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βIO-NUCLEONICS PHARMA, INC.

Utilizing Radiation to Improve Human Health

October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05; Att: CMS-1506P, or CMS-4125 P
7500 Security Blvd. C4-05-17
Baltimore, MD 21244-1850

By Fedex and e mail to: http:www.cms.hhs.gov/erulemaking

In Re: File Code CMS-1506-P, CMS-4125-P HOPPS CY 2007. Payment Rates Proposed Rule For 78492, (APC 0307), Myocardial Positron Emission Tomography (PET) Scan RHQDAPU

Dear Sir/Madam:

This is a formal submission of comments regarding a proposed payment decrease by combining single and multiple cardiac PET imaging (APC307) studies into one. Bio-Nucleonics is a small business that focuses on innovative solutions utilizing radiation to improve human health.

According to the American Heart Association, in 2006, more than 1.5 million Americans will have a first or recurrent coronary attack, and 600,000 will die. Cardiovascular disease is the nation's single largest cause of death, and more women die of the disease than of cancer. Around 7.2 million Americans age 20 and older have survived a heart attack, and 13% of middle-aged men have coronary arteriosclerosis, most of it clinically silent. Some 6.6 million have angina pectoris. Cardiac PET is a solution to the major question for cardiac care providers of how to detect and identify silent coronary artery disease in specific individuals, and how to define its severity in either the symptomatic or asymptomatic patient.

Bio-Nucleonics respectfully requests a payment rate review (Payment Rates Proposed Rule For 78492 and APC 307), myocardial PET scan, and upward readjustment for 2007 by the Centers for Medicare and Medicaid Services from the proposed cost rate of $721.26 to $2,484.88 in order to accurately reflect the real cost of providing a multiple study myocardial positron emission tomography (PET) scan. The rationale for this request follows.

A drastic decrease by more than two-thirds in the payment rate for a multiple cardiac PET procedure, caused by "bundling" single procedures and multiple procedures will serve to drive the underutilization of myocardial PET. The CMS is using a fundamentally flawed methodology for setting a payment rate, biased against a proven diagnostic tool, ultimately costing the CMS hundreds of millions of dollars of excess reimbursements for unnecessary invasive procedures. If the proposed reduced reimbursement goes into effect, CMS could see an increase in cardiac catheterizations, bypass surgery and heart transplantations resulting from false positive and false negative misdiagnosis or prognosis, leading to undesirable therapeutic approaches.

The level of reimbursement for a cardiac PET perfusion procedure was appropriately set by local Medicare providers for a rest/stress procedure. While these were acceptable payment rates, hospitals may soon experience a change in the way they are reimbursed for outpatient procedures performed on Medicare beneficiaries, and that change threatens to erode payment levels impacting the most needy of patients. The potentially negative impact on cardiovascular healthcare in America and taxpayers is all too obvious.

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The Reimbursement History of Cardiac PET

Cardiac PET has been validated by the Centers for Medicare and Medicaid Services (CMS) with coverage as a primary or initial diagnostic study for determining myocardial viability in patients with ischemic heart disease, and increased PET reimbursement by the CMS and private insurers reflects a growing understanding of its clinical value. Such changes encouraged physicians to use PET imaging to detect cardiovascular disease earlier, contributing to an overall improvement in patient outcomes. For 2006, the CMS appropriately increased the reimbursement for myocardial PET perfusion imaging involving multiple studies at rest and/or stress to $2,484.88. CMS came up with the new figure by analyzing claims data and splitting the ambulatory payment classification (APC) into single studies and multiple studies, similar to how SPECT myocardial perfusion imaging procedures are handled. The Society of Nuclear Medicine, the Academy of Molecular Imaging, the American Society of Nuclear Cardiology, and the CMS APC panel were among the proponents advocating the level splitting.

Historically, the FDA approved a PET radiotracer, as a cardiac perfusion agent in 1989, and HCFA afforded coverage for Medicare patients in 1994. It was unfortunate that because of insufficient reimbursement, the diagnostic advantages of cardiac PET languished for more than a decade. Payment rate is a critical component of coverage and has been the subject of much attention. Historically, In 1998 HCFA accorded 53.96 relative value units (RVUs) for oncologic PET studies, which equated to an average payment rate of $1,980. This RVU assignment was to reflect the total technical reimbursement for the procedure, including both the actual scan fee and the radiopharmaceutical charge. It is unfortunate that cardiac PET was treated much less favorably.

While there has been exponential growth in PET camera installations in the U.S. during the past decade, and in 2005, over 1 million mostly oncological and neurological PET scans were performed, cardiac PET has languished, becoming the "orphan" brother of oncological PET because reimbursement does not economically justify the purchase of a dedicated scanner. In facilities where there is no scanner time available because of oncological, neurological and research workloads, there is no coronary PET.

For 2007, however, the CMS proposes to "bundle" single and multiple myocardial PET Scans under one code, APC 0307, (CPT Codes 78459, 78491, 78492 and under the OPPS) and to reduce the payment rate for a heart image (PET) multiple study to $721.26, a catastrophic reduction that if enacted would essentially eliminate the delivery of cardiac PET diagnostic procedures to Medicare beneficiaries.

Rationale For Not "bundling" Single and Multiple Myocardial PET Scans Under One Code

1. The CMS is proposing "bundling" lower cost single studies with multiple studies into a single new code based upon the CY 2004 claims from a single hospital (See Page 196, Line 21). Contrary what the CMS states on Page 198 of its current proposal, hospital resources to perform single and multiple studies are not similar. A multiple study takes more time, requires the multiple administration of injectable drugs and radiopharmaceuticals, takes longer to read, reduces patient throughput (adding to the amortization cost of the scanner per study), and adds to the amount of administrative time required per patient.

2. CMS stated that "we now have more data to support our proposed payment rates... based on almost 1,500 single claims for both single and multiple scans and that this should be more reflective of the hospital resources required to provide the service to beneficiaries in the outpatient setting—and that based on this data, the differential median costs of single and multiple studies procedures do not support the present 2-level APC payment structure". In fact, only a very few hospitals perform over a thousand cardiac PET studies a year (Cleveland Clinic, Brigham and Woman's and Mount Sinai of New York). Thus the CMS data relied upon was only for one or two hospitals and continues to be flawed, skewing to single scans.

3. The new rate for a multiple cardiac PET study is based on a statistically insignificant small number of claims, wherein there is confusion on the part of billing clerks between single and

multiple scans. This has unfortunately resulted in a skewing; using the cost of a single scan to also cover more costly multiple scans.

4. We have surveyed the five leading hospitals performing cardiac PET and spoken to the billing clerks, administrative personnel and nuclear cardiologists. The results of these finding is that in four of these institutions the persons that enter in the data that is transmitted to CMS did not know that a multiple scan could be billed separately! Instead, in error, they were entering multiple studies as single ones. The result is that underreporting and "averaging" skews the figure that CMS has arrived at in its conclusion to eliminate reimbursement for multiple scans and pay for a multiple scan at the single scan rate.

5. For example, Brigham and Women's Hospital is participating in a multicenter clinical study to compare the diagnostic accuracy, cost-effectiveness, and prognosis of PET, and SPECT in coronary angiography. This medical center and other participants in a NIH funded study are appropriately reporting to the CMS at zero or near zero dollars because the expenses are being covered under a multi-year grant.

6. Nuclear cardiologists report that the majority of cardiac PET scans being performed are multiple studies, not single ones.

7. If enacted, the proposed cut is extreme and will unquestionably change how, where and if Medicare patients get the imaging services they need. The CMS cannot simply cut cardiac PET scan reimbursement radically without affecting patients. The cut is based upon a statistically insignificant data. A survey of reporting hospitals has shown that the persons responsible for data input confused single studies for multiple studies and, in fact, did not know how to distinguish between a single study and a multiple study.

8. CMS examined only 296 claims for single scans and 1,150 claims for multiple images. In fact, based upon a population of about sixty radionuclide generators, about 60,000 cardiac PET scans were performed in 2005 (4 scans per day X 60 sites X 250 days). Therefore, even when those scans paid for by private insurers are removed, the number of claims analyzed by CMS is simply statistically insignificant and the number of "so-called" single and multiple procedures used by CMS is unreliable and does not reflect the actual multiple studies that were performed.

9. If this proposed reimbursement elimination for multiple scans and resulting reduction is allowed to stand, it will result in the underutilization of PET cameras, which could be used to detect cardiovascular disease. An example is "hibernating" heart muscle, which results in equivocal results if a SPECT scan is utilized. The potential impact would be a disservice to Americans and increased treatment costs of invasive therapy (i.e. coronary artery bypass graft), paid for by CMS.

10. Unlike MRI, Cardiac PET is not a high volume procedure and is not widely used by Medicare patients.

11. Therefore, proposed new and the assignment of a single APC 0307 and HCPCS Code 78492, and a single reimbursement rate and the methodology utilized is simply flawed. The result will be that the proposed rate will be inadequate to ensure appropriate access for Medicare beneficiaries.

12. The decrease proposed simply does reflect the actual costs that are associated with providing patient care and the impact of this would be catastrophic for cardiac patients and their families, nuclear cardiologists and technicians, hospitals, the small businesses that provide mobile cardiac PET and pharmaceutical and medical device companies. The potential result upon the

CMS and the taxpayer would be a greatly increased financial burden and the substitution of more costlier and invasive medical procedures such as cardiac catheterizations.

13. Myocardial PET is an unusual case, specifically a low volume procedure. It is requested that special consideration be given in accordance with CMS reimbursement policy.

14. Fluctuation may have resulted in CMS utilizing erroneous or skewed cost data.

15. The median cost of this drug was not taken into account by CMS.

16. CMS does not base the payment rate on accurate claims data as required by statute. In accordance with the Regulatory Flexibility Act (RFA) as relates to underpayment the verifiable information presented herein reflects the actual, widely available, market-based pricing of mobile cardiac PET or the short-term rental or lease of a Rubidium-82 generator and infusion cart.

17. There has been massive underreporting of consumption and data corruption in the CMS-1506-P, CMS-4125-P HOPPS CY 2007 Payment Rates Proposed Rule.

18. The RFA requires Federal agencies to consider alternatives to their rules to ease the burden on small businesses.

19. Protections granted under the Administrative Procedures Act are being violated.

20. Bio-Nucleonics seeks redress in accordance with the Federal Advisory Committee Act.

21. Bio-Nucleonics respectfully requests that the CMS abide by own proposal on Pages 144 and 145 and to exempt Myocardial PET, also granting an exception to the 2 times rule limit on the variation of costs as Myocardial PET is an unusual case consisting of a low-volume item in terms of the number of procedures performed consisting of 2,979 claims as shown in the CMS-1506 P Document, Page 195, and the number of doses of the radionuclide (A9555) consisting of 3,837 units utilized in 2005 X$239.83, as shown in the CMS-1506 P Document, Page 283.

22. Decreasing reimbursement does not follow the spirit of CMS's own policy, or the recommendation of the APC Panel. The CMS specifically stated the following in the Federal Register, "In cases where costs show significant fluctuation, we believe it is appropriate to mitigate the potential for underpayment". It is requested that this objective be implemented for multiple study myocardial PET reimbursement.

23. The Regulatory Flexibility Act requires agencies to consider alternatives to their rules to ease the burden on small businesses. Our sales price is determined in great part by what the U.S. Department of Energy and the Federal laboratories charge for radioisotope feedstocks. The cost of a radionuclide and processing are much higher than conventional drugs and the profit margin is much less. If we discontinue production of any radiopharmaceutical (the likely result of decreased reimbursement) oncological and cardiac care costs will be driven up even higher, the quality of healthcare will be decreased and there is no assurance that we will be able to economically produce other radiopharmaceuticals; products that could save CMS many millions of dollars each year. This will further exacerbate a difficult state of affairs for us as an already disadvantaged small business and manufacturer of proven cost-effective radiopharmaceuticals.

24. In accordance with the RFA as relates to underpayment the verifiable information presented herein reflects the actual, widely available, market-based pricing for the rental of a Rubidium-82 Generator and Infusion Cart, for the time needed to perform a PET Scan, for nuclear medicine technician time, for disposables (catheters and the disposable tubing and valves that need to be

replaced daily) and for interpretation of the scan by a nuclear cardiologist. CMS's payment rate simply does not reflect the inherent costs and at which a broadly based, national sample are routinely able to procure this radiopharmaceutical. Respectfully, we ask the CMS to comply with its stated objective of "We believe it is appropriate to mitigate the potential for underpayment" as stated in the August 12, 2003 Federal Register.

The Economics of Cardiac PET

1. Using PET scanning rather than other types of imaging as the first tool to diagnose heart-vessel blockages is more accurate, less invasive and saves dollars, a study by University at Buffalo researchers has shown.

2. The broad-based Moran Study using 2006 Medicare claims data contradicts the view that imaging payments under HOPPS accurately reflects actual costs of performing a procedure. In fact, what would be paid is below the cost of performing a multiple study cardiac PET procedure.

3. The cost-savings that PET offers in being able to divert normal patients from receiving coronary angiography studies are considerable. The average cost of a PET study is about $1,480 (including Medicare patient and co-pay rates and technical and professional fees), compared to $3,270 for a cardiac catheterization.

4. By extrapolating these costs of one study's 233-person population, sending these patients for cardiac catheterization would have cost a total of $762,000. But by using PET instead after nondiagnostic SPECT, the cost would only be $528,000, even if 25% of the abnormal patients also went on to receive coronary angiography.

5. 890 sites reported they utilize a mobile service to provide PET or PET/CT imaging capability, resulting in a total of 1,400 sites offering PET imaging services. The 890 sites using mobile PET report using the mobile service for an average of 1.2 days per week per site. Assuming that the mobile vans are scheduled with no downtime between sites, an estimated 210 mobile vans serve these 890 sites. In 2001, the estimated average annual volume of clinical PET procedures per site was 385. Fixed PET sites conducted an average of 860 procedures per site in 2001, while mobile PET sites logged an average of 190 per site, and sites with gamma cameras that have coincidence-detection upgrades (NM-CD) performed 195 procedures per site. Currently, providers can offer PET procedures using a fixed PET scanner, a PET scanner in a mobile van. An estimated only 4 to 5% of PET scans were cardiac exams.

6. CMS pays separately for drugs on the basis of "the average acquisition cost of the drug". In fact, the average acquisition cost of the radionuclide is considerably more than what is reimbursed, (A9555, $239.83 a unit) because unlike most other radiopharmaceuticals, it is generator derived. Generators must be replaced at a cost of $28,500 a month, so if the patient load decreases, the cost per procedure increases dramatically. Many hospitals where myocardial PET is practiced utilize a mobile PET generator for a half a day or a day at a fixed cost. Therefore a multiple study takes more PET scanner time, more nuclear medicine technician time, longer scan and set-up time, more rental time, more supplies, more time to interpret the scan, and certainly costs more than a single study.

7. The radionuclide generator used to deliver a short-lived dose of the radionuclide used for myocardial PET costs about $500 an hour to rent, usually from a small business, and there is usually a minimum rental time, which is 4 hours or a full day. In some locations a mobile PET camera is utilized which can cost around $70,000 a month to rent. Typically, at most facilities only one to four cardiac PET scans are performed. The proposed CY 2007 payment rate of $721.26 for a multiple procedure is woefully inadequate to cover even a portion of these costs. At the 2007 proposed reimbursement rate, it is estimated that a hospital would have to perform more than eight

myocardial PET scans a week to break even, not including compensation for the nuclear medicine technologist, nuclear cardiologist, nurse or physician's assistant and an administrator.

8. Another potential consequence of the proposed CMS' rule will be increasing numbers of hospitals may substitute expensive but more highly reimbursable cardiac catheterization procedures, costing American taxpayers and the CMS hundreds of millions of dollars more for the treatment of cardiovascular disease than is already being spent. It is not known how the reimbursement figure was arrived at, what the relevant weight was or how the reduction was derived, but it certainly does not reflect the real acquisition cost of this drug. Clearly, this situation is untenable and needs to be expeditiously readjusted. The decreased usage of cardiac PET stress tests to detect cardiovascular disease will likely result in CMS paying at least $200 million more each year for cardiac catheterizations, balloon angioplasties and stenting, coronary artery bypass surgery and hear transplantations than it did in 2005, (10,000 patients at a $20,000 savings per patient), resulting from additional costs for procedures, supplies, hospital visits, CT Scans and tertiary care.

About Cardiac PET

Cardiac PET (positron emission tomography) is the newest and most powerful modality for detection and treatment of cardiovascular disease. PET is the newest, most powerful and accurate noninvasive test available to reveal or rule out the presence of coronary disease facilitating the most effective course of treatment. It not only provides an accurate assessment of blood flow to the heart, it indicates whether the appropriate treatment lies in transplant or bypass surgery. The advantage of the technology is that unlike SPECT, Cardiac PET enables evaluation of both myocardial perfusion and viability, delivering rapid patient throughput and superb image quality. The combination of PET and a diagnostic radiopharmaceutical enables delivery of the benefits of advanced cardiac PET stress testing to patients. This provides cardiologists with a new tool more sensitive and specific to cardiac disease than other imaging modalities, reducing equivocal results, saving the CMS and private insurers costs associated with invasive cardiac catheterization procedures, costly bypass surgery and non-beneficial drugs, shortened examination times, patient comfort, enables diagnosis of obese patients, delivers less than one tenth the radiation exposure of any other modality, and does not require additional technical training for physicians.

PET can more accurately define a host of disease processes that conventional, anatomic-based imaging alone (CT, X-Ray or MRI), oftentimes before symptoms appear. It traces molecular and functional processes in the body. PET can compliment any oncology, neurology or cardiology service, providing a non-invasive analytical tool for coronary artery disease, cancer and neurological conditions. Only PET delivers diagnostic performance in a fraction of the time that it takes for a conventional stress test. A myocardial perfusion study can be performed in only 40 minutes or less, compared to 2 to 3 hours for SPECT. This translates into added patient comfort, convenience and high throughputs.

The broader availability of PET imaging enhances diagnostic capabilities of patients that have or are suspected of having cardiovascular disorders or at-risk situations, early enough to make a difference. The clinical value of cardiac PET to deliver superb image quality is proven and well accepted. Regional myocardial perfusion can be evaluated to determine the presence and severity of coronary artery disease and impaired blood flow, response to treatment can be monitored and significant prognostic value has been demonstrated for predicting cardiac events including death and myocardial infarction.

Cardiac PET metabolic imaging PET can differentiate viable from nonviable myocardium in patients with ischemia is helpful in patient selection of those benefiting from revascularization, and can also identify "hibernating" tissue that may recover function after a procedure. Mismatch between blood flow and radionuclide uptake can predict post revascularization improvement, symptomatic relief and survivals. The information obtained can help avoid unnecessary and costly invasive procedures.

PET can be used to pinpoint the appropriate form of intervention, reducing the potential for equivocal results that may lead to high-risk procedures such as cardiac catheterization, transplantation and bypass surgery. Unlike any other imaging modality, PET perfusion stress testing is more specific than SPECT, giving rise to few false negatives, and is more sensitive, resulting in fewer false positives. Unlike PET, SPECT studies are

oftentimes compromised due to poor image quality or attenuation artifacts. PET can be used with improved diagnostic confidence in patients after an inconclusive SPECT scan. With PET there is considerably lower radiation exposure to patients and medical staff than SPECT.

Myocardial perfusion PET is both useful and prognostically predictive in a heterogeneous patient population with challenging SPECT scans. Cardiac PET following nondiagnostic SPECT resolved all of the patients except five, and these findings influence the coronary arteriogram rates. The majority of the patients in the study had a normal PET and were associated with a low likelihood of short-term events, obviating unnecessary coronary angiography.

If the proposed procedural "bundling" allowed to pass, this will further exacerbate a difficult state of affairs for us and others as already disadvantaged small businesses and manufacturers of cost–effective radiopharmaceuticals as well as the small businesses that provide mobile PET services. Please keep in mind that the RFA requires Federal agencies to consider alternatives to their rules to ease the burden on small businesses.

A reimbursement reduction by CMS in 2007, for multiple study myocardial PET could be an unfortunate one for the many thousands of Medicare recipients with cardiovascular symptoms or disease. The fact is that the drastic decrease in the payment rate proposed by CMS will result in the underutilization of a cost effective, proven diagnostic that needs to be expeditiously adjusted in order to accurately reflect the actual cost of a multiple scanning procedure.

CMS would be "shooting itself in the foot" and being "penny-wise and pound foolish" by setting the reimbursement rate for a dose of Strontium-89 so low that many hospitals, which are bottom line driven, will gravitate to procedures or to products where they can make a substantial profit.

As a potential result of this flawed CMS reimbursement proposed policy for myocardial PET for 2007, more and more Americans with heart disease or those suspected may be misdiagnosed needlessly, and their care and well being will be affected. With the CMS setting the standard, insurance companies are likely to follow suit, thus inflating the number of patients not receiving treatment. This flawed policy will result in increased costlier cardiac catheterization procedures, a decrease in quality-of-life and a dramatic rise in the cost of health care.

Also, what could be attributable to reduced CMS reimbursement for myocardial PET is that the uninsured will probably not be receiving this form of treatment at public hospitals, and the policy could also carry over to Medicaid patients. Since the number of uninsured is increasing nationwide, Medicaid costs are expected to increase even more dramatically and will be even further impacted unfavorably by the underutilization of this important diagnostic.

Through the use of myocardial PET, the CMS could achieve a substantial savings in health care treatment costs, at the same time through high specificity and accuracy only available with PET, decreasing the need for more invasive interventional procedures and improve the quality-of-life of patients suffering from cardiovascular disease. Pharmacoeconomic data supports this assumption.

Cardiac PET stress tests are used to check the health of the coronary arteries for functionally significant obstructions (narrowing), which can reduce blood flow to heart muscle and lead to the heart muscle becoming "starved" of oxygen. This condition is called coronary artery disease. Symptoms can include chest pain and shortness of breath. With coronary artery disease there is an increase in the possibility of a myocardial infarction (heart attack). PET cardiac scans are more accurate than other cardiac stress tests such as Thallium-201 SPECT (Single Photon Emission Computed Tomography) in the detection of heart disease and provide enhanced quantification. Because of this increase in accuracy, invasive catheterizations can often be avoided in those patients who do not need it. Knowing about these obstructions can help the

physician decide the best course of further diagnostic tests and treatment, such as catheterization, when necessary.

Because the radionuclides used in cardiac PET are so short lived, the patient must undergo pharmacological stress, and the radioisotope must be injected at peak stress through an infusion system. Clinical data show that cardiac PET's almost instantaneous ability to image a patient provides very high accuracy in identification of ischemia. In addition, it reduces a stress and rest test to 45 minutes, compared with routine SPECT myocardial stress imaging, which takes place over three to four hours.

Cardiac PET has also proven beneficial for difficult-to-image patients. Because of the limitations of SPECT, obese patients generally cannot be imaged. Those patients who need to undergo pharmacological stress are those who are usually the sickest; those are the patients for whom cardiac PET provides a significant advantages.

In one study, PET was able to resolve 98% of the nondiagnostic SPECT studies, reclassifying patients as either normal or abnormal. PET scans were normal in 170 patients (73%), and only 58 patients (25%) were reclassified as abnormal. Only three patients in the normal group went on to have coronary angiography within 60 days of PET (none of whom turned out to have significant coronary disease). Of the 58 abnormal patients, 29 were referred to coronary angiography within 60 days of PET and 18 had revascularization. Of the 29 patients who received angiography, 20 had significant coronary disease.

Conaway calculated the cost-savings that PET offers in being able to divert normal patients from receiving coronary angiography studies. The average cost of a PET study is about $1,480 (including Medicare patient and co-pay rates and technical and professional fees), compared to $3,270 for a cardiac catheterization. By extrapolating these costs to the study's 233-person population, Conaway said that sending all the patients to cardiac cath would have cost a total of $762,000. But by using PET instead after nondiagnostic SPECT, the cost would only be $528,000, even if 25% of the abnormal patients also went on to receive coronary angiography.

Rubidium-82 myocardial perfusion PET is both useful and prognostically predictive in a heterogeneous patient population with challenging SPECT scans. PET following nondiagnostic SPECT is resolute and these findings influence the coronary arteriogram rates. The majority of these patients had a normal PET and were associated with a low likelihood of short-term events, obviating unnecessary coronary angiography.

Cardiac PET specificity is 95% or greater versus 45% for SPECT and sensitivity for PET is 95% versus 88% for SPECT meaning a much lower incidence of false negatives and false positives, that can result in unnecessary but costly invasive procedures being performed. With cardiac PET, there is the potential to reduce cardiac care costs by 20% to 50%.

In a patient with symptoms suggestive of coronary artery disease, a central clinical issue is to determine whether a coronary angiogram is necessary for further work-up. A variety of non-invasive imaging tests, including PET and SPECT scans, have been investigated as a means of identifying reversible perfusion defects, which may reflect coronary artery disease, and thus identify patients who may benefit from further work-up with an angiogram.

The ACC/AHA guidelines note that PET imaging "appears to have better overall accuracy for predicting recovery of regional function after revascularization in patients with left ventricular (LV) dysfunction than single photon techniques (i.e., SPECT scans)."

PET has been most thoroughly researched as a technique to assess myocardial viability to determine candidacy for a coronary revascularization procedure. For example, a patient with a severe stenosis identified by coronary angiography may not benefit from revascularization if the surrounding myocardium is

non-viable. A fixed perfusion defect, as imaged on SPECT scanning or stress thallium echocardiography, may suggest nonviable myocardium. However a PET scan may reveal metabolically active myocardium, suggesting areas of "hibernating" myocardium that would indeed benefit from revascularization. The most common PET technique for this application consists of a perfusion tracer and a metabolic marker of glucose utilization. A pattern of uptake in areas of hypoperfusion (referred to as blood flow mismatch) suggests viable, but hibernating myocardium. The ultimate clinical validation of this diagnostic test is the percentage of patients who experience improvement in left ventricular dysfunction after revascularization of hibernating myocardium, as identified by PET scanning.

I share in the CMS objective of reducing the cost of healthcare, and am aware that under CMS reimbursement, hospitals sometimes get less than the actual cost for some products, irrespective of the impact of cost of living adjustments. However, the profit margin to hospitals, radiopharmacies and especially to us for a Myocardial PET Procedure, (78492), not a high volume procedure, saves money for CMS and the taxpayer.

Respectfully, we also ask the CMS to comply with its objective as stated in Section 1833(t) (9) (A) of the Act requiring the Secretary to revise the relative payment weights taking into account new cost data and other relative information and factors, in the Federal Register, wherein the CMS states that "we believe it is appropriate to mitigate the potential for underpayment", and in an 8/15/03 press release, quoting former Former Administrator Scully, "We want to make certain that Medicare pays for the drugs and services it covers..."

To reiterate, as of August, 2006, reimbursement is $2484, so that if the proposed 2007 Medicare reimbursement reduction is enacted, patient, hospitals and clinics would lose money on procedure. If the HOPPS reimbursement rate stands, hospitals will receive much less than the actual cost of providing the service including all discounts and rebates, even after patient co-pay. Medicare reimbursement will further exacerbate a difficult state of affairs for us as a small business manufacturer of radiopharmaceuticals. Bio-Nucleonics' suggests a proposed solution for reimbursement readjustment; an equitable and fair reimbursement rate of $2,484, reestablishing the 2006 rate for this procedure.

The CMS needs to reevaluate the potential impact on patients and take patient access into account when developing regulations to implement the proposed reduction. CMS should conduct a detailed analysis of offsetting savings and efficiencies brought about by the substitution of imaging for more invasive and costly procedures that do not reduce cost or improve quality. Early diagnosis saves money and lives. This is especially where cardiac PETcomes into play.

This is to thank the CMS staff in advance for taking the time to investigate this matter, for the opportunity of presenting a suggested solution for this problem to CMS and hopefully, to resolve this situation. Should you have any questions, please contact me at your convenience at 305 576-0996 or by e-mail at

Sincerely,

Stanley Satz
President

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Carl Zeiss Surgical Incorporated

October 10, 2006

VIA FED EX

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: **OPPS: Brachytherapy (CMS-1506-P)**

To whom this may concern:

These comments are submitted by Carl Zeiss Surgical, Inc. (Zeiss), a global leader in medical diagnostic and therapeutic technologies. Zeiss remains committed to developing innovative radiation cancer therapies to be used in a wide range of contexts, including the Intrabeam® Intra-Operative Radiation Therapy system (Intrabeam), which is used in the treatment of early-stage breast cancer.

Zeiss appreciates this opportunity to submit comments regarding the payment under the hospital outpatient prospective payment system (OPPS) for Intrabeam Intra-Operative Therapy. Intrabeam treats breast cancer using a unique brachytherapy source that should be paid separately as a brachytherapy device. The current hospital outpatient reimbursement for the Intrabeam procedure does not account for the cost of the brachytherapy device, resulting in underpayment for the Intrabeam procedure. This underpayment is hindering the adoption of this important technology, which offers tremendous benefits for the treatment of breast cancer.

I. BACKGROUND ON BREAST CANCER TREATMENT OPTIONS

Treatment of breast cancer varies by case and depends upon a range of factors, but generally includes a lumpectomy or mastectomy as well as adjuvant therapy, such as radiation, to decrease the likelihood of recurrence. Radiation can be delivered by one of two methods: external beam radiation or brachytherapy.

External beam radiation involves the use of linear accelerators or cobalt machines to deliver high-energy radiation to the entire affected breast from outside of the body. External beam radiation typically begins about one month after a lumpectomy and consists of five treatments per week for five to six weeks. Brachytherapy, on the other

hand, is internal radiation treatment given by placing radioactive material directly into a tumor or close to the tumor site. Brachytherapy for breast cancer is done in one of three ways: (1) the permanent implantation of radioactive seeds near the cancer site, (2) using numerous plastic catheters with the temporary introduction of high dose radioactive sources into the catheters, or (3) with Intrabeam.

II. INTRABEAM PROCEDURE

Intrabeam delivers radiation directly to the tumor site by a probe that is inserted into the tumor cavity after lumpectomy. Intrabeam therapy targets the specific tumor site and thus minimizes radiation exposure to the whole breast as compared to traditional external beam radiation. Moreover, because the radiation can be delivered as part of a patient's initial surgery, the procedure enables patients to return to their normal routines more quickly and results in significant overall cost savings for beneficiaries.

Currently, the Intrabeam is used in the treatment of breast cancer as either boost replacement or as single-dose radiotherapy. As a boost replacement, Intrabeam radiation therapy is used to treat patients diagnosed with early stage invasive breast cancer (T1-T2, <3 cm tumor size) who are candidates for breast conserving surgery followed by a traditional course of external beam radiotherapy. Intrabeam enables a physician to perform the boost treatment (replacing the conventional four to seven days of treatments) as a single, intra-operative dose immediately after lumpectomy, while the patient is still under anesthesia in the operating room.

As part of the currently ongoing international TARGIT trial, Intrabeam therapy is used as single-dose radiation treatment for post/peri menopausal women who are diagnosed with early invasive breast cancer (T1, <=2 cm tumor size; age >=45) and who are suitable candidates for breast conserving surgery. In the TARGIT trial, the single intra-operative dose of Intrabeam radiation replaces the entire conventional course of 35 or more radiation treatments over six to seven weeks in postmenopausal women or women with a low risk of local recurrence.

As an intra-operative treatment, Intrabeam therapy requires the services of a breast surgeon and a radiation oncologist, as well as the general resources associated with surgical procedures performed in the outpatient setting. The Intrabeam procedure is performed as follows: Immediately following tumor resection in the operating room, the surgeon measures the tumor site and selects a spherical Intrabeam applicator that will fill the tumor cavity. The surgeon then places the appropriate resposable applicator onto the probe of the Intrabeam's miniature x-ray source and inserts the ensemble directly into the tumor cavity, using surgical closure techniques to ensure contact between the breast tissue and the x-ray source. The surgeon also shields the skin and muscle from the x-ray source. The radiation oncologist then determines the prescribed dose of radiation and enters the information into the Intrabeam's control console. The Intrabeam radiation source is activated and delivers a high dose of low level energy (50KeV) radiation directly to the tumor site. The radiation is delivered over a period of time determined by the size of the tumor cavity, usually ranging from 25 to 45 minutes. After the radiation

treatment is complete, the surgeon removes the applicator/radiation ensemble and closes the surgical wound, ending the procedure.

III. INTRABEAM RADIATION SOURCE IS A BRACHYTHERAPY SOURCE AND SHOULD BE PAID SEPARATELY AS A BRACHYTHERAPY SOURCE

The current hospital outpatient reimbursement for Intrabeam does not account for the cost of the Intrabeam brachytherapy radiation source, and therefore the OPPS payment does not adequately cover the resource costs for providing Intrabeam therapy. Historically, the costs of Intrabeam were adequately covered and Intrabeam was included in the same APC (0312) as more conventional brachytherapy procedures. But beginning in 2004, CMS began making separate payments for the brachytherapy seeds and sources used in connection with certain brachytherapy procedures assigned to APC 0312. Because separate payment for seeds and sources was created and these resources were no longer accounted for in APC 0312, the payment for this APC decreased from $2,758.08 in 2003 to $199.90 in 2004. Since 2004 the hospital outpatient payment for Intrabeam has not accounted for the radiation source, resulting in a continued inadequate payment.

The radiation from Intrabeam is delivered directly into a tumor cavity, and therefore, by definition, it is a form of brachytherapy. The Intrabeam radiation source is a point source that is similar to other brachytherapy sources such as seeds or pellets. Intrabeam emits radiation from a point source in the form of x-rays created by an electron beam striking a thin gold foil target at the probe tip. Essentially, this tiny probe tip functions like traditional brachytherapy sources. In fact, after the electrons strike the gold, the gold atoms are temporarily elevated to an excited state that allows them to emit radiation. In this sense the Intrabeam radiation source is a true brachytherapy source. Furthermore, the characterization of the Intrabeam radiation source as a brachytherapy source is supported by Dinsmore et al.'s assessment of the Intrabeam radiation source: "this source produces a radiation field similar to that of a localized, low-energy brachytherapy source."[1]

The statutory provision that provides separate payment for devices of brachytherapy includes brachytherapy devices other than seeds. Section 1833(t)(12)(H) of the Act states that "with respect to devices of brachytherapy consisting of seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such services separately from other services . . ." (emphasis added). Such a brachytherapy radioactive source would include the Intrabeam radiation source. CMS has the flexibility to include the Intrabeam brachytherapy source within the definition of "brachytherapy source" because the activated gold in the Intrabeam source is a radioactive source as described in the above quoted statutory language. The statutory language does not command CMS to limit brachytherapy sources to only radioactive isotopes. If so, Congress would not have used the more general language "or radioactive

[1] M. Dinsmore, K.J. Harte, A.P. Sliski, D.O. Smith, P.M. Nomikos, M.J. Dalterio, A.J. Boom, W.F. Leonard, P.E. Oettinger, J.C. Yanch, A new miniature x-ray source for interstitial radiosurgery: Device Description. *Med. Phys.* 23, 45-52 (1996).

source." Therefore, the Intrabeam radioactive source is properly a radioactive source within the meaning of SSA § 1833(t)(12)(H).

We request that CMS designate the radiation source used in the Intrabeam procedure as a brachytherapy device and provide a separate payment for the source. This designation will result in payment for Intrabeam in the OPPS that more adequately reflects the cost of this procedure to hospitals and thus will provide for its greater availability to beneficiaries.

The failure to recognize the Intrabeam radiation source as a brachytherapy device with a separate payment would continue to jeopardize beneficiary access to a potentially revolutionary technology. Hospitals cannot reasonably be expected to offer a procedure for which they stand to lose thousands of dollars each time it is performed. Thus, maintaining the status quo for Intrabeam OPPS payment will likely result in the denial of access to Intrabeam for thousands of women diagnosed with breast cancer in the coming year.

We appreciate CMS's consideration of this important matter. If you have any questions or would like additional information, please contact me at 419-341-3199.

Sincerely,

Jeff Rospert (fax)

Jeff Rospert
Vice President of Sales
Carl Zeiss Surgical, Inc.

AKRON GENERAL MEDICAL CENTER®

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330-344-6000
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Alan J. Bleyer
President

October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

To Whom It May Concern:

Re: PPS-CMS-1506-P; CY 2007 Proposed Daily Rate for APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient psychiatric services

Akron General Medical Center is a not-for profit hospital that provides psychiatric services that encompasses a full continuum of services that include Partial Hospitalization and Outpatient services.

We are a long-standing provider of Partial Hospitalization services (since 1993). The initial shock of CMS-1506-P and another 15% rate reduction for CY2007 was an overwhelming blow. The very existence of this service will be threatened for the future if our facility must absorb this extreme revenue reduction again. It is very difficult to convince providers to continue programs year after year on a break-even basis at best.

A $37.64/day reduction in the daily rate will be impossible to absorb. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited in the services they can provide.

We are a member of the Association of Ambulatory Behavioral Healthcare, (AABH). Our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1506-P pp. 99-105 describes the CMS methodology of rate calculations for PHP each year since 2000. A close review indicates that CMS arbitrarily applies its' own bias assumptions and methodology on a different basis every year from CY2003 through CY2006. Only the methodology from CY2006 and CY2007 are the same and there is no calculation of a methodology. It is nothing more than an arbitrary decision by CMS.

2. We quote CMS on p. 105 to say "To calculate the CY2007 APC PHP per diem cost, we reduced $245.65 (the CY2005 combined hospital-based and CMHC median per diem cost of $289 reduced by 15 percent) by 15 percent, which resulted in a combined median per diem cost of $208.80."

3. CMS-1506-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00 in the last paragraph of p. 105. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas over the past two years. A daily per diem of $208.27 cannot be justified with these expenses.

4. CMS identified the Median cost of group therapy at $66.40. Our program offers 4 group services per day at a minimum. This summarizes to a median cost of $265.60. A per diem of $208.27 cannot be justified with these expenses.

5. Many of our patients are Medi-Medi's. Medicaid cuts are strongly threatened here in your state. If the 20% copay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to $166.62 ($208.27 x .80). A daily per diem of $208.27 cannot be justified with this situation.

6. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally tow years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

That being said:

7. Patients already have too few options for psychiatric care. Outpatient care is their best option. Outpatient services are a much less expensive alternative to hospital inpatient care or emergency departments. Rather than spending Medicare dollars on Outpatient services, Medicare will, most assuredly, spend more dollars on patients who use inpatient hospital units or emergency centers because -

8. Patients who need psychiatric care will go where-ever they have to go to get care. Why would CMS **not** support the less costly outpatient option? It is a fiscally responsible decision.

Based on the above issues, Akron General Medical Center asks that CMS:

- **Not implement** the PPS-CMS-1506-P; CY 2007 Proposed Daily Rate for APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient psychiatric services, until CMS examines the data and researches the numerous problems identified.

- **Consider a consistent methodology** that can stabilize the PHP per diem rate and avoid the drastic year-to-year fluctuations that threaten the very existence of the program services for this targeted, severely mentally ill population.

- **Allow energy, time and resources** to develop a reasonable payment methodology by working with provider and community organizations who would welcome the opportunity to work with CMS to develop a payment rate that is fair, consistent and predictable.

Thank you for your consideration of our comments. We look forward to your response. We are hopeful that we will be able to continue to treat the mentally ill and elderly in the most economically responsible way and at the lowest level of care possible.

Sincerely,

Christopher McGowan, MPS, ATR
Director
Psychiatric Services / Partial Hospitalization
Akron General Medical Center

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DUKE UNIVERSITY MEDICAL CENTER
Department of Radiation Oncology

October 5, 2006

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**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

Our hospital appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule. We appreciate the opportunity to provide comments to CMS regarding the proposed changes in payment for hyperthermia procedures (CPT 77600-77620) under the hospital outpatient prospective payment system for calendar year 2007.

Our hospital has been offering hyperthermia therapy for patients over the past **20** years. We are located in **Durham, NC** and provide cancer treatment to patients from a wide geographic area. Our hospital strives to offer the best clinical options to treat each patient's unique situation. When treatment is required for cancer, especially recurrent cancer, the option of offering hyperthermia therapy to patients sets our hospital apart from other facilities. The changes proposed by CMS for hyperthermia may not permit us to continue providing this cancer treatment option to patients.

Claims Data
Hyperthermia treatments (CPT 77600-77620) have an unstable history of median cost due to low procedure volume. As indicated in the table below, the median costs for 77605 increased significantly from 2003 to 2004, yet dropped each year from 2005 and 2006. In addition, CMS reports no single claims (and hence no median cost values) for 77605 in 2007. As the second highest hyperthermia procedure performed, and one of the most costly procedures, this raises questions regarding the accuracy of the CMS claims data used to set payment rates for these procedures.

Medians from Year to Year										
CPT	2003		2004		2005		2006		2007	
	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost
77600	255	$229.37	227	$190.53	395	$200.17	264	$224.34	163	$164.06
77605	175	$392.39	114	$624.09	118	$540.00	131	$460.49	NA	NA
77610	14	$186.79	5	$211.89	1	$231.07	7	$328.06	4	$308.95

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77615	4	$273.81	5	$490.67	34	$233.96	5	$365.80	25	$488.55
77620	0	0	0	0	0	0	1	$137.18	0	0

The percentage change in medians from year to year is significant due to low volume and the small number of facilities reporting procedures. For example, the percent change for this set of codes over the reporting period of 2003-2007 was substantial and seemingly unrelated. 77600 showed modest increase in 2004-2006, but dropped precipitously in the proposed 2006-2007 (-27%) while the medians for 77615 decreased substantially in 2004-2005 but increased the next two years.

Percent Change in Medians				
CPT	2003-2004	2004-2005	2005-2006	2006-2007
77600	-17%	5%	12%	-27%
77605	59%	-13%	-15%	-100%
77610	13%	9%	42%	-6%
77615	79%	-52%	56%	34%
TOTAL		-6%	33%	-32%

The payment rates for APC 314 have increased steadily from 2003-2006 (see table below) however, the proposed payment rate for 2007 is significantly lower than 2006 and is substantially lower than the actual costs to perform hyperthermia procedures at our hospital. .

APC 314 Payment Rates				
2003	2004	2005	2006	Proposed 2007
$199.54	$217.80	$251.20	$332.31	$225.17

Data reported to CMS to establish the median costs for 77600-77620 originates from very few hospitals, most likely contributing to the unstable medians. The table below lists the number of hospitals reporting 77600-77620 for 2004 vs 2005.

Number of Hospitals Billing Hyperthermia Codes					
Year	77600	77605	77610	77615	77620
2004	16	8	5	5	1
2005	16	0	0	8	0

It appears that a maximum of 16 hospitals across the US reported hyperthermia codes (77600-77620) under APC 314. This is an extremely low number of institutions to provide reliable data on median costs for CPT 77600-77620.

Hospital Cost to Charge Ratio (CCR)

There appear to be significant variances in hospitals cost to charge ratio (CCR) within the hospitals reporting costs for Hyperthermia. Hospital CCRs for hospitals reporting Hyperthermia procedures range from 14% to 50%. The top five hospitals reporting Hyperthermia procedures in the CMS database have very different CCRs as indicated below.

2005 Imputed Hospital CCR			
Hospital	Charge per line	Cost per line	Imputed CCR
Hospital 1	$1,005	$136	14%

Hospital 2	$1,800	$525	29%
Hospital 3	$1,337	$183	14%
Hospital 4	$3,747	$878	23%
Hospital 5	$1,588	$641	40%

In July 2006 the GAO published a report titled "*CMS's Proposed Approach to Set Hospital Inpatient Payments Appears Promising*". This report discussed the use of overall hospital CCR use on the hospital outpatient rate setting process. The GAO report stated that *"hospitals vary in how they allocate revenue center charges to cost centers on their Medicare cost reports. When estimating costs for purposes of weighting APCs, however, CMS uses its own system of mapping the hospitals' revenue center charges to cost center CCRs in order to convert the charges to an estimate of cost. This can be problematic since hospitals may allocate their revenue centers to cost centers in a different manner from CMS."*

The GAO sited that "some hospitals allocate charges from the same revenue center to separate cost centers; others allocate charges from several revenue centers to a single cost center. CMS's use of a single method in mapping charges to costs and then applying that methodology across all hospitals for purposes of cost estimation does not recognize the differences in hospital allocation decisions when estimating costs. As a result, some service costs are "*systematically overestimated and some are underestimated.*" Further, the report states that *"The differences between aggregate estimates using the OPPS method and hospitals reported costs indicate that a single approach to mapping cost center CCRs to revenue center charges is problematic because CCRs are applied to certain charges that do not capture the cost-to-charge relationship for those charges."*

Our hospital believes that the combination of low utilization, hospitals cost allocation methodology and CMS's application of hospital specific CCRs leads to the significant changes in median costs of APC 314 over the past five years. Clearly this has resulted in a payment structure which does not support the use of the technology to help cancer patients who would benefit from the use of this technology.

Procedure Cost

An analysis of hospital costs performed during 2006 reveal that the actual cost of hyperthermia significantly exceeds the APC value proposed by CMS. Members of the Society of Thermal Medicine (STM) were surveyed for costs related to three levels of hyperthermia treatment. The average costs for the facilities responding to the survey, regarding time and cost were as indicated on the table below.

The costs were calculated based upon the following components:

- Treatment suite (hours);
- Required hardware and software cost/per treatment;
- Required physics and engineering support (hours);
- Technical support time (hours);
- Nursing staff required (patient preparation and monitoring);
- Medical supplies and disposables; and
- Requirement administrative support.

CPT	Description	Estimated Hospital Cost

77600	Hyperthermia, externally generated; superficial (ie. heating to a depth of 4cm or less)	$885.00
77605	Hyperthermia, externally generated; deep (ie. heating to a depths greater than 4cm)	$1,205.00
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators	$1,005.00
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators	$1,005.00
77620	Hyperthermia generated by intercavitary probe(s)	$1,005.00

Recommendations

Our hospital requests that CMS review the following key issues related to hypothermia therapy including; unstable medians, low utilization, lack of cost data for 77605, application of overall hospital CCR and actual hospital cost survey results. We request that CMS consider an alternative payment option for APC 314 for calendar year 2007 as outlined below.

OPTION 1

CMS use external hospital survey data provided above to establish a more appropriate median payment rate of $1,005 for APC 314.

OPTION 2

CMS consider applying an average cost for 77605 from 2004-2006 to the 2007 medians in APC 314 to establish a more appropriate payment rate for 2007 of $398.75. The average cost for 77605 for 2007 is the average of the median cost from 2004-2006.

HCPCS	Description	Median Cost			
		2004	2005	2006	Proposed 2007
77600	Hyperthermia	190.53	200.17	224.34	164.06
77605	Hyperthermia	624.09	540.00	460.49	**541.53**
77610	Hyperthermia	211.89	231.07	328.06	308.95
77615	Hyperthermia	490.67	233.96	365.80	488.55
				Computed Median	**$398.75**

OPTION 3

Hold the payment rate for APC 314 at the current 2006 payment of $332.31 while more accurate claims data can be evaluated for 2008.

Hyperthermia therapy offers a cancer treatment option to patients with recurrence faced with no other option for treatment. Appropriate payment for hyperthermia treatment is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

Thank you for your consideration of these important issues.

Sincerely,

Ellen L. Jones

Ellen L. Jones, M.D., Ph.D.
Associate Professor
Dept. of Radiation Oncology
Duke University Medical Center

ONCURA

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October 6, 2006

Via Federal Express

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
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 Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule**

Dear Administrator McClellan:

These comments are submitted on behalf of ONCURA,[1] a leading manufacturer of state-of-the-art medical products and systems that employ novel hypothermic surgical technologies to destroy cancerous tissues. Our products include cryoablation systems, which offer highly effective and minimally invasive therapies for prostate and kidney cancer. Additionally, we provide brachytherapy source products for the treatment of cancer.

We appreciate the opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services ("CMS") on August 23, 2006, in the *Federal Register* which proposes changes to the Hospital Outpatient Prospective Payment System (the "OPPS") for 2007.

We wish to comment on the following two specific APC assignments related to cryotherapy:

APC 0674 (CPT 55873) - *Cryoablation of the Prostate*

APC 0163 (HCPCS 0135T) - *Percutaneous Renal Cryoablation*

We set forth more detailed comments below.

* * *

APC 0674 (CPT 55873) -- CRYOABLATION OF THE PROSTATE

In summary, we believe **the proposed payment of $6637.03 for cryosurgical ablation of the prostate (CPT 55873, APC 674) does not accurately reflect the costs incurred by hospitals in**

[1] ONCURA was created in July 2003 by the merger of Amersham's brachytherapy business with Galil Medical Ltd's urology business.

administering this procedure. Because this inadequate payment results from claims data that do not accurately reflect or capture the full costs related to this procedure on the UB-92 claims, we urge the agency to revise the proposed payment using actual hospital acquisition cost data provided by manufacturers, as many of the claims used to set the payment rate are grossly understated in terms of the actual amount that hospitals pay for the cryoablation devices. We believe this revision is necessary in order to ensure continued access to this groundbreaking technology. Oncura is prepared to submit the actual invoices that CMS could use to match specifically to the providers' claims that were used for rate setting purposes.

I. BACKGROUND ON CRYOSURGERY OF THE PROSTATE

A. Importance of Cryosurgery in Treatment of Prostate Cancer

In the United States, prostate cancer is the most common cancer in men and the second most common cause of male cancer deaths, and it is disproportionately prevalent within the Medicare population. Cryotherapy systems are designed to treat prostate cancer by destroying cancerous tissue through the application of extreme cold temperatures delivered by cryoablation probes.[2] The number of probes used for a given procedure can range from 5 to as many as 20, depending on the particular case and the type of cryotherapy system used.

Recurrent and residual disease after initial therapy for prostate cancer is fairly common, with rates ranging from 25 percent to 85 percent depending on the initial therapy and disease type. Local recurrence of prostate cancer presents a difficult challenge, because there are limited therapeutic options: additional radiation rarely is an option due to the limits on cumulative doses, hormonal therapy is not curative, and salvage prostatectomy has limited efficacy.

Cryosurgery is highly effective in treating prostate cancer, and it is essentially one of the only treatment methods currently available for radiation-failure prostate cancer cases.[3] Moreover, patients are demanding initial treatment options for prostate cancer that are minimally invasive.

B. Effect of Innovations on Clinical Outcomes and Cost of Procedure

One of the most important technological advancements in this mode of treatment has been the development of smaller and more advanced probes, which enable the application of cryoablation with far more precision. Specifically, these increasingly sophisticated probes allow the physician to target cancerous tissue without causing damage to surrounding healthy tissue. This approach substantially reduces the likelihood of serious complications often consequent to prostate cancer therapy -- such as

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[2] These probes are inserted through the perineum into the prostate. Argon gas circulating through the probes generates very low temperatures causing the formation of ice, which destroys targeted cancer cells.

[3] The importance of cryosurgery in treating prostate cancer is evidenced by two separate national Medicare coverage decisions issued by CMS in 1999 and 2001. Cryosurgery is safe, effective, and medically necessary and appropriate in certain patient populations -- specifically, those patients with stages T1-T3 prostate cancer. It has demonstrated effectiveness through an absolute analysis and a comparative analysis. Its results are comparable to brachytherapy (involving implantation of a radioactive seed) and external beam radiation.

incontinence -- which avoids needless patient pain and suffering and reduces Medicare costs. In addition to decreasing complications, technological developments in cryotherapy systems have enabled this therapy to often be administered in hospital outpatient facilities, which produces savings for Medicare and allows patients to go home in less than 24 hours.

Prior to the expiration of the device pass-through payment for cryoablation probes (C2618) at the end of 2003, OPPS payment policy generally had responded appropriately to the migration of cryotherapy to the outpatient setting by establishing new-technology pass-through payments under the OPPS for cryoablation probes (C2618) and by setting adequate OPPS APC payment levels for the procedure. Unlike most devices, cryoablation probes continued on the pass-though payment list through 2003. The growth of the procedure since the expiration of the pass-through payment has not been at the expected rate. We hope that the information we provide in these formal comments will enable CMS to continue ensuring the availability of this therapy by considering eliminating the claims that are clearly underestimating the cost of the devices for this procedure.

II. CURRENT 2006 OPPS PAYMENT FOR APC 674 AND PROPOSED 2007 OPPS PAYMENT FOR APC 674 IS BASED ON INACCURATE CLAIMS DATA

We are convinced that the current 2006 OPPS payment of $6628.02 for APC 674 is based on flawed claims data that understates the actual costs incurred by hospitals in administering this procedure. Oncura contracted with The Moran Company [4] to analyze the 2005 claims data set provided by CMS. Clearly, the median cost reflected in the claims data continues to under-reflect the actual cost of the procedure. Implementing the proposed 2007 payment rate of $6637.03 based on the median of $6557.73, listed on Table 18 of the proposed rule, will result in an inadequate payment rate to the hospitals.

A. Inaccurate Charge Reporting for Cryosurgery of the Prostate

Manufacturers are not permitted to suggest how hospitals should establish their charges and so the educational efforts with the hospitals have been very challenging. Under such circumstances, it is not surprising that the claims data compiled from reported hospital charges do not provide an accurate picture of the total cost of performing cryosurgery of the prostate.

The 2005 claims data set analysis provided to us by The Moran Company clearly shows that many hospitals have failed to submit claims to CMS for prostate cryosurgery that properly reflect the costs of supplies -- especially the cost of the cryoablation probes. The majority of the claims used to set the payment rates grossly understate the actual costs that the provider pays for the devices. Oncura's reimbursement group has had a significant number of discussions with our customers since the device dependant procedure edit was put in place in April of 2005. While we knew that a significant problem existed, it has been an astounding experience to see the number of hospitals that had claims returned because hospitals were not accounting for the cryoablation devices on the claims. When attempting to educate many of hospitals, the standard response that we have gotten is that they just want to get the C-Code on the claim so it passes through the edits and they get paid for the procedure. This respondent is

[4] The Moran Company is an independent health care research and consulting firm.

typically not someone who is in the finance or administration area of the hospital who would understand the impact of the claims data on rate setting and/or someone who is concerned about the charges on the claim accurately reflecting the cost of the device. Rather, the person coding the claims is usually a patient accounting claims clerk who is reviewing the denied claims and is responsible for resubmitting the claim. A standard response that we hear from our hospital clients is: "the payment for the device is bundled into the procedure so our main concern is to get the C-Code on the claim and get the claim processed and paid." They also tell us that they do not believe that they are able to establish charges based on the CCR methodology and that the standard sliding scale approach that they have used to set charges historically has worked well.

As a result, because we know how much hospitals pay for the cryoablation devices, we believe the current and proposed payment level cause hospitals to incur substantial losses when administering this therapy. We continue to have hospitals stopping this program based on the inadequate payments they receive. In the past, we have noted through analysis provided to the agency that hospitals frequently submit claims for this procedure that do not contain charges for probes in numbers sufficient to enable the procedure to be performed. While the claim edits put in place for the procedure have prohibited the claims from being processed without the device code, the challenge of appropriate charges being submitted on the claims remains a significant issue. Under such circumstances, it is not surprising that the claims data compiled from reported hospital charges do not provide an accurate picture of the total cost of performing cryosurgery of the prostate.

We also believe that this apparent self-defeating behavior of hospitals, i.e., not claiming the full charges for each case resulting in an underpaying APC, is due to a fundamental disconnect between the hospital personnel doing the claims coding and the hospital personnel who actually understand the Medicare HOPPS. We have tried to bridge this disconnect through educational efforts but are somewhat limited by the willingness of certain hospital personnel to get sufficiently motivated to correctly complete hospital claims and by the fraud and abuse laws and rules that cultivate an overly-cautious approach in manufacturer-hospital relations.

In addition, Anna Shields, former President of Shields Products & Services, has during the past 10 years consulted with and advised over 750 healthcare organizations nationwide.[5] According to Ms. Shields, there are several factors leading to healthcare facilities not capturing full charges on the claims. Therefore, claims data and cost reporting data to CMS is understated for services provided to patients. Ms. Shields indicated during our August 24, 2005, meeting last year with Herb Kuhn and CMS staff that of all the organizations that she has advised and consulted with nationwide, over 90% do not perform full-charge capture due to the following challenges:[6]

- Cash Flow Reimbursements
- Hospitals are judged externally on their financial viability from several benchmarks such as:
    - Overall Accounts Receivable (AR) days

[5] Ms. Shields has no affiliation with the cryosurgical manufacturers and is not a paid consultant for the cryosurgery industry.

[6] See attached report by Anna Shields.

  - Adjustments to Gross Charges (Contractual Adjustments)
  - Reserve for Bad Debt (Patient self-pay portion after insurance payment)
- Challenges in implementing full-charge capture (and true patient cost accounting) are multifaceted, but the biggest by far is the immediate out of pocket cost to the organization to implement – including by not limited to:
  - Redesign of materials management
  - Redesign of clinical documentation
  - Charge master (CDM) redesign
  - Abstracting/Coding and Case Management redesign
  - Billing, Claims and AR Tracking Systems redesign

Additionally, there are very few if any immediate positive incentives to hospitals in implementing full-charge capture. There are also significant fears, financial investment costs, painful reveals and potential negative external perceptions of implementing full-charge capture.[7] The same challenges and issues remain and continue to distort the payment rates.

B. Problem with Application of Cost-to-Charge Ratio to High-Cost Devices

As we have noted in the past, we believe CMS's methodology results in charge compression, particularly for the higher cost devices, and this phenomenon contributes to inadequate payment rates for prostate cryosurgery. This is further validated in the summary report provided by Anna Shields.[8] As stated above, our hospital clients generally do not use a single formula to establish device charges, but rather typically use a sliding scale, whereby a lower markup is applied to relatively high-cost devices, such as cryoablation probes. When CMS applies a cost-to-charge ratio, however, it fails to take into account this sliding-scale approach to establishing device charges. Thus, applying the cost-to-charge ratio to the charges for cryoablation probes used for prostate cryosurgery produces an overstated markup for the device, and results in cost finding that understates the actual cost of the device to hospitals. This methodology harms high cost device dependant procedures.

Applying the CCR when hospitals do not use the CCR factor to establish their markup on items is illogical. We are encouraged that CMS has contracted an outside group to study the charge compression phenomena for the IPPS and hope that valuable information can be gleaned from this study and applied to future payment methodologies for the OPPS which also results in payments that are grossly understated.

C. Inability to Report Charges for Supplies

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[7] See Id.

[8] See Id. Claims data provided by hospitals to CMS reflects inconsistent markup and charging methodologies, in order to maintain a "status quo" for gross charges to patients. Claims data is not truly reflective of full-charge capture, or accurate chart – to-charging methodology. Due to this, utilizing claims data and cost reporting data on which to base hospital reimbursement is understated in most cases, thus a reduction in reimbursement will significantly impact hospitals' ability to continue to offer this procedure to patients.

An additional problem with charge reporting for prostate cryosurgery is the inability of hospitals to report charges for a number of supplies without specific codes used in connection with the procedure. There are several supply items that are required to perform prostate cryoablation and are unlikely to be used or stocked by the hospital for any other procedure. These supplies -- such as urethral warming catheters, temperature sensor probes, and argon/helium gas (6,000 psi) -- are not insignificant costs to the hospitals. All are required in order to perform prostate cryosurgery safely and effectively. While the hospitals may have the ability to report such supplies under a supply revenue code, of the UB-92 claim forms that we have reviewed, we do not believe these supply costs are adequately reflected in the claims data. Again, the administrative burden to create and maintain supply charge master items that are not separately reimbursed or described by HCPCS codes results in many supply items being left off the UB-92 claim forms.

III. RECOMMENDATION FOR APC 674 – PROSTATE CRYOABLATION

We therefore suggest that CMS take the most conservative approach in limiting the claims data set to claims with the appropriate device code (C2618) and apply a minimum charge threshold amount based on the external data provided by the manufacturers accompanied by the provider table analysis from The Moran Company. In doing so, we believe that an adequate number of claims could be used for rate setting purposes.[9]

Basing payments on this defined claims data set would enable the agency to be confident that the payments for APC 674 reasonably relate more directly to the costs incurred by hospitals in performing cryoablation of the prostate. This relationship between payment and cost is critical to prevent Medicare OPPS payment policy from hindering the adoption of this emerging and groundbreaking therapy.

Percutaneous Renal Cryoablation HCPCS 0135T (APC 0163)

I. BACKGROUND ON RENAL CRYOSURGERY

In recent years, renal cryosurgery has become an increasingly important therapeutic option for Medicare beneficiaries suffering from renal cell carcinoma (RCC). With developments in the field of imaging, renal tumors are being detected in an early and asymptomatic stage. Cryotherapy systems are designed to treat renal cell cancer by destroying cancerous tissue through the application of extreme cold temperatures delivered by cryoablation probes.[10] At the 23rd World Urological Congress Meeting on Endourology, more than 23 papers were presented on renal cryotherapy. The May 2005 American Urological Association (AUA) annual meeting included an all day course on minimally invasive treatments

[9] As mentioned above, the $6000 charge threshold assumes a very conservative total device cost of $4000 multiplied by a conservative mark up factor of 1.5, which would assume a CCR of 0.665. If we were to use the average CCR established by CMS of 0.420, the assumed markup factor would have increased to 2.38 and the threshold charge to $9500, based on the minimum $4000 cost of the device. Using the more conservative limiting charge of $6000 and the higher CCR/minimal markup factor of 1.5 allows CMS to use a representative number of claims and results in a median of $7635.

[10] These probes are inserted through the skin percutaneously and into the kidney. Argon gas circulating through the probes generates very low temperatures causing the formation of ice, which destroys targeted cancer cells and tumor.

for renal cell carcinoma and the appropriateness of renal cryotherapy as a treatment for RCC. At the most recent AUA meeting in 2006, five year outcome data was presented which demonstrated that renal cryoablation results were comparable to partial nephrectomy results in small renal tumors. Additionally, the American Urological Association Health patient website states the following regarding cryotherapy of renal tumors:

> *Since renal tumor ablation is a relatively new procedure, long-term results are unknown. However, ablation may be less invasive than nephrectomy and may be useful in patients who cannot tolerate a more extensive surgery. Tumor ablation may also permit a better chance of preserving kidney function in situations when multiple tumors are present.*[11]

Many of the renal cryotherapy procedures performed to date have been performed on Medicare beneficiaries who are not candidates for traditional surgery, and many of these patients have only one functioning kidney. Percutaneous renal cryotherapy is often the most appropriate and only treatment option for these patients. Percutaneous ablation of renal tumors via cryotherapy enables the targeted destruction of select, small renal tumors in lieu of open or laparoscopic partial nephrectomy, and thus provides important benefits for patients by minimizing the invasiveness of the surgical intervention and the incidental damage to surrounding tissue. In some cases, this procedure has allowed physicians to treat the renal cell carcinoma and save enough of a single remaining kidney to avoid dialysis, resulting in significant savings to the Medicare program.

II. DISCUSSION

Oncura filed a New Technology Application for Percutaneous Renal Cryoablation in February of 2006. The HCPCS (0135T) for this procedure was new for 2006. We filed the application after learning that CMS had randomly assigned the procedure to a clinical APC for 2006 even though the procedure is new and there is no claims data by which to set the payment rates. Oncura, along with a renowned expert in this field, Dr. Bruce Shingleton, requested to meet with the CMS outpatient group to discuss our application but were told by CMS that a meeting was not necessary. Oncura received a letter on May 26, 2006, from Mr. James Hart which stated that percutaneous renal cryotherapy did not qualify for a "New Technology APC" for the following reason:

> *"The service is described by existing HCPCS codes or combination of HCPCS codes."*[12]

This reason did not make sense to us. Renal cryotherapy was assigned a brand new Category III CPT code. The AMA assignment of the Category III code (for emerging technology) further validates that this procedure is a new emerging technology and therfore not described by exisiting codes. It may be that Mr. Hart's "exisitng codes" response (a common denial reason for New Technology APC applications that have not been assigned a new CPT code) was mistakenly plugged into the response letter to our new technology APC application. Mr. Hart also indicated that the public may comment on the APC assignment

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[11] The AUA's on-line patient information resource, UrologyHealth.org, was written and reviewed by urology experts in partnership with the American Urological Association Foundation. Website address: http://www.urologyhealth.org.

[12] See attached letter from James L. Hart to Lisa Hayden dated May 26, 2006.

in the proposed 2007 rule making period. We respectfully disagree with CMS's determination that Percutaneous Renal Cryotherapy does not meet the criteria of a New Technology APC. For the following reasons, we believe that Percutaneous Renal Cryotherapy does meet the New Technology APC criteria as set forth by CMS:

Criteria 1: The service is one that could not have been adequately represented in the claims data being used for the most current annual OPPS payment update.

Percutaneous renal cryotherapy was previously reported under a miscellaneous CPT code and rarely performed in 2004 on an outpatient hospital basis. It is impossible to identify the claims that are related to percutaneous renal cryotherapy based on an unlisted procedure code.

Criteria 2: The service does not qualify for an additional payment under the transitional pass-through provisions established under section 1833(t)(6) of the Social Security Act and in Subpart G, Transitional Pass-through Payments in the regulations at 42 CFR 419.

The cryoablation probes which are the devices utilized for this treatment are described by HCPCS C2618, probe, cryoablation. The pass-through payment for this device expired in 2003. The cryoablation needle probes used for the percutaneous renal cryotherapy procedure are of a different type and configuration than those used for the prostate cryoablation procedures.

Criteria 3: The service cannot reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs.

As noted above, Percutaneous Renal Cryotherapy is not clinically homogenous to any of the procedures in the established APC groups.

Criteria 4: The service falls within the scope of Medicare benefits under section 1832(a) of the Act.

Percutaneous Renal Cryotherapy is a surgical treatment performed in hospitals for the treatment of renal cancer.

Criteria 5: The service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Social Security Act.

Many of the renal cryotherapy procedures performed to date have been performed on Medicare beneficiaries who are not candidates for traditional surgery, and many of these patients have only one functioning kidney. Percutaneous renal cryotherapy is often the most appropriate and only treatment option for these patients. Percutaneous ablation of renal tumors via cryotherapy enables the targeted destruction of select, small renal tumors in lieu of open or laparoscopic partial nephrectomy, and thus provides important benefits for patients by minimizing the invasiveness of the surgical intervention and the incidental damage to surrounding tissue. In some cases, this procedure has allowed physicians to treat the renal cell carcinoma and save enough of a single remaining kidney to avoid dialysis, resulting in significant savings to the Medicare program.

In the proposed rule, CMS stated the following:

> *during the March 2006 APC Panel meeting, a presenter requested that we reassign CPT code 0135T (Ablation renal tumor(s), unilateral, percutaneous,cryotherapy) to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures). The presenter provided information about the costs of performing these procedures and compared the resource requirements for the procedures to those for CPT code 47382 (Ablation, one or more liver tumor(s), percutaneous, radiofrequency), which is currently assigned to APC 0423. The presenter proposed reassignment of CPT code 0135T to APC 0423 because that is where CPT code 47382 is assigned, and stated that the costs of the two procedures are very similar. The APC Panel recommended that we assign CPT code 0135T to APC 0423 for CY 2007. CPT code 0135T is new for CY 2006 and therefore, we have no claims data on which to base our APC assignment decision. The procedure currently has an interim assignment to APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures), with a CY 2006 payment amount of $1,999.35. We are proposing to accept the APC Panel's recommendation to reassign CPT code 0135T to APC 0423 for CY 2007. We believe that assignment of CPT code 0135T to APC 0423 is clinically appropriate, and that the CY 2007 median cost ofAPC 0423 of $2,410 is reasonably close to our expectations regarding the resource requirements for the renal cryoablation procedure.*

Oncura also attended the APC Panel meeting in March of 2006. We made a brief public comment and urged the panel not to make a recommendation until CMS had the opportunity to review the New Technology application. The resources required by renal cryotherapy are not similar to those for CPT 47382. Radiofrequency of the liver is qualitatively different and Percutaneous Renal Cryotherapy is considerably more resource intensive than the other procedures assigned to APC 0423. This APC significantly underpays for the percutaneous renal cryoablation procedure. Unlike percutaneous renal cryoablation, the liver radiofrequency procedure involves a single probe. Depending on the size of the tumor and the size of the cryoablation needle probe selected, the percutaneous renal cryoablation procedure can require up to 4 probes. Because the probes required to perform percutaneous renal cryotherapy are no longer paid separately under OPPS (separate pass-through payment for these devices expired on December 31, 2003), the probes need to be accounted for in the payment for the procedure. APC 0423 doesn't begin to cover the cost of the procedure. Percutaneous renal cryotherapy requires the use of Cryotherapy equipment, cryoablation probes, temperature sensor devices, surgical disposable supplies, and the presence of specially trained staff, above and beyond what is necessary to perform the other procedures assigned to APC 0423.

As stated in the proposed rule, CMS has no claims data by which to set the payment rate for this procedure. We recommend that because percutaneous cryoablation of a renal mass is a relatively new procedure that has only rarely been performed in the outpatient setting, CMS should assign HCPCS 0135T to a New-Technology APC until meaningful outpatient cost data can be obtained for the procedure.

As noted above, percutaneous renal cryosurgery is an emerging technology that has rarely been performed in the outpatient setting. Based on the absence of a specific CPT code prior to January 1, 2006, the outpatient hospital cases performed prior to this date were coded under the general unlisted CPT 53899 according to AMA guidance. It is therefore currently impossible to use claims data to determine the actual procedure costs because the unlisted code is used to describe many different procedures other than percutaneous renal cryotherapy. As a result, there is very little information concerning the total cost to outpatient facilities of performing this procedure. Absent any available claims for this procedure, CMS should not assign this procedure to an established APC, rather the agency should assign the procedure to a New-Technology APC based on the actual cost to perform the procedure. This will enable the agency to collect sufficient cost information on which to base an appropriate clinical APC assignment in the future that will provide adequate payment for this important technology.

III. RECOMMENDATION FOR RENAL CRYOABLATION

Due to the lack of claims data for this procedure, we urge CMS to assign the 2007 payment for HCPCS 0135T to a New Technology APC. We believe the application denial for a New Technology APC was made in error. The assignment of a New Technology APC would ensure that the payment for Percutaneous Renal Cryotherapy cover the costs incurred by hospitals in performing this procedure. Adequate payment for new technology in the OPPS is necessary to prevent hindering the adoption of this emerging and groundbreaking therapy.

Conclusion

ONCURA appreciates the opportunity to submit comments on the Proposed Rule, and we are eager to provide CMS with any information or clarification that would enable the agency to ensure Medicare beneficiaries continued access to cryosurgery of the prostate. We recognize that a system as complex as HOPPS will continue to encounter challenges for specific types of services, including cryotherapy. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me or you may also contact Lisa Hayden at (703) 948-7685.

Sincerely,

James McGlone

James McGlone
President/CEO Oncura

Oncura, Inc., 401 Plymouth Road, Suite 130, Plymouth Meeting, PA 19462
T 484 530 3900 F 484 530 3999
www.oncura.com

SHIELDS
PRODUCTS & SERVICES

CMS Forum – Cryosurgery 08/24/05 10:00a-11:00a

Background on Presenter:

Anna L. Shields, PMP - President of Shields Products & Services, has been an IT professional for 20 years. During the past 10 years, she has consulted with and advised over 750 healthcare organizations nationwide (including acute, surgical, pediatric, psychiatric, and long term care facilities; sizes ranging from 12 bed to 600+ bed facilities; single and multiple entity healthcare organizations; private, public, government, educational and physician owned hospitals and healthcare clinics). In addition, she has consulted internationally with regional healthcare Directors of IT in Canada, responsible for 250 hospitals in three (3) provinces.

Her expertise, mission to improve healthcare delivery, approach to healthcare business culture and operational redesign; combined with her status as an independent consultant (consults with healthcare organizations directly - no affiliations or engagements with vendors or accounting/consulting firms), candid communication skills (honest, open, full-disclosure, real-world) and prior proven success as a project manager makes her a sought after industry expert adviser to healthcare executives - spanning over 100 hospitals nationally.

Shields mission to improve healthcare delivery is focused on three primary objectives:

1. Provide tools/education regarding integrated medical information systems technology - so that clinicians can continue to deliver quality patient care and improved patient outcomes
2. Assure that healthcare organizations can make a "margin" so they can achieve their "mission" – viable and sustainable financials that will allow them to continue to provide patient care services
3. Assure that current clinical and financial practices are compliant with federal and state regulations and guidelines; as well as preparing the organization to deal with constantly changing regulations and guidelines in healthcare

Ms. Shields has no affiliation with the cryosurgical manufacturers and is not a paid consultant for industry.

SHIELDS
PRODUCTS & SERVICES
CMS Forum – Cryosurgery

08/24/05 10:00a-11:00a

INTRODUCTION: Anna L. Shields, PMP - President of Shields Products & Services

OUTLINE OF TOPICS FOR DISCUSSION: There are several factors leading to healthcare not capturing all charges (therefore – claims data and cost reporting data to CMS is understated) for services provided to patients including but not limited to:

1. Cash Flow (reimbursement)
2. Hospital Financials are judged externally on their financial viability from several benchmarks – primary among them are:
    - Overall Accounts Receivable (AR) days
    - Adjustments to Gross Charges (Contractual Adjustments)
    - Reserve for Bad Debt (Patient self-pay portion after insurance payment)
3. Challenges in implementing full-charge capture (and true patient cost accounting) are multifaceted, but the biggest by far is the immediate out of pocket cost to the organization to implement - including but not limited to:
    - Redesign of materials management
    - Redesign of clinical documentation
    - Charge Master (CDM) redesign
    - Abstracting/Coding and Case Management redesign
    - Billing, Claims, and AR Tracking Systems redesign

Of the organizations that Shields has advised/consulted nationally, over 90% do not perform full-charge capture due to the above challenges. There are very few if any immediate positive incentives in implementing full-charge capture. There are significant fears, financial investment costs, painful reveals, and potential negative external perceptions of implementing full-charge capture:

- Fear of CMS/OIG audits and fear of reduced reimbursement and/or denials from other payors.
- Financial investment costs to the hospital are immediate, expensive, and come from the bottom line profitability.
- It is a painful reveal of their current status, some are not willing to rip off the "rose-colored glasses" and prefer to not confront challenges presented – due to executive administrative personal career agendas.
- It "gives off" a negative perception of hospital administration and financial management (admitting full-disclosure of previous practices and benchmarks to boards, banks, foundations, physicians, patients, etc.).

SUMMARY: Claims data provided by hospitals to CMS reflects inconsistent markup and charging methodologies, in order to maintain "status quo" for gross charges to patients. Claims data is not truly reflective of full-charge capture, or accurate chart-to-charging methodology. Due to this, utilizing claims data and cost reporting data on which to base hospital reimbursement is understated in most cases, thus a reduction in reimbursement will significantly impact hospitals' ability to continue to offer this procedure to patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

MAY 26 2006

Ms. Lisa Hayden
Reimbursement Manager, Oncura
401 Plymouth Meeting Road, Suite 130
Plymouth Meeting, PA 19462

Dear Ms. Hayden:

Thank you for submitting the application for the **percutaneous renal cryotherapy** service for consideration as a new technology service under Medicare's hospital outpatient prospective payment system (OPPS).

We have carefully reviewed the information in the percutaneous renal cryotherapy application. We reviewed this information based on the provisions for placement of a service into a New Technology APC established in the OPPS rule published in the Federal Register notice on November 30, 2001. Based on our review of the application submitted, it has been determined that this service does not meet our criteria to be assigned to a New Technology APC. Specifically, the percutaneous renal cryotherapy service does not qualify for a New Technology APC under the hospital OPPS for the following reasons:

- The service is described by existing HCPCS codes or combination of HCPCS codes.

We have determined that the percutaneous renal cryotherapy service is described by existing HCPCS code CPT 0135T, ablation, renal tumor(s), unilateral, percutaneous, cryotherapy, as your application indicates. Percutaneous renal cryotherapy has already been assigned to a clinical APC, as of January 1, 2006. Because the percutaneous renal cryotherapy service is already described by an existing HCPCS code, it is not eligible for assignment to a New Technology APC under the hospital OPPS, and the application has been denied. Please note that the public may comment on the proposed status indicators and APC assignments of services described by existing HCPCS codes, which will be published in the upcoming CY 2007 OPPS proposed rule.

Thank you for your application, and I hope this information is helpful. Should you have questions on this decision, please contact me.

Sincerely,

James L. Hart

James L. Hart
Director
Division of Outpatient Care

cc: John McInnes, Arnold & Porter, 555 12th Street NW, Washington, DC, 20004

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Cordis
a Johnson & Johnson company

Cordis Corporation,
a Johnson & Johnson Company
7 Powder Horn Drive
Warren, NJ 07059

October 6, 2006

Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C-4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P

Subject: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List (CMS 1506-P)

Requests concerning:

1. **Proposed addition of stenting codes 37205 and 37206 to the Ambulatory Surgical Center approved procedure list for 2007**
2. **Angioplasty codes associated with stenting which were not added to the 2007 list**

Dear Dr. McClellan:

Cordis Corporation is pleased to comment on the Centers for Medicare and Medicaid Services (CMS) OPPS Proposed Rule, published August 23, 2006 in the Federal Register, Volume 71, No. 163. Cordis Corporation is a member of the Johnson and Johnson family of companies and a leading manufacturer of coronary, peripheral and neurovascular advanced medical technologies.

We would like to thank CMS for its willingness to work with manufacturers, and especially for the agency's commitment to continued improvement of the prospective payment system for hospital outpatient patients. Cordis will comment no further on the OPPS rule other than to recognize the considerable effort CMS has put into the development of the OPPS proposed rule and the 2007 Ambulatory Surgical Center rules.

Proposed Policies Affecting Ambulatory Surgical Centers (ASCs) for CY 2007

Certain safety criteria are required to be met by CMS before a service may be added to the approved list of procedures performed in an Ambulatory Surgical Center. A procedure must be anticipated to be no more than ninety minutes in duration, require no more than four hours of recovery time, involve minimal blood loss and exclude major blood vessels. The CY 2007 ASC rule proposes the addition of CPT codes 37205 and 37206 for Transcatheter placement of intravascular stent (non-coronary) percutaneous, initial and each additional vessel, respectively.

Cordis Corporation has concerns about the addition of these codes to the approved procedure list without further examination and consideration of revision to safety criteria as well as requirements for additional staff training and full surgical backup. In 2005, CMS proposed and then declined to move forward with the addition of these codes to the ASC list on the basis of safety concerns. Cordis believes that CMS should be cautious about moving broad categories of procedures for peripheral vascular disease into settings of care where patients may have limited access to emergency care.

The referenced CPT codes cover all non-coronary stenting of arterial and venous vessels. While recognizing that CPT codes are not in the scope of this discussion and comment, Cordis believes that the delineation of non-coronary vessels is ambiguous as it relates to major blood vessels. Iliac and femoral arteries are major blood vessels and therefore do not meet the criteria for inclusion on the ASC list. However, Cordis also recognizes that there are other peripheral vascular procedures, for example venous procedures that have less risk and may have many benefits to being performed in an ASC.

Cordis Corporation has particular concern that procedures involving iliac and femoral arteries have the potential for complications, which could place patients being treated in an Ambulatory Surgery Center at unnecessary risk. Examples of complications that may be associated with the use of vascular stents in peripheral vessels at the time of the procedure include dissection, drug reactions to antiplatelet agents or contrast medium, hematoma, bleeding, hypotension, hypertension, pain at the access site, spasm, stroke, myocardial infarction, and vessel perforation or rupture. Complications that may develop post procedure include infection, restenosis of stented segment, aneurysm, embolization and or abrupt closure, which may ultimately result in decrement of renal function, gangrene, amputation, and even death.

Immediate Complications (At time of Procedure)	**Post-Procedure Complications (At Less than 30 Days)**	**Possible Clinical Outcome**
Vessel Dissection	Infection	Decrement of renal function
Drug reactions	Aneurysm	Gangrene
Hematoma	Restenosis of stented segment	Amputation
Bleeding	Embolization	Death
Hypotension, Hypertension	Abrupt Closure	
Pain at the access site		
Spasm		
Stroke		
Myocardial Infarction		
Vessel Perforation or Rupture		

In the CRISP study, (Cordis Randomized Iliac Stent Project in the U.S.) conducted from 1998 –2002, the cumulative major adverse ischemic event (MAIE) rate was 4.9% or 5 of 102 patients and included 2 deaths at 30 days, as well as 1 amputation for the Cordis stent and a 5.9% MAIE rate caused by stent thrombosis and target vessel revascularization for the comparator BSC's Wallstent™.

Sulzer IntraTherapeutics, Incorporated conducted a trial beginning in 2001 for Intracoil® Self-Expanding Peripheral Stent that also experienced a death within a 30-day period in their femoropopliteal trial. A total of 357 patients were enrolled in a multi-center U.S. clinical trial. The purpose of the study was to compare the IntraCoil stent to balloon angioplasty in the superficial femoral and popliteal arteries.

A different superficial femoral artery trial, GORE Viabahn® Endoprosthesis Delivery System, reported complications including distal embolization and vascular complications. A total of 244 cases were treated at 25 U.S. investigational sites. The purpose of the study was to compare the safety and effectiveness of the GORE Viabahn® Endoprosthesis to percutaneous transluminal angioplasty (PTA) in patients with chronic lower limb ischemia or chronic lifestyle altering claudication due to superficial femoral artery (SFA) atherosclerotic disease.

All of these study results indicate that peripheral arterial stenting may be related to adverse events that require backup and monitoring, as well as physician and staff training beyond the current criteria for performance of procedures in an ASC. In addition, these study results occurred in controlled clinical trials, events in real world settings might have higher incidence rates.

Study	**Adverse Event**	**MAIE ≤ 30 Days**	**Cumulative MAIE ≤ 30 Day**
CRISP			
Cordis Nitinol Stent®	Amputation	1.0% (1/102)	
	Death	2.0% (2/102)	4.9% Major Adverse Ischemic Event
WALLSTENT™	Stent Thrombosis	1.0% (1/101)	
	Target Vessel Revascularizat	5.9% (6/101)	5.9% Major Adverse Ischemic Event
IntraCoil®	**Amputation**	**0.0%**	
	Death	**0.7% (1/135)**	
	Bleeding	**0.7% (1/135)**	
	Major Vascular Complicatio	**3.7% (5/135)**	**16.3% Any MACE Event (Early - In hospital)**
VIABAHN®	Distal Embolization	3.5% (5/144)	
	Hematoma	0.7% (1/144)	
	Stroke	0.7% (1/144)	
	Vascular Complication	1.4% (2/144)	7.6% Any Major Event

Procedures Which Were Not Added to the CY 2007 List

CMS did not add any angioplasty codes to the list of approved procedures for 2007, even though stent placement is proposed for performance in an ASC. This practice is not consistent with other current Medicare payment rules, which require a suboptimal angioplasty before approval of a stent placement. If peripheral stenting procedures are added, it seems logical and appropriate to add angioplasty as well.

Conclusion

Cordis Corporation respectfully requests that CPT codes 37205 and 37206 for the Transcatheter placement of intravascular (non-coronary) stents be excluded from the list of approved procedures, as we do not believe that Medicare patients would benefit from the proposed change in policy.

Cordis also requests that if Medicare does not remove the 37205 and 37206 from the approved procedures list for CY 2007, that consideration be given to the addition of angioplasty to the approved procedures list to achieve consistency in Medicare payment rules.

Sincerely,

Liesl M. Cooper

Liesl M. Cooper, Ph.D.
Vice President of Health Economics
and Reimbursement
Cordis Corporation, a Johnson & Johnson company

St. Anthony Hospital

1000 N. Lee Street
PO Box 205
Oklahoma City, OK 73101

405.272.7000
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October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P

St. Anthony Hospital is a hospital and psychiatric provider in Oklahoma. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1506-P and another 15% rate reduction for CY2007 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction again. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A $37.64/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

Our organization stands firmly behind the comments Association of Ambulatory Behavioral Healthcare submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1506-P pp. 99-105 describes the CMS methodology of rate calculations for PHP each year since 2000. A close review indicates that CMS arbitrarily applies its' own assumptions and methodology on a different basis every year from CY2003 through CY2006. Only the methodology from CY2006 and CY2007 are the same and there is no calculation of a methodology. It is nothing more than an arbitrary decision by CMS. We quote CMS on p. 105 to say "To calculate the CY2007 APC PHP per diem **cost,** we reduced $245.65 (the CY2005 combined hospital-based and CMHC median per diem cost of $289 reduced by 15 percent) by 15 percent, which resulted in a combined median per diem cost of $208.80."

2. CMS-1506-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00 in the last paragraph of p. 105. As a facility, our costs

increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas over the past two years. A daily per diem of $208.27 cannot be justified with these expenses.

3. CMS identified the Median cost of group therapy at $66.40. Our program offers 4 group services per day at a minimum. This summarizes to a median cost of $265.60. A per diem of $208.27 cannot be justified with these expenses.

4. Many of our patients are Medi-Medi's. Medicaid cuts are strongly threatened here in Oklahoma. If the 20% copay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to $166.62 ($208.27 x .80). A daily per diem of $208.27 cannot be justified with this situation.

5. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

6. Based on the above issues, St. Anthony Hospital asks that CMS leave the per diem unchanged from the CY 2006 rate of $245.91. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had 80 admissions so far in CY 2006, and every one would be a high risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Joe M. Hodges, President
St. Anthony Hospital

The Charlotte Hungerford Hospital

I have read the comments that will be forwarded to you from Yale New Haven Hospital and believe that they make the appropriate points concerning the acuity of the Medicare patient population seen in their Shoreline ED, as well as the costs involved in providing care for the sickest patients---all of whom have unencumbered access to Yale's Shoreline ED door.
I believe therein lies the rub. Very sick patients now have an opportunity to stave off worsening morbidity and/or mortality by just walking in our doors. Emergency medicine actually saves lives in 2006. It didn't 50 years ago. Not only were there no Emergency Rooms in any of the hospitals in this country or the world, there weren't any Coronary Care Units, either. Then, we didn't have the scientific understanding nor the technology required to actually do very much for very sick people. "Artificial respiration" was lifting someone's arms at the shoulder a few times on a beach as late as the early 1960s. There was no CPR. Things have changed quite a bit.

Now we have the technology to save a person's life and some of us are trained to do it.

The grandmother of the young man who removes the snow from the hospital driveway in winter has chest pain. She starts to feel nausea. She has never felt so bad or so scared in her life. Her husband of 55 years, in the first few seconds of this real life drama, is in disbelief. He tries to talk to her, tries to calm her down. He's hoping this will pass but she tells him to call 911 and he does. He watches as her breathing becomes more difficult. This much adrenaline is making her pale and wet with sweat. An ambulance has been dispatched along with a paramedic.

She has a platelet clot in her left anterior descending artery. The cardiac muscle that lives on the oxygen brought by that little artery would have died in 1965. And grandmother might have died, as well, because when cardiac muscle doesn't get oxygen, the electricity that makes it squeeze the blood out into the brain, and guts, and arms, and legs, and into her own hungry heart muscle doesn't always work so well.

Not today. She is in our ED in 8 minutes after being grabbed by the ambulance crew. As soon as she arrives, two RNs are very busy, one on an arm placing another IV and then hooking up a 12 lead ECG; another in the Med Room at the Pyxis getting me chemicals such as TPa, Heparin, Metoprolol.... I have my eye on a monitor which is reading every heart beat and sensing instantaneously the exact amount of oxygen she has in her arteries. The staff is moving efficiently. I look into the eyes that sit just above the 100% oxygen rebreathing

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I have read the comments that will be forwarded to you from Yale New Haven Hospital and believe that they make the appropriate points concerning the acuity of the Medicare patient population seen in their Shoreline ED, as well as the costs involved in providing care for the sickest patients---all of whom have unencumbered access to Yale's Shoreline ED door.
I believe therein lies the rub. Very sick patients now have an opportunity to stave off worsening morbidity and/or mortality by just walking in our doors. Emergency medicine actually saves lives in 2006. It didn't 50 years ago. Not only were there no Emergency Rooms in any of the hospitals in this country or the world, there weren't any Coronary Care Units, either. Then, we didn't have the scientific understanding nor the technology required to actually do very much for very sick people. "Artificial respiration" was lifting someone's arms at the shoulder a few times on a beach as late as the early 1960s. There was no CPR. Things have changed quite a bit.

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mask that straddles her nose and mouth, and see that our patient is still awake and alert, and my fingers on her pulse tell me that she has a regular heart beat with good perfusing pressure. I see the ECG. Within minutes she is getting the IV chemicals that have been designed to break up the clot which I know is there. One of the nurses has run into the lab with her blood and I am told 15 minutes later that, at least at present, she has no dead heart muscle. She is about 50 minutes into this thing now. We've got our eyes and ears on her blood pressure, on the running heart monitor of her every heartbeat and its configuration, on her oxygen saturation, and I am softly talking to her saying "See me smiling, Hazel? You're doing just great!" I have already spoken to the Interventional Cardiologist at the Hartford Hospital, a helicopter is in the air and is 5 minutes away, my nurses are preparing the IV solutions that will be necessary for what will be only an 11 minute door to door helicopter shuttle directly to the Cath Lab. Her cardiac monitor suddenly begins to show unusual activity. For a minute our anxiety level begins to rise, but then she is back in a normal rhythm and the ECG signs of diminished oxygen in the part of her heart whose blood supply had been blocked is no longer obvious. The clot is gone. The area in danger is now filling with oxygen-loaded blood and we have ourselves a happy left ventricle. The helicopter comes and goes. It has been very smooth. Two hours later we get a call from Hartford. She received a stent in her left anterior descending artery and another in a tight right coronary artery. She is doing well, is in no pain. More importantly she is no longer in danger and will be home in a few days.

This exact scene occurs, exactly as I have painted it, in our ED, as well as other different potential life threatening/altering illnesses and/or injuries, all just as real, some almost as emotionally potent. We move with the same dispatch and with the same scientific base for diagnosis and treatment in the infant who is seizing, the dislocated shoulder, the hypotension from overdiuresis in the nursing home resident, the asthmatic who ran out of meds who is hardly able to breathe and who thought that maybe this time it would pass on its own, and the 15 year old who has considered suicide because he is teased by his peers when he won't assist them in stealing articles from a local grocery store. His dad is concerned, and rightly so. And then on a beautiful day in August we get an 11 year old with a heart rate of 253 brought in by his young mother. She tells me that he had open-heart surgery when he was 4 days old to repair a major congenital defect. He's fine now, too, with a pacemaker laid in at the Hartford Hospital, a week after we converted him back to normal rhythm. Not everybody can do this. Not everybody wants to do this. We're not always successful.

If we were staffed for, and had the expensive equipment for, real live human medical emergencies and we never really saw any, or saw them too rarely, we'd be wasting a lot of money. But, we need our staffing and our equipment. We know how to use it and we do, sometimes many times a day, occasionally not at all in a day, but our raison d'etre is well established by the sheer number of people who are walking around and have had major medical emergencies expunged completely by our staff, or had their problems dealt with in their incipiency so as to prevent greater morbidity and/or mortality.

We cost more than a clinic because we obviously need to provide a great deal more. A clinic doesn't have an ED trained doctor, doesn't need any R.N.s at all, doesn't need to keep expensive medications and equipment on hand, doesn't require more than a simple lab on premises, doesn't allow an ambulance to bring them a sick patient, doesn't need the number of bodies we need to be able to take care of the patients we see.

Nobody should ever do anything to put us in jeopardy. Our hours of service have nothing to do with the cost of the care we provide. The Charlotte Hungerford Hospital in Torrington, CT, which has taken on the job of maintaining this extension of their 24 hour ED, can't afford to provide this service 24 hours a day. The community is grateful for what they do have, and rightfully so. It would be the ultimate and most sad irony if CMS, in part designed to assure that our Medicare population has access to efficient and competent emergency medical care, would allow a rare but important piece of the patchwork of emergency access (the less than 24 hour hospital-owned ED seemingly native only to CT) to be paid far below their costs, and in so doing, potentiate the demise of these facilities.

I have to believe that this was an unfortunate oversight. An honest attempt was made to make a broad one-size-fits-all regulation to assure that only centers that provide true emergency care are paid to be open for same. I hope you now see that the regulation doesn't fit all. We need your help on this.

Data is included at the end of the additional note below. You will find the acuity levels that look specifically at the Medicare visits in two of the less than 24 hour hospital owned EDs in CT. They are compared to various local 24/7 EDs and to a Walk In Center which is the only one in our region of CT. I believe you'll find that this all follows cleanly and that the point is made. I am truly grateful for your attention to this matter. If I can be of any assistance in any of your deliberations I would be quickly available.

The following is a note I sent to Leslie Norwalk and Herb Kuhn. I'd like it to be part of this comment.

I am the Medical Director of the Hungerford Emergency Department in Winsted, CT. We are open from 9am-9pm every day of the year and see about 7500-8000 visits/year. We are situated in the old ER of a hospital which has been the only one to go out of service in the state of CT. This occurred about 10 years ago. The Charlotte Hungerford Hospital, located in a city south of us, under the approval of, and after due diligence by the State of CT Office of Health Care Access, reopened the ER in the old hospital about 18 months later, along with xray and lab. Connecticut is a state with a strict Certificate of Need process. Legitimate need for access of care is required for State approval. We do not have an excess of Emergency facility inventory in CT for that reason.

The ED in Winsted is appropriately staffed and equipped to be prepared to care for potentially unstable patients at risk for loss of life and/or limb in this region of CT and southern MA. We have saved many lives, and limbs, since we have reopened. We are a true ED. Ambulances bring us unstable patients. We serve a population that is to a great degree truly underserved, many of whom are over 65. They are mostly poor and relatively uneducated. Many have no insurance or have State insurance which limits them greatly by virtue of a shortage of available participating physicians. We see people who can be very far along in a disease process or have waited too long to have an injury cared for. We, often, are the first doctors they see. We are a structural part of the community.

The physicians are Board Certified and excellent. I am double Boarded in Internal Medicine and Emergency Medicine. The ER is almost break-even on a cost basis for the Charlotte Hungerford Hospital which runs it.... and this while it is being paid at ED rates by Medicare and other insurers. It is unreasonable and dangerous to put this facility at financial risk by being asked to accept "clinic" rates for medicare patients who present to us with true emergencies. Costs wouldn't be covered. This would be an unintended consequence caused by a CMS regulation created for an altogether different purpose, and would be diametrically opposed to CMS's mission. Our hours are designed to provide our full ED service, while not creating a financial hardship on an also vulnerable hospital that owns and runs it. It works.

This appears to be almost solely a CT problem. Neither the AHA, ACEP, IOM, nor the Rural Health Coalition has found any other less than 24 hour provider-based hospital-owned EDs outside of CT. I'm sure you'll hear about the Emergency Medical System we have from our State delegation. It is

superlative, and we, along with the other 3 less than 24 hour provider based hospital-owned EDs in our State, are an integral part of it.

Without being melodramatic but in trying to make a point.....I am able with the stroke of my pen to order a medication that will save someone's wife, child, or parent. I, my entire ER staff, and the people in our service area, are asking for a stroke from your pen.

A graph is appended as a means of comparing our ED Medicare acuity with 24 hour EDs, the Yale Shoreline 16 hour ED, and a representative Walk In/Urgent Care Center.

Your time is greatly appreciated,
Gregg Grinspan, MD
Medical Director, Hungerford Emergency Services at Winsted
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Charlotte Hungerford Hospital

----Emergency facility codes are based on acuity---------

Higher final number equals more hospital resources required (the sicker the pt.)

99281--- 99282---easily cared for in an urgent care/walk in facility---not very sick

99283 ----require suturing, IV, labs, xray, ECG, IV or IM meds, etc. (pneumonia, broken ankle, dehydrated child requiring IV fluid, chest pain determined not to be cardiac after testing in medical facility)

99284, 99285, 99286----progressively worse injury and/or illness---- Many 4s, all 5s and 6s, are admitted to the hospital.

Urgent visits---1,2
Emergent visits---3-6

Percentage of all Medicare visits that are of Emergent Acuity (3-6)
Data from 2005-2006

Charlotte Hungerford ED- Open 24/7----------86.1%

Yale New Haven Main Campus ED 24/7----------87%
(Level One Trauma Center)

New York Rural Hospital ED ----------24/7----------83.4%
Winsted 12 Hour ED----------70.1%
(Satellite ED of Charlotte Hungerford Hospital)

Yale 16 Hour Shoreline ED----------78%
(Satellite ED of Yale New Haven Hospital)

Walk In Center-Torrington----------(clinic)----------23.8%

Patients self select. Sicker patients know that if they feel they have a real emergency they don't go to their doctor's office, nor do they go to a clinic which is seen as a doctor's office without appointments. Equipment, staffing, and training required for emergencies don't exist in an urgent care center.

The only medical establishments that advertise to the population and provide emergency care in the State of Connecticut are Hospital Emergency Departments and the satellite provider-based Emergency

Departments seeing patients as an extension of the main hospital ED and under its license.

(The percentage of ED 3,4,5s seen in the Walk In Center were derived by the actual counting of procedures over a year period. The ED and Clinic codes do not line up well and required a hand count to compare apples to apples. In the letter to Herb Kuhn and Leslie Norwalk the % of 3,4,5s seen in the Walk In Center were over stated at 29.9%. I would ask that this inaccuracy be noted.)

Medicare payment for ED 3,4,5----------$247, $329, $475
Medicare payment for Clinic 3,4,5----------$135, $176, $203
I believe that payments originally were set up by CMS on a cost basis.

The Emergency Medical System in CT requires all ambulances to call the nearest ED radio to alert them of any patients on route to their facility.

Patients who do not require stabilization, but who require an operative procedure, the Intensive Care Unit, more provocative Radiologic scanning, or blood products are diverted to Charlotte Hungerford and bypass the Winsted ED. If they are not stable they must stop at Winsted to be stabilized.

These patients are not counted in the totals for Winsted, but do require our physicians to make medical decisions about appropriate placement via radio.