

Submitter : Ms. June Govern

Date: 01/28/2008

Organization : Cytogen

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1392-FC-416-Attach-1.DOC

#416

CYTOGEN

Cytogen Corporation
650 College Road East, Suite 3100
Princeton, NJ 08540

January 28, 2008

Mr. Herb B. Kuhn
Deputy Administrator
Centers for Medicare and Medicaid Services
Hubert H Humphrey Building
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

RE: **CMS-1932-FC** Radiopharmaceutical Payment Final HOPPS Rule

Cytogen Corporation (Cytogen) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the final rule for the hospital outpatient prospective payment system (72 Fed Reg 66,580 (November 27, 2007)) regarding payment for radiopharmaceuticals.

Cytogen is dedicated to improving the lives of patients with cancer by developing innovative products that target cancer progression. Specifically, Cytogen markets a diagnostic radiopharmaceutical, ProstaScint® (capromab pendetide), and a therapeutic radiopharmaceutical for cancer patients in need of bone pain palliation, Quadramet® (Samarium Sm 153 Lexidronam Injection).

ProstaScint is the first and only FDA approved product targeting prostate-specific membrane antigen (PSMA), a unique marker that is abundantly expressed on prostate cancer cells at all stages of disease. Prior to ProstaScint, there were no reliable, noninvasive tests to identify metastatic disease in newly diagnosed and recurrent prostate cancer patients. Two recently published large cohort studies show that high intensity signal outside the prostate has a poor prognosis; in one study, prostate cancer-specific death rates are 10 times higher in the group with such findings. ProstaScint is reported by hospitals using HCPCS A9507 and is been paid separately under the APC system.

Quadramet is a therapeutic radiopharmaceutical for cancer patients who experience bone pain. Bone pain is the most common type of pain associated with cancer that can be effectively managed with Quadramet. Quadramet is reported by hospitals using HCPCS A9605.

Recommendations

- 1. Cytogen recommends that CMS consider restructuring the tumor/infection imaging APCs to pay separately for high cost diagnostic radiopharmaceuticals OR develop composite APCs appropriate to the clinical features and resources of high cost radiopharmaceuticals in this APC.**

ProstaScint (A9507) has a median cost of \$1210-1317 in the CMS HOPPS data files. The APC values for tumor studies (APCs 406,414 and 408) range from \$322-\$981. These APC

payment values are intended to cover the cost of the hospital technical procedure costs as well as the radiopharmaceutical.

The current packaging of radiopharmaceutical and technical procedure cost for tumor studies does not satisfy the intent of the APC system, to package procedures that are clinically similar with resource homogeneity. The Tumor imaging APCs have a very wide cost differential and clinical use.

Since ProstaScint is the **ONLY tumor imaging agent** available for prostate cancer patients imaging, bundling it with low-cost tumor imaging agents is not appropriate. Cytogen recommends that CMS establish separate payment for diagnostic radiopharmaceutical in APCs 406, 414 and 408 or develop a composite APC for ProstaScint tumor studies.

- 2. Cytogen recommends that CMS accept alternative sources of data to determine appropriate average radiopharmaceutical costs for HOPPS. CMS should consider working with the nuclear medicine industry (nuclear pharmacies, manufacturers and society of nuclear medicine) to develop a standardized payment reporting methodology for Calculated Pharmacy Sales Price (CPSP) similar to ASP for other drugs. This CPSP payment methodology would permit CMS to establish a prospective payment methodology where appropriate. External manufacturer and survey data (Society of Nuclear Medicine) data could be provided to support appropriate payment for radiopharmaceuticals.**

Under the HOPPS payment system, charge compression continues to be a significant issue for hospital cost reporting of radiopharmaceuticals. Quadramet is a high cost therapeutic radiopharmaceutical that suffers from charge compression issues in the hospital outpatient setting.

For ProstaScint, the radiopharmacy must compound the 'cold kit' with Indium-111 prior to delivery of the dose to the hospital. Since Cytogen does not provide a prepared dose, or own radiopharmacies, Cytogen would not be in a position to report the hospital cost for ProstaScint for any hospital directly to CMS.

Quadramet is sold to nuclear pharmacies in a vial, then provided to the hospital as a unit dose ready for patient injection at the hospital department level. As a manufacturer, Cytogen can provide the cost of the vial, but not the unit dose of the product to CMS. Cytogen would be required to determine the cost of the compounding and nuclear pharmacy components. This is not within the knowledge or control of Cytogen since compounding fees are not determined by Cytogen.

Conclusion

CMS has implemented very significant changes in payment for radiopharmaceuticals in the 2008 final rule that may have an adverse impact on the quality of care for Medicare beneficiaries. The packaging of radiopharmaceuticals into one APC with a very significant range in cost to hospitals can impact the hospitals ability to provide the most appropriate diagnostic or therapeutic option for patients.

Cytogen agrees that the basis of a proposed payment system is to establish prospective payment rates when applicable, and some radiopharmaceutical bundling may be appropriate in the HOPPS environment, however, careful consideration must be applied to any bundling to assure continued beneficiary access to appropriate treatment.

We hope that CMS will consider the recommendations outlined above and work with stakeholders and hospitals to develop the most appropriate payment methodology for radiopharmaceuticals in the future. Cytogen believes that working directly with nuclear pharmacies, hospitals, manufacturers and the Society of Nuclear Medicine will permit the development of more appropriate payment and packaging options for radiopharmaceuticals.

Thank you again for the opportunity to provide comments in response to this final rule. We believe that the recommendations outlined above will facilitate the practical administration of reimbursement for radiopharmaceuticals and will ensure that patients continue to have access to these important diagnostic and therapeutic products.

Sincerely,
CYTOGEN CORPORATION, INC.



June Govern
jgovern@cytogen.com
609-750-8250

cc: Carol Bazell, MD, CMS Director, Division of Outpatient Care

Submitter :

Date: 01/28/2008

Organization :

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-FC-417-Attach-1.TXT

#417



Council on Radionuclides and Radiopharmaceuticals, Inc.

Henry H. Kramer, Ph.D., FACNP
Executive Director

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Via Hand Delivery and Email

January 28, 2008

Mr. Herb Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
Room.445-G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1932-FC
Comment on Radiopharmaceutical Payment in Final HOPPS Rule

Dear Mr. Kuhn:

On behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), I would like to thank you and your staff for meeting with CORAR on January 7, 2008 to discuss Medicare payment for radiopharmaceuticals under the hospital outpatient prospective payment system final rule (72 Fed. Reg. 66,580 (Nov. 27, 2007)).

This letter expresses our appreciation for your consideration during the meeting and serves as CORAR's comment on the final rule.

1. **CMS should restructure the tumor/infection imaging APCs to pay separately for certain high cost diagnostic radiopharmaceuticals or create composite APCs that are appropriately homogeneous in terms of clinical features and resources.**

Two radiopharmaceuticals (A9507 and A9565/A9572)¹ have mean costs of \$1400 to \$1700 (costs derived from CMS HOPPS data files). These two radiopharmaceuticals along with five/six other diagnostic radiopharmaceuticals have been bundled into newly configured APCs 406, 414, and 408 (Level I, II, and III Tumor/Infection Imaging) with 2008 payment rates at \$322, \$536 and \$981. These payment rates are intended to cover the procedure and radiopharmaceutical costs for other radiopharmaceuticals with mean costs in the range of \$400 to over \$3000.

¹ A9507 In 111 capromab per dose (Prostascint) used in the diagnosis of prostate cancer, A9565/A9572 In 111 petreotide per dose (OctreoScan) used in the diagnosis of primary and metastatic neuroendocrine tumors.

The three newly configured tumor/infection imaging APCs combine tumor and infection imaging procedures. These procedures are not clinically similar. The new APCs also bundle many diagnostic radiopharmaceuticals with widely varying costs and dissimilar clinical uses. The resulting APCs are inconsistent with the basic requirement that APCs be homogeneous clinically and with respect to resources. See attached APC Analysis for HCPCS codes A9507 and A9565 which contrasts the APC payment rates with the median costs per claim and mean costs per dose for these two tumor agents and related procedures. CORAR supports CMS effort to develop appropriate payment bundles but strongly urges that a restructuring is needed for these APCs.

CORAR recommends that CMS implement one of the following:

- a. Separate payment for all the diagnostic radiopharmaceuticals in APCs 406, 414, and 408,
- b. Separate payment for radiopharmaceuticals A9507 and A9565/A9572 (the distinctly high cost radiopharmaceuticals)
- c. Creation of separate composite APCs that bundle only tumor imaging procedures with the corresponding A9507 or A9565/A9572 radiopharmaceutical. A model of the logic flow chart for such composite APCs is attached along with a composite APC analysis chart of the associated data.

Furthermore, CMS has bundled into APCs 406, 414, and 408, special radiopharmaceuticals that are part of a therapeutic regimen: A9542 and A9544. As noted below, they should be paid separately.

2. CMS should recognize A9542 and A9544 as part of their therapeutic regimens.

A9542 and A9544² are the special dosimetric doses for the Zevalin and Bexxar therapeutic regimens, respectively. They are not diagnostic radiopharmaceuticals, but rather are a unique component to guide a larger therapy. FDA has not approved these products for separate use as diagnostic radiopharmaceuticals or otherwise, but rather, only as part of the therapeutic regimen.

Section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 requires that CMS continue to pay for therapeutic radiopharmaceuticals based on hospital charges reduced to costs from January 1, 2008 through June 30, 2008. To implement the plain meaning as well as congressional intent, CMS should treat A9542 and A9544 as part of the class of therapeutic radiopharmaceuticals and continue payment based on hospital charges reduced to costs, as this methodology applied to both the dosimetric and therapeutic doses for these radioimmunotherapeutic regimens in 2007.

CORAR recommends that CMS implement the changes proposed above effective January 1, 2008, or with the next quarterly update in HOPPS.

² A9542 In 111 Ibritumomab per dose, A9544 I 131 Tositumomab per study dose

3. CMS should accept alternate sources of data including manufacturers' estimates of average radiopharmaceutical prices when hospital charges under-report the appropriate prices.

Certain radiopharmaceuticals still do not reflect accurate data from hospital reported charges. There continue to be serious problems in charge compression especially for higher cost radiopharmaceuticals. Moreover, many radiopharmaceuticals are compounded by nuclear pharmacies or hospitals from different components. The manufacturer of the "cold" kit, may not have pricing for the "hot" kit of the radiopharmaceutical. Nevertheless, new communications are developing between nuclear pharmacies and manufacturers to better enable the generation of more accurate data. Manufacturers may be able to obtain new pricing information about compounding costs, and component costs from some nuclear pharmacies. This may enable manufacturers to estimate the average price of the radiopharmaceutical to the hospital.

In the absence of hospital average acquisition cost, average price is the statutory alternative. For conventional drugs, average price can be based on conventional average sales price (ASP). Such ASP information does not exist for most radiopharmaceuticals, but average prices can be estimated in some cases. This is especially true for high cost, low volume radiopharmaceuticals.

CORAR urges that CMS remain open and utilize manufacturer reported average prices. Such estimated average prices will need to be validated and certified in ways that are appropriate for the unique circumstances of radiopharmaceuticals. This approach is fully within CMS's authority under Social Security Act §1833(t) which extends discretion to CMS to make necessary changes and adjustments in drug prices. Furthermore, where ASP is available, the Social Security Act §1833(t)(14)(A)(iii)(II) requires CMS to use ASP to base reimbursement for "specified covered outpatient drugs" (SCODs) as that term is defined in the Social Security Act §1833(t)(14)(B)(i). This reimbursement methodology has been recommended to CMS by both radioimmunotherapeutic regimen manufacturers. Therefore, where available, CMS should base payment for radioimmunotherapeutic regimens on manufacturer-reported ASP and also ensure that hospitals are reimbursed for the cost of nuclear pharmacy compounding.

CORAR welcomes and requests the further opportunity to meeting with CMS in February to discuss these proposals in greater detail. Gordon Schatz (202.414.9259) will contact Dr. Carol Bazell to arrange such a meeting.

Thank you for your consideration.

Sincerely,

Tamar Thompson

Tamar Thompson
Co-Chair, Clinical Practice and
Reimbursement Committee

Fred E. Longenecker

Fred E. Longenecker
Co-Chair, Clinical Practice and
Reimbursement Committee

Attachments

Cc: Carol M. Bazell, M.D.

Submitter : Dr. William Fishkind

Date: 01/28/2008

Organization : OOSS and ASCRS

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachement

CMS-1392-FC-418-Attach-1.PDF

CMS-1392-FC-418-Attach-2.PDF

#418



AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

January 28, 2008

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-FC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 2021

Medicare Program: Final Changes to the Ambulatory Surgical Center Payment System and CY 2008 Rates

Dear Administrator Weems:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 1000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ambulatory surgical centers (ASC).

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing over 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures furnished annually in ASCs and hospitals.

We applaud CMS for its efforts, with respect to the final ASC payment regulation (CMS-1517-F) for the progress it made in aligning the ASC and hospital outpatient department (HOPD) payment systems. We remain concerned that elements of that rule embody the potential to stifle beneficiary access to the high quality and lower-cost care provided by ASCs. Our September 14 comments, attached hereto, referenced a number of procedures heretofore performed in ASCs that will likely be relegated to performance in the more costly HOPD setting because the new transition over four years to fully implemented rates will inadequately compensate ASCs for implantable ophthalmic devices, prosthetics, and tissue. Specifically, our organizations are disappointed that the agency has not made critical modifications to the rule's transition provisions. We would like to bring to the agency's attention two issues that arose with the issuance of the final rule.

Payment for Artificial Cornea Device (CPT 65570). Since the advent of the ASC program, CMS has paid on a pass-through basis for corneal tissue utilized in corneal transplant surgery. Under rare circumstances, when standard corneal transplant surgery fails or when it is anticipated by the surgeon that it will not succeed, an artificial cornea, known as a keratoprosthesis, may be utilized. One such device, the Boston Keratoprosthesis, has been implanted approximately 1200 times since 1992. The device is produced under the authority of the Massachusetts Eye and Ear Infirmary and provided to patients on a humanitarian basis at no profit to MEEI. OOSS and ASCRS join the American Academy of Ophthalmology in recommending that the N1 designation be removed from CPT code 65770, enabling the device to be paid on a pass-through basis at the same rate as in the HOPD.

Removal of Interim Physician Office Designation from Balloon Dacryocystoplasty/Dacryoplasty for Nasolacrimal Duct Obstruction (CPT 68816). OOSS and ASCRS disagree with CMS' determination that the balloon catheter dilation surgery described by CPT 68816 will be performed more than 50% of the time in the physician office setting. Patients undergoing this surgery -- typically neonates or children, but occasionally adults -- typically require anesthesia of the type offered in the HOPD or ASC. We are concerned that private insurance carriers will conclude that this procedure is inappropriate in the ASC, and in precluding reimbursement to the ASC, will force patients to undergo surgery in the hospital, at greater expense to the patient and the payer.

Thank you for providing our organizations with the opportunity to present our comments on the rule. Should you have any questions, please do not hesitate to contact our Washington representatives: Michael Romansky, Washington Counsel, OOSS at mromansky@ooss.org or at 301.332.6474; or Emily Graham, RHIT, CCS-P, CPC, ASCRS Associate Director of Regulatory Affairs at egramham@ascrs.org or 703.591.2220.

Sincerely,



Richard L. Lindstrom, MD
President, ASCRS



William Fishkind, MD
President, OOSS



AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

September 14, 2007

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 2021

RE: CMS-1392-P – Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Rates

Dear Administrator Weems:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 1000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ambulatory surgical centers (ASC).

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing over 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures furnished annually in ASCs and hospitals.

Overview

We applaud CMS for its efforts, with respect to the final ASC payment regulation (CMS-1517-F) for the progress it made in aligning the ASC and hospital outpatient department (HOPD) payment systems. We remain concerned that elements of that rule embody the potential to stifle beneficiary access to the high quality and lower-cost care provided by ASCs. As the ASC and HOPD systems will soon be intertwined, we are taking this opportunity to provide the agency with our views regarding how both programs can be improved.

The nation's 4,600 ASCs are committed to providing Medicare beneficiaries with access to the highest quality surgical care while lowering their cost-sharing obligations and assisting the

Medicare program in the containment of health expenditures. Studies conducted by a multitude of federal agencies (including CMS; the Government Accountability Office; the Medicare Payment Advisory Commission; the Office of the Inspector General, HHS; and the Federal Trade Commission) have lauded the work of ASCs, recognizing that surgery centers provide care at levels of quality equal to or surpassing hospital outpatient departments (HOPD), at lower cost to the program and to beneficiaries, and in a patient-friendly and convenient environment that leads to the highest levels of patient satisfaction.

Cataract surgery in the ASC is emblematic of the phenomenon of the ASC becoming the choice of physicians and beneficiaries for site of surgery. More than 2.7 million patients receive cataract surgery each year; in consultation with their ophthalmic surgeons, more than 60 percent of them select the ASC over the HOPD as their site of surgery. As for program savings, in 2006 alone, Medicare saved over \$400 (\$1,388 in the HOPD vs. \$973 in the ASC) each time the cataract operation was performed in an ASC rather than a hospital, translating to hundreds of millions of dollars in expenditures annually. Simply stated, with respect to cataract surgery, the highest volume Medicare surgical procedure, the ASC is the predominant choice of the Medicare beneficiary because the quality of care provided is demonstrably high and the cost savings to the patient and the program are significant.

As such, the Medicare program should provide incentives for services such as cataract surgery to be provided, and at a minimum, should not impede migration of surgical care to ASCs. We applaud the agency for expanding the array of procedures that can be furnished within and reimbursed in the ASC, including virtually all ophthalmic services; providing payment to ASCs for innovative drugs and devices that qualify in the hospital for pass-through status; adopting a more flexible interpretation of budget neutrality in terms of establishing payment rates; and providing for a more graduated four-year transition to the new system. In numerous ways, however, the final rule perpetuates payment inequities and falls short of neutralizing payment across sites of delivery.

Coverage of Procedures

OOSS and ASCRS are generally pleased with CMS' redesign of the process through which procedures are designated as appropriate for performance in an ASC. We support the adoption of MedPAC's recommendation, incorporated in its March 2004 Report to Congress, that clinical safety standards and the need for an overnight stay be the *only* criteria for excluding a procedure from payment of an ASC facility fee. For a quarter-century, CMS has permitted payment to ASCs only for services that have been specifically designated in advance by the agency as safe, effective, and less costly than care provided in the hospital, thereby depriving beneficiaries of access to, and the Medicare program of savings from, services that are commonly performed on non-Medicare patients in ASCs.

As noted above, we are delighted that, under the final ASC rule effective January 1, 2008, virtually every listed ophthalmic surgical code will be reimbursed in the ASC. However,

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we must evaluate the final rule with an eye towards assessing its potential impact on services that might become available in the future.

Safety Criteria

The agency is to be commended for having deleted certain criteria as indicia of whether a procedure should be excluded from coverage when performed within the ASC, e.g., discontinuation of the use of operating and anesthesia times and the extent to which the service is commonly furnished on an inpatient basis. We also concur with CMS' decision to exclude from coverage any procedure that is included on the "inpatient only" list; we are comfortable with this policy so long as CMS updates the inpatient only list on a regular basis. This should be the sole criteria for making a decision as to site of service that should otherwise be made by the surgeon in consultation with his patient.

The same criteria should apply to both the ASC and HOPD in determining the appropriateness of performing a surgical procedure in the outpatient settings. The agency insists that more extensive criteria apply for purposes of excluding services from the ASC: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; or, (4) are generally emergent or life-threatening in nature. These general exclusions actually parallel the exclusionary language under the HOPD coverage and payment system. We believe that the standards applied in the HOPD environment, coupled with the requirement that ASCs not perform surgical services requiring an overnight stay, provide ample safeguards for patient safety. The safety risk criteria should be modified to comport with the standards utilized to evaluate the safety of procedures performed in the HOPD.

Overnight Stay

In the final ASC rule, CMS has defined, for purposes of excluding a procedure from coverage within an ASC, a procedure requiring an "overnight stay" as one that contemplates the patient will be present in the facility at midnight. We believe that CMS should maintain its current policy that defines an overnight stay as an episode involving a stay of less than 24 hours in duration. Post-operative care is not a separately payable procedure nor does the nature of these services change after the stroke of midnight. While we envision that rarely will a patient be required to remain in the ASC after midnight, we object to the agency's position of utilizing an arbitrary time of day as a proxy for an appropriate length of stay.

Unlisted Codes

Another anomaly in CMS' effort to align the ASC and HOPD payment systems is the treatment of procedures for which there is not an appropriate CPT code. These services are reimbursed in the HOPD, but would not be eligible for payment in the ASC. The agency states that, without knowledge of the procedure's code, it cannot determine whether the procedure performed would have been excluded from the ASC payment under the rule's safety criteria. However, although an unlisted code doesn't allow the reporting of specific procedures, it does

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allow for reporting of the anatomic region of the service. With knowledge of the anatomic location, CMS can and should apply the safety criteria to the entire spectrum of services reportable by the unlisted code. Under such an analysis, the agency would determine that no procedure on the ocular muscle would compromise patient safety, and that, therefore, any service encompassed by 67399, Unlisted procedure, ocular muscle meets the safety criteria utilized to evaluate services furnished in the HOPD and should be reimbursed in the ASC. The same analysis would result in the conclusion that services encompassed by 67299, Unlisted procedure, posterior segment of the eye, should be covered in the ASC. It is imperative that CMS evaluate services billed under unlisted codes for safety, under like criteria, for both hospitals and ASCs.

Pass-Through Devices

Since the advent of the Medicare hospital outpatient prospective payment program, CMS has provided transitional pass-through payments to HOPDs for innovative devices, drugs and biologics. We are pleased that, in the final rule, ASCs that provide these products as an integral part of a covered service will also receive these same payments. We believe that a similar accommodation should be made to ASCs that utilize pass-through drugs and devices *following* the two-year transition period. In the HOPD, once the time the pass-through expires, the new prepackaged payment rate will incorporate the cost of the device (depending upon its level of utilization during the transition). Under the final ASC rule, the ASC will be at a substantial disadvantage since it will receive the HOPD's new rate, less a substantial discount (in 2008, the discount will be 35 percent), thereby compromising its ability to continue to provide services encompassing these products and depriving beneficiaries of access to services that were heretofore available in the ASC.

In the device-intensive services section of the rule, CMS acknowledges that ASCs will not likely be able to purchase costly medical devices at prices lower than hospitals and CMS will calculate the device portion of the procedure payment separately from the service portion. OOSS and ASCRS believe that the agency should treat payment for expired pass-through devices in a manner that is consistent with the intent of the device-intensive payment methodology and enable ASCs to continue to provide these vital services to Medicare beneficiaries.

Implantable Devices

As noted in the section above, OOSS and ASCRS are pleased that CMS has incorporated within the final ASC rule special provisions to augment payment for device-intensive procedures. Similar treatment should be afforded to procedures whose devices may not be so expensive as to qualify for device-intensive status, but for which the application of a four-year transition may preclude performance in the ASC. Under current rules, ASCs are paid a facility fee for a service and a separate payment under the DMEPOS fee schedule for an implant. Under the new rule, these services and items are bundled and paid on the basis of the discounted (in 2008, 35 percent) rate; however, because the rates are phased in over a four-year transition period, with only 25 percent of the final rate in the first year (50 percent in the second year *et*

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seq.), the cost of the device cannot be viably accommodated within the facility fee in the early years.

In ophthalmology, the glaucoma procedure, 66180 (aqueous shunt to extraocular reservoir) is performed when medical treatment for the glaucoma patient is no longer efficacious and the standard trabeculectomy may not be indicated or has failed. For these patients, it is necessary to insert a shunt to relieve intraocular pressure. Under the current payment system, the aqueous shunt device and the scleral tissue graft are billed separately from the ASC's facility fee; in CY 2007, the ASC is reimbursed \$717 for the facility fee and approximately \$560 for the device, or \$1,267. Under the new rule, the HOPD receives \$1,624 in 2008; however, because of the transition, the ASC would be reimbursed only \$940, a reduction of \$326 from the 2007 level. It would be financially impracticable for the surgeon to provide the service in the ASC, even though the procedure will have been furnished safely and effectively in these facilities for years.

Similar problems occur with respect to the provision of several ocular plastic implant services, including 65105 (enucleation of eye; with implant, muscles attached to implant); 65140 (insertion of ocular implant secondary; after enucleation, muscles attached to implant); 65155 (reinsertion of ocular implant; with use of foreign material for reinforcement); and 67912 (correction of lagophthalmos, with implantation of upper eyelid lid load). Likewise, the rule bundles payment for 65780 (amniotic membrane transplant) with the code assigned to the amniotic membrane tissue at levels that threaten the viability of the service within the ASC.

OOSS and ASCRS believe that CMS must modify the final ASC rule to ensure the continued availability to Medicare beneficiaries of services that incorporate costly medical devices or tissue and that have historically been safely and effectively furnished in the ASC environment. This can be accomplished by either paying the ASC the fully transitioned ASC payment in 2008-2011, or by including the 2007 device payment amount in the transition year payment calculations.

Office-Based Procedures

We applaud CMS for significantly expanding the ASC procedures list to include many ophthalmic surgical services that, although more frequently performed in the physician office setting, are often appropriate for conduct in the ASC setting. However, we continue to strenuously object to the agency's decision to cap payments for these services at the lesser of the amount allowable under the conversion factor (65% under the proposed rule) or the amount the physician would receive under the non-facility practice expense component of the Medicare Professional Fee Schedule. Simply stated, CMS has given with one hand and taken away with the other. This policy makes little sense and embodies the potential to force Medicare patients into the more costly HOPD, as well as compromise patient safety by providing financial incentives for the patient to be treated in the less regulated office setting.

There are many reasons why the physician might select the ASC, rather than the office operatory or treatment room, for the conduct of a particular service. First, the patient's clinical

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condition, including his age, size, comorbidities, prior operative experience might dictate that the ASC is the appropriate environment for surgery. Second, there are considerable variations in the ways in which physician offices are equipped and staffed. Third, the training, skills, and experience of the surgeon may warrant the choice of one setting over the other. Fourth, state certificate of need, ASC licensure, or professional scope of practice regulations, as well as the physician's professional or facility malpractice coverage, might impact upon the choice for site of surgery. All of these considerations might legitimately impact upon the selection of the ASC for performance of the surgical procedure. Our detailed comments submitted with respect to the NPRM provide many such examples.

CMS has presented no evidence that coverage of office-based services in the ASC will lead to overutilization. It is true that paying for these services at the new ASC rates might lead to higher Medicare costs, but only if more procedures migrate from office to ASC than from HOPD to ASC; this phenomenon is difficult to predict. Nevertheless, Medicare expenditures will definitely increase by orders of magnitude if these office-type services migrate, by virtue of the caps on ASC payments, to the HOPD setting, where reimbursement rates exceed ASC rates by at least 35% under the new payment system. The physician, in consultation with his patient, is professionally, legally, and ethically obligated to make the clinical decision as to whether the hospital, ASC, or office is the appropriate operative environment. The Medicare program should not provide, inadvertently or otherwise, reimbursement incentives which might impact upon these decisions.

OOSS and ASCRS strongly recommend that CMS reverse its policy in the final rule of designating procedures as "office-based" and subject to an arbitrary payment limitation. These services should be subject to the same payment methodology as all other covered services. Alternatively, if the agency is determined to designate services as "office-based" (by virtue of having been performed more than 50 percent of the time in physician offices) and subject to payment limitations, these caps should be applied to payments made to HOPDs as well as ASCs.

Secondary Rescaling of APC Relative Weights

As we noted in our comments to the proposed rule, OOSS and ASCRS strongly support the utilization of the same APCs and relative weights in creating a rational and coherent encompassing the services offered by both HOPDs and ASCs. However, under the final rule, the same weights will likely be used only in 2008, after which time the rescaling of ASC relative weights the second time will result in further divergences in weights and payments, exacerbating exactly the types of distortions that the new system was presumably intended to correct. The only legitimate basis for change in relative payments to HOPDs and ASCs should be changes in the relative costs of providing specific outpatient services. There is little basis for believing that these variations will occur, and to the extent that they do, they should be accounted for directly through adjustments to the conversion factor.

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 UMBER Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

Annual Inflation Update

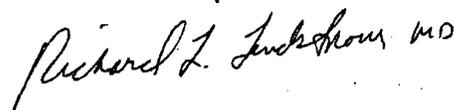
During the past quarter-century, ASCs have been provided annual updates on only a sporadic basis and facilities have received no adjustments for inflation for the period 2004-2009, notwithstanding the fact that our costs rise at rates that are identical to those of HOPDs. We appreciate that CMS recognizes that ASCs' costs rise and have included in the final rule a provision for annual updates. However, the adoption of the Consumer Price Update – Urban (CPI-U) makes little public policy sense. CMS has presented no evidence that hospitals' costs exceed those of ASCs for the provision of ambulatory surgical care to Medicare patients. Moreover, the adoption of different annual update measures is clearly inconsistent with the agency's stated goal of aligning the HOPD and ASC payment systems. OOSS and ASCRS reiterate that the final rule should be modified so that ASCs receive the same update factor as HOPDs, i.e., the hospital market basket (HMB).

Billing Systems

In the final rule, CMS maintains the requirement incorporated within the NPRM that facilities use the CMS 1500 form to submit claims for their services. In order to further promote alignment between the ASC and HOPD systems and consistency with commercial insurance administration, we recommend that CMS initiate a transition process for providers to utilize the UB-04 for ASCs.

Thank you for providing our organizations with the opportunity to present our comments on the rule. Should you have any questions, please do not hesitate to contact our Washington representatives: Michael Romansky, Washington Counsel, OOSS at mromansky@ooss.org or at 301.332.6474; or Emily Graham, RHIT, CCS-P, CPC, ASCRS Associate Director of Regulatory Affairs at egramham@ascrs.org or 703.591.2220.

Sincerely,



Richard L. Lindstrom, MD
President, ASCRS



William Fishkind, MD
President, OOSS

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OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 UMBER Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

Submitter : Mr. John Siracusa

Date: 01/28/2008

Organization : BIO

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

(See Attachment)

CMS-1392-FC-419-Attach-1.PDF

#419



January 28, 2008

BY ELECTRONIC DELIVERY

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

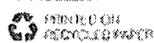
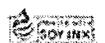
**Re: CMS-1392-FC (Medicare Program; Changes to the Hospital
Outpatient Prospective Payment System and CY 2008 Payment
Rates)**

Dear Administrator Weems:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) final rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and 2008 payment rates, published in the Federal Register on November 27, 2007 (the "Final Rule").¹ BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

In the past, BIO has applauded CMS's efforts to improve the OPPS and protect Medicare beneficiaries' access to drugs, biological therapies, and other innovative healthcare technologies. In the Final Rule, however, CMS abandons these efforts by expanding packaging and setting reimbursement for separately paid drugs at average sales price (ASP) plus five percent, with the intention of setting reimbursement at ASP plus three percent in 2009. By implementing these changes to the OPPS, CMS has disregarded the clear language of the Social

¹ 72 Fed. Reg. 66580 (Nov. 27, 2007).



Security Act (SSA) and the reasoned advice of the Advisory Panel on Ambulatory Payment Classification Groups (the APC Panel) and numerous stakeholders. We are deeply concerned that these policies will harm beneficiary access to critical therapies and will discourage future innovation.

As CMS begins to work on the proposed rule for 2009, we urge the agency to reverse course and establish payment for drugs and biologicals at no less than ASP plus six percent, adjust payments to ensure pharmacy service costs are adequately reimbursed, and make separate payment for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes as it does in the physician office setting. We urge CMS not to expand packaging for drugs and biologicals in 2009 as it suggests in the Final Rule. In addition, we urge the agency to adjust its calculations of the costs of drugs and biologicals to account for charge compression. Before the agency proposes any major changes to the OPPS methodology in the future, we urge it to make available to the public the data necessary to understand the full effect of the proposed changes, in sufficient time that stakeholders are able to perform their own independent analysis of it.

I. The Final Rule Fails to Comply with the Statutory Requirement to Reimburse Each Drug and Biological Therapy Without Pass-Through Status at the Average Acquisition Cost for the Drug for that Year with an Adjustment for Pharmacy Service Costs.

For 2008, CMS continues to use a flawed methodology to establish payment rates for separately paid drugs and biologicals that does not comply with the SSA's requirement to reimburse these therapies at the average acquisition cost for each drug for that year with an adjustment for pharmacy service costs.² As we explained in our comments on the 2007 and 2008 proposed rules, CMS's methodology of estimating aggregate average acquisition and pharmacy service and handling cost substantially underestimates the actual costs of acquiring and supplying separately paid drugs and biologicals and produces inaccurate and unpredictable results on a drug by drug basis, and likely does so in the aggregate as well. In the Final Rule, CMS compares the estimated total costs of drugs, as derived from claims data, to total costs calculated using ASP and concludes that ASP plus three percent represents hospitals' aggregate average acquisition cost and

² SSA § 1833(t)(14)(A)(iii)(I).

pharmacy service costs.³ As we explained in detail in our comment letter on the proposed rule, there are several significant problems with this methodology.

First, CMS does not account for increases in ASPs in its analysis. Instead of comparing estimated costs to contemporaneous ASPs, CMS compares costs derived from charges in the 2006 claims data to ASPs effective in the fourth quarter of 2007. The charges in the 2006 claims data do not include the increases in the prices of drugs and biological products that occurred in 2007. Because many hospitals update their charges only once each year, the claims data also may not include price increases from 2006. As a result of this discrepancy, CMS's estimated aggregate cost as a percent of ASP is too low. The effect of this error can be seen in the difference between CMS's aggregate cost estimates in the proposed and final rules. When CMS compared the 2006 claims data to ASPs based on data from the fourth quarter of 2006, it concluded that the aggregate average acquisition cost to hospitals was ASP plus five percent. When CMS compared the same 2006 claims data to updated ASPs from two quarters later, the estimated cost decreased to ASP plus three percent. If CMS compared costs derived from the 2006 claims data to ASPs from earlier in 2006, it is possible that the effect of inflation on the aggregate estimated costs would be even larger.

Second, CMS's analysis fails to account for the effects of charge compression by applying for each hospital a single cost-to-charge ratio (CCR) to all pharmacy charges. Hospitals tend to mark up their charges for more costly drugs less than their charges for lower priced drugs. Applying a single CCR to the higher cost, separately paid drugs produces charge compression, or inaccurately low estimates of these drugs costs. In 2004, the Government Accountability Office (GAO) found that CMS's OPSS ratesetting methodology produces rates that "do not uniformly reflect hospitals' costs" because it "does not recognize hospitals' variability in setting charges."⁴

These concerns were reinforced by the RTI International report on charge compression in calculating payments under the inpatient prospective payment system. This report found evidence of charge compression in hospitals' pricing for IV solutions when compared to other drugs,⁵ and the report recommended that

³ *Id.* at 66763.

⁴ Government Accountability Office, Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, Sept. 2004, at 15-16.

⁵ Kathleen Dalton, A Study of Charge Compression in Calculating DRG Relative Weights, Jan. 2007, at 10, <http://www.cms.hhs.gov/reports/downloads/Dalton.pdf>.

CMS disaggregate the CCRs for drugs and IV solutions to produce more accurate estimates of the costs of these therapies.⁶ Although CMS acknowledged the “obvious importance” of the RTI report’s findings, it did not implement an adjustment for charge compression in its calculation of payment rates for 2008. As a result, CMS greatly underestimates the true costs of separately paid drugs. Additionally, the agency’s estimated costs for all drugs, compared to ASP on a drug-by-drug basis, continue to vary widely. Our own analysis found that CMS’s methodology produces estimated average unit costs, stated as a percentage of ASP, that range from ASP minus 97 percent to ASP plus 7179 percent.

The aggregated estimated costs derived from CMS’s methodology clearly are not the “average acquisition cost for the drug for that year” that Congress intended to serve as the basis for payment for drugs and biologicals under the OPSS. The SSA requires Medicare to reimburse specified covered outpatient drugs (SCODs) at the “average acquisition cost for the drug for the year,” as determined by the Secretary using survey data.⁷ If acquisition cost data are not available, the payment shall be set at the average price for the drug established under section 1842(o), 1847A, or 1847B (e.g., ASP plus 6 percent or the rates determined under the Competitive Acquisition Program).⁸

Since the GAO concluded its survey of acquisition cost in 2004, neither GAO nor CMS has conducted the subsequent periodic surveys required by the statute and therefore CMS does not have the data necessary to set payment at average acquisition cost. We understand that these surveys are difficult to conduct, and in our prior comments to CMS, we generally have supported the use of ASP plus six percent as a proxy for acquisition cost instead of asking the agency to incur the administrative and financial burden of conducting additional surveys. We continue to believe that ASP plus six percent would be a reasonable payment for acquisition cost. We believe it is inconsistent with both the language and the intent of the statute to use aggregate costs derived from charges as a proxy for average acquisition cost and pharmacy service and handling costs for each drug when the methodology for calculating those costs is severely flawed and does not even approximate acquisition cost alone—much less acquisition *and* handling costs. Congress enacted these provisions because it disagreed with CMS’s use of claims data to set payment rates for these drug and biological therapies. The

⁶ *Id.* at 16.

⁷ SSA § 1833(t)(14)(A)(iii)(I).

⁸ SSA § 1833(t)(14)(A)(iii)(II).

statute requires CMS to use either an accurate methodology to determine average acquisition cost for each drug or the rates established under sections 1842(o), 1847A, or 1847B.

Third, in addition to underestimating the acquisition costs for these drugs, CMS fails to adjust payments to ensure that the costs of essential pharmacy services are adequately reimbursed. To provide drugs safely and prevent medication errors, hospitals incur the significant costs of complex and resource-intensive pharmacy services. In 2005, the Medicare Payment Advisory Commission (MedPAC) reported that pharmacy department wages, salaries, fringe benefits, and supplies made up 26 to 28 percent of pharmacy department direct costs.⁹ MedPAC noted that most hospitals do not set charges for handling costs and lack precise information about the magnitude of these expenses,¹⁰ therefore, to the extent that these costs are included in hospitals' charges for drugs, it is unlikely that the charges for any individual drug reflect the costs of the pharmacy services associated with providing that drug. Instead, these costs may be included in hospitals' charges for all drugs in the aggregate. Thus, any estimate of these costs also must consider all drugs dispensed by hospital pharmacies, not just the drugs that are separately reimbursed under the OPPS. When CMS's methodology is applied to all drugs with HCPCS codes, including the drugs that are packaged under the OPPS, the mean unit cost, on average, is ASP plus 12.6 percent. This rate is more likely to represent hospitals' pharmacy service costs plus drug acquisition costs in the aggregate than CMS's significantly lower estimate of ASP plus three percent or the 2008 payment rate of ASP plus five percent.

By failing to account for hospitals' significant costs of safely preparing and handling drugs and biological products, CMS disregards Congressional intent, the findings of the MedPAC, the APC Panel's recommendations, and the advice of numerous stakeholders. We believe that the reasons CMS gave in the final rule for 2007 for not setting payment at rates determined by its estimation methodology remain valid in 2008. Specifically, CMS noted that its methodology produced a payment rate for both drug acquisition and pharmacy service costs (ASP plus four percent) that was comparable to the GAO's survey data for acquisition cost only.¹¹ We see no reason to believe that ASP plus three or five percent is any more

⁹ Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

¹⁰ MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.

¹¹ 71 Fed. Reg. 68059, 68091 (Nov. 24, 2006).

appropriate in 2008 than ASP plus four percent was in 2007. CMS also explained in the final rule for 2007 that it needed “a better understanding of the full nature and magnitude” of hospitals’ overhead and pharmacy service costs and that “maintaining stability in the payment levels for drugs and biologicals should be considered in light of the inherent complexity in determining how to best account for pharmacy overhead costs.”¹² These considerations are equally valid today.

For these reasons, we urge CMS to set payment for all drugs without pass-through status at no less than ASP plus six percent in 2009, as required by the statute, and to make an adjustment for pharmacy service costs to ensure they are reimbursed adequately. To create a pool of available funds that best represents the cost of critical pharmacy services in the complex hospital environment, we propose that CMS set the payment for all drugs and biologicals at no less than ASP plus six percent. Separately paid drugs would be reimbursed at no less than ASP plus six percent, and for packaged drugs, the cost of the drug attributed to the cost of the associated procedure would be at least ASP plus six percent for the drug. CMS could then set aside in a separate pool the difference between estimated mean unit cost as calculated for all drugs with HCPCS codes (ASP plus 12.6 percent) and payment for acquisition cost (ASP plus six percent).

We have identified several methods CMS could use to allocate these costs among drugs and biological products, and we would like to meet with the agency to discuss the options. One approach would be to divide the pool evenly among all separately paid drugs and biological products and automatically make a flat payment for pharmacy services each time a hospital bills for one of these therapies. In effect, the pharmacy payment would be bundled into payment for the drug or biological product. CMS also could make payments based on a percentage of ASP. Alternatively, CMS could set different payments for each of three tiers of pharmacy services representing low, medium, and high complexity. CMS would assign all separately paid drugs and biological products to one of these pharmacy service categories and would make a payment for pharmacy services automatically each time a hospital bills one of these therapies. This would be similar to the plan recommended by the APC Panel.¹³ A third option would be for CMS to use the pool to reimburse specific pharmacy services. CMS could reimburse these services through composite APCs that would require hospitals to bill for both a

¹² *Id.*

¹³ APC Panel on Ambulatory Payment Classification Groups, Recommendations: March 7-8, 2007, at 2, http://www.cms.hhs.gov/FACA/Downloads/Mtg_Rpt_0372007.zip.

drug and a corresponding service to receive the full payment. We urge CMS to consider these options and work with hospitals, pharmacists, and other stakeholders to develop a fair payment methodology.

II. CMS's Intent to Expand Packaging Is Contrary to the Statute and Congressional Intent.

In the Final Rule, CMS indicates that it intends to extend packaging for drugs and biological products in future years.¹⁴ For 2008, CMS packages payment for all diagnostic radiopharmaceuticals and contrast agents. CMS explains that these therapies can be treated differently from other SCODs because the statutory packaging threshold has expired and the agency believes that these drugs "function effectively as supplies that enable the provision of an independent service, rather than serving themselves as the therapeutic modality."¹⁵ Moreover, CMS notes that these drugs could be considered to not be SCODs because CMS has not established a separate APC for them.¹⁶ These assertions ignore the clear language of the statute and Congressional intent. The statute defines a SCOD as a "covered outpatient drug for which a separate ambulatory payment classification group (APC) has been established" and that is a radiopharmaceutical or a drug or biological for which pass-through payments were made on or before December 31, 2002.¹⁷

We note first that the statute does not distinguish between drugs and biologicals that serve as a therapeutic modality and those that are used with other services.¹⁸ CMS has no authority to reclassify a drug or biological as a supply simply to avoid payment as a SCOD. Second, Congress did not intend for CMS to circumvent the statutory payment provisions for SCODS by establishing high packaging thresholds or packaging whole classes of therapies. To do so would render the statute's explicit payment instructions meaningless. When Congress enacted this definition, it established a packaging threshold of \$50 per administration for drugs administered in 2005 and 2006¹⁹ because it objected to the \$150 packaging threshold that was in effect in 2003. Congress intended for CMS to establish a low packaging threshold for all drugs and biological products, and

¹⁴ 72 Fed. Reg. at 66757.

¹⁵ *Id.* at 66767.

¹⁶ *Id.*

¹⁷ SSA § 1833(t)(14)(B).

¹⁸ *Id.*

¹⁹ SSA § 1833(t)(16)(B).

the absence of a statutory requirement regarding the packaging threshold after 2006 should not be interpreted as support for widespread packaging. We urge CMS to comply with the language and intent of the statute and not expand packaging beyond current levels.

III. CMS Should Adjust Its Calculations to Account for Charge Compression and Make Data Regarding the Impact of Future Proposals Available to the Public.

We urge CMS to adjust its calculations of the costs of drugs and biologicals to account for charge compression. CMS believes that "packaged payment provides payment at average acquisition cost,"²⁰ but as we described above, CMS's methodology of determining acquisition cost from claims data is deeply flawed and produces wildly inaccurate estimates. To ensure that the costs of drugs, biological products, and other therapies are accurately reflected in payments for associated procedures, CMS must adjust its calculations to account for charge compression.

Moreover, before the agency proposes any major changes to the OPSS methodology in the future, we urge it to make available to the public the data necessary to understand the full effect of the proposed changes in sufficient time that stakeholders are able to perform their own independent analysis of it. Although the agency has made available for purchase the claims file that it uses to set payment rates, it is not practical for many small firms to use this file. Acquiring the file requires going through a process to obtain a data use agreement and the resources required to use this file for meaningful analysis are beyond the means of small companies. Firms exist which do analysis for small firms, however, the cost of these analyses is not insignificant. The agency should provide more analytic tables, such as the tables of medians that are currently available on the CMS web site, that would allow more interested parties to understand the effects of the complicated methodology and meaningfully comment on the proposed changes. For example, the agency should provide tables that show a model of the effects of future packaging or a charge compression adjustment. Such tables could show rates before the policy change and after the policy change for every HCPCS code and APC. CMS also should release the background data in a timely manner, preferably before a formal proposal is made. The same transparency should apply to any significant change proposed for the OPSS. It is

²⁰ 72 Fed. Reg. at 66639.

Acting Administrator Weems
January 28, 2008
Page 9 of 9

impossible to analyze and comment on such complex issues during the limited comment period in the full and thoughtful manner that these issues deserve. We thank CMS for meeting with stakeholders to explain its methodology in 2007, but we believe the development of the final rule for 2008 would be greatly simplified if CMS provided this data to the public in advance of the comment period. We ask CMS to provide this information as soon as possible – well before the proposed rule is released – to allow stakeholders sufficient time to analyze it.

In conclusion, BIO urges CMS to consider carefully its approach to payment for separately paid drugs and biological products without pass-through status and its intentions to expand packaging. The Medicare statute establishes clear requirements for payment for these therapies, and CMS should not ignore these provisions. BIO urges CMS to continue to work with stakeholders to ensure that Medicare's payments for drug and biological therapies are appropriate to protect beneficiary access to care. At a minimum, these therapies should be reimbursed at ASP plus six percent, the rate applicable in physicians' offices, with an additional adjustment for pharmacy service costs. CMS should not expand packaging further. It is critical that CMS account for the costs that hospitals must undertake to provide safe access to drugs and biologicals and reduce medication errors in the complex environment of the delivery of hospital services. In addition, we urge CMS to adjust for charge compression in 2009. Before this and other major changes to the OPPS are proposed, we ask the agency to make available to the public the data necessary to understand the full effect of the proposed changes in sufficient time that stakeholders are able to perform their own independent analysis of it.

Thank you for your consideration of these comments. Please contact me at 202-312-9281 if you have any questions or if we can be of further assistance.

Respectfully submitted,

/s/

John Siracusa
Manager, Medicare Reimbursement
& Economic Policy

Submitter : Dr. Benjamin Sachs

Date: 01/28/2008

Organization : Tulane University

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#420

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
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. Shannon Milberger
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-421-Attach-1.DOC

#421

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 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 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 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,

Shannon Milberger
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Michelle Mirovsky
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-422-Attach-1.DOC

#422

January 26, 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,

Michelle Mirovsky
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Diane Nygaard
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-423-Attach-1.DOC

423

January 26, 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,

Diane Nygard
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Heather O'Dell
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-424-Attach-1.DOC

#424

January 26, 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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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 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).

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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,

Heather O'Dell
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Mary O'Dell-Strand
Organization : MAPS Medical Pain Clinics
Category : Nurse

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-425-Attach-1.DOC

425

January 26, 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,

Mary O'Dell-Strand
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Chris O'Hotto
Organization : MAPS Medical Pain Clinics
Category : Physical Therapist

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-426-Attach-1.DOC

426

January 26, 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 CMS's new proposals and classifications will hinder patient access.

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

Sincerely,

Chris O'Hotto
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Jane Olinger
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-427-Attach-1.DOC

427

January 26, 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 CMS's new proposals and classifications will hinder patient access.

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

Sincerely,

Jane Olinger
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Michelle Olson
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-428-Attach-1.DOC

428

January 26, 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,

Michelle Olson
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

429

January 26, 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,

Riah Olson
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Riah Olson
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-429-Attach-1.DOC

Submitter : Mr. Gary Pelletier
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-430-Attach-1.DOC

430

January 26, 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,

Gary Pelletier
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Joan Penn

Date: 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-431-Attach-1.DOC

431

January 26, 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,

Joan Penn
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Dr. Terry Pertile
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-432-Attach-1.DOC

#432

January 26, 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,

Terry Pertile
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Callista Peterson
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachments

CMS-1392-FC-433-Attach-1.DOC

433

January 26, 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,

Callista Peterson
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mr. David Peterson
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-434-Attach-1.DOC

4361

January 26, 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,

David Peterson
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Angie Pike

Date: 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-435-Attach-1.DOC

#435

January 26, 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,

Angie Pike
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Mr. Blair Ransom
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-436-Attach-1.DOC

436

January 26, 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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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 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).

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

Sincerely,

Blair Ransom
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Jennie Roman

Date: 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

#437

file:///T:/ELECTRONIC%20COMMENTS/ELECTRONIC%20COMMENTS/E-Comments/Active%20Files/Missing%20file1.txt

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
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. Nancy Scholz

Date: 01/28/2008

Organization : MAPS Medical Pain Clinics

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-438-Attach-1.DOC

#438

January 26, 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 CMS's new proposals and classifications will hinder patient access.

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

Sincerely,

Nancy Scholz
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Jillayne Skaug
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-439-Attach-1.DOC

#439

January 26, 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,

Jillayne Skaug
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Carmen Sminesvik
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-440-Attach-1.DOC

440

January 26, 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

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

Sincerely,

Carmen Sminesvik
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Desiree Sokol
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-441-Attach-1.DOC

#441

January 26, 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,

Desiree Sokol
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Heather Southam
Organization : MAPS Medical Pain Clinics
Category : Physical Therapist

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-442-Attach-1.DOC

442

January 26, 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,

Heather Southam
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Heather Spaeth
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-443-Attach-1.DOC

#443

January 26, 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

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Sincerely,

Heather Spaeth
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Denise Stanley
Organization : MAPS Medical Pain Clinics
Category : Other Health Care Professional

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-444-Attach-1.DOC

#444

January 26, 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

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

Sincerely,

Denise Stanley
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Ms. Marsha Thiel
Organization : MAPS Medical Pain Clinics
Category : Nurse

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-445-Attach-1.DOC

#445

January 26, 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

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

Sincerely,

Marsha Thiel
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Dr. David Schultz
Organization : MAPS Medical Pain Clinics
Category : Physician
Issue Areas/Comments

Date: 01/28/2008

GENERAL

GENERAL
attachment

CMS-1392-FC-446-Attach-1.DOC

466

January 27, 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

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

Sincerely,

David Schultz, MD
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Dr. Lee Michael Espeland
Organization : MAPS Medical Pain Clinics
Category : Physician

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-447-Attach-1.DOC

447

January 27, 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

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

Sincerely,

Lee Michael Espeland, MD
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Dr. Robert Long
Organization : MAPS Medical Pain Clinics
Category : Physician

Date: 01/28/2008

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1392-FC-448-Attach-1.DOC

#448

January 27, 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,

Robert Long, MD
MAPS Medical Pain Clinics
2104 Northdale Blvd, NW
Minneapolis, MN
55433

Submitter : Dr. Thomas Lee
Organization : Dr. Thomas Lee
Category : Physician

Date: 01/28/2008

Issue Areas/Comments

HCPCS codes

HCPCS codes

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 interventional spine 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,

Thomas S. Lee, MD
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