Submitter : **Dr. BJ Daneshfar** **Date: 01/20/2008**

Organization : **Acute & Chronic Pain and Spine Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

January 20, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

BJ Daneshfar, MD, FIPP, DABA, DABPM
24 Care Circle, Amarillo, Texas 79124
806-353-6100

Submitter : Dr. Timothy Lubenow **Date:** 01/21/2008

Organization : University Anesthesiologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Medicare GME Affilations

Medicare GME Affilations

Rush University Medical center
Chicago, Il 60612

CMS-1392-FC-288-Attach-1.DOC

#288

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

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Thank you for the opportunity to comment on the Final Rule.

Sincerely,
Timothy R. Lubenow MD

Timothy R. Lubenow MD
Rush University Medical Center
1750 West Harrison
Chicago, IL 60612
Phone number: 312.942.6504

Submitter : Dr. Joseph Jasper **Date:** 01/22/2008

Organization : ASIPP

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-FC-289-Attach-1.DOC

#289

January 21, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMS's new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

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In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,
Joseph F. Jasper, MD
DABIPP, FIPP, DABA
253-564-2009 Fax 253-564-7420
1628 South Mildred St #105
Tacoma, WA 98465-1613

Submitter : Dr. DAVID MCKELLAR **Date:** 01/23/2008

Organization : THE PAIN TREATMENT CENTER

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

ATTACHMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. James Bianco** **Date: 01/23/2008**

Organization : **Cell Therapeutics, Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attached comment regarding payment for Zevalin (ibritumomab tiuxetan).

CMS-1392-FC-291-Attach-1.PDF

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James A. Bianco, M.D.
President and Chief
Executive Officer
jbianco@ctiseattle.com

#291

BY HAND DELIVERY

January 23, 2008

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

Re: CMS-1392-FC (Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates) – Changes to Packaged Services (Diagnostic Radiopharmaceuticals; Payment for Drugs and Biologicals without Pass-Through Status That Are Not Packaged (Payment for Radiopharmaceuticals).

Dear Administrator Weems:

Cell Therapeutics, Inc. (CTI), a biotechnology company committed to developing and delivering innovative treatments for cancer, submits the following comments on the Centers for Medicare & Medicaid Services' (CMS) final rule with comment period regarding changes to the hospital outpatient prospective payment system (OPPS) and 2008 payment rates.[1] In these comments, we address provisions of the Final Rule that relate to payment for Zevalin® (ibritumomab tiuxetan).

Summary

CTI acquired the marketing, sales, and development rights to Zevalin in December 2007 from Biogen Idec. Zevalin is an anti-cancer regimen for patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphomas (NHL), including patients with rituximab-refractory follicular NHL. This therapy regimen can often be the last option for patients who are not responding to other treatments. Since FDA approval, Zevalin has had significant Medicare reimbursement challenges due to its classification by CMS as a radiopharmaceutical. Zevalin was approved by the FDA under a Biologics License Application. As discussed below, CTI respectfully requests that CMS classify Zevalin as a biological and pay for the treatment under the Average Sales Price (ASP) methodology.

The payment methodology for Zevalin in the 2008 Final Rule would significantly threaten beneficiary access to this critical therapy and could result in some centers closing their

[1] 72 Fed. Reg. 66,580 (November 27, 2007).

costs for the first six months of 2008. We look forward to working with CMS to determine an appropriate permanent payment methodology in 2009 and future years.

Background on Zevalin

Zevalin is in a class of biologics known as radioimmunotherapeutics. These products use biologically produced, highly specific, targeted proteins called monoclonal antibodies that bind to molecules expressed on cancer cells. By attaching a radioactive isotope to the antibody, radioimmunotherapeutics can deliver highly effective doses of radiation directly to cancer cells while minimizing the exposure of normal tissues to damaging radiation.

The Biologics License Application (BLA) for Zevalin was approved by the FDA's Center for Biologics Evaluation and Research on February 19, 2002. Zevalin was granted accelerated approval by the FDA, and the FDA press release noted that this "novel treatment regime" would provide another treatment option for NHL patients, in whom the antitumor effectiveness and duration of tumor responses to standard treatments diminishes after relapse following initial therapy.

The full FDA-approved Zevalin therapeutic regimen consists of two components: an initial *biodistribution dose*, followed by a *therapeutic dose*. The two doses use the same monoclonal antibody (ibritumomab tiuxetan), but different radioactive isotopes. The biodistribution dose uses indium-111 (In-111), while the therapeutic dose uses yttrium-90 (Y-90). These two distinct steps are inseparable parts of a therapeutic regimen as required by the FDA and outlined in product labeling.

In order to assure that the treatment regimen is safe and effective in a patient, the physician must first image the biodistribution – the body's uptake – of the monoclonal antibody. The therapeutic Y-90 radioisotope does not emit gamma radiation, and cannot be used for imaging purposes. Instead, physicians use the In-111 radioisotope – a gamma emitter – attached to the same monoclonal antibody for the biodistribution dose, allowing the necessary imaging. Because the purpose of the biodistribution dose is to ensure the safety of the therapeutic dose, it is critical that the same monoclonal antibody be used for both doses. Y-90 Zevalin is not administered to patients with altered biodistribution, as determined by imaging with In-111 Zevalin. After the physician confirms that the patient has acceptable biodistribution, the therapeutic dose of Zevalin is administered using weight-based dosing. This dose delivers the Y-90 isotope to directly attack the lymphoma.

Clinical Benefits of Zevalin

Zevalin is among the few treatment options that can produce long-term disease-free survival in some patients with relapsed indolent non-Hodgkin's lymphoma who no longer respond to conventional chemotherapy and the monoclonal antibody, rituximab. Zevalin thus represents an important treatment option for these lymphoma patients, and provides benefits that are distinct from those of other approved therapies.

The complete Zevalin therapeutic regimen is administered as two ten-minute infusions approximately one week apart. In view of the palliative nature of therapy for patients with

relapsed or refractory indolent lymphoma, the Zevalin regimen represents a far less burdensome therapy than repeated cycles of chemotherapy.

Prior Hospital Outpatient Payment for Zevalin

The reimbursement challenges for Zevalin are illustrated by the fact that the payment methodology has changed almost yearly since its approval. These changes are summarized in the below chart, followed by a history of Medicare payment for Zevalin.

Historical Medicare Hospital Outpatient Payment for Zevalin

Year	Methodology	Rate	
2002 (through September 30)	Miscellaneous J-Code	No separate payment; charges may trigger outlier payments	
2002 (after October 1)	Outpatient new technology transitional pass-through payment	78% of AWP (pass through pro rata reduction) Approximately $21,959	
2003	New Technology APC	In-111 Y-90 Total	$2,750 $20,000 $22,750
2004 (proposed)	External data	In-111 Y-90 Total	$2,260 $19,565 $21,825
2004 (MMA)	88% of AWP	In-111 Y-90 Total	$2,565 $22,210 $24,775
2005	83% of AWP	In-111 Y-90 Total	$2,419 $20,948 $23,367
2005 GAO Report	Survey	Y-90	$19,615
2006	Individual charges reduced to costs	Varied by claim	
2007	Charges reduced to costs	Varied by claim	
2008 OPPS Final Rule	In-111 packaged Y-90 at median cost	In-111 Y-90	Packaged $15,024
2008 Medicare Legislation (Jan-Jun)	Charges reduced to costs	Varies by claim	

When Zevalin first received FDA-approval, it was temporarily paid as a biologic under the transitional pass-through payment category. However, the decision in the 2003 OPPS Final Rule to classify Zevalin as a radiopharmaceutical prevented Zevalin from being eligible for the pass-through payment. Instead, both doses of Zevalin were paid under New Technology APCs.

Before the passage of the Medicare Modernization Act (MMA), CMS published the 2004 Hospital Outpatient Final Rule, which used "verifiable data" from external sources to establish a payment rate for Zevalin.

However, the MMA, signed in December 2003, required that radiopharmaceuticals, including Zevalin, be paid as a "specified covered outpatient drug." In 2004, the MMA required payment at a minimum of 88% of AWP, slightly raising the payment from the rate set by CMS. In 2005, the payment rate was again set at the statutory floor of 83% of AWP.

In subsequent years, the MMA required CMS to establish payment for specified covered outpatient drugs at "the average acquisition cost for the drug for that year . . . as determined by the Secretary taking into account the hospital acquisition cost survey data [collected by the Government Accountability Office (GAO) and the Secretary]."[2] In July 2005, the GAO published a survey of radiopharmaceutical purchase prices for CMS consideration in rate-setting.[3] The GAO report listed a cost for Zevalin that was almost identical to the rate determined by CMS in the 2004 Final Rule (before the passage of the MMA).

In its 2006 Hospital Outpatient Rule, CMS established a payment policy for separately payable radiopharmaceuticals, including Zevalin, that based payment on the hospital-reported charge for the radiopharmaceutical reduced to cost using hospital-specific overall cost-to-charge ratios (CCR). This resulted in a newly calculated payment for each claim submitted for a separately payable radiopharmaceutical, based on the reported charge on the claim.

CMS believed that this methodology provided the "best available proxy for the average acquisition cost" because "hospitals can appropriately adjust their charges for radiopharmaceuticals so that the calculated costs properly reflect their actual costs," and instructed that "it is appropriate for hospitals to set charges for these agents in CY 2006 based on all costs associated with the acquisition, preparation, and handling of these products so that their payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients."

After considering several alternative methodologies, the 2007 Final Rule maintained the 2006 methodology. CMS repeated its conclusion that these rates represented the best proxies for average acquisition cost.

CY 2008 OPPS Final Rule Regarding Payment for Zevalin

As written, the 2008 Final Rule would further exacerbate the reimbursement challenges. First, the CMS policy to set rates for therapeutic radiopharmaceuticals based on mean unit costs from CY 2007 data claims will reduce payment for the Zevalin therapeutic dose to well below the average acquisition cost of the drug. Second, the CMS policy to package payment for the biodistribution dose will eliminate payment for providers who administer this therapy by setting payment below actual costs. These policies are based on the CMS classification of Zevalin as a radiopharmaceutical.

---

[2] Social Security Act § 1833(t)(14).

[3] Government Accountability Office, "Hospital Radiopharmaceutical Prices." GAO-05-733R (July 14, 2005).

In the 2008 Final Rule, CMS classifies the In-111 of Zevalin as a "diagnostic radiopharmaceutical" and the Y-90 as a "therapeutic radiopharmaceutical." CTI is concerned that CMS' proposed reimbursement methodology for these two classes of drugs would limit Medicare beneficiaries' access to Zevalin. In particular, we believe that packaging payment for In-111 Zevalin and the rate-setting methodology for Y-90 Zevalin will result in inaccurate and insufficient payment for these unique therapies. We believe these proposals are inconsistent with the statutory requirement that payment should be based on acquisition costs, subject to any adjustments for overhead costs.

The CY 2008 payment rate for Y-90 Zevalin and other "therapeutic radiopharmaceuticals" is based on an estimate of mean costs derived from the CY 2006 claims data. The payment rate is calculated using the standard methodology of applying departmental specific cost-to-charge ratios (or the overall cost-to-charge ratio (CCR) if a departmental CCR is not available) to determine mean costs based on claims data. Payment for In-111 Zevalin and other "diagnostic radiopharmaceuticals" is packaged into the associated procedure. Both of these methodologies will reduce payment below actual product costs, even before considering overhead and procedure costs.

The CY 2008 payment rate for Y-90 Zevalin is $15,023.91, 23 percent less than the purchase price determined by the GAO in 2005[4] and well below the current list price of $25,238. GAO concluded that its survey resulted in acquisition cost estimates that were "sufficiently accurate for use in developing Medicare rates." CMS has not conducted surveys of hospital acquisition costs since the 2005 GAO report. Moreover, the Final Rule notes that the practice of hospital charge compression can result in inappropriately low payment for high cost items when rates are based on average costs using hospital CCRs. These factors suggest that the 2008 Final Rule payment rate is inappropriately low for Zevalin, and does not reflect the average acquisition cost.

The payment for In-111 Zevalin will be packaged in the procedure rate for the diagnostic service. A review of the CY 2006 Medicare cost data indicates that claims for In-111 Zevalin appear in several APCs. However, the majority of the In-111 Zevalin claims are found in APC 414 (Level II Tumor/Infection Imaging), which will have a payment rate of $536 – just 20 percent of the acquisition cost of $2,598.[5] Some In-111 Zevalin claims are found in APC 408 (Level III Tumor/Infection Imaging) which will be paid at $981 – 37 percent of the average acquisition cost.

Comparison of 2008 Hospital Outpatient Payment for Zevalin to Estimated Average Acquisition Cost

	In-111 Zevalin	Y-90 Zevalin	Combined
CY 2008 Payment Rate	$981*	$15,024	$16,005
Estimated Average Acquisition Cost	$2,598**	$19,615***	$22,213

[4] Government Accountability Office, "Hospital Radiopharmaceutical Prices." GAO-05-733R (July 14, 2005). The report is based on a survey of hospital-reported prices between July 2003 and June 2004.
[5] Society of Nuclear Medicine Preliminary Data (reflecting 2006 prices).

2008 payment as percentage of Estimated Average Acquisition Cost	37%	76%	72%

* Maximum payment, based on APC 408 (Level III Tumor/Infection Imaging), not accounting for overhead costs or procedure costs. APC 414 (Level II Tumor/Infection Imaging) has a payment rate of $536.
** Based on Society of Nuclear Medicine Survey
*** Based on 2005 GAO Survey

Legislative Modification to Payment for Radiopharmaceuticals

On December 29, 2007, the Medicare, Medicaid, and SCHIP Extension Act of 2007 was signed into law. Section 106 of the Act sets payment for certain radiopharmaceuticals at charges reduced to cost (amending § 1833 of the Social Security Act to include these products).

The legislation was designed to address concerns that insufficient reimbursement for radioimmunotherapies like Zevalin would lead to diminished access for beneficiaries. The text of the law extends the payment methodology to "therapeutic radiopharmaceuticals." It is our understanding that CMS reads this provision to only extend to the Y-90 component. CTI believes that it was Congress's intention to include *all* of the elements of the FDA-approved Zevalin radioimmunotherapeutic regimen within the scope of this language. We believe that Congress included this provision in order to address the well-documented disparity between the cost of radioimmunotherapies and the reimbursement rates proposed for 2008 by CMS.

The FDA-approved label for Zevalin specifically notes that "In-111 Ibritumomab Tiuxetan and Y-90 Ibritumomab Tiuxetan are components of the Zevalin therapeutic regimen." The label covers kits for the preparation of the two doses, and FDA treats the two doses as part of the same product. Moreover, both doses of Zevalin were included on a single BLA, and FDA approved both doses as part of a single approval letter and license. Based on this history at the FDA – including the most recent label supplement in November 2007 – there is no support for treating the two doses separately, and certainly no support for considering the biodistribution dose of Zevalin as a diagnostic radiopharmaceutical.

As CMS takes steps to implement section 106, CTI encourages the agency to include all doses of the Zevalin immunotherapeutic regimen within its scope. Accordingly, payment for both the biodistribution dose and the therapeutic dose would be paid based on hospital charges reduced to costs for the first six months of 2008. Because the provision only applies for the first 6 months of 2008, CTI would like to work with CMS on estimating acquisition cost for Zevalin for the third and fourth quarters of this year.

Calendar Year 2009 Payment for Zevalin

A. CMS Should Classify Zevalin as a Biologic

The reimbursement challenges for Zevalin largely stem from the decision by CMS in 2002 to pay for Zevalin as a radiopharmaceutical. As noted above, the FDA approved Zevalin under a Biologics License Application in early 2002. However, later that year, CMS classified

Zevalin as a radiopharmaceutical. In the FY 2003 hospital outpatient Final Rule published November 1, 2002, CMS concluded,

> *Because of the specific requirements associated with delivery of radioactive isotope therapy, any product containing a therapeutic radioisotope, including Y-90 Zevalin, will be considered to be in the category of benefits described under section 1861(s)(4) of the Act. Similarly, the appropriate benefit category for all diagnostic radiopharmaceuticals, including IN-111 Zevalin, is 1861(s)(3).*

Social Security Act sections 1861(s)(3) and (s)(4) do not appropriately describe the Zevalin regimen. These categories typically describe diagnostic tests and x-ray therapy. Idec Pharmaceuticals (the original manufacturer of Zevalin) filed comments with CMS on the 2004 hospital outpatient rule to challenge the classification as a radiopharmaceutical and argue that Zevalin is a biologic, but CMS did not change this determination. CMS has continued to classify Zevalin as a radiopharmaceutical.

The more appropriate benefit category for Zevalin would be 1861(2)(A) and (B) which specifically refers to "drugs and biologicals" which are not usually self-administered by patients. CMS has acknowledged that these classifications may be appropriate. On July 25, 2005, CMS concluded its National Coverage Analysis titled, "Radioimmunotherapy for Non-Hodgkin's Lymphoma" (CAG-00163N). With regard to the benefit category for Zevalin the decision memorandum states:

> *appropriate benefit categories may be found under §1861(s)(2)(A), services and supplies furnished as incident to a physician's service, and under §1861(s)(2)(B), hospital services incident to physicians' services rendered to outpatients.*

We believe the result of this determination would be a finding that the 1861(s)(2)(A) "incident to" benefit is the most appropriate classification for a biologic like Zevalin. CTI may request a National Coverage Determination of the appropriate benefit category for Zevalin.

B. CMS Should Pay Zevalin Based on ASP

CTI would like to work with CMS to establish a new payment methodology for Zevalin – that recognizes their FDA approval as a biologic. CTI believes that it would be more accurate to pay for Zevalin based on ASP, as other biologics are paid. CMS has concluded that ASP-based payment is the most accurate rate-setting methodology for other drugs and biologics, and we believe a similar conclusion is applicable to radioimmunotherapies. CTI proposes the following approach for the Zevalin regimen and does not discuss how an ASP approach may apply to the class of radiopharmaceuticals.

CMS has requested comments on how an ASP methodology may work for individual products. In the 2008 Final Rule, stated:

> *Therefore, to the extent that manufacturers or stakeholders believe that the ASP methodology that we currently use for the payment of*

separately payable drugs and biologicals under the OPPS is appropriate for their particular product, we seek comments on that approach and comments on how radiopharmaceutical ASP information could be used in future ratesetting.

Section 1847A of the Social Security Act establishes the ASP system, and notes that it applies to all "biologicals." It seems appropriate to treat products approved by the FDA under a BLA as biologicals. CTI would certify ASP based on the methodology described in section 1847A and implemented in subsequent CMS rulemaking and report Average Sales Price data for Zevalin on a quarterly basis.

CTI recognizes the unique difficulties in implementing an ASP methodology for radioimmunotherapies but CTI believes that it would be feasible for the company to collect and certify ASP. CTI would include both necessary components of the FDA-approved regimen (the biodistribution dose and the therapeutic dose) in the reported Average Sales Price. This would allow CMS to set a payment rate for both doses based on ASP. This approach would be consistent with the Social Security Act, and would better ensure patient access to these therapies.

Because Average Sales Price is a market-based methodology, we have focused on using a reporting and distribution structure that will accurately represent the actual price of the product, after taking into account all discounts and price concessions. CTI would certify an Average Sales Price based on actual direct sales of the drug to wholesalers on a quarterly basis (net of any discounts, rebates or price concessions). CTI would separately contract for the radioisotope and nuclear pharmacy compounding services that are necessary for manufacturing the final patient-specific unit dose. These costs cover necessary elements of the preparation of the patient-specific unit dose, and would not affect reported ASP, as discussed below. We believe this approach is consistent with the ASP reporting statute, and meets the goals of CMS to allow payment for biologics like Zevalin to be set based on market-based data.

The final patient-specific unit dose of Zevalin is the product of a complicated manufacturing and compounding process. In the final step of this process, a specialized nuclear pharmacy combines the monoclonal antibody Ibritumomab tiuxetan with a radioisotope that is, in many cases, provided by a different manufacturer. Due to the short half-life of these products, they are very unstable, and must be prepared shortly before they are administered. CTI has been working with the individual members of this manufacturing and distribution process to allow the company to certify a single ASP that represents the market price of the patient-specific unit dose. Additionally, at present the NDC for the Zevalin kit does not include the isotope. CTI notes that ASP is reported based on National Drug Code (NDC).

The separate contracts for the radioisotope and nuclear pharmacy compounding are necessary costs for the patient-specific preparation of Zevalin. For the purposes of ASP reporting, they would constitute a manufacturing cost or a bona fide service fee. In the 2007 Physician Fee Schedule Final Rule, CMS established the following definition for bona fide service fees:

fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on

behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

CMS went on to note that it would "interpret these elements of the definition to encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." The separate contracts for the necessary elements in the manufacturing and compounding process will be determined through arms-length negotiation and set at fair market value. Thus, these contracts will constitute bona fide services, and the fees will not affect the ASP reporting.

Conclusion

Developing an accurate payment methodology for Zevalin is critical to make this treatment available to patients. The stakes are high in terms of ensuring Medicare beneficiary access to these important therapies. CTI acknowledges the efforts CMS has taken to consider alternative methodologies for radiopharmaceutical payments, but we believe that a new approach is necessary to develop a payment rate for Zevalin that reflects true acquisition cost. We encourage CMS to include both doses of the Zevalin radioimmunotherapy regime under the scope of the recent legislative change to payment for radiopharmaceuticals.

CTI looks forward to working with CMS to establish an ASP methodology that would appropriately capture the market-based average sales price for the Zevalin regimen. We hope to meet with CMS in February to discuss this proposal further in order to improve the accurate reporting and payment for this product.

Thank you for your attention to this very important matter.

Respectfully submitted,

Jim Bianco, M.D.
CEO
Cell Therapeutics

Submitter : **Dr. Brian Block** **Date: 01/23/2008**

Organization : **Baltimore Spine Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access. The ASC setting is ofet the most efficient and safest site of service for interventional pain care. Patients who must go to the hospital setting incur higher costs and are exposed to a greater infection risk.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

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The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Brian M. Block, MD, PhD
Pain Medicine Specialists, PA
Baltimore Spine Center
Baltimore, Maryland

Submitter : **Dr. Paul Hubbell** **Date: 01/24/2008**

Organization : **Louisiana Society of Interventional Pain Practitio**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

January 23, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and new CMS proposals and classifications will hinder patient access.

I am concerned about the status indicator for CPT Codes 72285 and 72295 and the disallowance and non-payable issue which is related to discography. CMS pays separately for the radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly, but the rules do not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Code 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC, as it is a safe outpatient procedure to be performed in an ASC and it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and the importance of these discograms being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings, specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Paul J. Hubbell, D.D.S., M.D.
P.O. Box 7725
Metairie, Louisiana 70010
504 889 9753
504 889 1868 fax

Submitter : **Dr. John Stephenson** **Date: 01/24/2008**

Organization : **Dr. John Stephenson**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

January 24, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse. .

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

John H Stephenson, M.D.

Submitter : Dr. Osama Malak **Date:** 01/24/2008

Organization : Comprehensive Pain Care Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

CMS-1392-FC - Medicare and Medicaid Programs: Changes to the Hpsoital Outpatient Prospective Payment System and CY 2008 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2008Payment; Changes to Hospital Conditions of Participation; Changes Affecting Necessary Provider Designations of Critical Access Hospitals Rates

Submitter : Dr. Peter Kosek **Date:** 01/24/2008

Organization : Pain Consultants of Oregon

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attchment

CMS-1392-FC-296-Attach-1.DOC

#296

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As an interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access to pain treatments.

The issue relates to the update to the conversion factor. While ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary, and payments are less than the overhead that I have to provide appropriate nursing monitoring during and after an in office procedure.

A focus on the quality of services that CMS is paying for is in order. CMS should establish that these procedures should be performed by only well-trained qualified physicians in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. In Oregon, this accreditation is already required by the Oregon Medical Board. However, the cost of this accreditation is not included in CMS payments for office procedures
Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Peter Kosek, MD
Pain Consultants of Oregon
360 S Garden Way, Suite 101
Eugene, OR 97401
541-684-9452

Submitter : **Date: 01/25/2008**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I oppose the implementation of this interim rule as it will potentially decimate Maryland's case management and ACCU programs for vulnerable citizens. Services to individuals with disabilities and those already coping with devastating poverty will be curtailed significantly. Further investigation must be done before implementing this to determine potential impact on Medicaid beneficiaries in all of the states.

Submitter : **Date: 01/25/2008**

Organization : **Provider Roundtable**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attachment for complete comments.

CMS-1392-FC-298-Attach-1.DOC

#298

Asante Health System, OR
Avera Health, SD
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Erlanger Medical Center, TN
Forrest General Hospital, MS
Health First, Inc., FL
Lovelace Health System, NM
Mercy Medical Center, IA
Our Lady of the Lake Regional Medical Center, LA
Palomar Pomerado Health, CA
Saint Joseph's Hospital, WI
St. Joseph's/Candler Health System, GA
Saint Mary's Hospital, MN
Sheltering Arms Rehabilitation Hospitals, VA
Sisters of Mercy Health System, MO
Twin Lakes Regional Medical Center, KY
University Health System, TX
Vanguard Health System, TN

January 25, 2008

Submitted electronically: http://www.cms.hhs.gov/eRulemaking

Re: File Code CMS-1392-FC

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers from around the country who wish to provide comments on the 2008 Outpatient Prospective Payment (OPPS) Final Rule, as published in the *Federal Register* on November 27, 2007.

Introduction

The Provider Roundtable (PRT) is a group of providers representing 19 different health systems from around the country. The members of the PRT collaborated to provide substantive comments with an operational focus which CMS' staff should consider during the OPPS policymaking and recalibration process each year. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

We appreciate the opportunity to provide CMS with our comments, and recognize that providers must become involved in the comment process if OPPS is to improve with time. A full list of the current PRT members is provided in **Appendix A.**

Deleted: 1/25/2008

HCPCS Codes with Comment Indicator "NI"

The PRT has reviewed Addendum B and would like to bring attention to several HCPCS codes that are open for comment.

CPT 86486 (Skin test; unlisted antigen, each). We question why this code is assigned SI "A" when all the other codes in the family are assigned "X" and paid under APC 341. We realize this CPT replaces 86586 (which was also SI "A"), but we ask CMS to review for consistency with other skin tests and treat it in the same manner under APC 341.

86485	Skin test, candida		X	0341	0.0844	5.38	2.14	1.08
86486	Skin test, nos antigen	NI	A					
86490	Coccidioidomycosis skin test		X	0341	0.0844	5.38	2.14	1.08
86510	Histoplasmosis skin test		X	0341	0.0844	5.38	2.14	1.08
86580	TB intradermal test		X	0341	0.0844	5.38	2.14	1.08
86586	Skin test, unlisted	CH	D					

CPT 90776 (Therapeutic, prophylactic or diagnostic injection...each additional sequential intravenous push of the same substance/drug provided in a facility...)

This CPT code, although new for 2008, derives from the lineage of predecessor codes 90784 and C8952. We believe that this code should be assigned to APC 438 along with existing CPT codes 90774 and 90775. We understand CMS typically likes to collect claims data for two years before making an APC placement and payment determination. This makes sense particularly when a new code or service is being introduced and CMS has no experience with the code of service. We do not believe this is the case with CPT code 90776 as this code is for an IV push and CMS has robust claims data on IV pushes. Furthermore, we do not believe that the "cost" for this service has already been accounted for in current APC payment rates. When hospitals were allowed to bill for each occasion of 90784, it is our belief that this would have occurred on multiple-major claims; therefore when setting payment for current APC 438 those "each additional" charges would not have been considered. However, clinically, 90776 involves the same amount of work as 90774 and 90775, and therefore should be paid at the same APC payment rate.

CPT 96125 (Standardized cognitive performance testing...). We question why this code is assigned SI "A" when other codes in the family are assigned SI "Q" in various APCs. We ask CMS to review the clinical intention behind this code, and, if appropriate, assign SI "Q" and APC 382.

96116	Neurobehavioral status exam	CH	Q	0382	2.6169	166.68		33.34
96118	Neuropsych tst by psych/phys	CH	Q	0382	2.6169	166.68		33.34
96119	Neuropsych testing by tec	CH	Q	0382	2.6169	166.68		33.34
96120	Neuropsych tst admin w/comp	CH	Q	0373	1.2448	79.29		15.86
96125	Cognitive test by hc pro	NI	A					

Deleted: 1/25/2008

CPT 36592 (Collection of blood specimen using established central or peripheral catheter, venous, nos). The PRT does not believe this code should be unconditionally packaged. We believe that the work associated with drawing blood from a central or peripheral catheter would be no different than drawing from an implanted access device, and that 36592 should be assigned SI "Q" (just like 36591) so that it will be paid separately if it is the only APC service reported on a claim.

36591	Draw blood off venous device	NI	Q	0624	0.5689	36.24	12.65	7.25
36592	Collect blood from picc	NI	N					
36593	Declot vascular device	NI	T	0676	2.4824	158.11		31.62

Contrast Media – page 66643

The Provider Roundtable (PRT) believes it would be beneficial for ratesetting purposes to develop billing edits that would require reporting of contrast media along with procedures that require contrast. This would ensure that CMS is using accurate, complete cost data on these procedures. Most member facilities of the PRT are already reporting contrast separately, regardless of whether it is currently packaged.

Conclusion

The Provider Roundtable would sincerely like to thank CMS and its staff for reviewing and considering our comments. The PRT members are very encouraged by the policy-making process and appreciate how our input can have an impact on future year's rules and policies. We are very grateful to CMS for considering our comments in past years as well as again this year. We hope the operational issues we have outlined will be helpful to CMS in considering future system changes. If you have any questions please do not hesitate to contact:

Denise Williams, RN, CPC-H; Vanguard Health System, TN, (615) 665-6052

A full list of the provider roundtable members is included below in Appendix A.

Sincerely yours,

Members of the Provider Roundtable

Deleted: 1/25/2008

Appendix A: Current Members of the Provider Roundtable

Jennifer Artigue, RHIT, CCS
Director, Medical Records/HIM
Our Lady of the Lake Regional Medical Center
Baton Rouge, LA

Kathi Austin, CPC, CPC-H, CCP
Corporate Director Revenue Integrity
Sisters of Mercy Health System
St. Louis, MO

Barbara Bunge, RHIA, CCS, CCS-P
Coding Quality Specialist, HIM
Mercy Medical Center
Cedar Rapids, IA

Freda Brinson, CPC, CPC-H
Compliance Auditor
St. Joseph's/Candler Health System
Savannah, GA

Sandy Colson, CPC, CPC-H
APC Coordinator
Lovelace Health System
Albuquerque, NM

Kathy Dorale, RHIA, CCS, CCS-P
Director of Health Information Management
Avera Health
Sioux Falls, SD

Sharon Ford
Reimbursement Analyst
Twin Lakes Regional Medical Center
Leitchfield, KY

Janet Gallaspy, BS, RN, CPUR, CPC-H
Director of Patient Care Services, Outpatient Services
Forrest General Hospital
Hattiesburg, MS

Jerry Hill, MA
ChargeMaster Coordinator
University Health System
San Antonio, TX

Deleted: 1/25/2008

Bonnie Malterer, RHIT, BA
APC Coordinator, Outpatient Coding Supervisor
St. Mary's Hospital
Duluth, MN

Yvette Marcan, RN, MA, RHIA, CCS
Clinical Reimbursement Specialist
Health First, Inc.
Melbourne, FL

Kate McComb, CCP
Compliance Audit Manager
Palomar Pomerado Health
San Diego, CA

Terri Rinker, MT(ASCP), MHA
Director, Reimbursement Cycle
Community Hospital Anderson
Anderson, IN

Valerie A. Rinkle, MPA
Revenue Cycle Director
Asante Health System
Medford, OR

Julie Rodda, RHIT
Reimbursement Coordinator
St. Joseph's Hospital
Marshfield, WI

John Settlemyer, MBA, MHA
Director, Financial Services/CDM
Carolinas Healthcare System
Charlotte, NC

Jose Vivaldi, MS, OTR/L, MBA
Director, Outpatient Services
Sheltering Arms Rehabilitation Hospitals
Mechanicsville, VA

Denise Williams, RN, CPC-H
Corporate CDM Manager
Vanguard Health Systems
Nashville, TN

Julianne Wolf, RN, CPHQ
Charge master Senior Analyst
Erlanger Medical Center
Chattanooga, TN

Deleted: 1/25/2008

Submitter : Dr. Vijay Singh **Date:** 01/25/2008

Organization : NHC

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1392-FC-299-Attach-1.DOC

#299

January 25, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT C ode 722 85 (discography i nterpretation a nd supervision in c ervical spine) o r C PT C ode 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely, Dr. Vijay Singh

Submitter : Dr. Chandur Piryani **Date:** 01/25/2008

Organization : Niagara Health Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1392-FC-300-Attach-1.DOC

#300

January 25, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT C ode 722 85 (discography i nterpretation a nd supervision in c ervical spine) o r C PT C ode 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely, Dr. Chandur Piryani

Submitter : Dr. Katherine Liao **Date:** 01/25/2008

Organization : Niagara Health Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1392-FC-301-Attach-1.DOC

CMS-1392-FC-301-Attach-2.DOC

#301

January 25, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT C ode 722 85 (discography i nterpretation a nd supervision in c ervical spine) o r C PT C ode 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely, Dr. Katherine Liao

Submitter : Denise Williams **Date:** 01/25/2008

Organization : Vanguard Health Systems

Category : Hospital

Issue Areas/Comments

HCPCS codes

HCPCS codes

Vanguard Health Systems is a system of 15 hospitals located in four states. We appreciate the opportunity to comment on the APC assignment of CPT code 90776 (each additional sequential IV push same substance or drug).

CMS noted in the 2008 Final Rule with comment period that this code was to be assigned status indicator N due to a lack of claims data. Once this code has been reported for two calendar years, claims data would be available for rate-setting purposes.
We suggest that the claims data actually does exist but is not included in the single procedure claims that CMS uses for rate-setting. HCPCs codes 90784 and C8952 were reported on claims prior to CY 2007 that would have been considered multiple procedure claims and therefore not included in the annual rate setting process. We submit that CPT code 90776 requires the same resources as CPT codes 90774 (initial IV push) and 90775 (subsequent IV push of a different drug). These codes report the very same procedure performed in a particular order. Therefore, CPT code 90776 should be assigned to APC 0438 along with 90774 and 90775.

We also noted in Addendum B for the final rule that CMS set precedent for assigning a new CPT code to an APC without claims data. CPT codes 90769 90771 (subcutaneous infusion) have been assigned to an APC with an APC payment rate (APCs 0437, 0738, and 0440) when there is no specific claims data for rate setting based on CPT reporting. There have been no codes for reporting subcutaneous infusions in the past.

Following this same logic, we recommend and request that CMS assign CPT code 90776 to APC 0438, change the status indicator to S and set the payment rate equal to the payment for CPT codes 90774 and 90775.

Thank you for the opportunity to comment on this issue.

Submitter : Ms. Deb Vargo **Date:** 01/25/2008

Organization : NHC

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

please see attachment!

CMS-1392-FC-303-Attach-1.DOC

#303

January 25, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT C ode 722 85 (discography i nterpretation a nd supervision in c ervical spine) o r C PT C ode 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,
Ms. Deb Vargo, RN

Submitter : Mr. Daniel Freeman **Date:** 01/25/2008

Organization : NHC

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1392-FC-304-Attach-1.DOC

#304

January 25, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

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Thank you for the opportunity to comment on the Final Rule.

Sincerely,
Mr. Daniel Freeman

Submitter : Mr. Donald Moran **Date:** 01/25/2008

Organization : The Moran Company

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1392-FC-305-Attach-1.PDF

#305

1655 N. FORT MYER DRIVE, SUITE 1250 ARLINGTON, VA 22209 (703) 465-9970 FAX (703) 465-9969

January 25, 2008

Submitted Electronically

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-FC (for OPPS and ASC matters)
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

Dear Administrator Weems:

As major users of the Outpatient Prospective Payment System (OPPS) data for policy analysis of the Medicare payments to hospital outpatient departments, we strongly support the efforts that the Center for Medicare & Medicaid Services (CMS) has made to release sufficient information as a part of the annual OPPS rate setting process to allow for independent analysis of the impact of OPPS policies and payment rates. This information is invaluable in helping various interested parties develop informed comments to the agency on the effects of various changes it proposes and adopts each year.

The Moran Company is a health care research and consulting firm that assists clients in the health care industry to analyze and understand a variety of Medicare payment systems. As part of this effort, we purchase the OPPS select public use file (OPPS PUF) each year and produce a variety of analyses to aid our clients in submitting informed comments to CMS on its proposed and final rules setting Medicare payment rates to outpatient hospitals. We support the agency's willingness to release the OPPS PUF and also appreciate the willingness of the CMS staff and the staff of the Research Data Distribution Center (RDDC) to work with us to resolve issues related to this file. We believe that a few relatively minor changes could make the OPPS PUF more useful to the public, with corresponding benefits to CMS in the form of more informed comments on the proposed rule.

Our specific suggestions to improve the ability of outside parties to conduct independent analyses in a timely fashion are as follows:

Data release

Currently, the OPPS select public use file is not shipped to customers until several days or even weeks after the release of the rule. We would like to request that CMS consider shipping the data to end users on the same day as, if not before, the release of the rule.

This earlier release will allow analysts slightly more time to examine the data and simulate policy alternatives, leading to more informed and useful comments.

Data validation

Currently, validating the data received from CMS is an imprecise process. We can compare our total observation count with counts reported by the RDDC, and we can perform limited checks with some of the supporting statistics reported in the rule. We can also do some checks of counts at different stages by comparing against the "Claims Accounting" document. To help users ensure that they are using the exact same data used by CMS in the development of the rule, we request that CMS release with the rule additional summary statistics on the entire file. Specifically, we would like to request the following additional information:

- A table showing the total frequency of all HCPCS codes, not just "majors".
  - The frequency table is currently limited to those HCPCS codes that are "majors" and for drug lines through the HCPCS median files
- Summary statistics for all HCPCS codes, including minimum, mean, median, maximum.
  - Currently only those used as majors that become single procedure claims have this statistical detail in the medians files. This file is useful to check our replication of the CMS rate-setting methodology. However a file of summary statistics drawn earlier in the process would allow us to check that we are using the same claims prior to applying the rate-setting logic.
- For HCPCS codes that are conditionally packaged, a frequency table showing:
  - How many times each code is "converted" to a major;
  - How many times each code is packaged; and
  - Total number of occurrences in the data

These summary statistics should not be a significant burden to produce and would greatly assist outside analysts in verifying the public use file data prior to beginning their analyses. These additional data would be useful in resolving discrepancies our analysts have currently observed between our frequency counts for the final rule version of the public use file used in setting the 2008 rates and the frequency totals in the CMS medians files.

Enhanced description of logic flow

As CMS has been expanding and refining the logic used in the OPPS methodology – most recently with expanded use of Q status indicators (used in conditional packaging) and composite APCs – the logic has become significantly more complex. The rule and the claims accounting document provide information on the OPPS methodology. However, we have found that our efforts to replicate the CMS medians for this payment system have not been as successful as our work on other CMS payment systems, for example the inpatient prospective payment system (IPPS) and the Long term acute care hospital (LTACH) system. To assist clients in developing the most appropriate comments, we want to be able to replicate CMS's methodology as closely as possible. The current narrative descriptions in the rule and the claims accounting are helpful, but could be expanded for clarity. We request that CMS consider the following options:

- Expanding the narrative to provide more detail
- Releasing a graphic flow-chart showing the logic flow as it is programmed

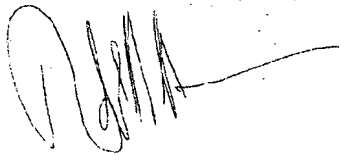
In particular, we would like to request additional detail on conditional packaging logic and on composite APCs. Select examples of areas where additional clarification on the conditional packaging logic could be most useful include:

- How are "bypass" lines treated on the claim? Are they treated as present on the claim when the conditional packaging determination is made or are they excluded?
- When there are multiple conditionally packaged codes on a claim, and the logic calls for comparing against the 2007 weights for the APCs those codes are assigned to, should the 2007 or 2008 APC mapping be used?

Any of these enhancements would allow outside analysts to more quickly understand CMS's logic, and allow for the drafting of informed comments.

We thank CMS for its diligent efforts in the development of the OPPS rule, the information it releases to members of the public seeking to understand this rule, and for this opportunity to submit comments.

Sincerely,



Donald W. Moran
President

Submitter : Miss. Bridget Anderson **Date:** 01/25/2008

Organization : MAPS Medical Pain Clinic

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Ms. Brooke Anderson **Date:** 01/25/2008

Organization : MAPS Medical Pain Clinic

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

#307

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

Submitter : Mrs. Lora Anderson **Date:** 01/25/2008

Organization : MAPS Medical Pain Clinic

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-308-Attach-1.DOC

#308

December 18, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned staff member of an interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

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The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Brooke Anderson
MAPS Medical Pain Clinic
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Brooke Anderson **Date:** 01/25/2008

Organization : MAPS Medical Pain Clinic

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-309-Attach-1.DOC

CMS-1392-FC-309-Attach-2.DOC

#309

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
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55433

Submitter : Ms. Bridget Anderson **Date:** 01/25/2008

Organization : MAPS Medical Pain Clinic

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-310-Attach-1.DOC

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