**Submitter :** **Mr. Ronald Napikoski** **Date: 08/28/2007**

**Organization :** **Lewistown Hospital**

**Category :** **Hospital**

**Issue Areas/Comments**

**Packaging Drugs and Biologicals**

Packaging Drugs and Biologicals

I am the Director of Cardiopulmonary Services at a small rural hospital in Central PA that uses contrast agents for echocardiography. If seperate payments for echo contrast agents are eliminated for hospital outpatients, we will be forced to reduce patient access to these agents.

**Submitter :** Mrs. cecilia yowell **Date:** 08/28/2007

**Organization :** OKlahoma Spine Hospital

**Category :** Hospital

**Issue Areas/Comments**

**GENERAL**

GENERAL

We have just heard that beginning next year CMS wil stop paying for the rechargeable APC code on Spinal Cord Stimulators. From the hospital side it is very easy for us to put in two different HCPC codes (about thirty minutes) and then it is automatic, but I am more concerned from the patient side of this. If the payment is reduced, I am afraid that physicians will stop putting these in and the patient becomes the loser not the facility or the physician. Sometimes this stimulator is the only alternative that the patient has for the quality of life to continue. I would appeal to you for all those patients out there that we can do anything necessary to keep this service tot he patient available.

**Submitter :** **Ms. Elizabeth McConville** **Date: 08/28/2007**

**Organization :** **Masspro**

**Category :** **Nurse**

**Issue Areas/Comments**

**Quality Data**

Quality Data

I noticed in the proposed rule Federal register Vol 72 No. 148 published August 2, 2007 page 42804, middle column, while providing an example for data submission deadlines, second paragraph middle column, it states the following:
"...required to submit quarterly data on finalized measures 4 months from the last day of the calendar quarter...The deadline for April - June 2008 discharges for example, would be November 1, 2009.
I believe it should read November 1, 2008.
Thank you,
Beth

**Submitter :** **Elizabeth McConvillw** **Date: 08/28/2007**

**Organization :** **Masspro**

**Category :** **Nurse**

**Issue Areas/Comments**

**Quality Data**

Quality Data

Regarding the proposed rule for HOP QDRP for hospital reporting of outpatient measures. I am concerned that validating the first month of abstracted data for these new measures puts the hospitals at an unfair risk of failing validation. The hospitals do not yet have abstraction rules available as the measures have not yet been defined for them. The first validation cycle should provide a hospital with the opportunity to evaluate if they have interpreted the rules correctly and make adjustments / re-educate as necessary. I believe, especially in light of the short time period alotted to hospitals to implement data collection and submission for these measures, that a period of learning to abstract these data elements would be fair and reasonable. I propose the final quarter of data in CY 2008 be targeted for APU.
Thank you

**Submitter :** **Bryan Orme** **Date: 08/28/2007**

**Organization :** **Bryan Orme**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Bryan Orme MD

**Submitter :** Ms. Eve Frazier **Date:** 08/28/2007

**Organization :** Covenant Health

**Category :** Hospital

**Issue Areas/Comments**

**Hospital CoPs**

Hospital CoPs

I am opposed to removal of the language which requires that an H&P be documented and ON THE MEDICAL RECORD within 24 hours. There are many physicians who continue to believe that a dictated but yet untranscribed H&P is good enough since it is "in the system". Having reinforcement in the COP is very important. It is also important that JCAHO and CMS agree on this matter and JCAHO still requires it be on the medical record.

**Submitter :** Dr. Carlos Wilton **Date:** 08/28/2007

**Organization :** Dr. Carlos Wilton

**Category :** Individual

**Issue Areas/Comments**

**Payment for Therapeutic Radiopharmaceuticals**

Payment for Therapeutic Radiopharmaceuticals

I am a Non-Hodgkin Lymphoma patient, diagnosed in December, 2005. My disease which had both an aggressive and an indolent component was successfully treated with traditional chemotherapy, but now the indolent component of the disease is back. My doctor and I are currently assessing my treatment options, including the radioimmunotherapy drugs, Bexxar and Zevalin.

I am alarmed to learn that the Department of Health and Human Services is proposing revised Medicare guidelines for reimbursing the cost of Bexxar and Zevalin, that would fail to cover hospitals' expenses for administering these life-saving drugs. The likely result of this is that many hospitals will no longer offer Bexxar to anyone.

As radioimmunotherapy drugs, Bexxar and Zevalin do not fit traditional treatment categories. It is important that revised reimbursement guidelines treat radioimmunotherapy medications as a category unto themselves, and that they not be compared against the cost of medications that are really very different.

I am 50 years old, and therefore years away from being eligible for Medicare. I have private medical insurance through the Presbyterian Church (U.S.A.), the denomination which I serve as a pastor. Even so, I am concerned that this move on the part of the government could result in these drugs no longer being available to me both now, and after I eventually retire.

One of these drugs could save my life. Please do not price them out of existence, by applying guidelines that are more appropriate for another category of medication.

The Rev. Carlos E. Wilton, Ph.D.
704 Forman Avenue
Point Pleasant Beach, NJ 08742
(732) 899-4858

**Submitter :** Dr. John Loeser **Date:** 08/28/2007

**Organization :** University of Washington

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachmcnt

CMS-1392-P-198-Attach-1.PDF

#198

*University of Washington*
*School of Medicine*
*Department of*
*Neurological Surgery*

1959 NE Pacific Street
Campus Box 356470
Seattle, WA 98195-6470

Academic: 206-543-3570
Academic Fax: 206-543-8315

Clinical Appointments:
206-598-5637
Clinical Fax: 206-598-6494

August 27, 2007

Department of Health and Human Services
Attn: CMS-1392-P
PO Box 8011
Baltimore, MD 21244-1850

Re: Implantation of Spinal Neurostimulators

To Whom It May Concern:

I write to express my concern about the proposed rule that will eliminate the separate APC for rechargeable neurostimulators. Rechargeable neurostimulators are a significant step forward in our ability to control intractable chronic pain. These new stimulators have greatly increased the programming capabilities, the number of electrodes that can be active at one time, and the duration of battery life for the implanted pulse generator. The first two features increase the likelihood that stimulation will effectively manage the patient's pain; the third feature will reduce the need for pulse generator replacements, and thereby save the patient operations and the cost of replacing the pulse generator. The proposed policy of lumping non-rechargeable with rechargeable neurostimulators will result in hospitals and insurance companies reducing the availability of modern neurostimulation and increasing the likelihood that patients will have to have additional operations. I believe that a separate ambulatory payment classification for rechargeable stimulators would be a much better system than the proposed lumping of rechargeable and chargeable stimulators together. Separate APCs will enable us to implant the most modern equipment with the longest battery life and will be an advantage to our patients. I believe it would be important to create new codes that differentiate between rechargeable and non-rechargeable neurostimulators. Although this might result in increased administrative burdens, it will help maintain our patients' access to the best equipment.

Yours truly,

John D. Loeser

John D. Loeser, MD
Professor of Neurological Surgery and Anesthesiology

**Submitter :** Dr. Todd Sitzman **Date:** 08/28/2007

**Organization :** American Academy of Pain Medicine

**Category :** Physician

**Issue Areas/Comments**

**Implantation of Spinal Neurostimulators**

Implantation of Spinal Neurostimulators

Under the proposed Hospital Outpatient and ASC rule changes, CMS would pay hospitals the same rate for rechargeable and non-rechargeable neurostimulators. I feel that this is grave mistake in the clinical care of Medicare (and ultimately all) patients experiencing chronic pain.

CMS proposes to group rechargeable and non-rechargeable neurostimulators in the same Ambulatory Payment Classification (APC) payment group, despite the approximately $6,500 cost differential and clinical advantages of rechargeable neurostimulators.

**Submitter :** Dr. Louis Raso **Date:** 08/29/2007

**Organization :** Louis J. Raso, M.D.

**Category :** Physician

**Issue Areas/Comments**

**Implantation of Spinal Neurostimulators**

Implantation of Spinal Neurostimulators

As you know, rechargeable neurostimulators have received transitional pass-through payment under Medicare s hospital outpatient prospective payment system (OPPS) since January 1, 2006, and their pass-through status will expire on January 1, 2008. Transitional pass-through payment was granted to rechargeable neurostimulators on the basis that these devices demonstrated substantial clinical improvement and that the technology would be inadequately paid under APC 0222, to which implantation of neurostimulator devices is assigned. Pass-through payment made rechargeable technology available to patients in the hospital outpatient setting. Without pass-through payments, many facilities would have found rechargeable neurostimulators too costly to implant, which would deny patients and CMS itself (in the form of long-term savings) the benefits of these devices.

With neurostimulators coming off pass-through status for CY 2008, CMS is proposing to retain the implantation of both rechargeable and non-rechargeable neurostimulators in APC 0222, despite very significant differences in the cost of the two devices. I am concerned that the proposed payment for APC 0222 of $12,313.94 thousands less than the average cost of rechargeable neurostimulators will create a strong financial disincentive for the use of rechargeable neurostimulators. CMS own data shows the median cost for implanting rechargeable neurostimulators is $18,088.71, while the median cost for non-rechargeable neurostimulators is $11,607.75, a difference of $6,480.96.

[In this area, you can articulate why the development of rechargeable neurostimulators represents a substantial advancement over non-rechargeable stimulators and the patient benefits offered by this new technology. The following is an example.]:

" Chronic pain patients requiring higher power needs to achieve pain relief can use their rechargeable system without concern for premature battery depletion.

" The increased battery life of rechargeable neurostimulators results in a reduction in the number of device replacement surgeries and other associated medical interventions. The reduced number of surgeries and other medical interventions results in less patient trauma and a substantial cost savings to the healthcare system over time.

" [Insert additional support comments.]

" [Insert additional support comments.]

I am urging CMS to create separate APCs for the implantation of rechargeable and non-rechargeable neurostimulators, which should adequately recognize the cost of both devices and allow the patient population indicated for rechargeable neurostimulators continued access under the hospital outpatient prospective payment system.

**Submitter :** **Ms. Ghio Imburgio** **Date: 08/29/2007**

**Organization :** **Ms. Ghio Imburgio**

**Category :** **Individual**

**Issue Areas/Comments**

**Payment for Therapeutic Radiopharmaceuticals**

Payment for Therapeutic Radiopharmaceuticals

I am concerned about the proposed deep cuts in reimbursement for radioimmunotherapy (RIT), Bexxar (I131 tositumomab) as outlined in this report http://www.cms.hhs.gov/QuarterlyProviderUpdates/downloads/cms1392p.pdf on pages; 45, 114 (Table 44), 353 and 409.

My spouse, Edward, was diagnosed in 2005 with mantle cell lymphoma (MCL): a rare, and difficult to treat, form of the disease. MCL was identified as a distinct type in the mid 1990 s and overall survival was believed poor at 3-5 years.

Historically, response to CHOP chemotherapy brought many patients to remission but, in most cases, relapse was certain. In the last few years MCL patients are enjoying longer life expectancy due to novel treatments and more intensive chemo regimens like R-hyper/CVAD . The addition of Rituxan during chemotherapy and as maintenance therapy has made an enormous difference. The problem is that traditional chemotherapy + Rituxan is harsh and many patients are not offered this combination due to toxicity and advancing years. Since his diagnosis my husband has endured R-hyper/CVAD, autologous stem cell transplant and is currently on Rituxan maintenance.

Its our hope that this aggressive treatment brought a cure. However if a relapse occurs such aggressive therapy will not be available due to toxicity and lifetime limits of doxirubicin.

The Lymphoma Research foundation reports that RIT in the forms of Bexxar and Zevalin is currently being tested for MCL. See http://www.lymphoma.org/atf/cf/%7B0363CDD6-51B5-427B-BE48-E6AF871ACEC9%7D/MANTLE%20CELL.PDF

I believe that to change reimbursement of this therapy to Medicare and Medicaid patients sets into motion a further disincentive to prescribe this emerging therapy. It seems inevitable that all patients will eventually lose access to this treatment as reported on lymphomation.org.

This means that hospitals would have to subsidize Medicare patients in order for them to receive either [RIT] drug. Since hospitals will not subsidize Medicare patients, these patients will have no access to the drugs. And since hospitals will not offer drugs to privately insured patients unless Medicare patients have access to the same drugs, this proposal means that Bexxar and Zevalin will effectively be denied to everyone.

When the cost of development cannot be recouped in a reasonable amount of time, drug companies discontinue them. This will devastate those who fight this disease and close the door to less toxic treatment options.

We must support companies that to develop varied treatment options and, more importantly, keep our eye on the prize. RIT has a good chance of becoming a broadly accepted, less expensive, front-line treatment for a variety of lymphomas. If so, it could save money, time and lives. I urge you to maintain current reimbursement for RIT.

Sincerely,

Ghio Imburgio

CMS-1392-P-201-Attach-1.DOC

#201

Dear Sir or Madam:

I am concerned about the proposed deep cuts in reimbursement for radioimmunotherapy (RIT), Bexxar (I131 tositumomab) as outlined in this report http://www.cms.hhs.gov/QuarterlyProviderUpdates/downloads/cms1392p.pdf on pages; 45, 114 (Table 44), 353 and 409.

My spouse, Edward, was diagnosed in 2005 with mantle cell lymphoma (MCL): a rare, and difficult to treat, form of the disease. MCL was identified as a distinct type in the mid 1990's and overall survival was believed poor at 3-5 years.

Historically, response to CHOP chemotherapy brought many patients to remission but, in most cases, relapse was certain. In the last few years MCL patients are enjoying longer life expectancy due to novel treatments and more intensive chemo regimens like R-hyper/CVAD . The addition of Rituxan during chemotherapy and as maintenance therapy has made an enormous difference. The problem is that traditional chemotherapy + Rituxan is harsh and many patients are not offered this combination due to toxicity and advancing years. Since his diagnosis my husband has endured R-hyper/CVAD, autologous stem cell transplant and is currently on Rituxan maintenance.

It's our hope that this aggressive treatment brought a cure. However if a relapse occurs such aggressive therapy will not be available due to toxicity and lifetime limits of doxirubicin.

The Lymphoma Research foundation reports that RIT in the forms of Bexxar and Zevalin is currently being tested for MCL. See
http://www.lymphoma.org/atf/cf/%7B0363CDD6-51B5-427B-BE48-E6AF871ACEC9%7D/MANTLE%20CELL.PDF

I believe that to change reimbursement of this therapy to Medicare and Medicaid patients sets into motion a further disincentive to prescribe this emerging therapy. It seems inevitable that all patients will eventually lose access to this treatment as reported on lymphomation.org.

> "This means that hospitals would have to subsidize Medicare patients in order for them to receive either [RIT] drug. Since hospitals will not subsidize Medicare patients, these patients will have no access to the drugs. And since hospitals will not offer drugs to privately insured patients unless Medicare patients have access to the same drugs, this proposal means that Bexxar and Zevalin will effectively be denied to everyone. "

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We must support companies that to develop varied treatment options and, more importantly, keep our eye on the prize. RIT has a good chance of becoming a broadly accepted, less expensive, front-line treatment for a variety of lymphomas. If so, it could save money, time and lives. I urge you to maintain current reimbursement for RIT.

Sincerely,

Ghio Imburgio

**Submitter :** Mr. Mark Covall **Date:** 08/29/2007

**Organization :** National Association of Psychiatric Health Systems

**Category :** Psychiatric Hospital

**Issue Areas/Comments**

**Partial Hospitalization**

Partial Hospitalization

See attachment.

CMS-1392-P-202-Attach-1.PDF

#202

National
Association
of Psychiatric
Health Systems

701 13th Street, NW, Suite 950
Washington, DC 20005-3903
Phone: 202/393-6700
Fax: 202/783-6041
E-mail: naphs@naphs.org
Web: www.naphs.org

**SUBMITTED ELECTRONICALLY:** http://www.cms.hhs.gov/eRulemaking

August 29, 2007

Mr. Herb Kuhn, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

**RE: CMS-1392-P: Proposed Changes to the Hospital Outpatient PPS**

***NOTE:* "PARTIAL HOSPITALIZATION" COMMENTS**
**and**
**"OTHER COMMENTS ON OPPS"**

Dear Mr. Kuhn,

As an association representing behavioral healthcare provider organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to provide comments on "Medicare: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates" as published in the August 2, 2007, *Federal Register*.

We are specifically providing comments on 1) the proposed partial hospitalization program (PHP) and community mental health issues and 2) other outpatient mental health services.

**ABOUT NAPHS**

Founded in 1933, NAPHS advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. Our members are behavioral healthcare provider organizations, including more than 600 psychiatric hospitals, general hospital psychiatric and addiction treatment units, residential treatment centers, youth services organizations, outpatient networks, and other providers of care. Our members deliver all levels of care, including partial hospitalization services, outpatient services, residential treatment, and inpatient care.

-continued-

## "OPPS: PARTIAL HOSPITALIZATION" COMMENTS

Partial hospitalization – specifically – has long been a level of care offered by NAPHS members. In our most recent *NAPHS Annual Survey*, more than half of all NAPHS members responding offered partial hospitalization services for their communities. Throughout the years, these NAPHS members have been a stable group of providers working hard to meet a community need. Patients may use partial hospitalization either as a transition from a hospital program or as an alternative to inpatient care.

NAPHS has been a major proponent and supporter of the Medicare partial hospitalization benefit since the inception of the benefit in the late 1980s. In fact, NAPHS worked with Congress in crafting the legislation, which became the basis for this benefit. The original intent of the benefit was to provide Medicare beneficiaries with an alternative to inpatient psychiatric care that would allow patients to move more quickly out of the hospital to a less intensive, "step-down" program or that would prevent the need for hospitalization. Before the advent of this benefit, Medicare's mental health benefit structure was limited to inpatient psychiatric hospital care or outpatient, office-based visits. The partial hospitalization benefit created an important intermediary service between outpatient, office-based visits and inpatient psychiatric care.

**Partial hospitalization cuts have been severe.**

NAPHS has heard from its members who provide partial hospitalization services under Medicare that the cost of providing this service exceeds the CMS partial hospitalization rate. The partial hospitalization payment rate, which declined by more than 12% in 2006, was further reduced by another 5% in 2007. CMS is proposing to again reduce the partial hospitalization rate by an additional 24% in CY08.

The impact has been that programs that have been the most clinically intensive have struggled to continue to operate these types of programs as payment rates have dramatically declined. **For the first time, CMS has clearly documented in the proposed outpatient PPS rule in the PHP section that PHPs that offer the most structured, clinically intensive programs have substantially higher median costs than other PHP programs.** The CMS analysis clearly shows the need to focus in on the PHPs that are meeting the highest acuity needs of Medicare patients and find ways to make sure that these programs can continue to meet this critical need.

**Restoring the partial hospitalization rate would ensure Medicare beneficiaries continuing access to this essential level of care.**

There are a number of reasons for improving payment for partial hospitalization.

**Congressional intent is to have an intensive benefit.**

**As authorized by Congress, Medicare beneficiaries eligible for PHP are individuals who would require inpatient psychiatric care in the absence of partial hospitalization. Moreover,**

**CMS in subsequent interpretive guidelines and program memorandum have stated that partial hospitalization programs are designed to treat patients who exhibit severe or disabling conditions related to an acute psychiatric condition or an exacerbation of a severe and persistent mental disorder. CMS also has stated that partial hospitalization may occur in lieu of either admission to an inpatient hospital or a continued inpatient hospitalization.** Clearly, the intent was to provide a highly structured, clinically intensive PHP for patients who either were stepping down from hospital care or were using PHP as a diversion from hospital care.

**As the new Medicare inpatient psychiatric prospective payment system (IPPPS) comes around to full implementation** (with major incentives to shorten the length of inpatient stays), **the importance of partial hospital services for step-down and diversion from inpatient services becomes more important to the successful functioning of the total system.** Medicare's transition to 100% IPPPS rates will be complete for cost-reporting periods beginning in 2008.

**Contrary to Congressional intent, the most intensive provider settings are being penalized.**

**CMS data shows that PHP programs providing four or more units of service per day** (in other words, programs that are highly intensive) **have a substantially higher median cost than the overall median cost per day.**

Hospital-based programs (in which 66% of their days have four or more units of service) have a median cost of $218 vs. $186 for their overall median costs. It should also be noted that although two-thirds of the days offered by hospital-based PHPs have four or more units of service, this understates the degree to which hospital-based programs are structured around four or more units of services. On some days in these programs, a patient may only get three services (due to leaving early for illness or other reasons). This number also does not take into account patients that would be transitioning out of the program. However, these programs' costs structures are based on a model of care that is prepared to deliver – and in most cases do deliver – four or more units of service per day.

Community mental health centers (in which 36% of their days have four or more units of service) have a median cost of $191 vs. $178 for their overall median costs.

**Adequate payment for partial hospitalization is essential.**

**To meet the original congressional intent of the PHP program (highly structured, clinically intensive), and CMS's directives, it is imperative to provide the necessary financial incentives to providers to offer the appropriate number of units of services per day to meet the clinical needs of the patient.** Currently, the most structured, clinically intensive programs, which generally provide four or more services per day, are penalized with lower payment rates than their median costs.

The PHPs that have been meeting the needs of the most "acute" Medicare patients should not be penalized for meeting this critical need, but in fact should receive the necessary payments to allow these programs to continue to offer this highly intensive model of care.

**To achieve this objective, there must be an upward adjustment to the payment level for PHP from the proposed rate.** The proposed rate reduction of 24% (resulting in a per diem of $178) is woefully inadequate and would continue to place a growing and real burden on those programs that are providing the most structured, clinically intensive programming, which will likely result in fewer of these programs being offered in the future. This would be totally contrary to Congressional intent and CMS expectations.

In fact, the proposed $178 per diem would be a massive cut -- $40 per-day less than the median per diem of the highly intensive hospital based PHPs that offer four or more services on a daily basis.

**We would propose that the rate remain at least at the $233 per day level to ensure that the highly structured, clinically-intensive PHPs are able to continue to offer these types of programs.** These are the types of programs that will be able to reduce hospitalizations – helping patients to stay out of the hospital, while reducing Medicare inpatient expenditures.

## OTHER PHP / OUTPATIENT COMMENTS

**We would ask CMS to do the same analysis they did for hospital-based programs on remapping revenue codes with CMHCs.**

Although CMS conducted an analysis on the mapping of revenue codes in hospital-based programs, CMS continues to use the overall cost-to-charge ratio for CMHCs. It is our view that if CMS collected the partial hospitalization cost-to-charge ratio in CMHCs (vs. the overall cost-to-charge ratio), the median costs would increase in CMHC PHPs. The reason we believe this to be the case is that in CMHCs that have PHPs and other outpatient services, the PHP would be the highest-cost service provided by the CMHC. Therefore, using the overall cost-to-charge ratio dilutes the PHP costs in CMHCs.

**We also encourage CMS to create more stability—not only in the PHP rate, but also in the other APCs for psychiatric services, such as the group psychotherapy rate.**

This particular APC has declined by 17% in 2007 and is proposed to be reduced further by close to 3% in 2008. Many Medicare beneficiaries can be cared for in less-intensive outpatient programs than PHPs. Unless the group psychotherapy APC rate and other psychiatric APCs cover the costs of delivering these services, this could lead to higher utilization of more costly outpatient services, like PHP, or could result in hospitalization.

**We would also ask CMS to begin to include CMHC PHP data from the CMS-2088-92 cost reports in the *Healthcare Cost Report Information System* (HCRIS).**

The inclusion of this cost report data in the HCRIS file would provide full transparency for industry review and analysis. The HCRIS file currently only includes the following cost report data:

- Hospital Cost Report (CMS-2552-96) for 06/30/07
- Skilled Nursing Facility Cost Report (CMS-2540-96) for 06/30/07
- Renal (CMS-265-94) for 06/30/07
- Hospice (CMS-1984-99) for 06/30/07
- Home Health Agency (CMS-1728-94) for 06/30/07

Currently, interested parties can only obtain hard copies of the CMHC 2088-92 cost report reports via Freedom of Information (FOI) requests from the fiscal intermediary.

## RECOMMENDATIONS

The National Association of Psychiatric Health Systems provides the following recommendations:

1. **Retain the partial hospitalization rate at least at the current $233 per day level to ensure that the highly structured, clinically-intensive PHPs are able to continue to meet the needs of Medicare beneficiaries who have the most acute psychiatric needs and are either stepping down from hospitalization or trying to avoid hospitalization.**

2. **Conduct an analysis to look at cost to charge ratios directly related to PHP within CMHCs (vs. overall cost-to-charge ratios) as done for hospital-based PHPs.**

3. **Analyze the group psychotherapy APC to better understand the reasons for the decline in the APC rate over the last couple of years.**

4. **Begin to include CMHC data from the CMS-2088-92 cost reports in the *Healthcare Cost Report Information System* (HCRIS).** The inclusion of this data would provide full transparency for industry review and analysis.

## CONCLUSION

Thank you for your consideration of our comments. We look forward to working with CMS and the Department of Health and Human Services to ensure that Medicare beneficiaries continue to have access to hospital-based outpatient mental health services.

Sincerely,

Mark Covall
Executive Director

**Submitter :** Ms. Roxann Davenport **Date:** 08/29/2007

**Organization :** Radon Professional Services

**Category :** Individual

**Issue Areas/Comments**

**Payment for Therapeutic Radiopharmaceuticals**

Payment for Therapeutic Radiopharmaceuticals

I am very concerned about the proposed deep cuts for reimbursement for radioimmunotherapy. I feel that the policy change will devastate lymphoma patients both present and future.

**Submitter :** Mr. Steve Haft **Date:** 08/29/2007

**Organization :** Radon Professional Services

**Category :** Individual

**Issue Areas/Comments**

**Payment for Therapeutic Radiopharmaceuticals**

Payment for Therapeutic Radiopharmaceuticals

I am very concerned about the proposed deep cuts for reimbursement for radioimmunotherapy. I feel that the policy change will devastate lymphoma patients both present and future.

**Submitter :** Mr. Tony Davenport **Date:** 08/29/2007

**Organization :** Radon Professional Services

**Category :** Individual

**Issue Areas/Comments**

**Payment for Therapeutic Radiopharmaceuticals**

Payment for Therapeutic Radiopharmaceuticals

am very concerned about the proposed deep cuts for reimbursement for radioimmunotherapy. I feel that the policy change will devastate lymphoma patients both present and future.

**Submitter :** **Philip M.D.** **Date:** **08/29/2007**

**Organization :** **Philip M.D.**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

skin substitute

#207

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

**Submitter :** **Date: 08/29/2007**

**Organization :** **Baptist Med Center**

**Category :** **Other Technician**

**Issue Areas/Comments**

**OPPS Impact**

OPPS Impact

I am a Registered Nurse @ BMC, Jacsonville ,Fl and assist with echo contrast agents.

If separate payment for echo contrast agents is eliminated for hospital outpatients I believe it will reduce patient access to echo contrast agents which give a more definitive diagnostic picture.

**Submitter :** **Mr. Donald Long** **Date: 08/29/2007**

**Organization :** **Lewistown Hospital**

**Category :** **Other Technician**

**Issue Areas/Comments**

**OPPS: Packaged Services**

OPPS: Packaged Services

I am a practicing echocardiographer at Lewistown Hospital and I echo contrast agents. If seperate payment for echo contrast agents is eliminated I believe it will limit patient access to echo contrast agents.

**Submitter :** **Date: 08/29/2007**

**Organization :**

**Category :** **Other Technician**

**Issue Areas/Comments**

**Packaging Drugs and Biologicals**

Packaging Drugs and Biologicals

I am a practicing Echocardiographer at Guthrie-Corning Hospital and I use echo contrast agents. If separate payment for echo contrast agents is eliminated for hospital outpatients, I believe it will reduce the accuracy of echo readings simply due to cost effectiveness. This will reduce the optimal diagnostic outcome for the patient's care.

**Submitter :** Kim Moore **Date:** 08/29/2007

**Organization :** ST. JOHN HEALTH

**Category :** Hospital

**Issue Areas/Comments**

**Cardiac Rehabilitation Services**

Cardiac Rehabilitation Services

Creating new codes for Cardiac rehab based on a per hour code will create a disconnect between Medicare and the other payers whom bill on a per session bases. Whenever these disconnects occur it creates additional administrative burden on hospitals and clinical staff. This appears to have been a stable area for the last couple of years and the rational for the proposed change is not apparent.

**OPPS: Packaged Services**

OPPS: Packaged Services

I'm concerned that the payment rates established under the packaging methodology may not appropriately reflect the cost of the procedure and the cost of the packaged item.

There appears to be no logic within the system that insures the components are properly matched on a claim before being used for rate setting. Claims used to calculate a CT with contrast must have a contrast charge on the claim to be able to use it for rate setting purposes. Claims with a single line item for a CT with contrast and no contrast material were used to set the APC rate, creating an erroneous rate and negative impact on the payment.

Erroneous claims where a contrast was charged with an E&M service, the contrast would have been combined with the E&M, which is not appropriate and would distort the payment in a positive way for E&M services.

The process of packaging can be achieved however additional logic is required in the process to insure accurate rate setting.

**Submitter :** KIM Moore **Date:** 08/29/2007

**Organization :** ST. JOHN HEALTH

**Category :** Hospital

**Issue Areas/Comments**

**Packaging Drugs and Biologicals**

Packaging Drugs and Biologicals

My comment is around the proposal to instruct hospitals to remove the overhead charge from the charge for the drug or biological and report the dollars separately on an uncoded revenue code line. The concerns are:

How other payers will handle this information and the added administrative burden of trying to accomodate this request.

The confusion this will cause for our patients when they receive itemized statements.

The rework required to build the data base within the Pharmacy system, if it is even possible. Many of the smaller community hospitals dealing with olders systems may not be able to accomodate this split. Many systems may require vendor modifications to accommodate at the hospital's expense.

The charge reconciliation process will be skewed and the credit process for unused drugs open to error for not removing the cost component when the drug is credited.

This proposal places an additional burden on hosptials that many can not afford at this time.

**Submitter :** Mr. Mitch Graham **Date:** 08/29/2007

**Organization :** Mr. Mitch Graham

**Category :** Individual

**Issue Areas/Comments**

**Payment for Therapeutic Radiopharmaceuticals**

Payment for Therapeutic Radiopharmaceuticals

To whom it may concern,

As a survivor of Lymphoma, I feel these new advances in medicine to treat Blood Cancers NEED to be allowed in order for people in need to survive if first line treatments do not work. If we do not support treatments, like these, that have shown to save peoples lives, then it is possible these treatments may not be around if you or I or anyone we know, heaven forbid, would need them.

Thank You!

**Submitter :** **Date: 08/29/2007**

**Organization :**

**Category :** **Ambulatory Surgical Center**

**Issue Areas/Comments**

**OPPS Impact**

OPPS Impact

August 28, 2007

Mr. Kerry Weems
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

ATTN: CMS-1392-P
Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective
Payment System and CY 2008 Payment Rates; Skin Repair Procedures
Dear Administrator Weems:
Duke Raleigh Hospital appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Duke Raleigh Hospital is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.
We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf?. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.
In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf s CPT procedure codes do not account for the actual clinical resource use in our experience.
We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.
Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf
We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.
Sincerely,
Patricia Howe, RN
Program Director

**Submitter :** Mrs. Dolores Schuette **Date:** 08/29/2007

**Organization :** St.Elizabeth's Hospital

**Category :** Hospital

**Issue Areas/Comments**

**Observation Services**

Observation Services

All observation services would be paid as part of the separately payable independent services with which they are billed. Nursing care is not a part of an independent service!
How is a hospital supposed to be reimbursed for our Nurses, Case managers, Dietary, Social Service, Housekeeping, Respiratory Care. Patients in observation are treated the same as every inpatient. They still require monitoring, feeding, positioning, bathing, assist to the bathroom. They need medication given to them, medication reconciliation and nursing care the same as an inpatient. The status of observation is not a level of care it is a status. Hospitals should be paid for taking care of these patients.

**Submitter :** **Ms. Brett Young** **Date: 08/29/2007**

**Organization :** **Desert Oasis Medical Group**

**Category :** **Physical Therapist**

**Issue Areas/Comments**

**GENERAL**

GENERAL

SKIN SUBSTITUTE
Please see attached

CMS-1392-P-216-Attach-1.DOC

#216

August 29, 2007

Mr. Kerry Weems
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

ATTN: CMS-1392-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **Skin Repair Procedures**

Dear Administrator Weems:

**Desert Oasis Medical Group, Wound Care Clinic** appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. **DOMG Wound Care Clinic** is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf®. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 — a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.

In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf's CPT procedure codes do not account for the actual clinical resource use in our experience.

We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of

Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.

Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf

We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.

Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact **Brett Young, (760) 320-8814.**

Sincerely,

Brett Young, MPT, CWS

Program Director

**Submitter :** Dr. Gail Grant **Date:** 08/29/2007

**Organization :** Cedars-Sinai Medical Center

**Category :** Physician

**Issue Areas/Comments**

**Quality Data**

Quality Data

With regard to the 10 measures proposed for the initial implementation of the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), I request that consideration be given to delaying the beginning of the data collection and reporting period from January 2008, as proposed to the third or fourth quarter of 2008 or, preferably, to CY 2009. Alternatively, a phased approach in which a subset of the 10 measures - preferably starting with the 5 ED AMI measures - could be implemented in 2008. The reason for the recommended delay is twofold: First, for most hospitals, data storage for hospital outpatient encounters is markedly different from that of inpatients, thus requiring different data collection mechanisms. Outpatient data is often stored in separate databases or systems from that of inpatient data. New or additioinal mechanisms will need to be put in place to retrieve that data for reporting to CMS. In other words, a hospital's current processes of data retrieval, collection, and reporting of the current inpatient quality measures cannot be readily or easily transferred and used for the proposed data reporting on outpatient measures. Hospitals will need time to implement additional processes - as well as staff - for the collection and reporting of this new measure set. Secondly, given that specifications for these measures will not be readily available until just a few months prior to the proposed Jan 1, 2008 start date for data collection, there will be insufficient time to review the specifications. Currently, for the inpatient measures, any changes, along with the detailed specifications of those changes, are released at least 4 months prior to implementation. In addition, it has not been the practice of CMS in the past to require reporting on new measures for purposes of the IPPS APU until they have been available for voluntary reporting as a part of HQA for several months. Hence, I strongly encourage CMS to delay implementation of the HOP QDRP to allow hospitals sufficient time to prepare and implement new processes and procedures for this entirely different data collection process, as well as to give them time to become familiar with the measure specifications.

**Submitter :** **Ms. Robyn Daniels** **Date: 08/29/2007**

**Organization :** **Blair Medical Associates Cardiology**

**Category :** **Nurse Practitioner**

**Issue Areas/Comments**

**Packaging Drugs and Biologicals**

Packaging Drugs and Biologicals

To Whom It May Concern:

If separate payment for echo contrast agents is eliminated for hospital outpatients, I believe it will reduce patient access to echo contrast agents for enhancement of the diagnostic. This will clearly lead to suboptimal studies to accurately evaluate & manage cardiac disease. There will be more potential for poor patient outcomes.

Sincerely,

Robyn J. Daniels, RN, MSN, ACNP-BC

**Submitter :** Dr. John Luckwitz **Date:** 08/29/2007

**Organization :** SW Washington Medical Center

**Category :** Physician

**Issue Areas/Comments**

**Implantation of Spinal Neurostimulators**

Implantation of Spinal Neurostimulators

As an full time pain physician I frequently offer spinal cord stimulation as an option to patients with intractable pain. There is a distinct objective benefit to offering rechargeable stimulator batteries (pulse generator). First is the safety factor : a patient with a nonrechageable battery will require at least one to two battery replacement surgeries, each with potential complications arising from surgery and anesthesia. Second this need for additional surgery translates into increased medicare costs over the long run. When one factors in the cost of the facility fee for the operation in addition to the a replacement battery every three to five years, the cost of a non rechargeable battery are significantly higher. From a technological or financial standpoint, rechargeable batteries offer significant advantages.

**Submitter :** Dr. Jeffrey Malumed **Date:** 08/29/2007

**Organization :** Premier Orthopedics

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

I would like to comment on the proposed tightening of the "Stark" physician self referral rule for Physical Therapy. I am President of our 27 physician Orthopedic group, in which we have over the entire Delaware county in PA, 5 P.T. sites. We not only perscribe therpy but monitor and evaluate regularly that appropiate treatment and length of treatment is followed. Th quality of therapy is significantly above what was offered in this area before our sites were built. All health insurance co. in our area have evaluated our utilization and Quality and continue to support us to provide a superior product. In PA, physical therpists are allowed to send pts. to their own centers without a doctors perscription for 30 days, no supervision, no monitoring, certainly not the quality the goverment wants to support. I would be happy to talk more about this if desired in the future. Sincerely, Dr. Jeffrey Malumed

**Submitter :** Mrs. Barbara V Johnson **Date:** 08/30/2007

**Organization :** None

**Category :** Nurse

**Issue Areas/Comments**

**Implantation of Spinal Neurostimulators**

Implantation of Spinal Neurostimulators

I am a Registered Nurse and also a pain patient. Fourteen years ago a patient assaulted me, and this eventually developed into a chronic pain problem. I was out of work for three years and the suffering was unbearable. Then I agreed to have a spinal cord stimulator implant and this has changed my life. I went back to work as a full time RN and I went back to school for my Nurse Practitioner degree (master s degree). I have been on Workman s Compensation since the injury.

I am rather appalled that the issue of payment for a rechargeable stimulator or payment for battery changes is in debate. How could you agree to pay for the initial insertion and then not cover the expense for caring for that device? It is like saying to a patient who has a pacemaker that is keeping him/her alive, We will pay to have the pacemaker inserted but when you need a battery change, you will have to die because we won t pay for a new one! If I can t have the battery changed, I will not be able to function and then I will be out on disability again. That is a much more expensive proposition that paying for a device. The other point is that a rechargeable device will have a longer life span, which means fewer surgeries for battery changes. In the long run that will save money, and reduce any chances of complications.

I ask that you reconsider this proposal. There are so many of us who are able to live without pain because of the stimulators. Chronic pain can cause so many complications, which can drive up medical costs. Why should we be denied access to this technology when we know that it is such a valuable healer.

#222

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

**Submitter :** **Dr. Johannes Czernin** **Date: 08/30/2007**

**Organization :** **Academy of Molecular Imaging**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**OPPS: Packaged Services**

OPPS: Packaged Services

AMI urges CMS to continue to pay separately for all diagnostic and therapeutic radiopharmaceuticals that are above the threshold for separate payment. CMS s proposal to bundle all diagnostic radiopharmaceuticals into procedural APCs will not result in appropriate payment for certain clinically appropriate radiopharmaceuticals and nuclear medicine procedures.

Please see the attached letter for discussion of this issue.

**PET/CT Scans**

PET/CT Scans

AMI believes that CMS s proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 is inappropriate and unsupported by reliable cost data. By assigning both PET and PET/CT to the same APC, CMS fails to recognize that PET/CT is a clinically distinct technology from conventional PET, with unique clinical benefits. Unlike traditional PET scans, PET/CT is a developing, state-of-the-art technology that will continue to be refined in coming years. The proposed reassignment of PET/CT would risk limiting beneficiary access to a service that now represents the standard of care for most oncology patients.

Please see the attached comment for a discussion of this issue.

CMS-1392-P-223-Attach-1.PDF

#223

AMI
ACADEMY OF MOLECULAR IMAGING

www.ami-imaging.com

August 27, 2007

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90095-1735
T: 310.267.2614
F: 310.267.2617
ami@mednet.ucla.edu



Mr. Herb Kuhn
Deputy Administrator (Acting)
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**ATTN: FILE CODE CMS-1392-P**

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **PET/CT Scans; OPPS: Packaged Services**

Dear Mr. Kuhn:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the CY 2008 Hospital Outpatient Prospective Payment System proposed rule, CMS-1392-P (the proposed rule). AMI is comprised of academicians, researchers and nuclear medicine providers utilizing molecular imaging technologies, including positron emission tomography (PET) and PET with computed tomography (PET/CT). AMI serves as the focal point for molecular imaging education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI speaks for thousands of physicians, providers, and patients with regard to this lifesaving technology, and has worked closely with CMS over the past three years to increase beneficiary access to both standard PET and PET/CT through the development of the National Oncologic PET Registry (NOPR).

## Summary

AMI believes that CMS's proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 is inappropriate and unsupported by reliable cost data. By assigning both PET and PET/CT to the same APC, CMS fails to recognize that PET/CT is a clinically distinct technology from conventional PET, with unique clinical benefits. Unlike traditional PET scans, PET/CT is a developing, state-of-the-art technology that will continue to be refined in coming years. The proposed reassignment of PET/CT would risk limiting beneficiary access to a service that now represents the standard of care for most oncology patients.

AMI also urges CMS to continue to pay separately for all diagnostic and therapeutic radiopharmaceuticals that are above the threshold for separate payment. CMS's proposal to bundle all diagnostic radiopharmaceuticals into procedural APCs will

not result in appropriate payment for certain clinically appropriate radiopharmaceuticals and nuclear medicine procedures.

**Background on Medicare Payment for PET/CT**

PET/CT procedures are identified by three CPT codes (78814, 78815, and 78816). In 2005 and 2006, these codes were assigned to New Technology APC 1514 and the payment rate was $1,250.

For CY 2007, CMS proposed to assign PET/CT to the same clinical APC as traditional PET. However, based on public comments and a concern regarding the accuracy of cost data, the CY 2007 final rule assigned PET/CT to a separate, new technology APC (1511) that paid $950, approximately $100 greater than a single PET scan.

In the current proposed rule, CMS again proposes placing PET/CT in the same clinical APC as traditional PET (0308). In the discussion, CMS states that PET and PET/CT "have obvious clinical similarity." AMI disputes this characterization.

**Assign PET/CT to a Separate Clinical APC**

PET and PET/CT are clinically distinct technologies that should be classified separately under the APC system. Separate assignment for these technologies is supported by both Medicare regulations and the differences in the technologies.

As CMS notes, all of the items and services within a given APC group must be "comparable clinically and with respect to resource use." With regard to CMS's determination of a clinically appropriate APC, the agency has stated:

> After we gain information about actual hospital costs incurred to furnish a new technology service, we will move it to a clinically-related APC group with comparable resource costs. If we cannot move the new technology service to an existing APC because it is dissimilar clinically and with respect to resource costs from all other APCs, *we will create a separate APC for such service*. (65 FR 18476, 18478 (April 7, 2000))

The combination of PET and CT into a single device, known as a PET/CT, represents a clinical breakthrough in imaging. The integration of the two scans provides the most complete non-invasive information available about cancer location and metabolism. PET/CT identifies and localizes tumors more accurately than either of the component images taken alone. In addition, PET/CT technologists can perform both scans without having to move the patient. The resulting images thus leave less room for error in interpretation.

The benefits of PET/CT to the patient are tremendous: earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy. A PET/CT image can distinguish between malignant and benign processes, and reveal tumors that may otherwise be obscured by the inflammation and fibrosis that result from therapies such as surgery, radiation,

and drug administration. PET/CT images often reduce the number of invasive procedures required during follow-up care, including biopsies, and may reduce the number of anatomical scans needed to assess therapeutic response. In some cases, the images are so precise that they can locate an otherwise undetectable tumor. For all of these reasons, PET/CT now represents the standard of care for most oncology patients.

FDA has consistently concluded in both premarket approvals and its regulations that PET/CT is a distinct medical device from PET. New PET/CT devices are specifically cleared by FDA for marketing under the 510(k) process on the basis of currently marketed (or predicate) PET/CT devices, not PET devices.

Moreover, PET/CT technology represents the state of the art imaging for oncology patients. Although CMS has found that 2006 claims data indicates similar resource costs for PET and PET/CT, it is likely that over the next few years the costs of PET/CT relative to PET will continue to diverge. No manufacturers are currently developing new PET scanners. As new PET/CT technologies are developed with different costs from PET, the resource dissimilarity will require a separate clinical APC for PET/CT.

**Continue Separate Payment for Diagnostic Radiopharmaceuticals**

In the proposed rule, CMS proposes packaging diagnostic radiopharmaceuticals into the payment for diagnostic nuclear medicine procedures, including PET and PET/CT, for CY 2008. AMI believes that it is inappropriate to treat diagnostic radiopharmaceuticals differently from other drugs and that claims data may not accurately reflect radiopharmaceutical costs, resulting in inappropriately low payments for PET and PET/CT.

CMS has traditionally paid separately for diagnostic radiopharmaceuticals that meet the cost threshold for packaging of drugs and biologicals under the OPPS. In the proposed rule, CMS proposes to package payment for all diagnostic radiopharmaceuticals, regardless of the per day cost. In the context of this proposal, CMS has argued that they see "diagnostic radiopharmaceuticals . . . functioning effectively as supplies that enable the provision of an independent service."

AMI believes that this is an inappropriate way to characterize radiopharmaceuticals used in PET/CT scans. Radiopharmaceuticals are unique drugs, and not supplies. Radiopharmaceutical such as FDG clearly qualify under the Medicare statute as specified covered outpatient drugs, and should be paid separately, consistent with the treatment of other drugs and biologicals. This methodology for drug payments is important to ensure that physicians are given the flexibility to use the most appropriate drugs for the clinical circumstances.

Although fluorodeoxyglucose (FDG) is commonly used in PET/CT scans, there are numerous radiopharmaceuticals in development that will be used with PET/CT in the near future. Packaging of radiopharmaceuticals into the PET/CT and PET APCs will undermine the resource homogeneity of the procedure APCs which can involve the use of several different radiopharmaceuticals with widely varying costs. As new drugs for PET/CT come to market, providers will experience substantial resource variation for PET/CT scans based on the different

costs for various radiopharmaceuticals. If CMS packages the costs of radiopharmaceuticals into the procedure APCs, this will be a substantial disincentive for the development of new and better drugs, which will limit research and development of better products.

The packaging approach threatens to undermine CMS's efforts to establish accurate payment for both nuclear medicine procedures as well as radiopharmaceuticals. AMI disagrees with CMS's assertion that the line item estimated costs in CMS "claims data offer an acceptable proxy for average hospital acquisition cost and associated handling and preparation costs for radiopharmaceuticals." Accurate cost data for diagnostic radiopharmaceuticals are needed to set appropriate payment rates, and AMI is concerned that implementation of diagnostic radiopharmaceutical revenue codes have not yet enabled accurate isolation of radiopharmaceutical data and average acquisition costs. CMS claims data may fail to accurately reflect higher cost radiopharmaceuticals. Other methodologies for determining average acquisition cost are more appropriate and accurate.

Finally, the packaging proposal may also raise operational difficulties for providers. CPT and HCPCS Level II coding nomenclature is silent to the indication for each nuclear medicine procedure. Combining these separate codes into one package would create an unnecessarily complex coding system for nuclear medicine procedures. Moreover, combining the costs of these separate codes may create wide variations in costs based on individual patient requirements and physician practices.

AMI requests that CMS continue to pay separately for all radiopharmaceuticals that meet the cost thresholds for drugs and biologicals. We also specifically encourage CMS to work with the Society for Nuclear Medicine, which has done extensive research regarding radiopharmaceutical acquisition costs.

**Conclusion**

AMI appreciates CMS's continuing efforts to ensure accurate payment for molecular imaging technologies that do not discourage physicians from using the most appropriate tools for their patients. In the final rule, AMI respectfully requests that CMS assign PET/CT to a separate clinical APCs, and continue to pay separately for radiopharmaceuticals that meet the standard cost threshold.

Please do not hesitate to contact me if you would like to discuss these issues further.

Sincerely,

Johannes Czernin, M.D.
President
Academy of Molecular Imaging

**Submitter :** Ms. Teri Dittrich **Date:** 08/30/2007

**Organization :** UCSD Medical Center

**Category :** Hospital

**Issue Areas/Comments**

**OPPS Impact**

OPPS Impact

I am a practicing sonographer and my institution (UCSD Medical Center, San Diego, CA) uses contrast agents especially during stress echo and in technically difficult and tricky to image patients. Many of these patients could not undergo diagnostic echocardiography without the enhancement that contrast agents provide. The other imaging options for these patients frquently are very invasive, take much longer, cost lots more, and require the use of RADIATION! Please do not eliminate the separate payment for echo contrast because you and your family members will want to have the best care available to you should you ever need an echocardiogram. If we have to pay an additional amount for the agent, our hospital will not be able to afford to let us use them and thus this proposal would create a financial disincentive to use a contrast agent, even when its use would be medically appropriate. This proposal should be dropped and that contrast agents should continue to be eligible for separate payment.

Because contrast agents require additional work to use, there are already underutilized, and the proposal will increase the financial disincentive to use them, even when its use is medically appropriate.

Thank you for your attention to this request.

Teri Dittrich
858-405-1855

**Submitter :** Mr. Michael Williams **Date:** 08/30/2007

**Organization :** Mr. Michael Williams

**Category :** Physical Therapist

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

**Submitter :** Mrs. Kymberly Glyde **Date:** 08/30/2007

**Organization :** University Hospitals Case Medical Center

**Category :** Other Health Care Professional

**Issue Areas/Comments**

**OPPS: Wage Index**

OPPS: Wage Index

I am a cardiac sonograph at University Hopitals Case Medical Center in Cleveland Ohio. I belicve it is very important for hospitals to receive seperate reimbursement for contrast agents used during echocardiograms. It is an essential element to the echocardiogram and patient care. Part of a quality echocardiogram is having the ability to see all cardiac structures well. This is a valuable tool. If the hospitals are forced to give up reimbursement for this product, it will impact patient quality care in a negative manner. Please reconsider this issue for the good of all of our patients.

Thank You

Kymberly Glyde RDCS

**Submitter :** Dr. Mylan Cohen **Date:** 08/30/2007

**Organization :** Maine Medical Center

**Category :** Physician

**Issue Areas/Comments**

**OPPS Impact**

OPPS Impact

Contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate.

Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.

IF CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

**Submitter :** Mr. Mark Dwyer **Date:** 08/30/2007

**Organization :** Southern NH Medical Center

**Category :** Other Health Care Professional

**Issue Areas/Comments**

**OPPS Impact**

OPPS Impact

This letter is to urge CMS to continue to provide separate reimbursement for echo contrast. I am a practicing cardiac sonographer at Southern NH Medical Center and I currently use echo contrast agents. I am concerned that if separate payment for echo contrast agents is eliminated for hospital outpatients, patient access to studies using contrast would be severly limited and Medicare expenditures for mor invasive follow-up procedures may increase.
Contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate. Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.
Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.

IF CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

Thank you for your attention,
Mark Dwyer, RDCS

**Submitter :** **Ms. Serena Bierig** **Date: 08/30/2007**

**Organization :** **St. Louis University**

**Category :** **Other Technician**

**Issue Areas/Comments**

**OPPS Impact**

OPPS Impact

I am a practicing sonographer involved in hospital outpatient as well as clinic outpatient echocardiography. We currently use contrast in both the hospital and clinical settings and are opposed to the proposal to eliminate a separate payment for echocardiographic contrast agents used in echocardiography. Contrast is not used in every patient, but rather those in which imaging is difficult. Contrast enables accurate interpretation in those patients in which imaging would otherwise be extremely difficult. Since it is not routinely used in every patient is should not be bundled. If it is bundled, contrast usage would decrease due to the lack of adequate reimbursement. This would result in an increase in other testing and duplication of charges. For example if a stress echo was performed without contrast resulting in images that were difficult to interpret(whereas contrast would have ensured accurate interpretation), then a second stress test such as nuclear would need to be performed resulting in a duplication of charges. This proposal to eliminate a separate charge for echo contrast should be dropped and that contrast agents should continue to be eligible for separate payment.

Although research has indicated that contrast agents increase accuracy, there is data that they may be underutilized. This proposal would further decrease usage by creating a financial disincentive, even when its use is medically appropriate.

Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

IF CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

Thank you for your consideration,
Serena Michelle Bierig

**Submitter :** **Ms. Debbie Neufelder** **Date: 08/30/2007**

**Organization :** **Welborn Clinic**

**Category :** **Other Technician**

**Issue Areas/Comments**

**OPPS Impact**

OPPS Impact

1) Contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate.

2) Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

3) Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.

4) IF CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

#231

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

#232

CMS-1392-P

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#234

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#235

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