy of Family Practice has asserted that the effective use of information technology (IT) is essential for the provision of high-quality care in the increasingly complex health care field.² Purchasers of care, including some large employers and the Centers for Medicare and Medicaid Services (CMS), are promoting EHR adoption and are considering programs to help finance the costs or to provide financial incentives to those who implement EHRs.³

In spite of this enthusiasm, the adoption of EHRs appears to be proceeding rela-

David Gans (dng@mgma.com) is director of practice management resources for the Medical Group Management Association in Englewood, Colorado. John Krlewski is the Wallace Professor in the Division of Health Services Research and Policy, University of Minnesota, in Minneapolis. Terry Hammons is senior vice president, Research and Information, at the MGMA. Bryan Dowd is a professor and director of graduate studies in the Division of Health Services Research, Policy, and Administration, University of Minnesota School of Public Health.

tively slowly, for a number of reasons.⁴ Because of the large number of systems being offered, it is not easy—especially for smaller practices—to identify which systems would meet a practice's needs. There is justifiable concern about the stability of many companies offering EHRs and whether the products will have adequate technical support. It is difficult for some physician practices—especially those that are small and physician-owned—to meet the managerial challenges and the capital costs of EHR systems.⁵ There are anecdotal descriptions of successful return on investment by practices that have implemented EHRs and credible projections of positive return on investment; however, we are not aware of an extensive, methodologically sound assessment in the literature.⁶

There are good reasons to expect clinical and perhaps economic benefits for practices implementing EHRs and considerable interest in furthering their adoption, but also a great deal of uncertainty. We assessed the rate and process of adoption of IT and EHRs by medical group practices through findings from a national survey conducted during January and February 2005 and a series of interviews and site visits to practices.

Study Data And Methods

■ **Data.** Our data are from a survey of a stratified random sample of group practices drawn from a national database of 34,490 medical groups that we assembled for a previous project.⁷ *Group practices* were defined as three or more physicians practicing together with a common billing and medical record system. We placed these 34,490 practices into sixteen sampling cells for our EHR study (four regions and four practice sizes), and we drew 50 percent random samples of the group practices in each cell. These practices were surveyed using a three-stage process: (1) All of those with e-mail addresses were asked by e-mail to complete a Web-based survey instrument, then (2) a paper survey was mailed to practices with no e-mail address and to those who had not yet responded to the Web survey with a request to complete the Web survey or return the mailed paper survey.⁸ These two requests resulted in 2,879 responses to the two surveys combined, with rates of response ranging from 13.6 percent for practices with five or fewer physicians to 26.9 percent for practices with twenty-one or more physicians. After reviewing the patterns of respondents and nonrespondents in each cell, (3) we conducted a telephone survey of a stratified sample of 750 nonresponding practices selected randomly from each cell. The telephone survey obtained a 97 percent response rate and so provided excellent data to detect nonresponse bias in the combined Web and mail survey results.

■ **Study methods.** The percentage of practices with EHRs was slightly higher among respondents to the combined Web and mail surveys (15.5 percent) than respondents to the telephone survey (13.4 percent); this difference is attributable in part to a higher fraction of larger practices (a higher percentage of which have EHRs) in the combined Web and mail survey respondents. To examine the potential for nonresponse bias from these surveys, we compared those responses with the

telephone survey responses for the principal question about whether a practice has an EHR system. The correlation between type of survey response and whether a practice has an EHR was not significant ($p = .09$). Because we had observed that the percentage of practices with EHRs differs greatly by size of practice (although not by geographic region), we then used logistic regression to compare rates of EHRs for telephone survey respondents to respondents to the combined Web and mail surveys, controlling for practice size. In this analysis, the percentage of practices with EHRs was, again, slightly higher among the combined Web and mail respondents than among the telephone respondents for the smaller groups, and again the variable for type of survey was not statistically significant ($p = .10$). We concluded that there might be a small but not statistically significant nonresponse bias in the combined Web and mail survey data, and we pooled data from the combined Web and mail survey and telephone survey for further analysis.⁹

The combined data were roughly evenly distributed among the four regions, with adequate numbers in each size cell for analyses by region, size and specialty of practice, and other factors. The overall response rate for the combined data set was 21.1 percent, ranging by size from 16.1 percent for practices with five or fewer physicians to 33.9 percent for practices with twenty-one or more, and by region from 17.6 percent for the eastern region to 24.7 percent for the western region.¹⁰

Study Results

■ **Adoption of EHRs.** Using the combined database, 15.0 percent percent of all respondents reported that they had EHRs. After the results were reweighted to adjust for our sample's being stratified by size of practice, an estimated 14.1 percent of the 34,490 group practices in our universe database had EHRs (Exhibit 1).

The fraction of practices that have implemented EHRs varies greatly by prac-

EXHIBIT 1
Type Of Health Record Used, By Practice Size, 2005

Number of FTE physicians in practice	Type of record (%)				
	Paper medical record filed in cabinet	Scanned image filed electronically using a document image management system (DIMS)	Dictation and transcription system combined with DIMS	EHR in a relational database	Other
5 or fewer	78.0	2.3	6.3	12.5	0.9
6-10	73.9	3.0	7.2	15.2	0.7
11-20	67.0	1.6	11.7	18.9	0.9
21 or more	65.8	3.1	10.7	19.5	1.0
All practices ^a	75.3	2.5	7.2	14.1	0.9

SOURCE: The information in this exhibit is derived from the authors' own analyses.

NOTE: FTE is full-time equivalent.

^a Percentage of all practices combined with an electronic health record (EHR) in the raw data was 15.0 percent, corrected to 14.1 percent after weighting to correct for having oversampled larger practices.

tice size, somewhat by specialty type and ownership, and minimally by region.¹¹ As others have found, smaller practices have lower EHR adoption rates.¹² We found that about 12 percent of practices with five or fewer full-time-equivalent (FTE) physicians have EHRs, while practices with more than ten physicians have higher rates (about 19 percent); these estimates, particularly for smaller practices, may be biased upward. The higher rates of adoption for larger practices could be explained by greater available financial resources and administrative capacity or by other factors.¹³

These data indicate that only about one-fifth of practices with twenty-one or more physicians have adopted these technologies; about 12–13 percent of practices with five or fewer physicians have EHRs. However, a substantial number of practices indicate that they are planning to adopt EHRs in the future (Exhibit 2). If these plans were to be fully carried out, about 60 percent of practices would have adopted EHR technologies two years from now, and 80 percent among the largest practices (twenty-one or more physicians). But even if the projections proved reliable, the data show that smaller practices are implementing at a slower rate than larger practices and that nearly half of practices with five or fewer FTE physicians currently do not have EHRs and have no plans to implement them within the next two years. Further, projections such as these must be regarded as quite uncertain; adoption may fall short of these plans. It will be important to track adoption and implementation over time to determine whether these intentions are realized, and to better understand factors that influence the rate of implementation.¹⁴

■ **What can these EHRs do?** To further evaluate what an EHR system means and can do, we asked the practices that have EHRs to indicate whether the EHR systems have each of the capabilities listed in Exhibit 3.¹⁵ The capabilities are ordered roughly from most likely to least likely to be present.

Overall, these EHRs have extensive capabilities, with nearly all allowing re-

EXHIBIT 2
Degree Of Electronic Health Record (EHR) Implementation, By Practice Size, 2005

Number of FTE physicians in practice	Degree of implementation (%)				
	Fully implemented for all physicians in all locations	Implementation in process	Implementation planned in next 12 months	Implementation planned in next 13–24 months	Not implemented and no plans to implement in next 24 months
5 or fewer	10.4	10.3	12.6	18.9	47.8
6–10	13.6	11.8	15.9	21.4	37.3
11–20	13.9	20.7	20.0	18.4	27.0
21 or more	11.0	28.5	15.7	24.2	20.2
All practices ^a	11.5	12.7	14.2	19.8	41.8

SOURCE: The information in this exhibit is derived from the authors' own analyses.

NOTE: FTE is full-time equivalent.

^aPercentage of all practices that have fully implemented an EHR for all physicians in all locations in the raw data was 15.0 percent, corrected to 11.5 percent after weighting to correct for having oversampled larger practices.

EXHIBIT 3
Electronic Health Record (EHR) Capabilities, By Size Of Medical Group, 2005

EHR feature/capability	Number of physician FTEs in practice (%)			
	5 or fewer	6-10	11-20	21 or more
Patient demographics	99	99	99	100
Visit/encounter notes	98	96	99	98
Patient medications/prescriptions	96	97	98	98
Presenting complaint	96	97	99	95
Physical exam/review of systems	97	96	97	96
Past medical history	95	95	99	95
Problem lists	94	93	94	96
Procedure/operative notes	92	93	97	96
Laboratory results	89	87	94	97
Drug interaction warnings	79	75	81	84
Radiology/imaging results	75	72	87	89
Consult/reports from specialists	78	81	86	84
Referrals to specialists	84	79	78	77
Drug reference information	76	80	78	79
Immunization tracking	80	72	64	75
Drug formularies	62	64	67	68
Clinical guidelines and protocols	64	62	71	64
Integration with practice billing system	84	83	83	75

SOURCE: The information in this exhibit is derived from the authors' own analyses.

NOTE: FTE is full-time equivalent.

ording and retrieval of the basic elements of the medical record (the first eight capabilities listed). Capabilities for managing results of laboratory and imaging tests and referrals are somewhat less available, and least available are several relating to prescribing drugs (except for the patient medication list), tracking immunizations, and using clinical guidelines and protocols. We do not discern consistent differences in capabilities by size of practice. Just over 80 percent of these practices' EHRs are integrated with the practice's billing system, which is necessary to realize some of the benefits to documentation of services provided and billed.

■ **What are the perceived benefits of EHRs?** We asked all respondents to provide a subjective evaluation of the (experienced or expected) benefit of EHRs to the practice, using a five-point scale ranging from 1 (no value) to 5 (very important value). Exhibit 4 provides mean values for practices that reported having EHRs.

Administrators of practices that have EHRs speak from experience and clearly believe that the EHRs make major contributions to their practices: Most of the scores were 4 ("important value") or higher. Improved access to medical record information was the highest-rated benefit, and improved workflow in the practice was second. It has been pointed out that redesigning and improving workflow is essential to fully realizing the benefits of IT. Scores for features that are important in the direct care of the patient are generally higher than those related to cost sav-

EXHIBIT 4**Perceived Benefits Of Electronic Health Records (EHRs) To The Practice, 2005**

Benefit to the practice	Mean rating
Improved access to medical record information	4.60
Improved workflow	4.49
Improved patient communications	4.28
Improved accuracy for coding evaluation and management procedures	4.28
Improved drug refill capabilities	4.21
Reduced medication errors	4.19
Improved charge capture	4.16
Improved clinical decision making	4.15
Improved claim submission process	4.13
Reduced medical records staff expenses	3.96
Reduced medical records storage costs	3.92
Reduced transcription costs	3.92
Reduced medical records transportation costs	3.64
Improved physician recruitment	3.31

SOURCE: The information in this exhibit is derived from the authors' own analyses.

NOTE: Based on a five-point scale ranging from 1 (no value) to 5 (very important value).

ings. Whether this results from a lag in achieving savings or the possibility that there are few realized savings is unknown, but it suggests that benefits to patient care are at least as important as improvements in the financial performance of the practice. We did not see consistent differences in benefits experienced by size of practice for practices that have EHRs. A separate analysis showed that practices that have not implemented EHRs and have no plans to do so in the next two years rate each of the (expected) benefits lower than practices that have implemented, are implementing, or plan to implement EHRs (data not shown). Different expectations of benefits presumably help explain these practices' decisions not to adopt.

■ **What are the barriers to EHR adoption?** To explore barriers to EHR adoption from the broadest perspective, we asked both those practices that have implemented EHRs and those that have not to rate the items shown in Exhibit 5 in terms of their importance as factors making EHR implementation difficult. None of the barriers was rated at 4 or above, and most were rated around 3 ("complicates implementation to some degree"). For those with and without EHRs, the top five barriers were related to aspects of costs and to concern about physicians' support and ability to use the new system. Practices that have implemented EHRs rated the "people barriers"—lack of support from physicians, nonphysician providers, and other clinical staff—higher than those that have not. As one might expect, practices that have not implemented EHRs and have no plans to do so within two years rate nearly all of these barriers higher than practices that have implemented, are implementing, or plan to implement EHRs (data not shown).

**EXHIBIT 5
Barriers To Implementing Electronic Health Records (EHRs), 2005**

Barrier	Mean rating		
	Practices with EHRs	Practices without EHRs	All practices responding
Lack of support from practice physicians	3.32	3.15	3.18
Lack of capital resources to invest in an EHR	3.31	3.58	3.54
Concern about physicians' ability to input into the EHR	3.18	3.40	3.37
Concern about loss of productivity during transition to EHR	3.04	3.24	3.21
Inability to easily input historic medical record data into EHR	2.97	3.24	3.20
Available EHR software does not meet the practice's needs	2.77	2.81	2.81
Insufficient return on investment from EHR system	2.74	3.15	3.09
Lack of support from practice clinical staff	2.73	2.43	2.48
Insufficient time to select, contract, install, implement EHR	2.70	2.88	2.86
Lack of support from practice nonphysician providers	2.68	2.31	2.37
Inability to integrate EHR with practice billing/claims system	2.67	2.90	2.87
Practice staff does not have skills or training to use EHR	2.65	2.62	2.63
Inability to evaluate, compare, and select appropriate EHR	2.60	2.86	2.82
Lack of support from practice administration	2.43	2.06	2.12
Security and privacy concerns	2.31	2.34	2.34

SOURCE: The information in this exhibit is derived from the authors' own analyses.

NOTE: Based on a five-point scale ranging from 1 (not a problem) to 5 (makes implementation very difficult).

Lack of capital resources and concern about loss of productivity during transition to an EHR system are rated among the top five barriers for practices that have implemented EHRs and those that have not. Our data show that for those practices that have implemented EHRs, the average initial cost was approximately \$33,000 per physician (somewhat higher per physician for smaller practices and lower for larger practices), with maintenance costs of about \$1,500 per physician per month (data not shown). Added to the monthly maintenance cost, the initial cost, even if amortized over five years at 8 percent interest, would translate into about a 10 percent reduction in take-home pay each year for most primary care practices. Because of the structure of the tax code, most practices do not have retained earnings, and, consequently, the capital equipment expenditures are funded directly from physician income. If the practice were to pay the initial costs in the first year, the reduction in take-home pay would be quite large. Taken together, this means that the substantial initial cost of EHRs, lack of good information about the return on investment in EHRs, and lack of access to capital and other financial resources are likely to greatly limit the adoption of those technologies, particularly for smaller primary care practices.

Preliminary analysis of our interviews suggests that a substantial fraction of practices also experience a reduction in practice productivity during implementation of 10–15 percent for at least several months. The interviews and site visits to

“The majority of practices are finding the transition to EHRs difficult even if the physicians and nurses are fully supportive.”

practices also indicate that many practices believe that their net revenue will eventually improve after implementing EHRs, but it is unclear whether this results from improved efficiency, capturing more billable service units, or reducing costs. Nor is there any clear agreement about the magnitude of either of these financial gains to the practice. We also found that for most practices, actual costs of implementation were higher than they had expected, with cost overruns averaging about 25 percent over the vendors' estimates.

Barriers such as lack of the ability to evaluate EHR proposals and systems and inability to find systems that meet the practices' needs also received relatively high scores. These barriers presumably could be lowered by providing information and decision support to practices. We did not ask what kinds of help were available to or used by practices, but we did ask what might help them.

■ **What could increase the rate or decrease the difficulty of implementing EHRs?** We asked about a number of actions that government or the private sector might take to make the EHR decision process easier: development of standardized questions to ask EHR vendors, model requests for proposal for EHRs and EHR contracts; information on integration capabilities of EHR products with various practice management systems; educational programs on how to select and implement an EHR system; and certification for EHR vendors. Practices with and without EHRs rated the importance of each of these actions relatively highly (between 3.4 and 4.2 on a five-point scale). Several professional organizations are providing this kind of information, and the CMS's recently launched Doctors' Office Quality Information Technology (DOQ-IT) program is intended to provide help through quality improvement organizations (QIOs) in many of these areas.¹⁶ It will be important to assess the effectiveness of these efforts.

We also asked a question of practices with EHRs that focused on what the “impact of possible federal government actions” would be on the EHR selection process. These actions included direct financial assistance (grants, tax credits, and low-interest loans), rewards for implementing IT by pay-for-performance programs, publishing agreed-upon industrywide technology standards, and modifying the Stark self-referral prohibitions to allow increased sharing of technology. All were rated between 2.9 and 3.5 on a five-point scale (3 equaled “some value”), but none were rated 4 (“important”) or 5 (“extremely important”). Practices without EHRs rated each of the items slightly higher, and we found no discernable pattern related to group size (data not shown). Perhaps federal action is less important than one might think, or perhaps practices consider it unlikely to happen in the near future.

■ **Use of other computer-based information systems.** Although this study fo-

cused on EHR adoption, we also explored other uses of computer-based information systems in the group practices. As found in previous studies, more than 90 percent of group practices now have computer-based billing systems and patient scheduling systems. These systems are not costly to install and provide immediate efficiency gains—an attractive combination, even for small primary care practices. As expected, most practices that have EHRs use them for tasks that are done manually in many other practices. Although 90 percent of practices with paper medical records reported that they write prescriptions manually, only 16 percent of practices with EHRs did so. Similarly, practices with EHRs are less likely to use manual methods to accomplish other tasks related to prescriptions, ordering and managing the results of laboratory and imaging tests, and referrals and consultations, but not all do, and a sizable fraction of practices without EHRs manage some of these tasks electronically (data not shown).¹⁷ Consequently, it appears that there is both some consistency and considerable variation in the patterns of use of manual and computerized mechanisms to manage clinical support functions, and having EHRs does not imply that it is used to manage all of these tasks. This variation suggests an opportunity to characterize and better understand the various adoption paths that practices take toward adopting an EHR system and to determine whether some are more likely than others to lead to success.

The purpose of our interviews and site visits with practice administrators and physician leaders in some of the practices surveyed was to gain a richer understanding of decisions to implement EHRs and other clinical IT, the process of choosing and implementing IT, perceptions of barriers and facilitating factors, and the benefits expected and realized. An early finding from our interviews is that the transition from computer-based administrative information systems to fully implemented EHRs is a major undertaking that creates dislocation among the clinical staff and is more complicated, more difficult, and more expensive than we or most practices expected. The majority of practices are finding the transition difficult even if the physicians and nurses are fully supportive.

OUR SURVEY RESULTS RAISED and only partially answered many questions about the adoption process, the motivations driving adoption, and the contributions of these systems to the success of physician practices and to national goals to reduce costs and improve quality of care. If the projections provided by the practices prove to be accurate, the growth of EHRs over the next two years will be dramatic. It is tempting to conclude that physician practices will adopt IT that promises to improve practice efficiency, quality, and service despite the paucity of evidence that EHRs reliably lead to these benefits, and of evidence that having an EHR reliably improves a practice's financial performance. Although the number of anecdotes continues to increase, we are not aware of large-scale studies to document financial consequences or clinical benefits.

The information gleaned from analyses of these data and our interviews and site

visits should enable a better understanding of these dynamics and how best to increase practices' success in choosing and implementing EHRs and other IT. The picture that is emerging is more complicated than we expected, and the difficulties that practices are encountering in choosing and implementing EHRs are greater. We suggest that more studies that include interviews and case studies—including spending time with clinicians, administrators, and patients in their practices—will lead to better understanding of the difficulties and of which strategies and tactics will increase practices' success in this important endeavor.

.....
 This study was supported by the Agency for Healthcare Research and Quality (AHRQ) under Task Order no. 5, "Assessing Adoption of Effective Information Technology by Medical Group Practices," through IDSRN Contract no. 290-00-0017 to the University of Minnesota, with the Medical Group Management Association (MGMA) Center for Research as subcontractor. The views expressed herein are those of the authors and do not necessarily represent the position of AHRQ or the U.S. Department of Health and Human Services.

NOTES

1. For a synthesis of a number of studies, see D.J. Brailer and E.L. Terasawa, "Use and Adoption of Computer-based Patient Records," October 2003, www.chcf.org/topics/view.cfm?itemID=21525 (29 July 2005); and R.H. Miller and I. Sim, "Physicians' Use of Electronic Medical Records: Barriers and Solutions," *Health Affairs* 23, no. 2 (2004): 116-126. See also A.M. Audet et al. "Information Technologies: When Will They Make It into Physicians' Black Bags?" *Medscape General Medicine* 6, no. 4 (2004), www.medscape.com/viewarticle/493210 (28 June 2005; registration required); N.F. Piland et al., *The Current Status of Electronic Medical Record and Practice Automation Systems in Medical Group Practices, Second Annual Report* (Englewood, Colo.: Medical Group Management Association Center for Research, December 2002); and R.H. Miller, J.M. Hillman, and R.S. Given, "Physician Use of IT: Results from the Deloitte Research Survey," *Journal of Healthcare Information Management* 18, no. 1 (2004): 72-80. Brailer and Terasawa point out that the estimates of EHR use vary among different studies for a variety of reasons, including the characteristics of the particular practices surveyed. We report percentages of practices that have EHRs rather than percentages of physicians; the latter would be higher than the former because large practices are more likely than small practices to have EHRs.
2. J.C. Martin, et al., "The Future of Family Medicine: A Collaborative Project of the Family Medicine Community," *Annals of Family Medicine* 2, Supp. 1 (2004): S3-S32.
3. For a recent review of pay-for-performance programs, see M.B. Rosenthal et al., "Paying for Quality: Providers' Incentives for Quality Improvement," *Health Affairs* 23, no. 2 (2004): 127-141.
4. See Brailer and Terasawa, "Use and Adoption of Computer-based Patient Records"; Miller and Sim, "Physicians' Use of Electronic Medical Records"; Audet et al., "Information Technologies"; and Piland et al., *The Current Status*. Regarding reasons for slow adoption, see C.J. McDonald, "The Barriers to Electronic Medical Record Systems and How to Overcome Them," *Journal of the American Medical Informatics Association* 4, no. 3 (1997): 213-221; Miller and Sim, "Physicians' Use of Electronic Medical Records"; Piland et al., *The Current Status*; K. MacDonald, J. Metzger, and M. Mann, "Achieving Tangible IT Benefits in Small Physician Practices," September 2002, www.chcf.org/topics/view.cfm?itemID=19898 (29 July 2005); and R.H. Miller, I. Sim, and J. Newman, "Electronic Medical Records: Lessons from Small Physician Practices," October 2003, www.chcf.org/topics/view.cfm?itemID=21521 (29 July 2005).
5. Audet et al., "Information Technologies"; Brailer and Terasawa, "Use and Adoption"; and L. Landro, "Doctors Say Office Technology Is Costly and Cumbersome," *Wall Street Journal*, 27 July 2003.
6. For examples of implementation, see S. Barlow, J. Johnson, and J. Steck, "The Economic Effect of Implementing an EMR in an Outpatient Clinical Setting," *Journal of Healthcare Information Management* 18, no. 1 (2004): 46-51; and Miller et al., "Electronic Medical Records." The cost-benefit analysis is in S.J. Wang et al., "A Cost-Benefit Analysis of Electronic Medical Records in Primary Care," *American Journal of Medicine* 114, no. 5 (2003): 397-403.
7. This group practice database is being assembled from multiple sources, including members and other contacts in the MGMA database, commercial databases, several professional associations including the

American Medical Association, and others under a contract from AHRQ to the University of Minnesota and the MGMA Center for Research. The total number of U.S. group practices is not known, but we estimate it to be somewhat larger than the 34,490 practices we identified, perhaps in the range of 40,000-50,000. Fewer than one-third of the practices are MGMA members.

8. The instruments used can be viewed at Medical Group Management Association Center for Research, www.mgma.com/research/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=152 (29 July 2005).
9. If there is a nonresponse bias in the Web and mail survey data (and therefore in the combined data), it is likely to result in a small (1-2 percent) overestimate of the fraction of practices with EHRs, and it is more likely to affect estimates for the smaller practices. This would be consistent with practices without EHRs being less interested in EHRs and less likely to respond to the Web and mail surveys.
10. Because there are many more small practices in the United States than large ones, even after we oversampled larger practices, the 3,629 practices responding broke into categories of 47.8 percent with five or fewer physicians, 24.3 percent with six to ten physicians, 13.3 percent with eleven to twenty physicians, and 14.6 percent practices with twenty-one or more physicians.
11. The definition of EHR in the survey was chosen in consultation with staff at AHRQ with intent to make clear that items in the EHR are searchable and retrievable. We assumed that this definition would be familiar to most practice administrators; we did not encounter any confusion expressed in comments on returned surveys or in our interviews. See Note 8.
12. For example, see Audet et al., "Information Technologies." Audet and colleagues also found that use of EHRs in solo physician practices is lower than in practices with two to nine physicians.
13. We observed variation by specialty type (multispecialty versus single specialty and particular specialties represented), by type of ownership, and by relationship to academic institutions (data not shown). The effects of these factors are generally smaller than that of size of practice, and they interact with each other and with size of practice and other variables; they will be analyzed using multivariate models (results not reported here). Variation by region was relatively small.
14. This survey was conducted confidentially (rather than anonymously), and contact information was collected for most respondents, enabling follow-up surveys of responding practices.
15. The remaining analyses rely on responses to the Web and mail surveys because these questions were not asked on the shorter telephone survey. By extension from the answers to the questions common to all the surveys, we think that any nonresponse bias is small and that nonrespondents would, if different from respondents, be slightly less positive about the benefits of EHRs.
16. The Doctors Office Quality Information Technology (DOQ-IT) program will provide support to small and medium-size practices selecting and implementing EHRs. For more information, see www.doqit.org.
17. It is likely that most practices, regardless of their commitment to becoming wholly computerized or "paperless," will for some time have to interact with some pharmacies, consultants, and diagnostic testing sources by nonelectronic means. For example, some radiology groups may be able neither to receive requests for studies nor to report the results electronically.

150



BERLEX

making medicine work

September 14, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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ATTN: FILE CODE CMS-1501-P

Dear Dr. McClellan:

Berlex, Inc. appreciates the opportunity to comment on CMS-1501-P, *Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates*, as published in the Federal Register on July 25, 2005.¹ Our comments relate to the "NonPass-Throughs" section of the proposed rule, specifically the proposal to package Q9953 (Inj Fe-based MR contrast, ml), because CMS is unable to determine the per administration cost of this item.

Company Background

Berlex, Inc., a U.S. affiliate of Schering AG, Germany, is a pharmaceutical company which develops and markets diagnostic imaging agents, treatments in the areas of female healthcare and specialized therapeutics for life-threatening and disabling diseases in the fields of the central nervous system, oncology and gastroenterology.

Among the Berlex diagnostic imaging agents available to Medicare beneficiaries is Feridex I.V.® (ferumoxides injectable solution)², a superparamagnetic iron oxide used in magnetic resonance imaging (MRI) since in 1996. Feridex I.V. was the first organ-specific MRI contrast agent available in the U.S. to facilitate the detection and evaluation of liver lesions. Feridex I.V., after diffusion through the blood stream, is taken up by the liver's reticuloendothelial system (RES). The absent or abnormal reticuloendothelial cell distribution in liver lesions facilitates their detection. Feridex I.V. will be billed in 2006 using HCPCS code Q9953 (Inj Fe-based MR contrast, ml).

Comment Summary

We commend CMS for many of the provisions regarding payment for drugs and biologics as outlined in the proposed rule, including ASP-based payment for non-packaged drugs and biologics, including imaging agents. We also agree in principle with CMS's proposed methodology for determining the packaging status for drugs for which

¹ Federal Register 70(41): 42674-43011, July 25, 2005.

² Feridex I.V.® is a registered trademark of Advanced Magnetics, Inc.

CMS does not have CY 2004 claims data (i.e., estimating average number of units per administration and multiplying by the payment rate using the ASP methodology).

The proposed rule states that this approach cannot be used for Q9953 (Inj Fe-based MR contrast, ml), the HCPCS code used to bill for Feridex I.V. (Feridex I.V. is the only FDA-approved product billed under Q9953), because CMS was unable to determine payment rates under the ASP methodology. However, ASP data are available with which to apply the standard methodology, and these data demonstrate that the average per administration cost of Q9953 exceed the \$50 packaging threshold, and thus Q9953 should be separately paid in CY 2006.

Below, we provide additional information on the clinical benefits of Feridex I.V. and provide ASP and dosing data that CMS can use to determine the average cost per administration of the product, according the methodology proposed by CMS for agents for which no CY 2004 claims data are available.

Clinical Benefits of Feridex I.V.

In 1996, Feridex I.V. was introduced as the first organ-specific magnetic resonance imaging (MRI) agent available in the U.S. Since then it has been used to facilitate the detection and evaluation of liver lesions associated with an alteration in the reticuloendothelial system (RES). As a superparamagnetic iron oxide (SPIO), Feridex I.V. is taken up by RES cells in the liver resulting in significant loss of MR signal intensity (darkening) while tissues with decreased or absent RES function retain their signal intensity. Because of this mechanism of action, Feridex I.V. is considered a "negative" contrast agent (i.e., the functioning liver decreases in signal intensity, not the lesion). Feridex I.V. affords both increased lesion conspicuity and increased lesion detection. The type of lesion for which improved detection with this contrast agent is most clinically useful is liver metastases.³

Diagnosis of metastases at an early stage can be difficult because small tumors are frequently not accompanied by detectable physical symptoms. Contrast-enhanced MRI exams using Feridex I.V. enable the imaging of liver lesions that may not be visible with CT scanning or ultrasound, the most widely used techniques for liver imaging. Feridex I.V.-enhanced MRI of the liver can complement or replace the other imaging modalities. In addition, the ability to identify metastatic tumors in the liver has a significant impact on physicians' treatment plans for cancer. Because treatment plans can vary widely based on the level of metastatic disease, proper staging is a critical component of patient management. When used in the appropriate clinical setting, such as for the determination of treatment for patients who are potential candidates for liver resection, Feridex I.V.-enhanced MRI may allow physicians to select the most appropriate treatment at the most appropriate time.

³ Blakeborough A, Ward J, Wilson D, et al. Hepatic lesion detection at MR imaging: a comparative study with four sequences. *Radiology* 1997; 203:759-765.

Therefore, the benefits of Feridex I.V. in the target patient population are significant and clinically meaningful in terms of both diagnosis and treatment.

Data Available to Calculate the Average per Administration Cost of Feridex I.V.

According to the proposed rule (page 42731):

There are several drugs, biologicals, and radiopharmaceuticals that were payable during CY 2004 or their HCPCS codes were created effective January 1, 2005 for which we do not have any CY2004 hospital claims data. In order to determine the packaging status of these items for CY 2006, we calculated an estimate of per day cost of each of these items by multiplying the payment rate for each product as determined using the ASP methodology by an estimated average number of units of each product that would be furnished to a patient during one administration.

The proposed rule further states that:

There are two codes 90393 (Vaccina ig, im) and Q9953 (Inj Fe-based MR contrast, ml) for which we were not able to determine payment rates based on the ASP methodology. Because we are unable to estimate the per administration cost of these items, we are proposing to package them in CY 2006.

We agree with CMS's proposed methodology for estimating the average per administration cost for products without CY 2004 claims data. However, we disagree that data are not available to apply this approach to Q9953. Information on the ASP and dosing for Feridex I.V. is provided below.

ASP for Feridex I.V.

Specifically, Berlex, Inc. has been submitting ASP data to CMS for Feridex I.V. since January 28, 2005. The most current submission, which was submitted to CMS on July 29, 2005, shows an ASP for Feridex I.V. of **\$143.42 per 5mL vial, or \$28.68 per ml**, based on quarterly sales of 131 cases (of 5-5mL vials) and 17 single vials. A copy of the most recent ASP data submission is provided as an Attachment to this letter. Although CMS has not included the Feridex I.V. ASP in its formal ASP postings, the data have routinely been submitted since January 2005 and audited by CMS and are available for use in determining the average per administration cost.

Per Administration Dosing of Feridex I.V.

Feridex I.V. dosing is weight-based. Per the FDA-approved Feridex I.V. package insert, the recommended dosage of Feridex I.V. is 0.56 milligrams of iron (0.05 ml Feridex I.V.) per kilogram of body weight. For an average patient weighing 70 kg, the per-administration dose of Feridex I.V. would be 3.5 ml. In standard clinical practice, the average per administration dose is between 4 and 5 ml, as patient weights typically

exceed 70 kg on average. However, we use the 3.5 ml dosage in our calculations to provide CMS with a conservative estimate of the average cost per administration of the product.

Average Cost per Administration

Assuming an ASP of \$28.68 per ml and an average dose of 3.5 ml, **the average per administration cost of Feridex I.V. is \$100.39**. This far exceeds the statutory \$50 threshold for separate payment under Medicare's hospital outpatient prospective payment system.

Summary

Feridex I.V. is a clinically important organ-specific imaging agent, used in MRI to diagnose liver lesions when medical information is necessary for clinical decisions. ASP data are available for Feridex I.V. and its associated HCPCS code, Q9953. The most current quarter ASP is \$28.68 per ml. Using average dosing of 3.5 ml per the Feridex I.V. package insert, the average cost per administration is \$100.39, far exceeding the \$50 statutory threshold for separate payment for drugs under Medicare's hospital outpatient prospective payment system.

Therefore, we respectfully request that CMS pay separately for Q9953 in the hospital outpatient setting in CY 2006.

If you have any questions about our comments, please contact me at telephone number 973-317-5523 or email address harold_goldstein@berlex.com. Thank you for your consideration.

Sincerely,



Harold A. Goldstein, MD
Vice President, Portfolio Management
Diagnostic Imaging
Berlex Inc.

Attachment

Manufacturer's Name	National Drug Code	Manufacturer's Average Sales Price	Number of Units
Berlex, Inc	59338070351	\$ 143.42	17
Berlex, Inc	59338070355	\$ 717.11	131