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September 22, 2006

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The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 *Federal Register*) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a *"seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."*

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate HOPPS payment. By excluding new and innovative brachytherapy

The
National Association for Proton Therapy

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OPPS

APC

September 29, 2006

Dana (2)
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Honorable Mark B. McCellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Proton Therapy Payment Rates

Dear Dr. McClellan:

The National Association for Proton Therapy (NAPT), founded in 1990, has great respect for the complexities of your mission and the challenges faced by CMS in the past several years under your effective leadership.

With that in mind, we are writing to you on matters of vast importance to the proton therapy community and cancer patients around the nation. In the past 16 years, about 16,000 patients have successfully battled cancer in the U.S. with proton beam radiation therapy. Worldwide, more than 50,000 patients have been treated. Proton therapy is a precise form of non-invasive treatment that targets cancer without harming healthy tissue surrounding the tumor site. Physicians are able to administer high levels of proton beams to the target site with minimum to no serious side effects or morbidity, compared to traditional radiation treatment. A factor that has caught the attention of the mainstream medical community.

Therefore, we offer our strong support for the proposed **CY'07 Hospital Outpatient Prospective Payment System** (OPPS) **Payment Rules for proton beam therapy.** They are **APC 0664** for simple proton therapies **(77520 and 77522)** and **APC 0667** for immediate/complex therapies **(77523 and 77525).**

This action will continue to ensure that the nation's proton centers will have the capability to provide full patient services and meet increasing demand for proton treatment.

We believe the opening of additional proton facilities in the U.S. will enable more multi-institutional and cooperative research – and will ultimately lead to more innovations in the field. We also believe the potential of protons is only beginning to be realized. New technological advances and collaborative trials will reveal more applications for proton therapy such as treatment of non-cancerous diseases like Parkinson's disease and epilepsy.

continued>

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Freestanding Proton Therapy Centers

On another equally as important matter, we want to express our concern for the manner in which the CMS has given significant latitude to its contracted Carriers, but ***limited guidance*** when it comes to determining payment rates for proton therapy. Our concern involves the freestanding proton facilities in the states of Texas, Florida, and Indiana and the rate inconsistency by Carriers in each locale. Therefore, we strongly recommend that:

CMS direct its Carriers on issues of payment for proton therapy for Freestanding Centers so that CMS contracted Carriers' determinations regarding proton therapy payment rates are in keeping with National Payment policy decisions currently in effect for HOPD facilities.

In conclusion, we want to thank you for your attention to these important matters and for your continuing support of proton therapy during your tenure at the CMS. Thank you also for your important contributions to the nation's health and well being. We wish you all the best in your next career move.

Sincerely yours,

Leonard J. Arzt
Executive Director
NAPT

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Gastroenterology Associates of North Texas, L.L.P.

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603-0
(15)
ASCs

October 12, 2006

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Leslie V. Norwalk, JD
Acting CMS Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Ms. Norwalk:

As a gastroenterologist in Fort Worth, Texas, about 40% of my patients are Medicare beneficiaries. Our own group performs about 7000 outpatient endoscopic procedures per year for Medicare patients in a single-specialty endoscopic ambulatory surgery center (EASC). If the current Ambulatory Surgery Centers PPS Proposed Rule is implemented my physician group of 14 gastroenterologists will no longer be able to perform endoscopy or colonoscopy for Medicare beneficiaries in the EASC.

Medicare reimbursement levels at 62% of HOPD rates will not meet the costs of capital investments and operational expenses for our two EASCs. This is not a sustainable business model for the EASC designed to perform only gastrointestinal endoscopic services. Some ASCs will survive accepting only private payers. Others will be forced to close. Certainly there will be no growth in endoscopic ASCs to fuel continued savings for CMS. Medicare beneficiaries will be forced to see gastroenterologists who perform endoscopy solely in the more expensive and less convenient hospital setting – just ask any Medicare beneficiaries in our practice who have had an exam done in the hospital, and in our facility. Medicare's facility costs will soar, and MC beneficiary access to life-saving colorectal cancer screening and other valuable GI services will plummet. In the Dallas-Fort Worth Metroplex there are over 200 gastroenterologists. Because of the demand for CRC screening, waiting time for appointments and colonoscopy often exceed 2-3 months – this with EASC accepting Medicare beneficiaries. This will only get worse as the gastroenterologists who work in EASCs must close their practices to new MC patients.

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Gastrointestinal endoscopy accounts for a very large volume of outpatient procedures. As long as the ASC rates remain even 10% lower than the HOPD, It is in the long-term best interest of CMS and Medicare beneficiaries to assure that ASC payment reform provides adequate incentives for the growth and expansion of accredited EASCs promoting continued migration of cases from the HOPD to the EASC. Case migration to EASCs decreases costs for CMS and Medicare beneficiaries.

Evidence-based studies show that compliance with colorectal cancer screening can reduce colon cancer death by 90%. This provides an obvious benefit to Medicare patients and a substantial cost benefit to CMS. Both the GAO and CMS have confirmed that the Medicare colorectal cancer screening benefit is underutilized. MEDPAC has endorsed the concept that medical procedures and services should be site neutral. A reimbursement policy that will severely restrict access of MC beneficiaries and increases costs to CMS is foolish. Over the past 5 years there has been a steady shift of endoscopic services from the HOPD to EASCs. Last year over 30% of outpatient endoscopies for Medicare beneficiaries were performed in the ASC. This shift in site of service has accrued to the substantial benefit of CMS with EASCs paid at 89% of the HOPD rate.

CMS is ignoring the stated priorities of the current Administration and the lessons of cost management in the private sector. President Bush and his staff have stated that ASCs are generally more cost-effective than the HOPD for medical services. When private insurers have sought to reduce total health care costs, they have encouraged patients to receive their medical services in the ASC rather than the HOPD. Blue Cross of California recently announced that it will pay a 5% premium to physicians for every GI endoscopy that is performed in the ASC, rather than in the HOPD.

CMS concept of budget neutrality in this proposal is shortsighted. First, CMS proposes to expand the list of procedures that are performed in the ambulatory surgery center. By substantially raising the reimbursement for vascular, orthopedic, general surgery, ENT, and urologic services, many more of these services will be performed in ASCs. Yet in assessing budget neutrality, CMS believes that the same pool of dollars should fully cover the ASC payment for the additional procedures that were previously performed in the HOPD. It is hard to believe that Congress expected the additional services to be covered with a neutral budget. It would be fiscally more rational for the calculations of budget neutrality to encompass procedures performed in all outpatient settings to account for shifts in site of service created by payment reform and the expanded ASC list.

The proposed rule's effect on gastrointestinal endoscopic ASCs virtually assures harm to Medicare beneficiaries. Currently we ASC facility fee for screening colonoscopy is

about 89% of the HOPD rate. Congress did the right thing for MC beneficiaries in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit. Since then CMS reimbursement policy has seriously impaired beneficiary access to that benefit. Since 1997, CMS has cut physician reimbursement for screening/diagnostic colonoscopies by almost 40% not accounting for inflationary decline. The current ASC Payment proposed rule would again put gastroenterology in the CMS cross-hairs with a 30% reduction in facility payment to endoscopic ASCs. This draconian reduction is proposed by CMS with absolutely no useful information about the cost of providing the endoscopic services. If CMS is committed to linking ASC payment to the HOPD rates, it must adopt an approach that will allow EASCs to remain accessible to Medicare beneficiaries maintaining rates at their current levels and with future adjustments comparable to the HOPD.

The unintended consequences of the ASC PPS Proposed Rule will be calamitous:

- MC patients' access to the life-saving benefits of colorectal cancer screening will be significantly limited by the loss of available EASCs. Those who can access CRC screening in the HOPD will wait longer for their care and pay more out of pocket for it. They also lose the substantial conveniences and comforts of the EASC setting for their procedures. Not the least of a Medicare beneficiaries risk is that of colon cancer which could have been prevented with adequate access to CRC screening.

- CMS outpatient facility costs will soar as Medicare recipients will see only those colonoscopists who work in the less efficient and higher cost HOPD setting. The 30% differential in cost between HOPD and ASC will achieve no savings if these procedures shift back to the HOPD. Additional costs will arise from the treatment of otherwise preventable colorectal cancers.

The current Ambulatory Surgery Centers PPS Proposed Rule is not a sustainable option for single-specialty endoscopic ASCs. To preserve patient access and continue Medicare savings, ASC payments for gastrointestinal endoscopic services should be maintained at their current levels and with future cost-of-living adjustments comparable to the HOPD rates.

Respectfully submitted,

Thomas M. Deas, Jr., M.D.
TMD:ch

PUGET SOUND
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ASC8

October 9, 2006

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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

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan:

I am a practicing gastroenterologist nurse practitioner in the City of Edmonds, Washington. I am writing to express my deep concern over CMS's proposed rule to change the payment system for ambulatory surgery centers (ASC).

I am a provider in Puget Sound Gastroenterology, PS serving the greater Seattle area. Puget Sound Gastroenterology, PS is a single specialty GI practice serving several locations including Seattle, Edmonds, Kirkland and the surrounding areas. We cover both King and Snohomish County, thereby, serving both urban and rural populations. About 26% percent of our patients are Medicare beneficiaries. Puget Sound Gastroenterology, PS includes 22 physicians and 4 Nurse Practitioners as well as many other medical professionals. The company employs roughly 240 employees to ensure the best possible care for our patients.

Puget Sound Gastroenterology has four ASC's and we perform approximately 20,000 procedures every year. These procedures include performing screening colonoscopies for high risk individuals and surveillance colonoscopies for those who have already been detected as having either polyps, or who have had cancerous lesions excised previously. Additionally, we see a very significant number of patients with other conditions- GI bleeding, inflammatory bowel disease, gastroesophageal reflux disease (GERD), and/or Barrett's esophagus for whom ready access to an appropriate, safe, cost-efficient site for GI endoscopy is critical to either restoring them to good health, or sustaining them in good health.

CMS is proposing to change the way the agency pays ambulatory surgery centers for their services, via facility fee payments. Both the GAO and CMS itself have stated that

the Medicare colorectal cancer screening benefit is underutilized. The federal government 's Medicare Payment Advisory Commission (MEDPAC) has repeatedly endorsed the concept that medical procedures and services should be site neutral. The current CMS proposal institutionalizes the concept of paying significantly more to hospitals than to the ASC's. This will reduce the capacity to provide GI screening colonoscopies and other GI endoscopic procedures by forcing a significant number of ASC's to close their doors to Medicare beneficiaries, if not to all patients, because Medicare's payment level will drop so precipitously that these ASC's can no longer meet their expenses and render a reasonable return on investment. Today, when a GI procedure, such as a screening colonoscopy is performed in an ASC, that ASC receives a facility fee which on the average amounts to 89% of the facility fee CMS pays to the hospitals if that same procedure is performed there.

Since 1997, CMS has already cut the physician professional component of payment for screening/diagnostic colonoscopies by almost 40%-- from a little over $300, to the current level of just around $200, and trending downward (these are raw dollars—if inflation were factored in the reduction amount would almost certainly be in excess of 50%). According to information from the American College of Gastroenterology, no other Medicare service has been cut this much. Now, CMS issues a new proposal which would further undercut and devastate the prospects for Medicare beneficiaries to receive a colorectal cancer screening colonoscopy. In terms of the specialty that would be hurt the most by the current proposal, once again, CMS has placed gastroenterology and colonoscopies for colorectal cancer screening in its cross hairs, as by far the biggest potential loser, with the prospect of cuts from 89% of the hospital payment to 62%.

Our practice will lose money on every Medicare patient that comes to our ASC. As a single specialty center we have no place to shift these costs to make up for the lost revenue. Many of our contracts with private health plans include negotiated reimbursement that is tied to Medicare rates. Therefore, not only would our reimbursement from Medicare be impacted but many of our other payers as well.

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. 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 colorectal cancer screening and many other surgical procedures will have to be cut. We are not of aware of any new procedures we are doing which would require any thing like this precipitous cut in screening colonoscopy benefits to offset a new expense. Colorectal cancer screening by colonoscopy has been proven to save lives and is the most effective screening tool for any preventable cancer. Curtailing the availability of this powerful colon cancer prevention strategy by grossly under funding for the service is hardly acting in the best interests of America's seniors.

It seems clear that 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 our 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,

Dana Driskell

Dana Driskell, ARNP

Cc: American College of Gastroenterology
American Gastroenterological Association

TRIDENT GASTROENTEROLOGY ASSOCIATES, P.A.

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Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
PO Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan:

Trident Gastroenterology is a specialty medical practice located in North Charleston, South Carolina. We, as physicians, feel obligated to share our thoughts with you on the proposal cuts in Medicare reimbursement for Ambulatory Surgery Centers (ASC) and professional services. This is not a "form" letter. Deeper cuts in physician reimbursements from Medicare could fundamentally change the nature of our particular practice especially as it pertains to Medicare beneficiaries. We do not want to implement these measures, but, in order to survive as a profitable business, we may have no choice.

Currently, our GI group owns and manages a two-room GI ASC for endoscopic procedures in our main building. South Carolina requires a certificate of need application and other certifications before a State license for an ASC is granted. This process cost us approximately $125K.

The ASC is well-equipped and staffed with professionals who have had considerable training in GI Endoscopy. Patients prefer our center over the big, often impersonal hospital outpatient department. The cost savings for patients and payers are significant. The ASC and our clinical office is equipped with an electronic medical record system. We continue to invest in the practice to improve patient care and overall efficiency. Naturally, such innovation is expensive. With current reimbursement, the practice can continue to provide these superlative services and remain profitable.

However, with a patient population that is 35% Medicare and 12% Tricare, the proposed cuts for 2007 forward would be devastating for us. GI endoscopic

Digestive Disorders
Liver Disorders
Pancreatic Disorders

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Endoscopy
Colonoscopy
ERCP
Endoscopic Ultrasound

Marie C. Walsh
Administrator

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Digestive Disorders
Liver Disorders
Pancreatic Disorders

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Endoscopy
Colonoscopy
ERCP
Endoscopic Ultrasound

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procedures currently are probably the most deeply discounted services we provided by physicians. The proposed cuts could lead to the following alterations in our practice structure:

1. Medicare patients will have to wait longer for appointments as we limit these patients' contacts per month.
2. Elimination of inpatient services where most patients have government-sponsored insurance (or none!)
3. Drop out of SC Medicaid Program.
4. A shift in Medicare Endoscopy patients to the hospital outpatient Department.
5. A freeze on the hiring of the additional staff and physicians.
6. Lack of investment in innovative technology.
7. Elimination of our cost-effective program for Medicare Colorectal Cancer Screening.

We want to continue full participation in the Medicare Program. We went into medicine to provide care for all of our patients. These proposed, unfair and poorly conceived cuts will have an enormous negative impact on the Medicare beneficiaries who need medical care.

In summary, we at Trident Gastroenterology hope that these proposed cuts are never realized. Any additional reductions in Medicare reimbursement for GI specialists are not sustainable. We could conceivably be forced out of business. This would be disastrous for the patients who depend on us every day. Please work with Congress to come up with fair and reasonable solution to the Medicare finance problem that avoids any further physician reimbursement cuts. Thank you for your consideration.

Sincerely,

Salvatore A. Moscatello, D.O.

Marc D. New, M.D.

Todd L. Snyder, M.D.

David A. Florez, M.D.

Judd B. Adelman, M.D.

Gregory C. Goodear, M.D.

CC: Jim DeMint, US Senate
Lindsay Graham, US Senate
Henry Brown, US House of Representatives