Memorial
HEALTH
University Medical Center

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September 10, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS –1392– P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1392-P – Medicare: Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule (72 *Federal Register* 42628).

Dear Mr. Weems:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule concerning the Hospital Outpatient Prospective Payment System. Memorial Health University Medical Center (MHUMC) is a 530 bed teaching hospital with Level I Trauma Center status located in Savannah, Georgia.

This letter will focus on the proposed changes to Quality Data Reporting (pages 42799-806), Specified Covered Outpatient Drugs payment policies (pages 42733-736) and Packaged Services (pages 42648-690).

I. Quality Data (pages 42799-806)

"Proposed Hospital Outpatient Measures"

For CY 2008, CMS is proposing to require hospitals to report data on 10 quality measures addressing care provided to adult patients in a hospital outpatient setting. Of these 10 measures, five relate to adult patients who are treated in an emergency department for acute myocardial infarction (AMI) and then transferred to another facility, one is related to the treatment of heart failure, two address surgical care improvement, one measures the treatment of community acquired pneumonia, and one is related to diabetes care.

"Outpatient Measures" Comment

We would request that CMS provide additional details on the reporting of the five AMI quality measures. These measures are designed to capture the quality of outpatient care in hospital emergency departments for adult patients with AMI who are treated and then transferred to another facility for further care. Our facility, and likely others of similar size, does not transfer these patients. Clarification is requested

regarding the patient population on which a facility must report these quality measures, specifically whether it is all ED patients who present with AMI, or only those who are transferred to another facility. If the intended population is only those patients who are transferred to another facility, as we believe it is, our facility will have no data to report on the first five proposed quality measures.

Additionally, we are concerned with the potential administrative burden of reporting the heart failure and pneumonia quality measures. Tracking these two data elements will require extensive chart abstractions, creating an unnecessary burden on providers.

Finally, we disagree with CMS' decision to include the Hemoglobin A1c test in the quality measures. Hemoglobin A1c tests are performed almost exclusively in physicians' private offices, which are typically not established as outpatient departments of a hospital.

II. OPPS: Specified Covered Outpatient Drugs (pages 42733-736)

"Proposed Payment Policy"

For CY 2008, CMS is proposing to require hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead charge on an un-coded revenue line on the claim.

CMS is also proposing to reduce the payment for separately payable drugs and biologicals from ASP +6 to ASP +5.

"Proposed Payment Policy" Comment

We disagree with CMS' proposal to require hospitals to remove the pharmacy overhead charge from the charge for the drug and biological and instead report a separate pharmacy overhead charge. This would require hospitals to maintain two charges for each of potentially thousands of drugs, potentially requiring separate computer systems. For bills to non-Medicare payers, the system would have to add the two charges together before posting to the bill; for Medicare bills, the system would simply pass the individual charges for each drug to the bill, and add together all of the overhead charges and pass this charge to an un-coded line on the Medicare bill. Additionally, the proposed rule does not provide any guidance as to what constitutes overhead and handling costs.

We also disagree with CMS' proposal to reduce the payment for separately payable drugs and biologicals by one percentage point. The payment for drugs in a physician office setting remains at ASP +6. We urge CMS to provide a consistent payment policy across providers for drugs and biologicals.

III. OPPS: Packaged Services (pages 42648-690)

"Proposed Changed to Packaged Services"

For CY2008, CMS is proposing to expand packaging and bundling, so that more services that are currently paid separately would receive a single APC payment, with seven specific areas identified in the proposed rule. In addition, the Agency is proposing to implement two "composite APCs" that would

bundle payments for two specific outpatient encounters: Low Dose Rate (LDR) Prostate Brachytherapy and Cardiac Electrophysiologic Evaluation and Ablation.

"Proposed Changes to Packaged Services" Comment

While we are supportive of CMS' efforts to increase efficiency in care delivery, we are concerned that the packaging proposal has not been thoroughly analyzed. Due to the complexity of the OPPS payment system, we have been unable to properly analyze the financial impact on our facility. We urge the Agency to delay expansion of packaged services to allow for additional analysis to be performed, both by CMS and by the individual institutions.

Thank you for considering our remarks on the proposed rule. If you have any questions about our comments, please feel free to contact me.

Sincerely,

Mike Thompson

Mike Thompson

Manager of Reimbursement, MHUMC

Cc: Bob Colvin, President and CEO, MHUMC
Maggie Gill, COO, MHUMC
Phil Norris, Interim CFO, MHUMC
Darcy Davis, Vice President of Finance, MHUMC
Tracy Thompson, Director of Public Policy, MHUMC

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SOCIETY OF
CHEST PAIN
CENTERS

September 12, 2007

Attention: CMS-1392-P

Kerry N. Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1392-P: Medicare Program: Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates

Specifically: APC packaging proposal for observation services

Dear Mr. Weems:

The Society of Chest Pain Centers would like to thank you for the opportunity to submit our comments post testimony to the APC Advisory Panel and Centers for Medicare and Medicaid Services (CMS) as it relates to the CMS packaging of observation services in the 2008 Hospital Outpatient Prospective Payment System (OPPS). The Society of Chest Pain Centers represents 376 accredited chest pain centers and several thousand unaccredited facilities.

Our Society was represented on September 5, 2007 by professionals who have enthusiasm and dedication to making our health care system the finest in the world. The individuals presented a powerful presentation that included important facts well beyond the superficial changes proposed by CMS. As the only professional medical society made up of a blend of specialties, we feel we can offer a helpful view to the changes proposed. These views included statistics for mortality/morbidity, clinical outcomes, volumes, and costs which aligns nicely with our national health care initiatives, safety, efficiency and economics. Our society is dedicated to providing unified and systematic strategies to assist in the reduction of heart attack deaths in the United States.

We would like to ensure our views on the proposed changes are officially recorded by CMS. For the record, the Society of Chest Pain Centers submits that the proposed changes would be critically debilitating to facilities across the nation attempting to provide optimal patient care within the CMS guidelines. We recommend keeping the OPPS in its current form regarding unpackaged observation services. Although CMS noted concern for exponential growth in the use of observation, these claims calculated to less than 1% of total claims submitted. It is also important to note that this exponential growth came with no change in the cost of care and in many cases reduced costs to the overall payment system by avoiding inappropriate admissions or the use of unnecessary services. The proposed changes, incentivizing hospitals to preferentially use DRG admissions, since the APC is bundled, could result in an $11 billion dollar increase in cost of care to CMS. Alternatively, a study by A. Kugelmass, et al. indicated that mortality decreases by 37% when hospitals use an APC system for chest pain. The consequences of removing such a system are unknown.

As the demand on emergency department services continues to rise, so too is the use of observation services expected to similarly increase. Close monitoring of the use of observation services should be continued by CMS, but packaging of services at this time would be detrimental to both inpatient and outpatient services across the nation and could have negative consequences well beyond its intended range. We have also included documents as a reminder of past efforts to create and maintain observation service in its current format. The Society of Chest Pain Centers appreciates the open mind provided by CMS in the form of the APC Panel Meetings.

Sincerely,

Wayne Friestad

Wayne Friestad, MD, FACEP
President

Raymond Bahr, MD – President Emeritus, Board of Trustees
Sandra Sieck - Board of Trustees
Frank Peacock, MD – Founding Member, Board of Trustees
Mike Ross, MD – Board of Trustees

Enclosure

Second Annual Advisory Panel Meeting
Topic of Interest: Unpackaged APC 0339
September 5, 2007

Attendees:
Sandra Sieck RN
Raymond Bahr MD
Frank Peacock MD

Final Rule 2002
66 FR 44690-91: Consideration of a separately payable observation code APC 0339.
Purpose : Impact Mortality and Morbidity

Statistics:

Observation of carefully selected emergency patients has been extensively studied and shown to provide improved health care outcomes.

1. **A ten-fold decrease in the error rate for "missed myocardial infarction" (the rate in which heart attacks are inappropriately sent home.)**
    a. Chest Pain 5-6% of ED visits (80% present to the ED)
    b. Chest Pain a symptom commonly associated with fatal cardiovascular disease, leading cause of death (42%)
    c. 4-5% missed MI rate (inadvertently discharged home with twice the death rate of patients admitted (25%)
    vs.
    d. 0.4% with observation.
    Graff Am J Card 1997:80;563-568.

2. **A reduction in health care costs by one half to one third.**
    a. $2764/patient * 5M/visits= 13.8 B
    vs.
    $403/patient average cost * 5 M visits= 2B
    Difference of= 11.8B
    b. 60-70%% of ED chest pain patients are admitted, only 10% have an acute MI and 10% unstable angina. The remainder are considered to be low probability resulting in 3-5% inadvertently being released home.

3. **A reduction in patient length of stay.**
    a. Inpatient admission: 2-3 Length of stay
    vs.
    b. Observation: 12-16 hrs(accelerated protocols)

4. **An improvement in patient satisfaction.**
    a. 3.39-3.75 CPOU
    vs.
    b. 2.86-3.26 Inpatient

5. **Bottleneck ED throughput with bundling services (proposed ED Level V)**
    a. Traditional ED Services: 2-4 hrs (overcrowded)
    b. Observation Services: 12-16 hrs(in ED for increase payment of $23)
    c. Inpatient Services: 2-3 Days (unnecessary admission)

The current proposed APC rule appears to jeopardize these health care innovations.
The proposed payment structure does not cover the costs of providing services it appears that the actual total cost of the proposed rule will have a substantial increase in cost of care.

Observation Usage:

1. Number of ED's utilizing observation units
    a. 22% metropolitan ED
    b. 27-40% general ED

Claims Data:

2003 56,000 obs cases
2004 77,000 obs cases
2005 124,000 obs cases
2006 271,000 obs cases

Increase of claims has shown successful outcomes

Decrease medical errors
Decrease patient cost
Decrease hospital length-of-stay
Decrease unnecessary admissions
Decreased missed MI
Increase patient satisfaction
Increase ED efficiency

A move back in time to having these patients bundled under the ED level of service or admit patients will increase health care costs, increase missed heart attacks, and decrease patient satisfaction. A new era of time has forth the health care system to create efficiency with expedited care at a lower cost while impacting patient satisfaction scores.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

NOV 16 2000

Dr. Raymond D. Bahr
Society of Chest Pain Centers and Providers
The Paul Dudley White Coronary Care System
St. Agnes Health Care
900 Certain Avenue
Baltimore, MD 21229

Dear Dr. Bahr:

I am writing to follow up on our recent conversations regarding payment for observation for chest pain under Medicare's outpatient prospective payment system (PPS).

The outpatient PPS, which became effective August 1, 2000, pays for observation by "packaging" these services with other services, such as surgery, that may lead to a period of observation. For instance, the payment rate for an emergency room visit includes a portion that represents payment for observation. Hospital costs for providing operating rooms, nursing services, or supplies are treated similarly. Thus, when we were setting up the outpatient PPS, we identified aggregate payments for observation in the 1996 claims files on which the system is based, and included these payments in the ambulatory payment classification (APC) payments for emergency visits, surgery, or other such services. In fact, well over $200 million in observation costs were "packaged" in this way.

You and your colleagues have raised with us concerns about lack of explicit payment for observation for chest pain under the outpatient PPS. The issue, as we understand it, is that although hospitals are being paid for these services as part of the APC payments, the lack of a payment visibly associated with observation for chest pain may lead hospitals to cut back on providing such observation. Chest pain centers have been put forth as an important focus for addressing chest pain symptoms, and you are concerned that lack of explicit payment may interfere with diffusion of this innovation among hospitals.

We believe that your concerns are important and would like to attempt to address them. We packaged observation services because these services, in general, appeared subject to abuse, and we believed would be appropriate to associate these services with the underlying services that preceded the observation and thus permit care givers to manage these services within a single bundled payment. In the case of chest pain, we are prepared to consider revising our policy (through notice and comment rulemaking) to provide separate identification of payment for a well-defined set of observation services if the concerns about potential abuse can be addressed. You and your colleagues have generously shared with us some suggestions about how this might be accomplished, and we believe these suggestions are promising.

We expect to advance a formal proposal under which we would specify particular circumstances where separate payment would be made for observation associated with chest pain and would set rules designed to prevent abuse. Such a proposal would be designed to permit separate payment under the outpatient PPS for observation of chest pain in well-defined circumstances; any new APC for this purpose would have to be funded by making non-trivial reductions in the payment for existing APCs. This proposal would appear in the spring of 2001 in the upcoming notice of proposed rule-making for the outpatient PPS. As with other such changes in the system, it would be open to public comment, and we would finalize the proposal in response to those comments later in the year. The change would take effect on January 1, 2002. We are sorry we are not in a position to move more quickly to address your concerns.

We very much appreciate the thoughtful input you and your colleagues have provided us, and we look forward to bringing this matter to a satisfactory outcome.

Sincerely,

Thomas A. Gustafson, Ph. D.
Director
Purchasing Policy Group
Center for Health Plans and Providers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Heart, Lung, and
Blood Institute
Bethesda, Maryland 20892

March 27, 2002

Dear Chest Pain Center Advocate:

The Society of Chest Pain Centers and Providers (SCPCP) and the National Heart, Lung, and Blood Institute (NHLBI) are working together in a new effort to deal with an urgent problem. Four out of five people who suffer a heart attack do not get to the hospital early enough to benefit fully from treatments that can prevent heart damage and death. Both organizations have a similar goal–to turn this trend around by increasing awareness of early heart attack warning signs and the actions that can save a life when a heart attack occurs.

Now you can join in this effort by helping to spread the messages of a new national campaign–"Act in Time to Heart Attack Signs." The campaign features easy-to-use materials for professional, patient, and community education. The "Quick Reference Card" for health care providers gives the T.I.M.E. method for dealing with patients' concerns about a heart attack. The Small Group Session Kit is a handy "talk in a box" with everything needed for an effective 1-hour presentation in a hospital-sponsored class, a work site, or community meeting. The enclosed flyer gives descriptions and ordering information for all the materials, which are available at a nominal cost. To order, fill out the form included in the flyer, enclose payment, and send to the address indicated. Or order online at http://emall.nhlbihin.net.

Chest Pain Centers represent more than just a single hospital's approach to a community's heart attack problem. They provide a unified and systematic strategy to help reduce heart attack deaths in the United States. To accomplish this lofty goal, Chest Pain Centers need to take a giant step forward, shifting the paradigm of care to a more community-based focus. The SCPCP and NHLBI now have the tools to help you implement an effective program to raise public awareness about the early heart attack symptoms that most people do not perceive as important enough to check out. Chest Pain Centers now have observational services that allow patients to benefit from a community-penetrating awareness strategy and to enter care earlier. EHAC–Early Heart Attack Care–is an awareness program developed by Chest Pain Centers for carrying out community education strategies for patients with prodromal chest symptoms. To order EHAC information, call 410-368-3200, fax 410-368-3207, or email info@EHAC.org.

EHAC and the "Act in Time to Heart Attack Signs" campaign provide a wide range of complementary messages, materials, and strategies. We urge you to use these resources in your work to help prevent heart damage and save lives in your community.

Sincerely,

Raymond D. Bahr, M.D.
Chair
Cardiac Outreach Committee
Society of Chest Pain Centers and Providers

Mary Hand, R.N., M.S.P.H.
Coordinator
National Heart Attack Alert Program
National Heart, Lung, and Blood Institute

Enclosure

Minutes to conference call with HCFA – November 22, 2000

HCFA staff present –

- Tom Gustafson
- Paul Rudolf MD JD

Observation work group –

- Raymond D. Bahr, MD, Society of Chest Pain Centers and Providers, Cardiologist
- Lou Graff, MD, Society of Chest Pain Centers and Providers
- Wayne Powell and Dr. Schaeffer, American College of Cardiology
- Mary McDonald Hand, National Heart Attack Alert Program
- Mike Ross, MD, Society of Chest Pain Centers and Providers, Emergency Physician
- Tony Joseph, MD, Society of Chest Pain Centers and Providers, Emergency Physician
- Lee Garvey, MD, Society of Chest Pain Centers and Providers, Emergency Physician
- Sandra Sieck, MD, Society of Chest Pain Centers and Providers, Critical Care Nurse.
- Bob Stomel, MD, Society of Chest Pain Centers and Providers, Cardiologist
- Andy Cohen, MHSA, FACHE
- Jim Espinosa, MD, Society of Chest Pain Centers and Providers, Emergency Physician

1. HCFA seemed very supportive of our issue and convinced of its benefits. Because of federal regulations, among other issues, our proposal could not be adopted without going through the formal public comment process. This takes about one year. They accept the majority of our proposal as is, and will contact individuals for additional feedback as needed while they work out the final details.
2. There is always uncertainty. With a change in HCFA and government leaders, things could change. Because of this no promises can be made.
3. Input from hospital organizations is important before this goes to the public. This will help avoid unanticipated negative comments against this proposal. Names were given of individuals we might contact to share our six-point proposal with.
4. If the published proposal looks good we will want to have as many members as possible write in and support the proposed rule.
5. HCFA (Paul Rudolf) is willing to do anything in its limited power to convince hospitals not to give up hope on observation services, including:
   a. A letter has been sent to Dr. Bahr that could be shared publicly. It has undergone clearance for release within HCFA. This could be shared with hospital administrators.
   b. HCFA has a web page that uses a "push" feature to a question – answer site. This could be used to address the question of "how does a hospital get paid for providing observation services currently?"
   c. HCFA was asked wither the observation patients might qualify as outliers. This will be looked into.
6. Paul Rudolf emphasized the importance of having hospitals that are providing observation services use the 762 revenue code so HCFA can study this data. He also mentioned unresolved questions regarding at what time would the service would start so that it is distinctly separate from the emergency APC.
7. Interest was expressed in working on the quality aspects of this issue. HCFA will make appropriate referrals.

M.R. 11/22/00

ASTRO
AMERICAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY

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September 14, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates and Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Mr. Weems:

The American Society for Therapeutic Radiation and Oncology (ASTRO)[1] appreciates the opportunity to provide written comments on the "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates" published in the *Federal Register* as a proposed rule on August 2, 2007. Our comments focus on the following issues which are presented in the order in which they appear in the proposed rule: (1) APC relative weights and the bypass list; (2) packaged services; (3) new HCPCS and CPT codes; (4) the 2-times rule; (5) new technology APCs; (6) SRS treatment delivery services; (7) payment for therapeutic radiopharmaceuticals; (8) brachytherapy; (9) inpatient procedures; and (10) quality data.

I. APC Relative Weights - Bypass List (72 FR 42636)

CMS generally uses single procedure claims to set the median costs for APCs because of the difficulty encountered while ensuring that packaged costs are appropriately allocated across multiple procedures performed on the same date of service. For several years, CMS has used a list of codes that do not have significant packaged costs to be "bypassed" when determining which claims can be used to set the median costs. The effect is to convert multiple procedure claims to ''pseudo'' single procedure claims. By bypassing specified codes that do not have significant packaged costs, CMS is able to use more data from multiple procedure claims. The

[1] ASTRO is the largest radiation oncology society in the world, with more than 9,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing healthcare environment.

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use of a bypass list is critical to radiation oncology because most claims have more than one procedure code. Before the inclusion of certain radiation oncology services on the bypass list, the median costs for radiation oncology services were based on a small fraction of the total claims and the resulting APC payments were unstable and inaccurate.
CMS proposes to continue using the codes on the CY 2007 OPPS bypass list but to remove codes that are proposed for packaging for CY 2008 (see our comments on this proposal in the section that follows). CMS also proposes to remove codes that were on the CY 2007 bypass list that "ceased to meet the empirical criteria under the proposed packaging changes when clinical review confirmed that their removal would be appropriate in the context of the full proposal for the CY 2008 OPPS."

The following eight radiation oncology codes are among the codes proposed for deletion from the bypass list:

CPT Code	CPT Descriptor
77280	Therapeutic radiology simulation-aided field setting; simple
77285	Therapeutic radiology simulation-aided field setting; intermediate
77290	Therapeutic radiology simulation-aided field setting; complex
77295	Therapeutic radiology simulation-aided field setting; three dimensional
77332	Treatment devices, design and construction; simple (simple block, simple bolus)
77333	Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus)
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)
77417	Therapeutic radiology port film(s)

By removing these codes from the bypass list, more claims will remain multiple procedure claims and fewer claims will be used for rate-setting. This is a step backwards for radiation oncology. We are particularly concerned about the effect of removing the therapeutic radiology simulation-aided field setting codes (77280-77295) on the high dose rate (HDR) brachytherapy codes (77781-77784) since these are often billed together. This change in the bypass list interacting with packaging Image Guided Radiation Therapy (IGRT) codes, which also appear on HDR brachytherapy claims frequently, results in fewer single claims being used and less accurate payment rates for HDR brachytherapy and other codes.

More specifically, for all HDR brachytherapy claims, 14% of the HDR brachytherapy procedures had a corresponding IGRT line, whereas only 2% of the claims used for rate-setting had IGRT packaged. Further, contrary to CMS' intention to create more pseudo single procedure claims as a result of packaging, for HDR brachytherapy procedures CMS is creating far fewer, a 14 percentage point drop from 62% to 48% of total frequency. We believe this drop can be attributed largely to interaction of the proposed packaging of guidance procedures and the proposed changes to the bypass list.

In the HDR brachytherapy example, two radiation oncology CPT codes (77280 and 77290) that often appear with the HDR brachytherapy codes were removed from the bypass list. When the

proposed CMS methodology is applied (including the packaging proposal described in the next section of our comments and the proposed changes to the bypass list), the number of pseudo single claims that CMS uses to set rates for the HDR brachytherapy codes decreases substantially. The packaged guidance procedures are needed for the HDR brachytherapy radiation treatment (77781-77784) and not for setting the radiation fields (77280 and 77290. An unfortunate consequence of removing these codes from the bypass list seems to be that the costs of the guidance are simply eliminated from many of the claims used to calculate the median costs.

As shown in the table below, when the IGRT costs are included in the calculation of the costs for HDR brachytherapy procedures (in accordance with the packaging proposal described in the next section of our comments), the average IGRT costs per HDR brachytherapy procedure range from $10.45 to $24.16. However, once both the new CMS packaging methodology and bypass list are applied, the allocated average IGRT costs over the family of codes drop to a range of $0.86 to $3.17, due to the fact that only 2% of the single claims have IGRT while 14% of the claims have IGRT on the same date.

CPT Code	**CPT Descriptor**	**Added Cost of IGRT Before Use of Revised Bypass List (All Claims)**	**Added Cost of IGRT After Use of Revised Bypass List (Single Claims)**
77781	Remote afterloading high intensity brachytherapy; 1-4 source positions or catheters	$ 24.16	$ 0.86
77782	Remote afterloading high intensity brachytherapy; 5-8 source positions or catheters	$ 10.45	$ 1.86
77783	Remote afterloading high intensity brachytherapy; 9-12 source positions or catheters	$ 13.12	$ 2.04
77784	Remote afterloading high intensity brachytherapy; over 12 source positions or catheters	$ 22.37	$ 3.17

We are troubled by the end result which is a drop in the APC payment rate for APC 313 *Brachytherapy* in 2008 from $789.70 to $739.46. This decrease is alarming because IGRT is packaged and the median cost has gone down. It would appear that those claims with IGRT are not becoming pseudo singles at least in part because the bypass list no longer includes important radiation oncology codes. As a result, the costs of the IGRT are not being included in the median costs of the codes assigned to this APC.

ASTRO requests that CMS not delete the eight radiation oncology codes listed on the first table in this section above from the current list of bypass codes. While these codes may not have met the empirical tests for inclusion on the bypass list, we believe there is minimal associated packaging with these codes and that a re-review by your clinical staff will confirm that their removal would <u>not</u> be appropriate in the context of the full proposal for the CY 2008 OPPS.

II. OPPS: Packaged Services

The proposed rule includes a variety of discussions and proposals related to expanded packaging of services under the OPPS. We will address three of these in this section of our comments.

1. Proposed Packaging of Guidance Services (72 FR 42654)

As an initial step toward creating larger payment groups for hospital outpatient care, CMS proposes to package payment for items and services in the seven categories into the payment for the primary diagnostic or therapeutic modality to which CMS believes these items and services are typically ancillary and supportive. CMS refers to the codes they are proposing to package as "dependent services" and uses the term "independent service" to refer to the codes that represent the primary therapeutic or diagnostic modality into which they are proposing to package payment for the dependent service.

One of the seven categories proposed for packaging are guidance services, specifically those codes that are reported for supportive guidance services such as ultrasound and fluoroscopy that aid the performance of an independent procedure. Table 8 of the proposed rule "Guidance HCPCS Codes Proposed for Packaged Payment in CY 2008" includes the following 5 radiation oncology codes that are used in Image Guided Radiation Therapy (IGRT):

CPT Code	CPT Descriptor
76950	Ultrasonic guidance for placement of radiation therapy fields
76965	Ultrasonic guidance for interstitial radioelement application
77417	Therapeutic radiology port film(s)
77421	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy
77014	Computed tomography guidance for placement of radiation therapy fields

Because these dependent guidance procedures support the performance of an independent procedure and they are generally provided in the same operative session as the independent procedure, CMS believes that it would be appropriate to package their payment into the OPPS payment for the independent procedure performed. However, as CMS appropriately notes, guidance services differ from some of the other categories of services that they are proposing to package for CY 2008. Hospitals sometimes may have the option of choosing whether to perform a guidance service immediately preceding or during the main independent procedure, or not at all, unlike many of the imaging supervision and interpretation services, for example, which are generally always reported when the independent procedure is performed. Thus, hospitals have several options regarding the performance and types of guidance services they use.

CMS believes that hospitals utilize the most appropriate form of guidance for the specific procedure that is performed. Appropriately, CMS does not want to create payment incentives to use guidance for all independent procedures or to provide one form of guidance instead of another. Likewise, we do not believe CMS should create payment incentives to avoid the use of quality-enhancing services for financial reasons. CMS expects to "carefully monitor any

changes in billing practices on a service-specific and hospital-specific basis to determine whether there is reason to request that Quality Improvement Organizations (QIOs) review the quality of care furnished or to request that Program Safeguard Contractors review the claims against the medical record."

In the case of IGRT, we share CMS' concern about the potential impact of the proposed packaging to the quality of care. The use of IGRT is increasing within and across hospitals as the added benefits of more precise radiation therapy become more widely recognized. We are extremely concerned that the packaging of IGRT will hamper the adoption and continued use of this valuable service.

In addition, we are concerned that the proposed payments for radiation oncology services may not reflect the full costs of the packaged services. The proposed reduction in payment for APC 0313 Brachytherapy from $789.70 to $739.46 highlights our concerns. As shown in the table below, the claims for the family of HDR brachytherapy codes (77781-77784) that also have IGRT codes on the claims have average IGRT costs ranging from $73.59 to $213.32.

CPT Code	CPT Descriptor	Average IGRT Cost on Brachytherapy Claim
77781	Remote afterloading high intensity brachytherapy; 1-4 source positions or catheters	$ 213.32
77782	Remote afterloading high intensity brachytherapy; 5-8 source positions or catheters	$ 156.87
77783	Remote afterloading high intensity brachytherapy; 9-12 source positions or catheters	$ 73.59
77784	Remote afterloading high intensity brachytherapy; over 12 source positions or catheters	$ 120.83

Despite the packaging of IGRT into the HDR brachytherapy codes, the median costs of the APC decreased. This anomalous drop in median costs may relate to the elimination of certain radiation oncology codes from the bypass list. Regardless of the cause, to preclude separate payment for IGRT and then to decrease the payments for the services to which they are packaged is an unacceptable consequence of the CMS proposal.

Consistent with the recommendations of the APC Panel during their September 2007 meeting, ASTRO urges CMS to withdraw its proposal to package the IGRT codes 76950, 76965, 77417, 77421 and 77014.

2. Proposed Packaging of Diagnostic Radiopharmaceuticals (72 FR 42667)

CMS proposes to package payment for diagnostic radiopharmaceuticals into the payment for diagnostic nuclear medicine procedures for CY 2008 to encourage hospitals to use the most cost efficient diagnostic radiopharmaceutical products that are clinically appropriate. CMS identified

diagnostic radiopharmaceuticals as those Level II HCPCS codes that include the term "diagnostic" along with a radiopharmaceutical in their long code descriptors. The diagnostic radiopharmaceutical HCPCS codes proposed for packaged payment in CY 2008 are listed in Table 17 of the proposed rule. CMS inappropriately included in Table 17 the following two codes that describe critical components of radioimmunotherapy:

A9542 Indium IN-111 ibritumomab tiuxetan, diagnostic, per study dose, up to 5 millicuries
A9544 Iodine I-131 tositumomab, diagnostic, per study dose

Radioimmunotherapy is completely distinct from the broader class of radiopharmaceuticals which are generally used for medical diagnostic purposes. Radioimmunotherapy involves the combination of a monoclonal antibody and a radiation emitting molecule or isotope. The monoclonal antibody attaches to a specific molecule on the cancer cells and the isotope emits radiation to kill the cells to which the monoclonal antibody has attached. This revolutionary and underutilized therapy results in the killing of cancer cells while sparing normal tissue cells.

Two radioimmunotherapies have been approved by the FDA for the treatment of certain types of non-Hodgkin's lymphoma. The brand names are Zevalin and Bexxar. The monoclonal antibody in Zevalin is ibritumomab tiuxetan while the monoclonal antibody in Bexxar is tositumomab. These therapies differ from traditional chemotherapy in that the entire treatment takes place over 7-14 days in several steps that comprise a single therapeutic intervention as opposed to multiple repeated cycles with traditional chemotherapy

Zevalin and Bexxar therapies involve in part the intravenous administration of two distinct radiolabeled components on different days. The initial administration uses a lower level of radioactivity. It is used to assess the biodistribution of Zevalin or to calculate the therapeutic dose of Bexxar. For both products, a nuclear scan is performed after this administration; perhaps this is why CMS considers this component of therapy to be diagnostic. However, the scans are not truly diagnostic because the patient's diagnosis of non-Hodgkins lymphoma is already known. Rather, this component of radioimmunotherapy is an integral part of the FDA-approved therapeutic regimen. It represents the initiation of therapy, not the diagnosis of disease. The primary purpose of every component and step of radioimmunotherapy is therapeutic, not diagnostic.

Regardless of how the products are classified, the proposed packaging of this component of Zevalin and Bexxar therapies will result in grossly inadequate payment for the products. A nuclear medicine procedure used in the assessment of the biodistribution of Zevalin or in the calculation of the dose of Bexxar is 78804 *Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging.* The 2008 proposed payment for code 78804 is $1,022.88. However, the estimated hospital acquisition cost for the Zevalin code A9542 is approximately $2,800; for the Bexxar code A9544 it is approximately $2,600. Although packaging is intended to encourage hospitals to use the most cost efficient diagnostic radiopharmaceutical product that is clinically appropriate, for this patient population there are no other products available. With payment rates that will not cover even half the cost of the products, patient access to the radioimmunotherapy will be impeded, as hospitals may no longer be able to make this therapy available to Medicare beneficiaries.

We strongly urge CMS to withdraw its proposal to package codes A9542 and A9544. Additional comments regarding Zevalin and Bexxar are provided in section VII of our comments below.

3. Composite APCs - Prostate LDR (72 FR 42679)

To further address growth in the OPPS and create stronger incentives for efficiency, CMS proposes a new concept of "composite APCs" and proposes to create two such APCs in CY 2008. In a composite APC, Medicare would pay a single rate for a service which is described and reported with a combination of HCPCS codes on the same date of service (or different dates of service) rather than continuing to pay for the individual services under service-specific APCs.

The proposed rule says that composite APCs will be considered where the claims data show that combinations of services are commonly furnished together. CMS believes that composite APCs will enable use of more valid and complete claims data, create hospital incentives for efficiency, and provide hospitals with significant flexibility to manage their resources that does not exist when payment is made on a per service basis. The two composite APCs proposed for CY 2008 are:

1) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC
2) Cardiac Electrophysiologic Evaluation and Ablation Composite APC

Our comments address the LDR prostate brachytherapy composite APC. LDR is a treatment for prostate cancer in which needles or catheters are inserted into the prostate, and then radioactive sources are permanently implanted into the prostate through the hollow needles or catheters. The needles or catheters are then removed from the body, leaving the radioactive sources in the prostate forever, where they slowly give off radiation to destroy the cancer cells until the sources are no longer radioactive. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles or catheters and application of the brachytherapy sources. LDR prostate brachytherapy cannot be furnished without the services described by both of these codes.

CMS proposes to create a composite APC 8001, titled "LDR Prostate Brachytherapy Composite," that would provide one bundled payment for LDR prostate brachytherapy when a hospital bills these two CPT codes as component services provided during the same hospital encounter:

— 55875 *Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy*; and
— 77778 *Interstitial radiation source application; complex.* These two CPT codes are assigned status indicator "Q" to signify their conditionally packaged status.

Hospitals that furnish LDR prostate brachytherapy would report CPT codes 55875 and 77778 and the codes for the applicable brachytherapy sources in the same manner that they currently report these items and services (in addition to reporting any other services provided), using the same HCPCS codes and reporting the same charges. CMS will require that hospitals report both

CPT codes resulting in the composite APC payment on the same claim when they are furnished to a single Medicare beneficiary in the same facility on the same date of service.

ASTRO is cautiously supportive of this proposal with the exception of the packaging of image guidance which we believe should continue to be eligible for separate payment as discussed in the previous section of our comments. Also, we believe this major change in the APCs must be closely monitored to be certain that access to this important therapy is not compromised by this change in payment policy. We recommend that CMS report back on this specific issue in the future.

III. OPPS: New HCPCS and CPT Codes (72 FR 42701)

CMS proposes to continue the policy of recognizing new mid-year Category III CPT that the AMA releases in January for implementation the following July through the OPPS quarterly update process. Five Category III CPT codes that were implemented in July 2007 are listed in Table 27 of the proposed rule. One of the five codes is the radiation oncology code 0182T *High dose rate electronic brachytherapy, per fraction* which is proposed for assignment to APC 1519 New Technology - Level IXX with a proposed payment rate of $1,750.

The new Category III code 0182T *High dose rate electronic brachytherapy, per fraction* was approved by the CPT Editorial Panel during their October 2006 panel meeting. The request for this new Category III code was submitted by ASTRO. At the time of our application, there were no CPT or HCPCS codes that described the delivery of HDR x-ray radiation therapy utilizing an x-ray tube. In our application, we explained that this technology utilizes electronically-generated photons, not radioactive isotopes and that it has different resource costs than the current high dose rate (HDR) brachytherapy codes listed in CPT which describe the delivery of HDR radiation therapy using a radioactive source and high dose rate afterloader.

The table below lists the APCs and proposed 2007 payment rates for the three major families of brachytherapy that are described in CPT (intracavitary radiation source application, interstitial radiation source application and remote afterloading high intensity brachytherapy):

APC	APC Title	Proposed 2008 Payment Rate
0312	Radioelement Applications	$534.48
0313	Brachytherapy	$739.46
0651	Complex Interstitial Radiation Source Application	$981.88

Please note that the proposed payment rate of $1,750 for CPT code 0182T *High dose rate electronic brachytherapy, per fraction* is more than three times the payment rate for APC 0312, more than double the payment rate for APC 0313 and nearly double the payment rate for APC 651. While we applaud CMS for promptly incorporating new technologies into the OPPS and we acknowledge the problems faced by CMS in establishing payment rates for new technologies for which no hospital charge data is available, we are concerned that the payment rate of $1,750

is excessive relative to these other brachytherapy services and that it will encourage the adoption of an emerging technology where the risks and benefits have not been clearly established.

While we cannot be certain of the charges that hospitals might submit and we have not done a formal analysis of the resource costs associated with 0182T *High dose rate electronic brachytherapy, per fraction*, we are confident that they should be more in line with the other brachytherapy codes.

For Category III codes that will be issued in the future, we also recommend that CMS contact the relevant physician specialty society regarding any OPPS issues related to the outpatient hospital coding and payment of the services and procedures described by these codes. We understand that CMS must sometimes act quickly and that the views of stakeholders other than physicians must be considered. However, we believe physician specialty societies are in a unique position to provide advice because of their technical expertise, their day-to-day interactions with patients and the absence of financial incentives under the OPPS.

IV. OPPS: 2 Times Rule (72 FR 42703)

Section 1833(t)(2) of the Act provides that the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (referred to as the "2 times rule"). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services.

APC 0664 Level I Proton Beam Radiation Therapy is included in Table 28 of the proposed rule "Proposed APC Exceptions to the 2 Times Rule for CY 2008." We support the CMS decision to make an exception to the 2 times rule for this APC since this therapy is offered in only two facilities in the country. However, because of our concerns over the proposed reductions in payment for proton beam radiation therapy, we compared the payment rates and median costs in 2007 for the codes that describe these services to the proposed payment rates and median costs that have been proposed for 2008. As shown in the table below, the payments are proposed to be decreased by 27 percent, consistent with a significant reduction in median costs.

HCPCS	Description	APC	Payment Rate 2007 Final	Payment Rate 2008 Proposed	% change	Median Cost 2007	Median Cost 2008	% change
77520	Proton trmt, simple w/o comp	0664	$1,161.29	$ 845.50	-27%	277.19	267.2	-4%
77522	Proton trmt, simple w/comp	0664	$1,161.29	$ 845.50	-27%	1154.52	835.04	-28%
77523	Proton trmt, intermediate	0667	$1,389.37	$1,011.71	-27%	1381.26	999.19	-28%
77525	Proton treatment, complex	0667	$1,389.37	$1,011.71	-27%	734.54	708.07	-4%

Proton beam therapy is another form of precise radiation treatment for cancer that minimizes damage to healthy tissue and surrounding organs. However, it is an extremely complex and expensive technology that is currently offered in only two hospitals in the United States. To our knowledge, the charges for proton beam therapy by these institutions have not been reduced. Consequently, we believe there may be an error in the underlying data or in the analysis of the median costs.

We ask that CMS re-check its calculations and make any necessary corrections in the final rule. If there is a valid reason, consistent with the CMS methodology of calculating median costs and APC payments that accounts for the decreased median costs we then ask that CMS take into account that for any service provided by only two hospitals, the payment rates for the service will be highly dependent on the idiosyncrasies of billing and charging practices of those two hospitals.

We believe that other major medical centers are considering or have committed to adding proton beam therapy to their arsenal of weapons for the treatment of cancer. A 27 percent reduction in payment will discourage if not eliminate the further adoption of this useful technology. We recommend that CMS maintain the current rates for APCs 0664 and 0667 for 2 to 3 years, pending the collection of additional charge data from other hospitals that will adopt this technology in the future.

V. Other Services in New Technology APCs (72 FR 42705)

There are five procedures currently assigned to New Technology APCs for CY 2007 for which CMS believes the data are now adequate to support their reassignment to clinical APCs. One of these is a radiation oncology related procedure: CPT code 19298 *Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance*. For CY 2008, CMS proposes to reassign this procedure from APC 1524 New Technology - Level XXIV with a payment rate of $3,250 to APC 0648 Level IV Breast Surgery with a payment rate of $3,372.

ASTRO supports this proposal which also has the effect of placing the three surgical codes related to the placement of the catheters for breast brachytherapy (CPT codes 19296, 19297 and 19298) into the same APC.

VI. SRS Treatment Delivery Services (72 FR 42716)

The proposed rule includes a review of the complex history of the coding and APC assignments for this category of radiation oncology services. For CY 2007, the CPT Editorial Panel created four new SRS Category I CPT codes: 77371, 77372, 77373, and 77435.

Of the four CPT codes, CPT codes 77371 and 77435 were recognized under the OPPS effective January 1, 2007, while CPT codes 77372 and 77373 were not. CPT code 77372 has been reported under one of two HCPCS codes, depending on the technology used, specifically, G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session) and G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment). CPT code 77373 has been reported under one of three HCPCS codes depending on the circumstances and technology used, specifically, G0251 (Linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment); G0339 (Image-guided robotic linear

accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment); and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment).

CMS received requests from ASTRO and other stakeholders to recognize CPT codes 77372 and 77373 under the OPPS rather than continuing to use the current Level II HCPCS codes. CMS notes that the hospital claims data continues to reflect significantly different hospital resources that would lead to violations of the 2 times rule were they to reassign certain procedures to the same clinical APCs in order to crosswalk the CY 2006 historical claims data for the four G-codes to develop the median costs of the APCs to which the two CPT codes would be assigned if they were to be recognized. Therefore, CMS proposes to continue to assign HCPCS codes G0173 and G0339 to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), HCPCS code G0251 to APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), and HCPCS code G0340 to APC 0066 (Level II Stereotactic Radiosurgery, MRgFUS, and MEG) for CY 2008.

ASTRO remains opposed to the continued use of G codes when CPT codes exist that describe the same services. The existence of codes that describe the same services is extremely problematic for hospitals since not all payers recognize Medicare's temporary HCPCS codes. We recommend that APCs 0065, 0066 and 0067 be combined into a single APC containing the following codes:

CPT Code	CPT Descriptor
77372	Srs, linear based
77373	Sbrt delivery
95966	Meg, evoked, single
95967	Meg, evoked, each addÆl
95965	Meg, spontaneous
0071T	U/s leiomyomata ablate <200
0072T	U/s leiomyomata ablate >200

Based on the median costs of the codes currently assigned to this APC, we estimate the median cost of this collapsed APC would be approximately $2,618. We acknowledge that collapsing three existing APCs creates a violation of the 2 times rule. However, we believe an exception should be made since the services described by the current G codes are appropriately described by the new CPT codes. The advantages of our recommendation include a reduction in the number of APCs for SRS, thus providing more clarity to hospitals when billing for SRS and SBRT procedures. In addition, ASTRO believes our recommendation to use existing CPT codes whenever possible instead of G codes is similar to the recent APC panel recommendations made during the September 2007 panel whereby the Panel recommended the use of existing CPT codes for cardiac rehabilitation services instead of the CMS proposed G codes.

VII. OPPS: Payment for Therapeutic Radiopharmaceuticals (72 FR 42738)

In CY 2006 and CY 2007, non-packaged radiopharmaceuticals were paid based on a hospital's charge for each radiopharmaceutical agent adjusted to cost using each hospital's overall cost CCR. This has been considered an interim step while CMS collected better data and explored alternative payment methodologies for setting payment rates.

For the CY 2008 proposed rule, CMS proposes to package payment for all diagnostic radiopharmaceuticals (see our comments in section I. B. above on the adverse impact of this proposal on radioimmunotherapy). For therapeutic radiopharmaceuticals, CMS proposes that their CY 2008 payment be based on CY 2006 claims data. Costs would be determined using the standard OPPS rate-setting methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges and defaulting to hospital-specific overall CCRs if appropriate departmental CCRs are unavailable. Included on the list of therapeutic radiopharmaceuticals proposed for this payment methodology in CY 2008 are the codes for the "hot" doses of the radioimmunotherapy regimens, Zevalin and Bexxar. Our comments that follow address only these two products.

CMS believes that the CY 2006 claims data reflect both the radiopharmaceutical charge and associated overhead charges and asserts that setting CY 2008 prospective payment rates based on CY 2006 hospital claims data provides an acceptable combined proxy for average hospital acquisition costs and radiopharmaceutical handling. However, CMS acknowledges having received stakeholder reports that costs for the most expensive radiopharmaceuticals are understated in OPPS claims data and specifically invites comment on how the proposed CY 2008 OPPS payment rates for therapeutic radiopharmaceuticals compare with the acquisition and associated handling costs of an efficient provider.

While we do not have external data on hospital acquisition costs and the costs of radiopharmaceutical handling for Zevalin and Bexxar, we are confident that the proposed payments are grossly nonrespresentative and that CMS must make an exception to the proposed payment methodology or patients will not have appropriate access to these valuable therapies. To assess the reasonableness of the proposed payment rates, we looked to the published Average Wholesale Prices (AWPs) in the July 2007 RedBook. We acknowledge that AWPs may not be closely related to actual acquisition costs but it is the experience of our members that hospitals are unable to obtain significant rebates or discounts when acquiring these products. Thus, the actual acquisition costs are undoubtedly closer to the published AWPs than the proposed payment rates. We also looked to the published payments established by Medicare carriers for Zevalin and Bexxar "hot" doses when they are administered in physicians' offices. A comparison of the proposed OPPS payment, the AWPs and the carrier fee schedule amounts shown in the table below clearly indicate that the proposed payment rates will be insufficient to cover the hospitals' estimated acquisition costs (as reflected by the carriers' fee schedule amounts), let alone the compounding and handling costs associated with these complex products.

CPT Code	CPT Descriptor	Proposed CY 2008 Payment	July 2007 Red Book AWP	NHIC, Noridian & TrailBlazer Fee Schedules
A9543	Y90 ibritumomab, rx (Zevalin)	$12,030	$25, 239	$23,977
A9545	I131 tositumomab, rx (Bexxar)	$8,283	$24,102	$22,897

We note that in the proposed rule, CMS considered but rejected continuation of the current methodology of payments based on individual case charges reduced to costs using hospital-specific overall CCRs because of a belief that such cost-based payments do not provide appropriate economic incentives for efficiency. In the case of radioimmunotherapy, the proposed payment rates simply cannot be viewed as providing appropriate economic incentives for efficiency. On the contrary, they create a very powerful economic incentive not to use radioimmunotherapy. For patients with certain types of non-Hodgkins lymphoma, hospitals are likely to turn to traditional, but often less effective, chemotherapy because those drugs are reasonably paid at ASP + 6 percent.

To assure continued access to radioimmunotherapy by Medicare beneficiaries, we urge CMS to make an exception to its proposed payment policy for therapeutic radiopharmaceuticals and to continue in 2008 the current methodology of paying for Zevalin and Bexxar based on individual case charges reduced to costs using hospital-specific overall CCRs. We recognize this may be viewed as a temporary solution to a complex problem. However, it will provide another year to evaluate other options, including the use of the Federally-reported average manufacturer's prices (AMPs) when these prices become publicly available (late in 2008 or early in 2009) or the use of average sales price (ASP) data if the manufacturers of the products would agree to report this information. We note that all the products used in the complete Zevalin and Bexxar regimens have been assigned National Drug Codes (NDCs) to which Medicare prices could be assigned.

VIII. OPPS: Brachytherapy (72 FR 42747)

Section 1833(t)(2)(H) of the Act, as amended by section 107(b)(1) of the TRHCA, requires separate payment groups based on stranded and non-stranded devices on or after July 1, 2007. To implement this requirement, CMS created six new HCPCS codes to differentiate the stranded and non-stranded versions of iodine, palladium and cesium sources. These six new HCPCS codes replaced the three prior brachytherapy source HCPCS codes for iodine, palladium and cesium (C1718, C1720, and C2633), all of which were deleted as of July 1, 2007.

Because CMS is required to create separate APC groups for stranded and non-stranded sources and because the CY 2006 billing codes did not differentiate stranded and non-stranded sources, CMS proposes to make certain assumptions when they estimate the median costs for stranded and non-stranded (low activity) iodine-125, palladium-103, and cesium-131 based on the CY 2006 aggregate claims data. CMS proposes to calculate median costs for stranded sources based on the 60th percentile of the aggregate data and the 40th percentile of the aggregate data for non-stranded sources. The difference in the proposed payments for the codes is shown in the table below:

HCPCS Code	Long Descriptor	Proposed CY 2008 Payment Rate
C2638	Brachytherapy source, stranded, Iodine-125, per source	$42.86
C2639	Brachytherapy source, non-stranded, Iodine-125, per source	$31.91
C2640	Brachytherapy source, stranded, Palladium-103, per source	$62.24
C2641	Brachytherapy source, non-stranded, Palladium-103, per source	$45.29
C2642	Brachytherapy source, stranded, Cesium-131, per source	$97.72
C2643	Brachytherapy source, non-stranded, Cesium-131, per source	$51.35

The increased payment for each of the sources may not seem significant on a per source basis but when the number of sources used per procedure is taken into account, the increased payment for stranded sources becomes significant, as shown in the table below.

Source	Increased Payment for Stranded, per Source	Total Increased Payment for Stranded, Assuming 50 Sources	Total Increased Payment for Stranded, Assuming 100 Sources
Iodine-125	$10.95	$547.59	$1,095
Palladium-103	$16.95	$847.50	$1,695
Cesium-131	$46.37	$2,318.50	$4,637

ASTRO acknowledges the statutory requirement to create separate APC groups for stranded and non-stranded brachytherapy sources. However, we are concerned that the extent of the increased payments may encourage the utilization of stranded sources for other than clinical reasons and create perverse incentives in the marketplace. ASTRO encourages CMS to consider a revision of the proposal to calculate median costs for stranded sources based on the 60th percentile of the aggregate data and the 40th percentile of the aggregate data for non-stranded sources so that payment rates in CY 2008 do not create such drastic payment differentials for brachytherapy sources in absence of claims data.

IX. OPPS: Inpatient Procedures (72 FR 42771)

During the March 2007 APC Panel meeting, CMS solicited input on the appropriateness of removing 13 procedures currently on the OPPS inpatient list because they widely performed on an outpatient basis. The APC Panel recommended that CMS remove the 13 procedures from the OPPS inpatient list for CY 2008 and assign them to clinically appropriate APCs as shown in

Table 56 of the proposed rule. Included in Table 56 is CPT code 61770 *Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for placement of radiation source* which CMS proposes to assign to APC 0221 *Level II Nerve Procedures* with a proposed payment rate of $2,041.

ASTRO supports this proposal. APC 0221 *Level II Nerve Procedures* includes other procedures that are comparable clinically and whose resource costs should also be comparable, e.g., 61720 *Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus.* Because 2007 will be the first year for which payment will be made under the OPPS, we recommend that CMS re-evaluate the APC assignment for code 61770 when actual charge data becomes available.

X. Quality Data (72 FR 42799)

Under amendments to the Social Security Act made by section 109(a) of the MIEA–TRHCA, CMS is required to establish a program under which hospitals will report data on the quality of hospital outpatient care using standardized measures of care to receive the full annual update to the OPPS payment rate, effective for payments beginning in CY 2009. CMS refers to the program established under these amendments as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). These amendments are consistent with CMS plans described in the CY 2007 OPPS/ASC final rule.

In the proposed rule for CY 2008, CMS identifies 10 quality measures that are both applicable to care provided in hospital outpatient settings and likely to be sufficiently developed to permit data collection consistent with the timeframes defined by statute. These measures address care provided to a large number of adult patients in hospital outpatient settings, across a diverse set of conditions, and were selected for the initial set of HOP QDRP measures based on their relevance as a set to all hospitals.

In addition, CMS seeks public comment on 30 additional measures, which have been identified as hospital outpatient-appropriate measures and are under consideration for inclusion in the HOP QDRP measure set, for CY 2010 or subsequent calendar years. One of the potential indicators is "Radiation therapy is administered within 1 year of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer."

ASTRO strongly supports inclusion of this radiation oncology measure in the Hospital Outpatient Quality Data Reporting Program measure set. We believe this quality measure is critical to ensuring evidence-based and well-coordinated cancer care. This measure emphasizes the importance of coordinating patient transitions between surgeons and radiation oncologists and is consistent with well-established National Comprehensive Cancer Network clinical practice guidelines for oncology supporting the benefit of postoperative radiation in lowering local recurrence rates. This measure was also endorsed by the NQF on May 9, 2007.

This measure also addresses a key gap in care among breast cancer patients who too frequently do not receive the recommended adjuvant therapy following surgery. A study published in the June 20, 2007 *Journal of Clinical Oncology* by researchers at Mount Sinai School of Medicine

found that 34% of female breast cancer patients did not receive adjuvant radiation therapy because of a combination of system failures, surgeon perceptions, and non-adherence. Further, this study, funded by the Agency for Healthcare Research and Quality as well as the National Center for on Minority Health and Health Disparities, found that this gap in care is particularly pronounced in minority women.

We also believe this measure should be assigned a high priority because it is one of few measures that accounts for effective care coordination, which is vital in caring for cancer patients, and addresses the significant number of Medicare beneficiaries with breast cancer. Additionally, increasing performance on this measure is anticipated to narrow the gaps in care for minority women. According to the American Cancer Society, an estimated 178,480 new cases of invasive breast cancer are expected to occur among women in the United States during 2007. An estimated 40,460 women a year will die from breast cancer.

Furthermore, we would note that the AMA-PCPI Oncology Workgroup, which is co-hosted by ASTRO, has decided not to develop, through a consensus based process, a physician-level measure of radiation therapy post-breast conserving surgery, and thus this measure will be removed from the 2007 Physicians Quality Reporting Initiative. The workgroup felt that this measure is most appropriate at the facility level, as the gaps in care are typically related to systems failures. We are pleased that CMS included this measure in this proposed rule. ASTRO agrees with that decision and strongly recommends incorporation of this measure in the HOP QDRP in 2008. As physicians who provide radiation therapy for women with breast cancer, we believe including this quality indicator will help to ensure all Medicare beneficiaries with breast cancer are evaluated and offered the most appropriate therapy and will help to overcome the barriers and biases that lead to under use of this important therapy.

Conclusion

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Trisha Crishock, MSW, Director, Health Policy and Economics Department at (703) 502-1550.

Respectfully,

Laura Thevenot

Laura Thevenot
ASTRO, Executive Director

cc: Herb Kuhn
Kenneth Simon, MD
Edith Hambrick, MD
Carol Bazell, MD, MPH
Trisha Crishock, MSW

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QUAIL
Surgical & Pain Management Center

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September 12, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: **Comments on CMS-1392-P; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (High – Energy Extracorporeal Shock Wave Therapy)**

Dear Sirs:

I believe that I am uniquely qualified to comment on the use of extracorporeal shock wave technology (ESWT) for the treatment of Lateral Epicondylitis and Plantar Fasciitis. I am an anesthesiologist, the medical director of a surgery center, and have personally undergone ESWT treatment for Plantar Fasciitis of my right foot.

Studies show that the efficacy rates of high energy ESWT are greater and better patient outcomes are achieved, when patients are treated with the appropriate high energy level. Treating with the proper high energy level, typically results in the patient requiring only a single treatment. However, it is difficult if not impossible, for patients to tolerate sufficient energy levels to achieve maximum clinical efficacy without general anesthesia, which can only be safely administered in a facility such as a hospital or ambulatory surgical center (ASC).

It is not safe for a patient to receive general anesthesia in an office setting, especially for Medicare aged patients who often have multiple co-morbidities. Patient safety is better assured in an operating room setting with the appropriate monitoring, personnel and equipment. Performing high energy ESWT in a physician office allows for too many different treatment protocols (inappropriate low energy levels) with varying clinical outcomes. Since patients are unable to tolerate the recommended higher energy levels of ESWT without general anesthesia, this ultimately increases costs to the Medicare program due to ineffective and multiple repeat procedures.

I urge the Centers for Medicare and Medical Services not to adopt the proposed Payment

QUAIL
Surgical & Pain Management Center

Indicator for High-Energy ESWT for plantar fasciitis. Although the final rule on ASC payments recognizes the appropriate site of service as a facility setting, the proposed 2008 payment schedule suggests that the procedure is performed mostly in the physician office setting, which I believe to be incorrect. Further, unless the appropriate payment indicator is recognized, Medicare beneficiaries will be denied access to highly effective treatment. Therefore, I request the agency to retain the Payment Indicator (G2) for CPT code 28890, as published in the final 2008 ASC rule.

Sincerely,

Peter J. Kasprzak, M.D.

Peter J. Kasprzak, M.D.

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TEXAS HEALTH RESOURCES

September 13, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1392-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (Vol. 72, No. 148), August 2, 2007.

Dear Mr. Weems:

On behalf of Texas Health Resources (THR) and its 13 faith-based, nonprofit community hospitals throughout north Texas, including Harris Methodist Hospitals, Arlington Memorial Hospital and Presbyterian Healthcare System, we appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year (CY) 2008 hospital outpatient prospective payment system (OPPS).

THR is commenting on several OPPS proposals. Most importantly, we have serious concerns about the proposed packaging rules, requirements for outpatient quality measure reporting, and replaced devices. THR makes the following recommendations.

OPPS: PACKAGED PROPOSAL

Increasing Packaged Services

THR supports efforts to package more services into larger payment bundles. However, we understand that underlying analysis behind the proposal needs further examination. Our concern is that the assertions of CMS' impact tables yield very different impacts by the types of hospital. Secondly, particular attention is needed regarding the proposal to package observation services. CMS should simplify and clarify definitions and instructions for the reporting of observation services. THR urges CMS to exclude at this time observation services from its final packaging strategy. THR supports the continuation of separately payable status for observation services.

Composite Ambulatory Payment Classifications (APCs)

Concerning the creation of two "composite" APCs, THR urges CMS to evaluate the impact of the new bundles on payment adequacy and access to care before expansion of this new policy to other services.

OPPS: QUALITY DATA

Quality Measures

THR agrees that CMS should continue the precedent of tracking Hospital Quality Alliance (HQA) in the implementation of the hospital quality reporting programs. However, the HQA has only preliminarily approved these measures because several of them have not yet been endorsed by the National Quality Forum (NQF), and all of them need work to further refine the specifications for data collection. The HQA will not proceed with measures that do not receive NQF endorsement or that are not fully specified and tested to ensure proper data collection can be achieved. As a result, THR urges CMS to delay data collection until CY 2009, so that the measures can be thoroughly field-tested and receive NQF endorsement, the data specifications can be finalized, and the data collection software is fully operational. There is no requirement in the statute that data collection begin on January 1, 2008. THR urges data collection to begin in 2009 when the hospitals and vendors are fully prepared to commence the program.

Timing of Implementation

The timeline for implementation of outpatient reporting will be extremely difficult due to the complexities of building data collection information systems. Even hospitals with developed electronic health records will need additional time to comply, and development costs will be significant. THR supports the American Hospital Association's (AHA) recommendation that encourages "...CMS to delay data collection on the outpatient measures until the measures have been fully field-tested and received NQF endorsement, the data specifications have been finalized, and the data collection software is fully operational. There is no requirement in the statute that data collection begin on January 1, 2008. For CY 2009 payment purposes, data collection could begin later in the year when the hospitals and vendors are fully prepared to commence the program."

Data Submission Timeframe

THR urges CMS to make sure data collection software is available on the first day of the data submission period. Programming must be complete and tested.

Data Validation

For CY 2009, THR recommends that data validation be conducted as a learning tool for hospitals. There should be no minimum reliability threshold required for the annual payment update. Reliability thresholds should start at lower levels and gradually rise to 80 percent.

Reconsiderations Process

THR advocates that the reconsideration process be straightforward, transparent, and timely. Clear guidance on how to submit appeals must be provided, and CMS must expedite appeal decisions.

REPLACED DEVICES

THR supports the AHA recommendation that the reduced payment threshold be increased from 20 percent to 50 percent.

CMS should consider industry concerns about proper billing of devices being evaluated during a warranty service period. Hospitals frequently do not know whether a manufacturer will agree that a returned device is covered under the warranty.

Hospital Clinic Visits
CMS should not implement new codes that differentiate between new and established patient clinic visits. Payments should be based upon resources used, not based upon whether a patient has been seen in the hospitals within the last three years.

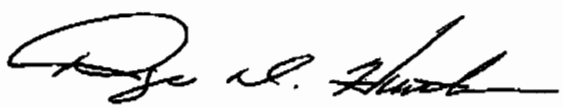
Emergency Department Critical Care Visits
THR recommends that the criteria for payment for critical care services a minimum of 15 minutes of critical care or the patient expires in spite of the administration of critical care services.

Proposed ED Treatment of Guidelines for 2008
CMS should develop or approve national guidelines for the reporting of hospital ED or clinic visits.

Inclusion of Separately Payable Services in Visit Levels
THR agrees with AHA that "In the absence of national guidelines, clarification from CMS as to whether separately payable procedures may now be included in hospital-specific guidelines is clearly needed."

Thank you for the opportunity to share our comments. If we can provide you or your staff with additional information, please do not hesitate to contact Joel Ballew, Director of Government Affairs, at 817-462-6794 or by e-mail at JoelBallew@TexasHealth.org.

Sincerely,



Douglas D. Hawthorne, FACHE
Chief Executive Officer
Texas Health Resources

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September 13, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1392-P
Comments on CMS Proposed Rule on Hospital Outpatient Prospective Payment System for 2008
Radiopharmaceuticals and Nuclear Medicine

Dear Mr. Weems:

Covidien Imaging Solutions, (formerly Tyco Healthcare/Mallinckrodt) as a manufacturer and marketer of radiopharmaceutical products is submitting these comments to the Centers for Medicare and Medicaid Services in response to the proposed changes to the Medicare hospital outpatient prospective payment system (HOPPS) for 2008. 72. Fed. Reg. 42,628 (Aug. 2, 2007).

We respectfully request that CMS *not move forward* with its proposal to package all diagnostic radiopharmaceuticals for 2008 but rather continue separate payment for all radiopharmaceutical products that meet the designated per day cost threshold ($55 for 2007).

Concerns

CMS' proposal to package diagnostic radiopharmaceuticals into the nuclear medicine procedure APCs is flawed for the following reasons:

1. Data analysis demonstrates that packaging of all diagnostic radiopharmaceuticals disrupts the clinical and resource use comparability standards associated with APC groupings. This creates financial disincentives for hospitals to use clinically appropriate diagnostic radiopharmaceuticals for patient care.

2. CMS acknowledges their understanding that radiopharmaceuticals are always intended to be used with a nuclear medicine procedure. However, CMS utilizes a rate setting methodology that allows claims without a diagnostic radiopharmaceutical HCPCS code to be utilized in the rate setting process. Data analysis demonstrates that inclusion of claims without a diagnostic radiopharmaceutical HCPCS code into the rate setting process consistently results in a lower median cost for the nuclear medicine APC.

3. Data published in the Aug 2nd Fed. Reg. Notice Table 15 (page 42668) details that for the highest volume nuclear medicine procedure, (procedure code 78465 which is a rest/stress nuclear cardiology procedure) only 9% of the total single bill claim volume was utilized to set the payment rate for the procedure. We believe that a 9% sample is not adequate to establish an appropriate payment rate and request that CMS explore options to expand the number of claims utilized for rate setting purposes.

4. CMS does not apply any appropriateness or medically reasonable edits to the paid claims files for both diagnostic and therapeutic radiopharmaceuticals as well as nuclear medicine procedure/radiopharmaceutical groupings. The lack of these appropriateness edits has, we believe, unfavorably impacted the median and mean cost calculations for select products/procedures

Summary Recommendations

1. CMS should continue to pay separately for diagnostic and therapeutic radiopharmaceuticals that meet a $55 per dose threshold (proposed $60 threshold for 2008).

2. CMS should create and utilize appropriateness edits of hospital reported claims data, and implement methodologies to ensure that claims utilized for rate setting appropriately and accurately capture the costs of radiopharmaceuticals and nuclear medicine procedures.

3. CMS should work throughout 2008 with stakeholders to develop more accurate, transparent data analysis and payment methodologies for these important specified covered outpatient drugs and their associated procedures for implementation in 2009.

Detailed Analysis

1. Data analysis/median cost simulations conducted by an outside consulting firm demonstrates the proposed change in packaging of all diagnostic radiopharmaceuticals disrupts the clinical and resource use comparability standards associated with APC groupings.

    a. Attachments 1-2 provides detailed analysis of select APC groupings which clearly demonstrate that packaging of the diagnostic radiopharmaceutical results in a significant loss of comparability both from a clinical and resource use perspective.

        i. Attachment 1-APC 408- Within this APC the range of median costs varies six fold ($303-$1819). Also each of the various tumor imaging radiopharmaceuticals most often associated with this APC are very specific to the type of tumor being imaged so packaging results in a loss of clinical comparability.

ii. Attachment 2-APC 414- Within this APC the range of median costs varies six fold ($207-$1629). This APC also combines infection imaging procedures with tumor imaging procedures with each of the various radiopharmaceutical products having very different clinical indications so once again there is a loss of clinical comparability within this APC due to packaging

2. CMS acknowledges their understanding that radiopharmaceuticals are always intended to be used with a nuclear medicine procedure. However, CMS utilizes a rate setting methodology that allows claims without a diagnostic radiopharmaceutical HCPCS code to be utilized in the rate setting process. Data analysis demonstrates that inclusion of claims without a diagnostic radiopharmaceutical HCPCS code into the rate setting process consistently results in a lower median cost for the nuclear medicine APC.

a. Attachment 3 demonstrates the finding that excluding claims that do not contain a radiopharmaceutical HCPCS code from the rate setting process has a significant impact on the median cost calculation for the APC

i. Attachment 3- APC 406-Note a simulated median cost rise from $283 to $359 for this APC

ii. A similar rise in simulated median cost calculation can also be seen in APC's 408 and 414 (Attachments 1 and 2)

3. Data published in the Aug 2nd Fed. Reg. Notice Table 15 (page 42668) details that for the highest volume nuclear medicine procedure, (procedure code 78465 which is a rest/stress nuclear cardiology procedure) only 9% of the total single bill claim volume was utilized to set the payment rate for the procedure. We believe that a 9% sample is not adequate to establish an appropriate payment rate and request that CMS include procedure code 93017 on the by-pass list.

a. Attachments 4 and 5 demonstrate that by placing procedure code 93017 on the by-pass list the number single claims available for rate setting rises dramatically

i. Attachment 4- APC 377- Level II Cardiac Imaging-Note a simulated increase in claims utilized for rate setting (from 9% to 80%)

ii. Attachment 5-APC 398- Level I Cardiac Imaging- Note a simulated increase in claims utilized for rate setting (from 48% to 73%)

4. CMS does not apply any appropriateness or medically reasonable edits to the paid claims files for diagnostic and therapeutic radiopharmaceuticals as well as nuclear medicine procedure/radiopharmaceutical groupings. The lack of these appropriateness edits may have a significant impact on the median and mean cost calculations for select radiopharmaceuticals.

a. For example:

Three diagnostic radiopharmaceutical products in our portfolio experienced significant coding nomenclature changes.

i. The HCPCS code descriptor for Tc99m labeled Red blood cells (A9560 in 2006) was changed from a per mCi description in 2005 to a per dose description in 2006

ii. The HCPCS code for Tc99m Mertiatide (A9562 in 2006) was changed from a per mCi description in 2005 to a per dose description in 2006

iii. The HCPCS code for In-111 Pentetreotide (A9565 in 2006) was changed from a per 3 mCi description in 2005 to a per mCi description in 2006

Analysis of the paid claims files for each for these individual codes still reveals tremendous variation in the units billed as you can see in Attachments 6-8. We believe this lack of data integrity is of concern

We reiterate our request that CMS allow for separate payment of diagnostic and therapeutic radiopharmaceuticals that meet the designated threshold in 2008 utilizing the current methodology. We respectfully request that CMS work throughout 2008 with stakeholders to develop more accurate, transparent, data analysis and payment methodologies for these important specified covered outpatient drugs and their associated procedures for implementation in 2009.

Thank you

Lisa Saake RN, MSN, MBA
Director, Healthcare Economics
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E-mail lisa.saake@covidien.com

Attachments/ Cc:Carol Bazell

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APC 408 Summary

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

[illegible] 78804 (APC 408)	Tumor Type per Package Insert	Median Cost Simulation for Claims with Four Diagnostic Radiopharmaceuticals Proposed to be Bundled into APC 408 Level III Tumor/Infection Imaging					
		Number of Single Claims	Median Cost per Single Claim	Mean Cost Per Single Claim	Minimum Cost per Single Claim	Maximum Cost per Single Claim	Coefficient of Variation
78804 Only Line on Claim	N/A	93	**364**	537	47	5,539	114
A9507 - In111 capromab	Biopsy-proven prostate cancer, clinically-localized in patients at high-risk for pelvic lymph node metastasis. Post-prostatectomy patient with a rising PSA in whom there is a high clinical suspicion of occult metastatic disease.	56	1,277	1,988	571	10,269	91
A9542 - In111 ibritumomab dx	Part of therapeutic regime-in patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkins lymphoma	94	1,819	2,675	310	28,165	133
A9556 - Ga67 gallium	Demonstrate the presence and extent of Hodgkins disease, lymphoma, and bronchogenic carcinoma. May be useful as an aid in detecting some acute inflammatory lesions	114	457	526	142	2,223	68
A9565 - In111 pentetreotide	Primary and metastatic neuroendocrine tumors bearing somatostatin receptors	377	1,305	2,252	251	14,210	113
Bundled Revenue Code Only (no other HCPCS on claim)	N/A	16	**303**	308	99	455	26
Other HCPCS Code	N/A	122	1,071	1,123	177	2,932	62
Total - All Single Major Claims		872	1,070	1,679	47	28,165	134
CMS Median Cost File Statistics		1,268	1,010	1,630	117	14,987	128
Total Frequency (per CMS)		2,318					
2008 Proposed Payment Rate		1,023					
SMAJ claim with Packaged Radiopharm (per NPRM Table 17)		**756**	**1,169**	**1,857**	**142**	**28,165**	**128**
% of SMAJ with Packaged Radiopharm		**87%**					

Minimum Median Cost per Case (78804 Only) **303**
Minimum Median Cost w Radiopharmaceutical on Claim **457**
Maximum median Cost w Radiopharmaceutical on Claim **1,819**

Observations:

1. APC 408 contains only one procedure code - CPT 78804
2. Example of four different radiopharmaceuticals that were used with this one procedure code in the 2006 single claims data.
3. The median cost for single claims varies widely depending on the radiopharmaceutical used (coefficient of variation is 113.82)
4. Combined procedure and radiopharmaceutical mean costs range from $2,697 to $536.
5. APC 408 - Level III Tumor/Infection Imaging is proposed to be paid at $1,022.88

Data Source: 2006 Medicare Outpatient claims as released in the 2008 OPPS proposed rule file.

Methodology notes: This data is not wage index adjusted or trimmed, nor does it include pseudo-singles. This is the primary reason for the difference in our calculated values in row 11 versus CMS' numbers in row 13.

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APC 414 Summary

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

Radiopharmaceutical with APC 414	Tumor Type per Package Insert	Median Cost Simulation for Claims with Select Diagnostic Radiopharmaceuticals Proposed to be Bundled into APC 414 Level II Tumor/Infection Imaging					
		Number of Single Claims	Median Cost per Single Claim	Mean Cost Per Single Claim	Minimum Cost per Single Claim	Maximum Cost per Single Claim	Coefficient of Variation
APC 414 Procedure Only Line on Claim	HCPCS: 78802, 78803, 78805, 78806, 78807	978	265	320	20	1,128	63
Bundled Revenue Code Only (no other HCPCS on claim)		313	207	272	47	1,199	75
A9521 - Technetium Tc-99m exametazine, up to 25 mCi		3,141	529	644	94	11,795	78
A9547 - In-111 oxyquinoline, dx, per 0.5 mCi		2,317	545	640	103	5,605	57
A9556 - Ga-67 gallium citrate, per mCi	Demonstrate the presence and extent of Hodgkins disease, lymphoma, and bronchogenic carcinoma. May be useful as an aid in detecting some acute inflammatory lesions	1,301	328	379	67	3,152	70
A9565 - In-111 pentetreotide, per mCi	Primary and metastatic neuroendocrine tumors bearing somatostatin receptors	1,244	1,068	1,657	63	14,210	111
A4641 - Diagnostic imaging agent		662	638	757	145	6,933	75
A9507 - In-111 capromab pendetide, up to 10 mCi	Biopsy-proven prostate cancer, clinically-localized in patients at high-risk for pelvic lymph node metastasis. Post-prostatectomy patient with a rising PSA in whom there is a high clinical suspicion of occult metastatic disease.	305	1,198	1,361	199	10,076	68
A9560 - Tc-99m labeled RBC, up to 30 mCi		210	973	1,138	110	10,269	95
A9500 - Tc-99m sestamibi, up to 40 mCi		165	367	432	140	1,456	48
A9542 - In-111 ibritumomab, dx, up to 5 mCi		143	1,629	2,357	260	28,165	129
A9508 - Iodine I-131 iobenguane sulfate, per 0.5 mCi		139	1,073	1,323	284	7,369	70
78890 - Nuclear medicine data proc		69	649	734	123	3,099	77
Other HCPCS Code		656	391	608	25	18,212	155
Total - All Single Major Claims		11,643	521	743	20	28,165	127
CMS Median Cost File Statistics		14,682	472	621	34	7,575	87
Total Frequency (per CMS)		25,129					
2008 Proposed Payment Rate		478					
SMAJ claim with Packaged Radiopharm (per NPRM Table 17)		10,042	579	806	25	28,165	121
% of SMAJ with Packaged Radiopharm		86%					

Minimum Cost per Case (APC 414 Only) 207
Minimum Cost w Radiopharmaceutical on Claim 328
Maximum Cost w Radiopharmaceutical on Claim 1,629

Data Source: 2006 Medicare Outpatient claims as released in the 2008 OPPS proposed rule file.

Methodology notes: This data is not wage index adjusted or trimmed, nor does it include pseudo-singles.

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APC 406 Summary

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

Radiopharmaceutical with APC 406	Tumor Type per Package Insert	Number of Single Claims	Median Cost per Single Claim	Mean Cost Per Single Claim	Minimum Cost per Single Claim	Maximum Cost per Single Claim	Coefficient of Variation
		Median Cost Simulation for Claims with Single Diagnostic Radiopharmaceuticals Proposed to be Bundled into APC 406 Level Tumor/Infection Imaging					
APC 406 Procedure Only Line on Claim	HCPCS: 78800, 78801, 78015, 78016, 78018	2,138	236	299	15	1,486	69
A9528 - I-131 sodium iodide capsule(s) per mCi		1,384	353	483	53	6,165	87
Bundled Revenue Code Only (no other HCPCS on claim)		734	339	569	54	5,676	125
A9500 - Tc-99m sestamibi, up to 40 mCi		500	224	318	51	2,648	67
A9516 - I-123 sodium iodide capsule(s), per 100 microcuries		382	548	657	108	3,413	71
A9530 - I-131 sodium iodide sol per mCi		201	320	360	75	2,138	67
A9529 - I-131 sodium iodide sol per mCi		191	309	453	118	2,260	74
A4641 - Diagnostic imaging agent		125	316	497	87	3,457	86
Other HCPCS Code		116	243	268	43	811	48
Total - All Single Major Claims		7,160	309	437	15	28,838	123
CMS Median Cost File Statistics		8,559	283	356	40	4,158	77
Total Frequency (per CMS)		10,675					
2008 Proposed Payment Rate		287					
SMAJ claim with Packaged Radiopharm (per NPRM Table 17)		**3,118**	**359**	**511**	**51**	**6,165**	**98**
% of SMAJ with Packaged Radiopharm		**44%**					

Minimum Cost per Case **224**
Minimum Cost w Radiopharmaceutical on Claim **224**
Maximum Cost w Radiopharmaceutical on Claim (excludes lines with therapeutic product) **548**

Data Source: 2006 Medicare Outpatient claims as released in the 2008 OPPS proposed rule file.

Methodology notes: This data is not wage index adjusted or trimmed, nor does it include pseudo-singles.

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Analysis of APC 377 - Level II Cardiac Imaging: Procedures billed on MMAJ Claims

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

Question: APC 377 includes one CPT® code: 78465. Why are <10% of occurences used in setting the payment rate?

From CMS Median Cost File

APC	Definition	SI	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean Cost	"True" Median Cost	CV	%Used in Median Cost Calculation
0377	Heart image (3d) multiple	S	765.25	51,583	566,252	189.57	3035.09	843.58	755.79	48.16	9.1%

	Claim Type per CMS	Count	Percent
SMAJ	Single Major Procedure (all used for median cost calculation)	30,636	5%
MMAJ	Multiple Major Procedures (some used for median cost calculation)	535,434	85%
OBS	Observation (None used for median cost calculation and not in above table)	60,237	10%
Total	**Untrimmed total volume**	**626,307**	**100%**

Median cost is based on set of 30,636 SMAJ + 16,063 (3% of MMAJ) + set of MMAJ pseudo-singles with 93017 on different date of service.
Is it clinically realistic to perform procedure without a cardiovascular stress test?

Simulation of Median Cost if 93017 is added to bypass list (includes application of CMS cost trimming methodology and wage index adj):

APC	Definition	SI		Single Frequency	Total Frequency	Trimmed Minimum Cost	Trimmed Maximum Cost	Mean Cost	"True" Median Cost	CV	%Used in Median Cost Calculation
0377	**Heart image (3d) multiple**	**S**		**454,102**	**566,252**	**249.58**	**2840.44**	**909.96**	**840.39**	**41.26**	**80.2%**

Summary of claims with multiple major procedures:

Other HCPCS on claim with 78465	Definition	Procedure Type	HCPCS Appears on Bypass in Proposed Rule	Count of Claim Lines with Procedure	Percent of Claim Lines with Procedure (Procedures with >= 10% Lines)
78465	Heart image (3d), multiple	J	No	535,434	100%
93017	**Cardiovascular stress test**	**J**	**No**	**520,036**	**97%**
78478	Heart wall motion add-on	M	No	481,843	90%
78480	Heart function add-on	M	No	478,754	89%
A9500	Tc-99m sestamibi, up to 40 mCi	M	No	300,137	56%
A9502	Tc-99m tetrofosmin, up to 40 mCi	M	No	203,728	38%
84484	Assay of troponin, quant	B	No	185,385	35%
93005	Electrocardiogram, tracing	J	Yes	149,297	28%
82550	Assay of ck (cpk)	B	No	134,488	25%
36415	Drawing blood	B	No	130,922	24%
J0152	Adenosine injection, dx, 30 mg	M	No	129,504	24%
85025	Automated hemogram	B	No	117,470	22%
82553	Creatine, MB fraction	B	No	114,464	21%
A9505	Tl-201 thallous chloride, per mCi	M	No	103,713	19%
J1245	Dipyridamole injection	M	No	89,018	17%
G0378	Hospital observation per	M	No	87,650	16%
80048	Basic metabolic panel	B	No	78,515	15%
93307	Echo exam of heart	J	No	71,864	13%
93320	Doppler echo exam, heart	M	No	70,079	13%
93325	Doppler color flow add-on	M	No	69,920	13%
85610	Prothrombin time	B	No	69,056	13%
71010	Chest x-ray	J	Yes	65,010	12%
80053	Comprehen metabolic panel	B	No	64,261	12%
85730	Thromboplastin time, partial	B	No	59,629	11%
80061	Lipid panel	B	No	58,378	11%

Procedure Type Key:

J	Major Procedure
B	Bypass Procedure (Does not impact single status)
M	Minor Procedure (HCPCS code that has status 'N')
Blank	No HCPCS Code Present

Note: 'B' Indicator indicates fee paid item in CMS 2006 claims file.

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Analysis of APC 398 - Level I Cardiac Imaging

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

From CMS Median Cost File

APC	Definition	SI	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean Cost	"True" Median Cost	CV	%Used in Median Cost Calculation
0398	Level I Cardiac Imaging	S	346.52	40,207	82,718	43.14	9770.38	398.69	342.23	62.71	48.6%

Simulation of Median Cost if 93017 is added to bypass list (includes application of CMS cost trimming methodology and wage index adj):

APC	Definition	SI		Single Frequency	Total Frequency	Trimmed Minimum Cost	Trimmed Maximum Cost	Mean Cost	"True" Median Cost	CV	%Used in Median Cost Calculation
0398	Level I Cardiac Imaging	S		60,833	82,718	72.41	2561.16	509.01	432.65	62.26	73.5%

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APC Update Impact - trend based on 2006 Medicare outpatient claims

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

HCPCS code A9560-Tc99m labeled Red Blood cells, diagnostic **per dose** up to 30 mCi
Would expect to see one unit billed
Units billed per CMS 2006 paid claims files

units	Occurences
Medically appropriate units	
1	**20,643**
Potentially incorrectly coded	
2	518
3	138
4	16
5	45
6	13
7-14	22
15	11
16-17	11
18	16
19	18
20	557
21	84
22	129
23	185
24	119
25	843
26	155
27	167
28	77
29	52
30	477
31	29
32	33
33	20
>33	38

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APC Update Impact - trend based on 2006 Medicare outpatient claims

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

HCPCS code A9562-Tc99m Mertiatide, diagnostic **per dose** up to 15 mCi
Would expect to see one unit billed
Units billed per CMS 2006 paid claims files

[redacted]	Occurrences
Medically appropriate units	
1	19,362
Potentially incorrectly coded	
2	630
3	75
4	40
5	378
6	124
7	155
8	275
9	105
10	1,659
11	165
12	83
13	20
14	11
15	20
16	66
17	14
18-19	13
20	16
>20	35

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APC Update Impact - trend based on 2006 Medicare outpatient claims

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

HCPCS code A9565-Indium In-111 Pentetreotide diagnostic per mCi
Would expect to see 3- 6 units billed
Units billed per CMS 2006 paid claims files

units	Occurences
Potentially incorrectly coded	
1	1328
2	431
Medically appropriate units	
3	75
4	19
5	167
6	1144
Potentially incorrectly coded	
7	170
8	26
20	16
30	151
Other Units	30

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September 11, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1392-P Proposed Changes to the HOPPS and 2008 Payment System

To Whom It May Concern:

By way of background, DMS Imaging, Inc. (DMSI) provides mobile imaging services in many parts of the United States. Virtually all of our services are provided to patients at critical access hospitals and small rural clinics. We are proud of our service to patients who would otherwise have to travel or perhaps even delay care if mobile imaging services were not available.

"DIAGNOSITIC RADIOPHARMACUETICALS"
This letter is to comment on the packaging of radiopharmaceuticals, in particular F-18 FDG.

We do not support CMS's position to package radiopharmaceuticals, because we believe the proposed price does not accurately reflect all costs associated with the acquisition, delivery and handling of the radiopharmaceutical. We believe there are several factors that could be contributing to misrepresentation of the estimated cost.

First, this technology is fairly new and there have many changes on how to code and to submit the claims for this technology. In our business we have worked with dozens of facilities to help them both in appropriately identifying their total costs and instructing them in how to calculate the appropriate charge that should be submitted per the CMS instructions as outlined in the November 10, 2005 Federal Register. Moreover, based on 2006 claims, the average cost was estimated at $235.76 and in 2007 CMS is assuming the estimated average cost is $279.29, an increase of over 18 %. In our opinion this increase in cost is being driven in part by facilities starting to understand the payment methodology and knowledge of appropriate claims submission which more accurately reflect the true cost of the radiopharmaceutical. However, we also believe that there are

many facilities who are still not submitting accurate claims which will skew the claims data and will lead to incorrect assumptions in determining the dollar amount assigned to the radiopharmaceutical.

Second, in our experience as a national provider of PET/CT services we acquire approximately 24,000 doses of FDG on an annual basis. With our purchasing power at this level we have negotiated what we feel are very competitive rates in the industry. Our average acquisition cost including delivery is $256.38. When factoring in handling, administration of the drug, and other overhead costs, our actual costs far exceed the average cost of $279.29 as determined by CMS in the provider-specific data file. Based on our experience we know a majority of facilities, particularly in rural areas, have acquisition costs much higher than us. This is due in part to not having large volume discounts and having to deal with the logistics of transporting the doses to the rural locations. Many rural facilities have increased transportation and delivery charges they are required to pay to get the FDG to the facility before the radiopharmaceutical decays. It is not uncommon for facilities to incur several hundred dollars in additional transportation charges to acquire the drug on a timely basis.

Because we believe the claims data is not consistent and could be incomplete, we recommend CMS not implement the packaging of radiopharmaceuticals at this time, but continue reimbursing facilities using the current methodology. We also recommend CMS instruct facilities in the proper manner in which charges should be calculated and claims submitted to ensure uniform claims data. Lastly, we recommend CMS revisit this issue in the future when the technology matures and the claims data improves.

Respectfully Submitted,

Mark Doda

Mark Doda
Chief Operations Officer
DMS Health Group

GE Healthcare

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Director, Reimbursement Strategy
Medical Diagnostics
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Via Federal Express

September 13, 2007

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244
Attn: CMS 1392-P

Dear Mr. Weems:

GE Healthcare is a unit of General Electric Company with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, disease research, drug discovery and biopharmaceuticals. Worldwide, GE Healthcare employs more than 42,000 people committed to service healthcare professionals and their patients in more than 100 countries.

We appreciate the opportunity to submit these comments on the proposed changes to the 2008 Hospital Outpatient Prospective Payment System (HOPPS) rule published on August 2, 2007 (72 Fed. Reg.,148).

Our comments relate to Section V. B. – "Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals".

Summary of Concerns

CMS proposes a significant change in payment methodology from previous years. That is, the agency proposes to package payment for drugs with a per day cost less than $60 into the payment for the procedure. Our comments focus, in particular, on the effect of the proposal on radiopharmaceuticals and contrast agents. All diagnostic radio-pharmaceuticals would be packaged while therapeutic agents with a per day cost greater than $60 would be paid separately. All contrast agents would be packaged into the payment for the procedure regardless of cost.

We understand CMS' objectives in developing a packaging policy for radio-pharmaceuticals and contrast agents and believe that an appropriately designed policy can achieve CMS' objectives and maintain access to these medical imaging drugs for Medicare beneficiaries. We are concerned that the proposed methodology for packaging diagnostic radiopharmaceuticals and contrast agents will lead to a wide range of unintended and harmful consequences. Most concerning is the stifling effect that the proposed policy will have on the development of new medical imaging drugs.

Therefore we recommend that CMS work with stakeholders to re-examine the process for editing claims and refine the packaging methodology. For contrast materials, we request that CMS delay adoption of the packaging proposal until the questions concerning the editing process are resolved. In the interim, pay for contrast materials with a per day cost that exceeds $60. For radiopharmaceuticals, we support the $200 threshold recommended by the APC Panel for both therapeutic and diagnostic radiopharmaceuticals for 2008, and that CMS should engage stakeholders to determine an appropriate threshold level for 2009 and beyond.

Payment of Radiopharmaceuticals

GE Healthcare is one of two companies that is both a radiopharmaceutical manufacturer and operates a network of nuclear pharmacies. Radiopharmaceuticals are a unique class of drugs that are distinguished from contrast agents by a very different supply chain. Every radiopharmaceutical requires preparation, overseen by a specially trained nuclear pharmacist, prior to patient administration. This extra step in the supply chain does not allow radiopharmaceutical drug manufacturers to report ASP under the current methodology.

We believe that an ASP-type methodology can be developed using some combination of nuclear pharmacy and manufacturer reporting that will meet CMS' requirements for approximating radiopharmaceutical costs provided that the threshold for payment is sufficiently high to minimize an excessive reporting burden on nuclear pharmacies. However, the threshold cannot be so high that it hinders the development of new radiopharmaceuticals.

GE Healthcare and other companies are developing new diagnostic radio-pharmaceuticals that may be of benefit to the Medicare population. Arbitrarily packaging these new drugs because they are diagnostic would discourage their use and limit access to care. On the other hand, we and other stakeholders' recognize that charge compression leads to inappropriately low reimbursement rates for expensive radiopharmaceuticals when using CMS claims data. Therefore we recommend that CMS not use its claims data, trimmed or otherwise, to set reimbursement rates for radiopharmaceutical drugs.

We support the $200 threshold recommended by the APC Panel for both therapeutic and diagnostic radiopharmaceuticals for 2008 and that CMS should engage stakeholders to determine an appropriate threshold level for 2009 and beyond. We recommend that CMS continue to use the current cost-to-charge ratio methodology for payment of radiopharmaceuticals above the $200 threshold in 2008. We appreciate that CMS views this as a temporary policy but changing the payment methodology at this point in time would be as equally detrimental to the quality of the payment system as would the adoption of the packaging policy in the proposed rule.

We also recommend that CMS work with other stakeholders to develop an ASP-type methodology for implementation in 2009. Some combination of manufacturer and/or nuclear pharmacy reporting has a high probability of meeting CMS requirements and appropriately setting payment rates for radiopharmaceuticals.

Payment of Contrast Agents

Contrast agents, unlike radiopharmaceuticals, are not a requirement for every medical imaging procedure. CMS accounts for this difference in CT and MR imaging through the use of procedure codes that designate "procedures without contrast", "procedures with contrast", and "procedures without contrast, followed by contrast." Packaging of contrast agents without a procedural distinction for contrast agent utilization would result in overpayment for procedures without a contrast agent and underpayment for procedures with a contrast agent, thereby creating adverse incentives for determining contrast media utilization. For this reason, we believe that contrast agents should be paid separately until procedural codes are in place to differentiate between without and with a contrast agent. Currently, the echocardiography code descriptors do not have such a distinction.

CMS should also consider that new contrast agents will be developed for specific patient subsets in CT, MR, and potentially new medical imaging modalities. Arbitrarily packaging these new contrast agents will discourage their use and limit access to care. **We recommend that CMS continue to pay separately for contrast agents that exceed the threshold applied to other non-radiopharmaceutical drugs, $60 as proposed for 2008.**

We believe that different payment methodologies for contrast agents within the same "class" would create confusion for providers. In the case of LOCM Contrast Agents, where the per day cost falls below the threshold for a majority of procedures, we agree with CMS' proposal to package contrast agents in the "class" (Q9945, Q9946, Q9947, Q9948, Q9949, Q9950, and Q9951) to avoid confusion.

Effect of the Claims Editing Process

The comments submitted to the APC Advisory Panel at their September 5 meeting had a recurring theme: the claims editing process needs refinement as demonstrated by the many examples of payment aberrations.

One of the key concerns echoed by stakeholders is that the resulting packaging proposal is too extreme and does not assure the resource homogeneity or the clinical appropriateness of an Ambulatory Payment Classification (APC). CMS has not provided a "crosswalk" of the costs that are captured within the relevant APCs. This step is particularly important for the future, more expensive drugs that will come to market as GE Healthcare and others develop personalized medicine.

We offer the following examples that illustrate the impact that the proposed rule would have on the providers that utilize our products.

Example 1: CMS proposes to move echocardiography (code 93350) from APC 269 Level II Echocardiography to APC 697 Level I Echocardiography. This represents an increase in payment of $108.54 or 54.9%. However, the increase does not cover the cost of the ultrasound contrast, code Q9956. The payment rate for a dose of this drug, per the third quarter 2007 Medicare ASP rates, is $148.82.

The above payment inadequacy is exacerbated by the fact that the echocardiography procedure code descriptors do not distinguish between procedures performed with and/or without contrast, as do the code descriptors for the CT and MR modalities.

We recommend that CMS continue to pay separately for Echocardiography Contrast Agents (HCPCS Codes Q9955, Q9956, and Q9957) until procedure codes are established that appropriately reflect without and with a contrast agent.

Similarly, we would recommend that CMS reconsider their proposal to move CT colonography to APC 332 (CT without contrast). Instead, CT colonography should remain in APC 333 (with contrast).

Example 2: An increase of approximately $220 in 2008 is proposed for APC 414 Level II Infection Imaging. Ceretec, A9521, is used for both infection and brain imaging. The process for infection imaging is more labor-intensive than that of brain imaging.

When Ceretec is used for the former indication, the process would include costs such as a vial of the drug (approximately $598 per the 2007 Red Book average wholesale price) plus a fee for the labeling of the white blood cells. In such a case, the provider's cost for the drug would be closer to $900. Therefore, the $220 proposed increase for the APC would not cover the provider's costs for the infection imaging process. This also needs to be reconciled with the fact that the 2006 claims data indicate that the mean unit cost for Ceretec is $341.42.

Pass-Through Drugs

We understand that CMS plans to continue pass-through status for drugs. However, we would appreciate confirmation as to the payment methodology for both contrast media and radiopharmaceuticals. CMS has indicated that "...the payment rate for a radiopharmaceutical with pass-through status would be adjusted accordingly". We ask that CMS confirm whether they plan to use average wholesale price as the method of payment.

Data Resources

We are committed to working with CMS and our trade group and professional societies to find a better methodology for deriving prospective payment rates, including an appropriate threshold for separate payment. A new and better methodology should be developed based upon a stable, credible source of data. To that end, we suggest that CMS consider the use of external data, including that of Medicare carriers. Even if CMS does not utilize the external data in its entirety for rate setting, it could be used to challenge the accuracy of the CMS proposals.

In addition, a secondary, thorough comparison of claims and invoices from rural and urban areas is needed in order to analyze the difference in cost, both for price as well as handling costs. Moreover, in order for mean costs to be valid, any rebates paid by manufacturers for product doses must be accounted for.

Recommendations

Thank you for the opportunity to comment on the proposed HOPPS regulation. In summary, we recommend that CMS:

1. Delay the adoption of the proposed rule for radiopharmaceuticals and contrast agents and work with stakeholders to re-examine the process for editing claims and refine the packaging methodology;

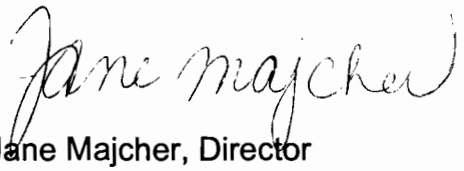
2. Pay separately for all radiopharmaceuticals with a per day cost that exceeds $200 (per the current cost-to-charge ratio methodology) and for contrast agents with a per day cost that exceeds $60;

3. Create new codes or modify existing code descriptors to reflect ultrasound procedures with and without contrast;

4. Review the claims editing methodology on a regular basis to assure that future rate setting will reflect more accurately the cost and clinical appropriateness associated with technological advances.

If CMS wishes to discuss this comment letter in greater detail, I can be reached at 609-514-6701 or at jane.majcher@ge.com.

Sincerely,



Jane Majcher, Director
Reimbursement Strategy

Carrington Health Center

September 11, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1392-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (Vol. 72, No. 148), August 2, 2007.

Dear Mr. Weems:

Carrington Health Center appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar (CY) 2008 outpatient prospective payment system (PPS). Carrington Health Center is a Critical Access Hospital located in Carrington, ND. We currently service a population base of 8,000 – 8,500 patients. This service area covers entire or portions of 5 counties in east central North Dakota that would be considered rural and many times frontier territory. The majorities of the population base we serve are elderly and in the Medicare age group. It is difficult for this age group to remain mobile and many times this group is already traveling 30-45 plus miles to see a health care provider. We are constantly striving to provide services the patients in these areas require in order to remain healthy. Carrington Health Center is considered to be the main health care provider in this area.

We support the comments submitted to CMS by the Catholic Health Association and the American Hospital Association. But we would like to add the following comments on an issue of particular concern to us and the communities we serve:

Necessary Provider Critical Access Hospitals (CAH)
CMS proposes to clarify that if a CAH operates a provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008, it must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads).

CMS believes that the necessary provider CAH designation cannot be considered to extend to any facilities not in existence when the CAH originally received its necessary provider designation from the state. In the case of a necessary provider CAH that violates the proposed requirement, CMS would terminate its provider agreement. This could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

Approximately 850 of the 1300 CAHs nationally are necessary provider CAHs and are therefore within 35 miles of another hospital or CAH. Catholic Health Initiatives, our parent organization, operates 21 CAHs and several of them are necessary providers. These hospitals operate numerous rural health clinics and other provider-based facilities. In some cases, additional sites or relocation of existing off-campus sites will be needed to better serve the needs of patients in these rural communities.

We have been looking at a community 26 miles East of Carrington Health Center that we feel could benefit from having a Rural Health Clinic established to provide care for the residents in that community. Under this new proposed legislation, we will no longer look at establishing a clinic as it would be cost prohibitive to loose our CAH designation. As mentioned above, Carrington Health Center is considered to be the major health care provider in the community and it is imperative that we seriously look at all avenues of revenue enhancement in order to keep our facility thriving in the future. Carrington Health Center is aware that without our hospital in this community to promote economic development the community will die out. Converting back to a PPS hospital is not an option to enhance viability of our facility into the future.

If this proposal is adopted, Carrington Health Center will be significantly limited in or prohibited from opening new off campus provider-based sites, or converting existing sites to provider-based status. CMS states in the proposed regulation that these new restrictions are "consistent with our belief that the intent of the CAH program is to maintain hospital-level services in rural communities while ensuring access to care." **These arbitrary limitations on provider-based service locations will have the exact opposite effect – access to services will be reduced.**

CAH provider-based entities are located in different places for various reasons. Hospitals consider available land, natural boundaries, increased need, preference of physicians and other practitioners, etc. While community members may be willing to travel a distance to a hospital for urgent care or services not available elsewhere, beneficiaries may need something closer to home for more routine visits, therapy, lab work, etc. By forcing CAHs to have services on-campus, CMS will be leaving some community members without access to services. The proposed rule will also prevent CAHs from replacing outdated facilities with new, more modern provider-based facilities in locations that best suit the needs of their population.

We are particularly concerned that CMS does not appear to exclude rural health clinics from the proposed rule. Clinics are often a way that CAHs recruit physicians to practice

in the area. By hiring a physician at one of the CAHs' provider-based clinics, the CAH guarantees that there is a physician in the area to serve on the medical staff of the hospital. There are small communities nationwide that would not have a physician without a rural health clinic.

It should be noted that many state necessary provider plans, which were approved by CMS, used criteria such as population, income and age demographics for areas to determine if a hospital could qualify as a necessary provider. It would seem reasonable that new off-campus sites within geographic areas used to establish necessary provider status should not affect continuing necessary provider status.

We urge CMS to rescind this proposal to avoid limiting access to health care services in rural areas.

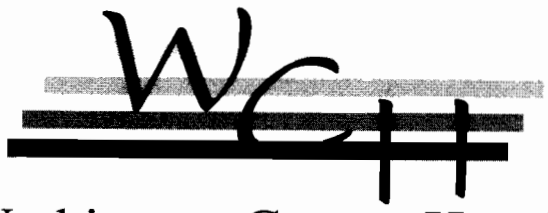
Thank you for providing us with an opportunity to comment. Please contact me at 701-652-7165 for additional information.

Sincerely

Mariann Doeling

Mariann Doeling
Executive Vice President

P.O. Box 707
958 U.S. Hwy. 64 E.
Plymouth, North Carolina 27962



Washington County Hospital

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Phone: 252-793-4135
Fax: 252-793-1530
E-mail: wchonline.com

September 13, 2007

Centers of Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Changes to CAH Conditions of Participation

Gentlemen:

This letter is to comment on the notice of proposed regulations for Provider Based Facilities of CAHs as published in the August 2, 2007 Federal Register under the title, Proposed Changes Affecting CAHs and Hospital Conditions of Participation. This proposed rulemaking will be effective January 1, 2008 if implemented.

Washington County Hospital converted to Critical Access Hospital status in October, 2002 under the necessary provider provision. This conversion has allowed our hospital to remain a viable entity to serve the healthcare needs of our community Our current payer mix is 50.4% Medicare, 19.6% Medicaid, 18.1% Blue Cross, commercial and managed care, 9% self-pay and charity care, and 2.9% other. Conversion to Critical Access status, given our case mix in a rural community, has allowed our hospital to stabilize financially and continue to provide needed acute care services to the residents of Washington County, North Carolina.

I am very concerned about the provisions in the proposed rule which will eliminate the potential of a necessary provider, or any CAH, to establish a provider based location including a department or a remote location or an off campus distinct part psychiatric or rehabilitation unit on or after January 1, 2008 that does not meet the distance criteria for CAH from another hospital or CAH. The penalty for establishing such a unit can be the loss of CAH certification. CMS proposes "...any off campus location must satisfy the distance requirements, without exception and regardless of whether the main provider CAH is a necessary provider CAH." This proposal has significant potential to create a negative situation for Washington County Hospital. It will impact access to care for Medicare beneficiaries in our rural community.

We believe that potential access will be diminished in our rural community because we are experiencing a growing inability to recruit or retain physicians in private non-provider based practices. Currently, we are converting an existing hospital practice to a Rural

Health Clinic and intend to use this model to recruit additional physicians to our rural area of eastern North Carolina. New physicians graduating from medical school today want to be in an employed practice model as opposed to a private practice model. We are also finding that we must offer compensation packages that are higher than other communities to attract physicians to serve in a rural area. Our strategy for physician recruitment is to add more physicians to this model and create satellite locations throughout the county to better serve our rural and dispersed population. Our hospital is located in the western most area of the county and the population in the eastern part must travel to our location to receive healthcare services. In order to meet the unmet need in the county, the County Commissioners are requesting federal funding to build a facility further east in the county to develop a satellite Rural Health Clinic that would be staffed and operated by the hospital. With the proposed regulations, this would not be possible without Washington County Hospital losing its designation as a CAH.

As you are aware, a strong primary care base in a community is needed to support other specialties such as general surgery, orthopedics, gynecology, ophthalmology, urology, gastroenterology, etc. Our hospital operates an outpatient clinic that is served by specialty physicians who travel over an hour to serve our community. Without a primary care base, this clinic would not be possible and a significant erosion of access for our population would occur. This lack of access would create an inability of many of our elderly adults to receive needed appropriate services provided by Washington County Hospital as a critical access hospital in our local area.

If we are not able to expand our provider based Rural Health Clinic to outlying areas of our county, physicians will not locate to these areas and our community will be denied access to healthcare. Without the ability of the hospital to provide these services, reimbursement is not going to be sufficient to allow our financial resources, which are strapped, to undertake the necessary financial support or salary requirements needed to recruit or retain our doctors.

We believe that these regulations as proposed will effectively strangle and completely blunt the development of needed and necessary rural health services by Critical Access Hospitals in response to community health needs. We recommend that the Conditions of Participation for CAHs regarding off-campus or provider-based facilities are poorly conceived and unnecessary and thus should be eliminated from the proposed rule and further CMS consideration. Thank you for your consideration of this matter.

Sincerely,

Jeffrey M. Judd
Chief Executive Officer

Life Recovery Systems HD, LLC
The Sid Wolvek Research Center

September 12, 2007

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Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

VIA FEDERAL EXPRESS

RE: **Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates**

Dear Acting Administrator Weems:

These comments are submitted by Life Recovery Systems HD, LLC, a relatively new company focused on ground breaking, innovative medical devices for the emergency medical care market. Our mission is to save and preserve the quality of lives.

We manufacture the ThermoSuit™ System (TSS), which is cleared for marketing by the FDA and intended for "[t]emperature reduction in patients where clinically indicated . . ."[1] The primary clinical indication for TSS is the cooling of patients with out-of-hospital cardiac arrest. Many peer-reviewed studies in prestigious medical journals have proven the benefit of hypothermia for out-of-hospital cardiac arrest patients.[2] The evidence for hypothermia after cardiac arrest is so compelling that the American Heart Association amended its Postresuscitation Support guidance to recommend hypothermia for post-arrest patients.[3] We appreciate this opportunity to comment on the proposed rule published in the Federal Register on August 2, 2007.[4] Our specific comments follow.

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1 K061023 510(k) Summary, page 4, *available at* http://www.fda.gov/cdrh/pdf6/K061023.pdf.

2 *See* Sterz F, et al. Mild therapeutic hypothermia to improve the neurologic outcome after cardiac arrest. *N Engl J Med.* 2002;346:549-556; *See also* Bernard SA, et al. Treatment of comatose survivors of out-of-hospital cardiac arrest with induced hypothermia. *N Engl J Med.* 2002;346:557-563.

3 *Circulation* 2005;112;84-88.

4 Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates, 72 Fed. Reg. 42628 (August 2, 2007) (the Proposed Rule).

I. Background

CPT 99186 (Hypothermia; total body) is packaged under the OPPS. CMS considers this CPT code to describe all total body hypothermia techniques, ranging from primitive and inexpensive ice bags applied to the patient to advanced systems such as TSS. At the March 2007 APC Panel Meeting, LRS requested that the APC panel recommend that CMS provide separate payment for more advanced and more costly hypothermia systems such as the TSS (as compared to older methods that have been traditionally used for hypothermia and coded with 99186 -- i.e., ice bags, cooling blankets, etc.).

Advanced hypothermia systems reflect much more sophisticated and resource intensive procedures, such as TSS or invasive catheter cooling systems. Total body hypothermia performed on post-cardiac arrest patients can be an inpatient procedure, but some hospital emergency rooms induce hypothermia and stabilize patients prior to transfer to another facility that is equipped to provide definitive care. In these cases, the cost of hypothermia is born by the hospital outpatient department.

At the March 2007 meeting, the APC panel recommended that CMS reevaluate the packaged status of 99186 (Hypothermia, total body) based on current research and the availability of new therapeutic modalities. In the Proposed Rule, CMS has recommended that all hypothermia techniques remain packaged under 99186. All hypothermia methods are treated the same, regardless of cost. CMS's reasons for maintaining the packaged status for all hypothermia techniques are that it believes that the billing of hypothermia under the OPPS would be "extremely rare" and that packaging "encourages hospitals to use the most cost-effective item that meets the patient's needs."[5] We believe that these assertions are incorrect and we respond to each and make a recommendation below.

II. The proposed rule mistakenly assumes that billing for advanced hypothermia under the OPPS would be "extremely rare"

CMS is correct that some patients admitted to the ER and then cooled may be admitted to the hospital for further treatment and that these patients' treatment would be paid under the IPPS. However, there are a significant number of hospitals in the U.S. that accept patients into the ER after an out-of-hospital arrest but do not have the facilities (such as a cardiac catheterization lab or open heart surgery facilities) to provide definitive care and therefore must transfer the patient to a better equipped facility once the patient is stabilized. According to the most recent

[5] *Id.* at 42690.

American Hospital Association statistics, there are approximately 5,756 registered hospitals in the U.S., and 4,137 of these hospitals do not have cardiac catheterization lab or open heart surgery facilities. Many patients brought to such facilities after an out-of-hospital cardiac arrest would need to be transferred to another facility for more definitive care. If a patient is brought into the ER and then subsequently transferred to another facility, the payment to the first facility for hypothermia provided in the ER would be under the OPPS. Therefore, OPPS billing for this service would not be uncommon given the number of U.S. hospitals that are not equipped to admit post-arrest patients and provide definitive care and the recent availability of advanced hypothermia techniques.

III. Packaging as a means to promoting cost effectiveness in the OPPS assumes that an acceptable trade-off exists between very inexpensive hypothermia methods and more costly advanced hypothermia methods.

In the Proposed Rule, CMS suggests that describing all hypothermia technologies with CPT 99186 and packaging this code in the OPPS encourages the most cost-effective resource utilization for hypothermia. However, this assertion is based on several incorrect assumptions.

The Proposed Rule states: "In situations where there are a variety of supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the most cost-effective item that meets the patient's needs."[6] This statement assumes that under certain circumstances, rudimentary technology such as ice bags and simple cooling blankets are viable alternatives to advanced hypothermia methods. This assumption is not true, which is why traditional hypothermia methods have not been adopted by hospital ERs despite strong clinical evidence for hypothermia in post-resuscitation patients.

In the Proposed Rule, CMS documents the very low utilization of therapeutic hypothermia in 2006:

> Claims data indicate that this code [99186 (Hypothermia, total body)] was billed 39 times under the OPPS in CY 2006 . . . The proposed CY 2008 median cost for this code is $35, with individual costs ranging from $17 to $69, likely reflecting the costs associated with traditional methods of inducing total body hypothermia, such as ice packs applied to the body.

Although the clinical data supporting hypothermia is very strong, older methods have not been adopted because packing a patient in ice is ineffective, very slow, cumbersome, unwieldy, and is difficult to control.[7] The small number of claims and minimal cost means that hypothermia has essentially no effect on the median costs of the services with which it is packaged. Therefore, advanced hypothermia services will receive a payment of effectively $0 for 2008. If CMS is correct and the volume of these services remains low in the OPPS, it is also

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6 *Id.*

7 *See* Merchant RM, et al. Therapeutic hypothermia after cardiac arrest: Unintentional overcooling is common using ice packs and conventional cooling blankets. *Crit Care Med.* 2006;34:S490-S494.

unlikely that packaging these costs will have an effect on future median costs for services with which hypothermia is packaged.

In order to make advanced hypothermia available to Medicare beneficiaries, CMS should create a G code for advanced hypothermia and pay separately in the OPPS for this service. Otherwise, hospitals that transfer their out-of-hospital arrest patients to better-equipped hospitals will not be able to provide a service that is a part of the American Heart Association resuscitation protocol.

IV. Conclusion

We believe that CMS has the tools to solve this problem. We also believe that Medicare beneficiaries who suffer an out-of-hospital arrest deserve the improved quality of life that is provided by advanced hypothermia techniques. Thank you for considering our comments.

Sincerely,

John Di Liddo
Vice president Marketing & Business Development
Life Recovery Systems, HD, LLC