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OPPS

Drugs

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Rec'd 9-14-06

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September 8, 2006

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

Re: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule; OPPS: Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

Dear Administrator McClellan:

Amgen is writing regarding the calendar year 2007 Medicare Hospital Outpatient Prospective Payment System (OPPS) proposed rule (Proposed Rule), which the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register on August 23, 2006.[1] As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs" following the agency's convention) for Medicare beneficiaries. For this reason, we provide information on the "Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals" section of the Proposed Rule as it applies to all separately payable drugs and to our innovative biological product, Aranesp® (darbepoetin alfa), in particular.[2]

Amgen commends the agency on its proposal to use a free market-based approach to set the OPPS payment rates for separately payable drugs, including Aranesp®. The proposed average sales price (ASP) based payment methodology for all separately payable drugs allows the payment rates for these products to reflect market dynamics and encourages the desired market adaptations that manufacturers and hospitals make to remain competitive. Regarding Aranesp® in particular, we are pleased that CMS continues to apply its free market-based approach and does not propose to change its current position on an "equitable adjustment" to the payment rate for Aranesp® and that the agency proposed to continue using the ASP methodology to establish the 2007 OPPS payment rates for Aranesp®. In the 2006 Final Rule, CMS specifically addressed its rationale for not applying an "equitable adjustment," and the facts that led the agency to its decision in 2006 hold true

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1 71 Fed. Reg. 49506–49977.

2 Aranesp® is indicated for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies and for the treatment of anemia associated with chronic renal failure, including patients either on dialysis or not on dialysis.

for 2007. Specifically, CMS correctly noted that "[t]he ASP data represent market prices for this biological" and "this method will permit market forces to determine the appropriate payment for this biological."[3] For these reasons, CMS made the final decision not to apply an "equitable adjustment" under Section 1833(t)(2)(E) of the Social Security Act to the payment rate of Aranesp® in Calendar Year 2006. We recommend that CMS continue this policy for Calendar Year 2007 by finalizing the payment methodology for Aranesp® as proposed.

Below, we present further evidence to support the treatment of Aranesp® under the Proposed Rule and provide information on the proposed payment methodology for separately payable drugs.

By proposing to continue the use of market-based pricing and not applying an "equitable adjustment" to the payment rate for Aranesp®, Medicare and its beneficiaries will pay the same or less for comparable clinical outcomes.

For several years before the implementation of the 2006 Final Rule, OPPS payments for separately payable drugs were determined under different methodologies, and CMS had applied an "equitable adjustment" using a dose conversion ratio despite extensive submissions showing the clinical comparability of Aranesp® and Procrit® as well as lower costs of Aranesp®. With the implementation in 2006 of market-based payment rates for all separately payable drugs, including Aranesp®, it became clear that an "equitable adjustment" is not needed. Since payment is proposed to continue using market-based pricing in 2007, CMS correctly does not propose to implement "equitable adjustment" in the case of Aranesp®. As we demonstrate below, there is a wealth of clear and compelling clinical and economic data to support the agency's decision not to apply an "equitable adjustment" in 2007.

Clinical practice guidelines support the clinical comparability of Aranesp® and Procrit® at commonly administered doses.

The treatment of Aranesp® under the Proposed Rule is fully consistent with well-established clinical practice guidelines, which have been validated by randomized, comparative clinical trials. Most notably, the National Comprehensive Cancer Network (NCCN) *Clinical Practice Guidelines in Oncology™: Cancer and Treatment-Related Anemia* and the *U.S. Pharmacopeia Drug Information (USP DI®)* monograph list the commonly used initial dose of Aranesp® at approximately 200 micrograms (mcg) every other week (Q2W). Consistent with an additional dosing regimen recently added to the label for Aranesp® and current clinical trials, the aforementioned guidelines now also reference once every-three-week (Q3W) dosing of Aranesp® as a new treatment option.[4,5] Amgen's clinical submissions to CMS in 2003, 2004, and 2005 demonstrated that Aranesp® under these guidelines achieve comparable clinical outcomes to commonly administered doses of Procrit®.[6,7,8]

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3 70 Fed. Reg. 68651.

4 *Clinical Practice Guidelines in Oncology™: Cancer and Treatment-related Anemia.* 2006. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

5 Rodgers, G. M., Ed. *NCCN* Practice Guidelines in Oncology: Cancer- and treatment-related anemia, National Comprehensive Cancer Network. Available at: http://www.nccn.org/professionals/physician_gls/PDF/anemia.pdf. Accessed March 27, 2006.

6 "Darbepoetin Alfa Briefing Document" prepared for the meeting between Amgen and CMS on April 28, 2003.

7 Data from Amgen Inc., submission on the 2005 OPPS proposed rule, dated October 7, 2004.

A recent report from the Agency for Healthcare Research and Quality (AHRQ) provides evidence to support the proposed OPPS reimbursement policy and confirms the validity of the clinical practice guidelines.

As we discussed in our submission on the 2006 Proposed Rule, Amgen's submissions in 2003 and 2004 had been validated by randomized, head-to-head clinical trials, which represent the highest standard of evidence to evaluate the comparability of two drugs.[9,10] These new trials have been added to the established evidence base regarding the comparability of clinical outcomes of Aranesp® 200 mcg Q2W and Procrit® 40,000 international units (IUs) every week (QW) for chemotherapy-induced anemia patients. Among these studies was a properly powered, 1,200-person, non-inferiority trial that represents the largest comparative clinical trial in the published literature to date.

Further adding to the abundance of rigorous analysis in this area, AHRQ earlier this year published the results of a study investigating the clinical efficacy, safety and effectiveness of erythropoiesis-stimulating agents (ESAs) in treating chemotherapy-induced anemia. This report, *Comparative Effectiveness of Epoetin and Darbepoetin for Managing Anemia in Patients Undergoing Cancer Treatment*, was produced by the agency's Effective Health Care Program, the first federal program designed to compare alternative treatments for significant health conditions and make the findings public.[11] To study ESA's, AHRQ reviewed the body of clinical evidence on cancer induced anemia patients. Importantly, notable highlights from the AHRQ report include the following:

- the evidence shows no clinically significant difference between epoetin alfa and darbepoetin alfa in hemoglobin response;
- there was no statistically significant difference between epoetin alfa and darbepoetin alfa in reducing the need for transfusion; and
- studies directly comparing epoetin and darbepoetin showed no statistically significant difference in the rates of thromboembolic events (*i.e.*, blood clotting).

In the report, AHRQ singles out one study as anomalous and not consistent with the agency's findings. This study, the Ortho Biotech-funded Waltzman trial (2005) did not attempt to assess the comparability of clinical outcomes between Aranesp® at 200 mcg Q2W and Procrit® at 40,000 IUs QW.[12] Instead, the authors of the trial attempted to demonstrate superiority based on a previously unused biomarker as the endpoint. Importantly, the AHRQ report made a specific point of criticizing this Ortho Biotech-funded trial, concluding that:

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8 Data from Amgen Inc., submission on the 2006 OPPS proposed rule, dated September 15, 2005.

9 Glaspy, J., CVadhan-Raj, S., et al. (2006) "Randomized comparison of every-2-week darbepoetin alfa and weekly epoetin alfa for the treatment of chemotherapy-induced anemia: The 20030125 study group trial." Journal of Clinical Oncology 24(15): 2290-2297.

10 Schwartzberg, L., L. Yee, et al. (2004). "A randomized comparison of every-2-week darbepoetin alfa and weekly epoetin alfa for the treatment of chemotherapy-induced anemia in patients with breast, lung, or gynecologic cancer." Oncologist 9(6): 696-707.

11 Seidenfeld, J., M. Piper, J. Bohlius, et al. (2006) Comparative Effectiveness of Epoetin and Darbepoetin for Managing Anemia in Patients Undergoing Cancer Treatment Review No. 3 (Prepared by Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center under Contract No. 290-02-0026.). Rockville, MD: Agency for Healthcare Research and Quality. 2006. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

12 Waltzman, R. et al. (2005) "Randomized comparison of epoetin alfa (40,000 IU weekly) and darbepoetin alfa (200 mcg every two weeks) in anemic patients with cancer receiving chemotherapy." Oncologist 10: 642-650.

- the primary endpoint of the trial—early hemoglobin rise (*i.e.,* 1-g/dL rise in 4 weeks)—is not a useful clinical predictor; and
- the study adjusted the dosing for inadequate initial response at different times in the two arms, with a potential for biased results.[13]

The AHRQ report is consistent in its findings with another recently published and thorough meta-analysis of the clinical ESA data, *Recombinant human erythropoietins and cancer patients: Updated meta-analysis of 57 studies including 9,353 patients.*[14] The AHRQ study is yet even more evidence supporting the clinical comparability of Aranesp® and Procrit® at commonly administered doses. Amgen will continue to share new clinical developments regarding Aranesp® with CMS as findings become available.

A change in the Aranesp® label expands treatment options to improve patients' lives.

Amgen continues to conduct research on its marketed products to further innovation and improve patients' lives. To that end, the U.S. Food and Drug Administration (FDA) recently approved Q3W dosing of Aranesp® for the treatment of chemotherapy-induced anemia (CIA) in patients with myeloid malignancies. With this added dosing regimen, Aranesp® is now the only ESA approved by the FDA for Q3W administration. Previously, the Aranesp® label included QW dosing. In addition to the label, there is a significant base of high quality, peer-reviewed clinical data that support the efficacy of Aranesp® dosing at an Q2W interval.

Amgen's decision to further study the efficacy of Aranesp® at different dosing amounts and intervals was driven by the following goals:

- reducing patient burden, and
- enabling greater physician flexibility.

A significant number of patients receive chemotherapy treatment administered Q3W, and now anemia management can be delivered at the same interval. Synchronizing anemia management with chemotherapy treatment reduces the number of needle sticks patients must receive and should result in a decrease in patient trips to the doctor.

Physicians should have as many treatment options as possible to meet the needs of their patients. Multiple dosing intervals for supportive care products will allow physicians to synchronize anemia treatment with different chemotherapy regimens.

The additional FDA approved recommended starting dose is 500 mcg Q3W for Aranesp® with a step-down in dose as hemoglobin levels approached a common clinical measure. Due to dose reductions and withheld doses in the clinical trial, the average weekly dose was 125 mcg over the course of treatment studied.[15] Furthermore, a recently published study in *The Oncologist* presents the findings from an initial starting dose of 300 mcg Q3W which resulted in comparable clinical outcomes to other commonly administered doses. That

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13 Seidenfeld, J., M. Piper, J. Bohlius, et al., p. 40.

14 Bohlius J, et al. (2006) "Recombinant human erythropoietins and cancer patients: Updated meta-analysis of 57 studies including 9,353 patients. Journal of the National Cancer Institute. 98(10):708-14.

15 Canon, J. et al. (2006) "Randomized, double-blind, active-controlled trial of every-3-week darbepoetin alfa for the treatment of chemotherapy-induced anemia." Journal of the National Cancer Institute. 98(4): 273-284.

study, after dose adjustments, found an average weekly dose of 105.4 mcg.[16] Thus, patients will likely be treated Q3W with either a "step-down" or "step-up" approach depending on clinical circumstances.

Aranesp® costs Medicare and beneficiaries the same or less than Procrit®.

Aranesp® is less expensive than Procrit® at the payment rates that CMS published in the Proposed Rule. By applying the proposed payment rates for doses based on the aforementioned clinical guidelines and randomized controlled trials, the Medicare program will pay less for Aranesp® than Procrit® and achieve comparable clinical outcomes at both Q2W and Q3W dosing intervals. Table 1 presents estimated costs under Q2W dosing regimens, while Table 2 presents cost analysis of Q3W dosing regimens cited above. The estimated costs below are conservative and do not include any potential savings that may result from decreased office visits.

Table 1: Aranesp® Administered Q2W Costs Less Than or About the Same as Procrit®[17]

Assumptions[18]	**Procrit®**	**Aranesp®**
OPPS Payment per Billing Unit	$370.00 *(ASP + 5 Percent)*	$300.00 *(ASP + 5 Percent)*
Weekly Dose	40,000 IUs *(40,000 IUs QW)*	100 mcg *(200 mcg Q2W)*
Administration Services	CPT® code 90772 (injection SC/IM)	
Injections (APC 0437) per 2 weeks[19]	2 at $25.28	1 at $25.28
Weekly Payment Comparison[20]	***Medicare and Beneficiary Payments are $82.64 Less per Patient, per Week with Aranesp® on Average***	

Based on Q2W dosing referenced in clinical guidelines, the Medicare payment would be, on average, $82.64 less per week, per patient for Aranesp® than Procrit®. Of that total amount, beneficiaries would be responsible for $16.53 less per week in Part B copayments.

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16 Boccia R, et al. (2006) "Darbepoetin alfa administered every three weeks is effective for the treatment of chemotherapy-induced anemia." Oncologist 11:409-417.

17 This analysis assumes commonly administered doses based on clinical guidelines and randomized controlled trials.

18 This comparison assumes the provision of one administration service on the date that the product is delivered. Because actual services rendered depend on the needs of specific patients, patients may receive an administration service, an outpatient visit, either service, or some other combination of services on a particular date of service.

19 The amount used in this analysis represents the 2007 proposed national average Medicare payment allowable, including the beneficiary copayment, for APC 0437 (CMS-1506-P).

20 Additional cost of using Procrit® calculated at an additional product cost of $70.00 weekly and additional administration costs of $12.64 weekly. Estimated federal Medicare savings are $66.11, and beneficiary savings are $16.53 per week using Aranesp® over Procrit®.

Table 2: Aranesp® Administered Q3W Costs Less Than or About the Same as Procrit®[21]

Assumptions[22]	**Procrit®**	**Aranesp®**
OPPS Payment per Billing Unit	$370.00 *(ASP + 5 Percent)*	$316.20 to $375.00 *(ASP + 5 Percent)*
Weekly Dose	40,000 IUs *(40,000 IUs QW)*	105 to 125 mcg *(Starting dose of between 300 and 500 mcg Q3W)*
Administration Services	CPT® code 90772 (injection SC/IM)	
Injections (APC 0353) per 3 weeks[23]	3 at $25.28	1 at $25.28
Weekly Payment Comparison[24]	***Medicare and Beneficiary Payments are between $11.85 to $70.65 Less per Patient, per Week with Aranesp® on Average***	

As presented in Table 2, for doses administered Q3W, Medicare would spend between $11.85 and $70.65 less per week on average for Aranesp® than on Procrit®. Of this amount, beneficiaries would save between $2.37 and $14.13 weekly.

Furthermore, the less frequent Q2W and Q3W dosing regimens available with Aranesp® may offer fewer needle sticks and improved convenience for patients and the potential for fewer outpatient visits, thereby reducing the treatment burden on patients, healthcare professionals, and caregivers compared to the weekly anemia treatment available with Procrit®.

Ortho-Biotech's own sponsored economic analysis of the Waltzman trial found Aranesp® to be less costly overall than Procrit®.

Amgen is not alone in noting that Aranesp treatment has lower overall costs than Procrit®. Ortho Biotech had sponsored an economic analysis based on their own head to head trial of Aranesp vs. Procrit® (Waltzman et al. 2005), comparing the total costs associated with a broad range of clinical services. Table 3 summarizes a study published recently in *Pharmacoeconomics*, in which Reed et al. found that mean total costs for treatment with Aranesp® was $14,101 in the Aranesp arm (79.5 days) and $14,976 in the Procrit® arm

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21 This analysis assumes commonly administered doses based on clinical guidelines and randomized controlled trials.

22 This comparison assumes the provision of one administration service on the date that the product is delivered. Because actual services rendered depend on the needs of specific patients, patients may receive an administration service, an outpatient visit, either service, or some other combination of services on a particular date of service.

23 The amount used in this analysis represents the 2007 proposed national average Medicare payment allowable, including the beneficiary copayment, for APC 0437 (CMS-1506-P).

24 Additional cost of using Procrit® calculated at an additional product cost of - $5.00 to $53.80 weekly and additional administration costs of $16.85 weekly. Estimated federal Medicare savings are $9.48 to $56.52, and beneficiary savings are $2.37 to $14.13 per week using Aranesp® over Procrit®.

(77.0 days) and included costs for study medications, their administration, and other related services. The difference, as noted in Table 3, in total costs between the Aranesp® and Procrit® arms was $875 over the course of treatment on average.[25]

Table 3: Duke Research Institute Economic Analysis of Ortho Biotech Waltzman Data Supports the Current OPPS Policy

Costs	Procrit® (n=175)	Aranesp® (n=177)	Difference
Direct medical costs (drugs, injections, and other services)	$14,525	$13,676	$849
Indirect costs (patient time)	$451	$425	$26
Total direct medical and indirect costs	**$14,976**	**$14,101**	**$875**

In light on the clearly demonstrated lower or comparable costs of Aranesp®, CMS should finalize the proposed payment rate for the product.

Amgen supports the proposed ASP-based payment methodology for drugs and without pass-through status and encourages CMS to finalize this proposal.

ASP is a market-oriented measure that reflects the true, average cost of purchasing drugs and biologicals; thus taking into account market dynamics. As such, we support the ASP methodology and market-based pricing. However, any decisions that CMS makes regarding the actual level of reimbursement should ensure that payments to providers is adequate to cover all aspects of the product beyond solely the acquisition of the drug. Inadequate reimbursement may jeopardize beneficiary access to care. Therefore, we encourage CMS to consult with the provider community to ensure that payments are sufficient to support access to appropriate and beneficial therapies. The agency should also consider the appropriateness of having different payments for the same products in similar settings and whether this could lead to inappropriate shifts in access to care across clinical settings.

In summary, Amgen agrees with the agency's proposed payment for Aranesp® and the use of market-based pricing to reimburse for separately payable outpatient drugs.

As CMS prepares to finalize changes to OPPS for 2007, we recommend the following:

- Maintain market-based treatment of Aranesp® in order to achieve significant Medicare payment reductions and savings for beneficiaries, and
- Continue to use the market-based ASP percent methodology to set payment rates for separately payable outpatient drugs.

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25 Reed, et al. "Economic evaluation of weekly epoetin alfa versus biweekly darbepoetin alfa for chemotherapy-induced anaemia: Evidence from a 16-week randomised trial." Pharmacoeconomics: 24(5): 479-494.

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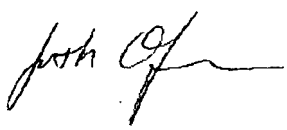
Amgen appreciates this opportunity to provide important information and looks forward to working with you to ensure that Medicare beneficiaries treated in the hospital outpatient setting continue to have access to new and important biological therapies. Please contact Sarah Wells Kocsis by phone at (202) 585-9713 or by email at wellss@amgen.com to arrange a meeting or if you have any questions regarding our response. Thank you for your attention to this important matter.

Regards,



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(42)

ASC 8

September 28, 2006

Dana (2)
Joan
Carol
Alberta

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Dear Dr. McClellan:

I am a practicing gastroenterologist in Greensboro, NC with LeBauer HealthCare. I am writing to express my deep concern over Medicare's proposed rule to change the payment system for ambulatory surgery centers.

I use an ASC and perform about 1,000 endoscopic procedures every year, including many to screen for colorectal cancer. About 30 percent of my patients are Medicare beneficiaries. My practice, LeBauer HealthCare, has 55 physicians and 8 of them are Gastoenterologists who actively use our ASC called LeBauer Endoscopy Center. We serve patients primarily in Guilford County but we see many patients from Rockingham County, Randolph County, Forsyth County and Alamance County.

Medicare is proposing to reduce its ASC payment for endoscopy more than 25% by 2008. The rates Medicare is suggesting are below the costs of performing these endoscopic procedures, including screening for cancer. Our practice will lose money on every Medicare patient that comes to our ASC. Our only choice will be to treat Medicare beneficiaries at the hospital, which is considerably more expensive. It will also cost our patients more in out of pocket expenses and will probably delay their care because our hospital does not have the capacity to handle this additional caseload on a timely basis.

This is unfair to our patients and a needless expense for Medicare. Medicare says that it has to set rates this low because Congress requires that the new payment system be budget neutral and many new procedures are going to be added to the ASC list of covered services in 2008. In order to pay for these new services, reimbursement for endoscopy and many other surgical procedures will have to be cut.

The ASC is a safe, economic site for these services and is very popular with our elderly patients because of its convenience. It would be a disservice to these beneficiaries to adopt Medicare's proposal.

Sidney F. LeBauer Medical Center | 520 North Elam Ave. | Greensboro, NC 27403 | (336) 547-1700 | Fax (336) 547-1717
Greensboro Center for Digestive Diseases | 520 North Elam Ave. | Greensboro, NC 27403 | (336) 547-1745 | Fax (336) 547-1824
LeBauer HeartCare | 1126 N. Church St., Suite 300 | Greensboro, NC 27401 | (336)547-1752 | Fax (336) 547-1858
Guilford-Jamestown Office | 4810 W. Wendover Ave. | Jamestown, NC 27282 | (336) 547-8422 | Fax (336) 547-1824
Asheboro Family Physicians | 375 Sunset Ave. | Asheboro, NC 27203 | (336) 625-4215 | Fax (336) 626-0919
Brassfield Office | 3803 Robert Porcher Way | Greensboro, NC 27410 | (336) 286-3442 | Fax (336) 286-1156
Stoney Creek Office | 945 Golfhouse Rd. West | Stoney Creek, NC 27377 | (336) 449-9848 | Fax (336) 449-9749
LeBauer HeartCare at Annie Penn | 612 S. Main St. | Reidsville, NC 27320 | (336) 951-4823 | Fax (336) 951-4550
LeBauer HeartCare at Morehead | 518 S. Van Buren Rd., Suite 3 | Eden, NC 27288 | (336) 623-7881 | Fax (336) 623-5457
www.LeBauer.com

Congress needs to change its instructions on budget neutrality to avoid this result. I know we can continue to provide services to Medicare patients in the ASC and save Medicare money if the reimbursement rules make sense. This proposal, however, does not pass that test.

Thank you for your careful consideration of this request. I urge you to convey these concerns to the leadership of the Committees that handle Medicare and to encourage action this year to correct this problem.

Sincerely,

Malcolm Stark, MD

Malcolm T. Stark, MD
LeBauer HealthCare

1M
OPPS

September 12, 2006

MT
Marjorie (2)
Joan
Carol
Alberta

The Honorable Mark McClellan, MD
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850.

RE: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates for MRgFUS

Dear Dr. McClellan:

I know what fibroids feel like because I am a uterine fibroid survivor and was a uterine fibroid sufferer (Uterine Artery Embolization performed in 2001). As a uterine fibroid patient advocate I have spent endless hours creating a website (www.hopeforfibroids.org) to help women who are researching alternatives to hysterectomy. I am also activately involved as a Moderator for a Uterine Fibroid Resource Center Discussion Group Forum (http://www.obgyn.net/fibroid-resource-center).

All the fibroid treatments have a good reason to exist, and for the women who are told they have only one option - hysterectomy MR guided Focused Ultrasound Surgery may be the only way to avoid major surgery, time away from their jobs, and experiencing complications from the anesthesia, medications, and possible infections after a procedure. Many women I have been in touch with are terribly afraid of major surgery. At health fairs I have met women who became angry when they realized treatments such as this one exist, but the insurance payment programs do not cover it. I am sure every treatment at one time went through the same payment code adjustment problems, and the codes were changed to reflect the correct reimbursement amount.

Please take in to consideration that uterine fibroids cause physical problems, and they can also cause enormous stress and mental anguish. Month after month of having extremely heavy bleeding, and never knowing if the gushing of blood will stop can wear a woman down physically and emotionally. The fibroids growing and pushing the body organs can cause severe symptoms, and depending where the fibroids are located and their size can cause the pain to be unbearable. Fibroids can cause tremendous problems for businesses because employers lose their workforce to fibroid emergencies and treatment recovery sick leave.

Attending health fairs and moderating a fibroid discussion group has given me the opportunity to see firsthand how huge this medical problem is for women, and the effect it has on our society. Statistics for the United States show, 58% of all women between the ages of 35 and 49 are diagnosed with symptomatic uterine fibroids. Thirty-five to fifty percent of women will seek treatment for their symptoms, of which 400,000 will undergo a surgical procedure to relieve the symptoms of uterine fibroids. Fibroids are symptomatic in 30% of women ages 25-55. About 250,000 women undergo surgery for fibroids each year.

Magnetic Resonance Guided Focused Ultrasound (MRgFUS) integrates magnetic resonance imaging (MRI) with focused ultrasound energy to create a non-invasive technology that ablates tumors without cutting the skin (similar to stereotactic radiosurgery). In the same manner that radiation or light can be focused with a magnifying glass, ultrasound energy can be focused electronically into an intense beam to heat small areas to a temperature that can kill tumor cells. Most importantly, using MRI images allows for precise visualization of the

ultrasound beam aimed at tumors and non-cancerous tissue growths such as fibroids, without destroying or harming healthy tissues. Following the procedure, most patients are able to return to work and normal activities within 1 to 2 days. Patients who have a surgical treatment for their uterine fibroids, which require hospitalization, undergo a recovery period of 7 to 42 days.

While the vast majority of women are not Medicare beneficiaries, Medicare payment is used as a benchmark for private insurers and thus, CMS's actions are critical to helping establish appropriate access for women with uterine fibroids. I am hoping that you will make the necessary changes to the coding to cover the procedure's costs so that doctors can continue to provide this fibroid option to women.

I thank you for taking time from your busy schedule to read my comments concerning this VERY important issue. I hope and pray as you make your decision that you will be thinking of all the women, families, and doctors who will be affected by this payment code, as well as the future of MRgFUS being available to fibroid sufferers.

Best Regards,

Hope Waltman

Hope Waltman, President
Hope For Fibroids Organization
102 Locust Way
Carlisle, PA 17015
Phone: (717) 258–9533
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Email: hope@hopeforfibroids.org

Hope For Fibroids Org.
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Fibroid Forum www.obgyn.net

18 OPPS

NT
Marjorie (2)
Joan
Carol
Alberta

UNIVERSITY of VIRGINIA HEALTH SYSTEM

DEPARTMENT of NEUROLOGICAL SURGERY

September 11, 2006

The Honorable Mark McClellan, MD
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

As the Professor of Neurosurgery at Department of Neurosurgery at the University of Virginia Health System I am pleased that CMS offers the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians interested in offering this technology to patients. We believe that this technology has tremendous potential to improve health outcomes, and the uterine fibroid application is only the first of many to come.

MRgFUS requires treatment planning using volumetric MR images for three-dimensional visualization of the targeted tissue and surrounding organs. The thermal dose to be delivered is determined during the planning phase, and continuously monitored during treatment. The patient is positioned on the treatment table with the pelvis directly over the transducer integrated into the special patient table. As the treatment is delivered, the MR thermal imaging system continuously measures temperature changes inside the body in real time. As each succeeding treatment point is identified, the therapy system commands the imaging system to move the acoustic transducer and set the MR scanner to the right scanning coordinates. The patient is strapped to the table to prevent movement. Fiducial markers, placed on the planning images, are monitored during treatment to ensure no patient movement. Following the treatment, anatomical MRI contrast enhanced images are used to evaluate treatment outcome.

The CPT codes used to describe MRgFUS include 0071T and 0072T. These CPT codes are assigned to and APC that does not allow

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institutions to offer this technology to Medicare beneficiaries. The time and resources associated with MR guided Focused Ultrasound, including about three to five hours of continuous MRI usage, are much greater and should be assigned to an APC with appropriate clinical and resources. We are requesting that CMS consider placing these procedure codes into a similar APC (APC 127 – Stereotactic Radiosurgery) which has a more appropriate clinical and resource cost assignment.

While stereotactic radiosurgery (APC 127) is best known to treat brain tumors, the applications are expanding to prostate, spine, and liver. In our hospital, in addition to the Gamma Knife for treating brain tumors, we have acquired the Tomoblate to treat patients with even small cancers in the lungs, liver, kidney, bones and there are now many different techniques which provide treatment therapy. We find that there are many similarities between MRgFUS and SRS including:

1) Treatment objective is non-invasive tumor destruction
2) The surgery is conducted using an external source of energy which penetrates into the body to reach the tumor
3) Imaging technology is required
4) Extensive treatment planning is involved with continuous monitoring during treatment
5) Expensive capital equipment in dedicated specialized treatment rooms
6) Lengthy procedure time ranging from 2-5 hours

One major difference between the two procedures is that MRgFUS is much more labor intense. The surgeon must spend the entire treatment time interacting with the system while using MRgFUS, whereas stereotactic radiosurgery is not interactive.

I would like to also point out that with regard to MRgFUS, although the vast majority of women are not Medicare beneficiaries, Medicare payment is used by non-Medicare payers to establish reimbursement to hospitals and physicians. This being the case, CMS's actions are critical to helping establish appropriate payment and access to all beneficiaries. The appropriate APC assignment will be a signal to all payers that the ability to offer medical procedures that are less invasive, less traumatic and offer faster recovery should be accepted.

I thank you for your consideration to reassign CPT codes 0071T and 0072T to APC 127, offering a more clinical and resource reimbursement option for this procedure. The reassignment will allow

the hospital outpatient departments and women to have access to this important treatment option.

Our hospital and patients appreciate CMS's consideration of this important issue.

Very truly yours,

Neal F. Kassell, M.D.
John A. Jane Professor of Neurosurgery

cc: Rep. Eric Cantor
ACR

BRIGHAM AND
WOMEN'S HOSPITAL

HARVARD
MEDICAL SCHOOL

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Clare M. C. Tempany, M.D.
Professor of Radiology
Director, Clinical MRI & Clinical Research
Director, Clinical Focused Ultrasound

19-0
(3) APC

Dana (2)
Joan
Carol
Alberta

September 11, 2006

The Honorable Mark McClellan, MD
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention:CMS-1506-P, or CMS-4125PP.O.Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

As a physician with the Brigham & Women's Hospital, I am pleased to have the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

CPT codes 0071T and 0072T are currently assigned to APCs 195 and 202 with national unadjusted payment rates of $1,595 and $2,454, respectively. The procedures in the current APC assignments are less resource intensive procedures for the hospital to offer making the APC assignments for CPT 0071T and 0072T inappropriate. The time and resources associated with MR guided Focused Ultrasound, including about three to five hours of continuous MRI usage, are much greater and should be assigned to an APC with appropriate clinical and resources. The hospital charges for the MR guided focused ultrasound procedure range from $18000 to $24000. Thus, I request we would ask that CMS consider assignment to **APC 127** which has a more appropriate clinical and resource cost assignment.

MR guided Focused Ultrasound has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians offering this technology to patients in this area. While the vast majority of women are not Medicare beneficiaries, Medicare payment is used as a benchmark for private insurers in setting payment rates for hospitals and physicians, and thus, CMS's actions are critical to helping establish appropriate payment and access. The appropriate APC assignment will be a signal to all payers that the ability to offer medical procedures that are less invasive, less traumatic and offer faster recovery should be accepted by health insurers.

I thank you for your consideration to reassign CPT codes 0071T and 0072T Magnetic Resonance Imaging Guided Focused ultrasound ablation of fibroids (leiomyomata) to an APC with a more clinical and resource cost that is appropriate. The reassignment will allow the hospital outpatient departments and women to have access to this important treatment option.

Our hospital and patients appreciate CMS's consideration of this important issue.

Very truly yours,

Clare Tempany M.D.

Professor of Radiology, Harvard Medical School
Brigham & Women's Hospital

DUKE UNIVERSITY MEDICAL CENTER
Department of Obstetrics and Gynecology

19-1

September 13, 2006

The Honorable Mark McClellan, MD
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

As a physician with privileges at Duke Hospital, and as MD - Dept of Ob/Gyn at Duke University I am pleased to have the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

CPT codes 0071T and 0072T are currently assigned to APCs 195 and 202 with national unadjusted payment rates of $1,595 and $2,454, respectively. The procedures in the current APC assignments are less resource intensive procedures for the hospital to offer making the APC assignments for CPT 0071T and 0072T inappropriate. The time and resources associated with MR guided Focused Ultrasound, including about three to five hours of continuous MRI usage, are much greater and should be assigned to an APC with appropriate clinical and resources. The hospital charges for the MR guided focused ultrasound procedure range from $18000 to $24000. We would ask that CMS consider assignment to APC 127 which has a more appropriate clinical and resource cost assignment.

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Our hospital and patients appreciate CMS's consideration of this important issue.

Very truly yours,

Millie Behera

Millie Behera, MD - Dept of Ob/Gyn

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DUKE UNIVERSITY MEDICAL CENTER

Haywood L. Brown, M.D.
Roy T. Parker Professor and Chair
Department of Obstetrics and Gynecology

19-2

September 13, 2006

The Honorable Mark McClellan, MD
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

As a physician with privileges at Duke Hospital, and as the Chair of the Department of Ob/Gyn at Duke University I am pleased to have the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

CPT codes 0071T and 0072T are currently assigned to APCs 195 and 202 with national unadjusted payment rates of $1,595 and $2,454, respectively. The procedures in the current APC assignments are less resource intensive procedures for the hospital to offer making the APC assignments for CPT 0071T and 0072T inappropriate. The time and resources associated with MR guided Focused Ultrasound, including about three to five hours of continuous MRI usage, are much greater and should be assigned to an APC with appropriate clinical and resources. The hospital charges for the MR guided focused ultrasound procedure range from $18000 to $24000. We would ask that CMS consider assignment to APC 127 which has a more appropriate clinical and resource cost assignment.

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Our hospital and patients appreciate CMS's consideration of this important issue.

Very truly yours,

Haywood Brown, MD – Professor and Chair, Dept of Ob/Gyn

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haywood.brown@duke.edu

The American Society of Interventional Nephrology (otherwise referred to as ASDIN) is the society which represents over 95 % of the interventional nephrologists in the United States as well as many radiologists who specialize in interventional procedures for dialysis accesses. Because of this ASDIN represents major stake holders affected by proposal CMS1506P.

We support many aspects of this proposal by CMS. We are especially supportive of the intent to improve access for Medicare recipients to dialysis access maintenance procedures. The proposal to evolve from a list of allowed procedures to a list of disallowed procedures goes a long way towards achieving this goal. However there are several aspects of this proposal which we feel are counter productive and will have the effect of inhibiting access to appropriate care for end stage renal disease (ESRD) recipients of Medicare.

Currently access procedures are reimbursable in either the office setting or the hospital setting and, to a markedly lesser extent, in the ASC setting. Adequately and appropriately reimbursing these procedures in an ASC setting will not change the frequency of these procedures. It will however, improve patient access to care. By shifting procedures out of the hospital it will provide a net savings to the Medicare system and should rightly be encouraged.

As CMS is well aware, the state of vascular access for dialysis in the United States is such that marked improvement is necessary. To this end, the KDOQI (Kidney Disease Outcome Quality Initiative) practice guidelines were developed as a joint effort of multiple organizations and then embraced by the nephrology community. Supporting organizations include the National Kidney Foundation, the American Society of Nephrology and the Renal Physicians Association. As documented in the USRDS database, vascular access in the United States has been improving since implementation of these guidelines. KDOQI mandates the development of facilities and mechanisms to improve timely access to dialysis access maintenance procedures. In addition it was recommended that these procedures be moved to the outpatient setting. To further these goals, effective January 1, 2005 CMS changed the reimbursement guidelines for procedures done in place of service 11 (POS 11) or an extension of a physician's office setting. Since the reimbursement changes have been implemented, over 30 freestanding centers for the performance of vascular access procedures have been built by physician practices throughout the United States. These centers perform more than 50,000 access related procedures annually. All of these procedures have been moved from the hospital setting. Many more centers are currently planned. Currently, the vast majority will function in POS 11. The current proposal has the intent of similarly improving access to procedures performed in the ASC setting.

Because of the nature of dialysis access procedures, specialized radiology equipment and supplies are necessary. This equipment must be provided in an ASC dedicated to dialysis vascular access procedures. The specialized equipment and supplies are not easily transferable to other uses if dialysis access procedures are to continue to be the main focus of the ASC. This focus is necessary to achieve the desired improved access to care for ESRD patients with dialysis access problems discussed below. Because of

this, these centers cannot "blend" in other procedures to counter a 38 percent decrease in reimbursement per procedure. In addition, the cost per procedure does not go down 38 percent with an increasing volume of access procedures. Also, CMS has proposed a reduction in reimbursement for multiple radiology procedures done on the same day. CMS already imposes a 50 % reduced reimbursement for multiple surgical procedures performed on the same day. If in addition to this, if the proposed reduction in reimbursement for multiple radiology procedure is superimposed the combined effect would be prohibitive.

KDOQI and the Fistula First initiative have set as goals an increase in fistula prevalence in ESRD patients to greater than 65%. To facilitate this effort the National Kidney Foundation, American Society of Nephrology, Renal Physicians Association and Fistula First Initiative have advocated making interventional procedures more available to patients, especially in the outpatient setting. The proposed cuts will make performing access related procedures in an ASC a financially marginal endeavor from the perspective of operating revenues. This will have the effect of retarding the shift of access related procedures to the outpatient departments from the inpatient settings. It will also have the effect of reducing access to care for Medicare recipients who suffer from ESRD. Since the hospital setting is both less efficient and more expensive, the result will be an increase in Medicare expenditures.

The proposed list of procedures prohibited from reimbursement in an ASC includes 35475 and 37206. 35475 is the code used by interventional physicians performing procedures (i.e. balloon angioplasty or PTA) at the arterial anastomosis of a fistula or graft and the proximate feeding artery. When applied to the repair and maintenance of vascular access for dialysis, these procedures are very safely performed in an ASC. Indeed, they are currently frequently performed safely in POS 11. Data from three sources is provided. The first is an ASC setting with low volume of procedures coding 35475. The second is a single Access Center which performs greater than 3,000 procedures per year all on dialysis vascular access. The third is a large number of procedures from multiple access centers all functioning as POS 11 and managed by a common entity.

no. proc.	% major complications
14	0 %
455	0 %
1,968	< 0.3 %

In each case the number of major complications is miniscule and well within the professional guidelines for each center and the national guidelines published by the Society for Interventional Radiology. Thus, excluding procedures performed on dialysis vascular access which would be coded as 35475 would be inappropriate as well as counterproductive. These procedures can be safely and effectively performed in an outpatient setting. Prohibiting this code would also have the affect of limiting access to care for ESRD patients as these patients would have to have a second procedure and anesthesia to open these lesions at a separate time. Since they would need a way to achieve dialysis access in the meantime, a large number of otherwise unnecessary catheter insertion procedures would be necessitated and the cost to the Medicare program from both additional procedures would go up significantly.

37206 is the code utilized by interventional physicians for placement of additional vascular stents in the venous system. These procedures have been safely performed in the outpatient setting for years. In addition, the initial placement of a stent in the venous system, coded 37205, is not on the list of excluded procedures. In our opinion, this prohibition is logically inconsistent, not medically indicated and would necessitate repeat and additional procedures which could otherwise be avoided.

We recommend and request that 35475 and 37206 both be removed from the list of excluded services when applied to dialysis access.

Lastly is the issue of frequent procedures and budget neutrality. Interventional access procedures are a very cost effective means of treatment for dysfunctional dialysis accesses. They are much less costly than equivalent surgical procedures. Thus, increasing access procedures and reducing surgical and hospital based procedures will not increase overall Medicare expenditures. Therefore, reducing ASC reimbursement in the name of budget neutrality is neither appropriate nor fair. For every ASC performed procedure there is a net savings to the ESRD system as opposed to the procedure being performed within a hospital setting.

We feel that the intent of the CMS proposal CMS1506P is excellent. However, certain features of the proposed implementation will make the proposed goals elusive or impossible to achieve. To this end we have tried to make positive suggestions to further the common goal of achieving better care and better access to care for Medicare recipients with ESRD.

In summary, ASDIN respectfully suggests and requests the following.

1. We support the proposed shift from a list of approved procedures to a list of disallowed procedures.

2. We support improving access to outpatient vascular access procedures in the ASC setting for ESRD patients.

3. We maintain that shifting procedures to the ASC from the inpatient setting will not change the absolute number of procedures performed as these are essential procedures to sustain life on dialysis.

4. There will be a major savings to the Medicare system from this shift. Therefore, reducing reimbursement for budget neutrality is not logical. There will result a net savings without the reduction.

5. ASC access centers are of necessity highly specialized facilities dedicated to a specific purpose. The equipment and set up are not routinely useful to other procedures performed in the ASC setting. Thus, these centers will feel an effect from the proposed reimbursement cuts which cannot be mitigated by "blending" in other procedures.

6. CMS has also proposed reimbursement cuts for multiple radiology procedures. The combined effect, if implemented, of both the 38 % reduction in ASC reimbursement and reduction for multiple radiology procedures will severely and disproportionately penalize ASC facilities dedicated to dialysis vascular access.

7. The above proposals will retard the shift in dialysis access procedures to the outpatient setting. This will result in lost opportunity for savings to the Medicare system and reduce access to care for Medicare recipients.

8. We request the removal of codes 37206 from the list of disapproved procedures on the basis of safety and consistency. We request the removal of code 35475 from the list of disapproved procedures when applied to dialysis vascular access. Data documenting the safety of such procedures in the outpatient setting is supplied for low and high volume facilities.

9. Maintaining 37206 and 35475 on the list of disapproved procedures would result in multiple procedures which could otherwise be avoided.

Donald Schon, MD, FACP

Councilor for Regulatory Affairs

Ted Saad, MD, FACP

President ASDIN

The Committee of Officers and Councilors of ASDIN on behalf of the membership:

Arif Asif, MD

Timothy Pflederer, MD

Jack Work, MD

Gerald Beathard, MD

Michael Levine, MD

Kenneth Abreo, MD

Tom Vessely, MD

Tony Besarab, MD

Linda Francisco, MD

Rick Mishler, MD

Stephen Ash, MD

Terry Litchfield

21-0
(125)
ASC8

Mark McClellan, MD
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P and CMS-1512-PN
PO Box 8014
Baltimore, Maryland 21244-8014

Dana (2)
Joan
Carol
Alberta

Dear Dr. McClellan:

As a patient, I am writing to express my concern and opposition to CMS' proposal to reduce markedly the Medicare fee schedule by virtue of the SGR, the budget neutrality aspect of Medicare fees and to the proposed change the payment structure for separate facility fees at ambulatory surgery centers (ASCs).

I am concerned that CMS' proposal would unfairly and arbitrarily shift fees with minimal objective data, and would significantly compromise the quality of care I receive. These dramatic cuts likely will result in some physicians significantly reducing (or even eliminating) Medicare patients from their practice, and reduced access for Medicare patients at ambulatory surgery centers. Some physicians may not be able to afford to spend as much time with their Medicare patients. I am especially concerned about CMS' attempts to create incentives to steer patients toward specific settings for economic reasons rather than maintaining site neutrality.

Citizens who are growing older deserve better! CMS should suspend its plans to implement the proposed changes to the five-year review, budget neutrality adjustment to the Medicare fee schedule, should defer indefinitely the ambulatory surgery rules and should revise the unfair SGR.

Very truly yours,

(Name) David P. Smalley

(Address) 6910 Ivy Lane

(City, State, Zip) Godfrey IL
62035

22

Advanced Surgery Center, Inc.
STONCREST CENTER
10900 S.E. 174TH PL. SUMMERFIELD, FL 34491
PH: (352) 245-9562 FAX: (352) 245-9563

September 25, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATT: CMS – 1506 – P
PO Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

This letter is written to make general comment regarding the CMS proposed Ambulatory Surgery Center (ASC) payment system changes:

The current proposal leaves too many open questions on issues involving the processes used to determine site-of-service classification, outpatient procedures listings, ratio and equity in ASC to HOPD reimbursement rates, and a fair and realistic time frame in which ASC's would be able to absorb the impact of these critical changes and implement any possible remedial measures and practices. All of these points mentioned are basic to the eventual survival and success of ASC's, individually and collectively.

In setting the framework for a newly-developed payment system, I urge the Centers for Medicare and Medicaid Services to consider carefully, ***as a whole*** (rather than in part), the valid recommendations of the various ASC industry organizations, particularly the associations AAASC and FASA, and the Crapo-Herger legislation introduced in the U.S. Houses of Congress, and to incorporate these recommendations.

Medicare advocates high quality patient care in a cost-effective environment as a driving force of healthcare – nothing embodies and delivers this concept more clearly than the ASC outpatient surgery center setting. This proposal from CMS as it now stands threatens to ensure the demise, or at least the reduction of, this valuable resource of services to the patient population that Medicare serves.

I will be writing to my legislative representatives as well to express my concerns regarding the importance of this matter.

Thank you for your consideration.

Sincerely,

Caicedo M.D.

Frank Caicedo, MD
Medical Director

23

Submitter : Kim Mcqueen Date: 10/04/2006

Organization : Carolina Kidney Care Procedure Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I support the position as outlined by the American Society of Diagnostic and Interventional Nephrology (ASDIN).