CMS-1392-P-474 Medicare

Submitter : **Mrs. Linda Ost** **Date & Time:** **09/08/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments
Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

I am a dystonia patient and I serious concerns about CMS's proposal to reduce the payment rate to hospials for physican -injected drugs. I receive injections of botulism toxins to alleviate the debilitating dystonic symptoms. The injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician injected drugs for 2008, and instead maintain the current payment formula. Any reduction in reinbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulism toxin. Not just anyone can inject it successfully yo relieve spasms. Also, this chang in policy would destory the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

Respectfully,

Linda J. Ost

CMS-1392-P-475 Medicare

Submitter : **Mrs. Erin Dale** **Date & Time:** **09/08/2007**

Organization : **St Joseph's Hospital**

Category : **Other Technician**

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am an echo tech that currently uses contrast. My concern is that if separate payment for echo contrast agents is eliminated for hospital outpatients, patient access to studies using contrast would be severely limited and Medicare expenditures for more invasive follow-up procedures may increase. Also, contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate. Underutilization of contrast agents is not in the best interest of Medicare patients or Medicare itself, as inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests. Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures. IF CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

Please take this into consideration.

Thank you,
Erin S. Dale, RCS

CMS-1392-P-476 Medicare

Submitter : **Ms. Rita Gehlsen** **Date & Time:** **09/08/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments
Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:

Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with focal dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS s proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given. Mr. Weems, I am a senior citizen depending on Social Security to help ends meet. It is critically important or me to receive whatever assistance I can to help meet the cost of my very expensive Botox injections. Without these injections, I will suffer chronic pain in my neck and shoulders that will become ever more dibilitating. Thank you for allowing me to provide these comments.

Rita Gehlsen
909 Ravenswood Drive
Grapevine, Texas 76051

CMS-1392-P-477 Medicare

Submitter : **Ms. marion culjak** **Date & Time:** **09/08/2007**

Organization : **none**

Category : **Nurse**

Issue Areas/Comments
Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (or the form dystonia you have), both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician- injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

CMS-1392-P-478 Medicare

Submitter : **Miss. Alene Cartwright** **Date & Time:** **09/08/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments
Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with blepharspasm and facial and neck including swollowing, both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to see at all and to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

Alene Cartwright

CMS-1392-P-479 Medicare

Submitter : **Mrs. Amy Danos** **Date & Time:** **09/08/2007**

Organization : **GE Healthcare**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS Impact

OPPS Impact

I have been a Cardiac Sonographer for 18 years and have seen first hand the impact Echocardiography has made in clinical diagnosing of cardiac disease. The evolution of technology has provided healthcare professionals with tools to accurately diagnosis and treat medical conditions that only 10 years ago could not be visulaized. The advances in cardiac ultrasound has changed patient outcomes, decreased hospital admissions, and improved quality of life for patients. The introduction of Contrast to Echocardiography was again another advancement made to improve ultrasound limitations and change patient outcomes.
My concern over the bundling of contrast into Echo procedures is that this will cause an even greater under utilization of contrast for technically difficult exams. This puts patients at a higher rise for missed pathology and inaccurate diagnosis.
Contrast agents used w/ Echo are relativley inexpensive to begin with. There needs to be a higher status of quality assurance and separation for procedures performed with or without contrast. This bundling approach would be a dis-service and endangerment to public health. Patients will be put at risk and providers will be force to treat conditions from a finance perspective rather than a medical necessitity. Medicare cuts should be well thoughtout and correctly focused. By short changing patients during diagnostic procedures, patinets will suffer and the entire medical community loses. Please consider the impact this proposed bundling of contrast into Echo procedures will have on patient outcomes and quality of care.

CMS-1392-P-480 Medicare

Submitter : **Mrs. Sherri Bletzacker** **Date & Time:** **09/08/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (or the form dystonia you have), both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician- injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

CMS-1392-P-481 Medicare

Submitter : **Mr. Joel Hoffman** **Date & Time:** **09/09/2007**

Organization : **Mr. Joel Hoffman**

Category : **Other Technician**

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am writing to contest the proposed elimination of reimbursement for ultrasound microbubble contrast agents. I was previously a cardiac sonographer that made frequent use of echocardiographic contrast. On numerous occasions, using contrast allowed for a diagnostic study. This resulted in a faster, definitive diagnosis for my patients. Without the contrast, the patient would have had no diagnosis, or a repeated study in a different modality. Echo contrast is already underutilized, the reimbursement only provides a "break even" for the facility, yet it is tremendously helpful in providing a diagnosis for a number of patients. I suggest either leaving the reimbursement at a revenue neutral point, or raising reimbursement for its use, but not decreasing or eliminating it, which will create a greater disincentive for its use.
Thank you.

CMS-1392-P-482 Medicare

Submitter : **Ms. moya devine** **Date & Time:** **09/09/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
Thank you for allowing me to provide these comments.
Sincerely,
Moya Devine

CMS-1392-P-483 Medicare

Submitter : **Ms. Vicki Simpson** **Date & Time:** **09/09/2007**

Organization : **St. John Medical Center**

Category : **Hospital**

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Contrast agents are used when we are unable to visualize 2 or more segments of the left ventricle (our main pumping chamber). Ultrasound has its limitations; with the increase in obesity in the population it is increasingly difficult to obtain adequate images without using them. Due to time constraints, the use of contrast agents is already underutilized. It takes additional time; after evaluating the images which have already been obtained and determining them inadequately visualized, to stop, find someone to start an IV and help with the injection of the contrast agent. When we are reimbursed for its use, it barely covers the cost of the agent. Using contrast agents prevent many patients from having more costly or invasive procedures.
This proposal will increase the disincentive to use the agents even when medically appropriate.
Color Doppler should not be packaged into the cost of the echocardiogram either. It takes at least a third of the time of performing an echocardiogram to adequately evaluate the bloodflow through the 4 heart valves.
I hope you find another area in which to cut costs.
Thank you,
Vicki O. Simpson, RDCS

CMS-1392-P-484 Medicare

Submitter : **Mr. Kenneth Korshin** **Date & Time:** **09/09/2007**

Organization : **Individual**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

RE: CM-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

Gentlemen:

I am writing to vehemently protest the proposed changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.

Five years ago, I was rescued by RIT after all else failed, and so from a very personal standpoint, I know how effective it is. But more important than my personal experience, scientific studies consistently show that RIT is the most effective single agent available for the treatment of some forms of lymphoma. It has few side effects, and because it is given in a period of only one week, patients are able to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment periods and cause significantly more side effects which add to both the cost of treatment and the reduction in patient productivity. Worse, these traditional treatments are known to be less effective than RIT.

If the proposed reimbursement change is adopted, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

It is highly doubtful that I would be alive today had RIT not become available in the nick of time. All patients deserve the same chance of a successful outcome, but they will not have that chance if the proposed change is adopted. And so it is that I urge you in fact, I beg you to consider patients first and to deny the proposed changes in reimbursement to these drugs. Thank you for your consideration.

Sincerely,

Betsy de Parry
Ann Arbor, Michigan

CMS-1392-P-485 Medicare

Submitter : **marcia Froehlig** **Date & Time:** **09/09/2007**

Organization : **marcia Froehlig**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

RE: CM-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

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Sincerely,

Betsy de Parry
Ann Arbor, Michigan

CMS-1392-P-486 Medicare

Submitter : Mr. John Healy **Date & Time:** 09/09/2007

Organization : NSTA

Category : Individual

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

As a patient with Dystonia(Spasmodic Torticollis) for 50 years I ask that you not change the present payment system for Doctors injecting Botullism shots.
Thanking you in advance.

CMS-1392-P-487 Medicare

Submitter : **Dr. Brad Johnson** **Date & Time:** **09/09/2007**

Organization : **Univ of South Florida, Dept of Surgery**

Category : **Physician**

Issue Areas/Comments
OPPS: Packaged Services

OPPS: Packaged Services

see attached

CMS-1392-P-487-Attach-1.WPD

#487

University of South Florida
COLLEGE OF MEDICINE

Vascular Surgery

HARBOURSIDE MEDICAL TOWER
SUITE 650, 4 COLUMBIA DRIVE
TAMPA, FLORIDA 33606
PHONE: (813) 259-0921
FAX: (813) 259-0606
www.hsc.usf.edu/SURGERY/VASCULAR/vas.html

Division of Vascular Surgery

Dennis F. Bandyk MD FACS
dbandyk@hsc.usf.edu

Brad L. Johnson MD FACS
bjohnson@hsc.usf.edu

Martin R. Back MD FACS

Murray Shames MD, FACS

Paul Armstrong MD

Nurse Practitioner
Mary Ekers RN, ARNP

Vascular Fellows
Joe Chauvapun MD
Robert Brumberg MD

Administrative Assistants
Syrae Henning
Emma Murphy

Research
Sarah Bullard RN

CMS-1392-P.

To whom it concerns:

Intravascular ultrasound (IVUS) has become an integral part of endovascular treatments for vascular disease. In carotid artery stenting (CAS) I use it to determine the correct size of the stent and the best type of stent to place based on plaque composition performed by IVUS. Failure to adequately reimburse for IVUS will lead to my hospitals denying my use of it and therefore increase then number of strokes during CAS.

Thanks for your attention to this important matter.

Brad Johnson, MD

CMS-1392-P-488 Medicare

Submitter : **Ms. Rita Jones** **Date & Time:** **09/09/2007**

Organization : **Dundy County Hospital**

Category : **Hospital**

Issue Areas/Comments

OPPS Impact

OPPS Impact

September 9, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Delivered Via On-Line Form: http://www.cms.hhs.gov/eRulemaking

Subject: CMS-1392-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals made affecting the Critical Access Hospital (CAH) program. I am a hospital administrator at Dundy County Hospital in Benkelman, Nebraska.

In December 2000, we received our CAH designation which was a life-saver for our facility, our community, and last-but not least, our patients. The CAH program has allowed enough cash-flow for us to maintain quality services in a modest well-kept older facility. We currently operate an attached Rural Health Clinic (Quality Healthcare Services) and one in a neighboring community (Stratton Medical Clinic). While there are only 18 miles between the clinics, our off-site clinic is located in a wing of an assisted living complex which allows those patients easy access to care. There are so many more issues that effect our Medicare population aside from who is paying for the service, access being a HUGE issue.

Due to these concerns, I respectfully ask that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAHs. As stated above, such provisions would have a devastating impact on the access to quality health care in my rural community. This is the opposite of the intention of the CAH program, which is to provide the financial stability for small, rural hospitals to serve their communities. Such provisions would eliminate our flexibility to provide the care needed to rural seniors.

Thank you for considering these comments. Please contact me if you have any questions.

Sincerely,
Rita A. Jones
Administrator

CMS-1392-P-488-Attach-1.DOC

#488

September 9, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Delivered Via On-Line Form: *http://www.cms.hhs.gov/eRulemaking*

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Thank you for considering these comments. Please contact me if you have any questions.

Sincerely,

Rita A. Jones

Rita Jones
Administrator

CMS-1392-P-489 Medicare

Submitter : **Mr. Rolando Chacon** **Date & Time:** **09/09/2007**

Organization : **Blue Ridge Health Care**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Paymen Services Provided in ASCs

Physician Paymen Services Provided in ASCs

Please discontinue Physician self referral services for Physician own PT reheb clinic.

CMS-1392-P-490 Medicare

Submitter : **Ms. Luanne Nulf** **Date & Time:** **09/09/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments
Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Generalized Dystonia, both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS s proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments.
Sincerely,
Luanne Nulf

CMS-1392-P-491 Medicare

Submitter : **Ms. Luanne Nulf** **Date & Time:** **09/09/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Generalized Dystonia, both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS s proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments.
Sincerely,
Luanne Nulf

CMS-1392-P-492 Medicare

Submitter : **Date & Time: 09/09/2007**

Organization :

Category : Other Health Care Professional

Issue Areas/Comments

Quality Data

Quality Data

This represents a significant increase in the burden of data abstraction and it is unclear why hospitals have to collect the same data that they are already collecting for inpatients in very sufficient numbers.

CMS-1392-P-493 Medicare

Submitter : **Dr. Anthony Don Michael** **Date & Time:** **09/09/2007**

Organization : **Advanced Heart and Medical Center**

Category : **Physician**

Issue Areas/Comments

OPPS Impact

OPPS Impact

1.Contrast Agents are currently underutilized and the proposal will lead to disincentivisation to use contrast even when medically appropriate and necessary.
2.Underutilization of contrast agents will make it impossible to perform Echo Stress testing which is inexpensive and as accurate as the much more expensive nuclear stress test.
3. In the Medicare population, the simple acquisition of an echocardiogram with Dobutamine stress performed in the prehospital or in hospital phase is accurate in ruling out significant coronary artery disease and obviating the need for cardiac catheterization with its attendant cost and risks.
4. More recently developed contrast agents can be used to image infarcted tissue as well as ischemic tissue. This is much less expensive than the use of PET scanning to detect ishemic tissue and infarcted tissue in the myocardium.
Conclusion: Not paying for contrast will ultimately lead to a net increase in cost, especially in female patients and in those in the Medicare age category.
T. Anthony Don Michael, M.D.; Ph.D
FACP,FACC, Clinical Professor of Medicine, UCLA

CMS-1392-P-494 Medicare

Submitter : **Dr. maxine Spicer** **Date & Time:** **09/09/2007**

Organization : **Three Village Women's Health**

Category : **Physician**

Issue Areas/Comments

Physician Paymen Services Provided in ASCs

Physician Paymen Services Provided in ASCs

September 9, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P (Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Deputy Kuhn:

As a practicing gynecologist I am pleased that the CMS has offered the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians offering this technology to patients. We believe that this technology has tremendous potential to improve health outcomes and the uterine fibroid application is only the first of many to come.

I welcome CMS proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. It shares many similarities with these procedures both clinically and in terms of resources required:

1) Treatment objective is non-invasive tumor destruction

2) The surgery is conducted using an external source of energy which penetrates into the body to reach the tumor
3) Imaging technology is required
4) Extensive treatment planning is involved with continuous monitoring during treatment
5) Expensive capital equipment in dedicated specialized treatment rooms
6) Lengthy procedure time ranging from 2-5 hours

However the payment rate for this procedure continues to be far below the costs incurred to provide this service and does not reflect the treatment planning component that is required to perform the MRgFUS procedure.

I recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV Stereotactic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotactic Radiosurgery assignment would permit MRgFUS to be classified into an APC with similar clinical and resource homogeneity.

The MRgFUS procedure provides excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals and outpatient centers to offer this less invasive procedure option to patients with uterine fibroids. We urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127 which more accurately reflects the clinical and economic resources utilized.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Maxine L. Spicer MD FACOG

CMS-1392-P-495 Medicare

Submitter : **Mrs. Joan Barrett** **Date & Time:** **09/09/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments
Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

6200 Red Haven S.E.
Caledonia, MI 49316

September 10, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1392 P
P.O. Box 8011
Baltimore, MD 21244 1850

Dear Mr. Weems: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Spasmodic Torticollis a form of dystonia, which is a movement disorder resulting from sustained involuntary muscle spasms, I have serious concerns about CMS s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
Thank you for allowing me to provide these comments.
Sincerely,
Joan I. Barrett

6200 Red Haven S.E.
Caledonia, MI 49316

September 10, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1392 P
P.O. Box 8011
Baltimore, MD 21244 1850

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Spasmodic Torticollis, a form of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS s proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments.
Sincerely,
Joan I. Barrett

CMS-1392-P-496 Medicare

Submitter : **Sharon Smith** **Date & Time:** **09/09/2007**

Organization : **Sharon Smith**

Category : **Individual**

Issue Areas/Comments
Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Benign Essential Blepharospasm, a type of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally. Without them I would not be able to work, drive, or lead a normal life.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area in which we have far too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. (I know this from personal experience.) Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

Sharon Smith

CMS-1392-P-497 Medicare

Submitter : Dr. Kevin Mikielski **Date & Time:** 09/09/2007

Organization : Osteopathic Cardiology Associates

Category : Physician

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I am writing to recommend that the proposed "bundling" of contrast agent use in the general echocardiogram "package" be reconsidered. The use of contrast agents can be an extemely important adjucnt to both rest and stress echocardiograms. The contrast agent costs money and therefore, we should be reimbursed for its use. In addition, injecting the agent requires extra time and personel as it cannont be done by the echocardiographer. Please reconsider the proposal of "packaging" the contrast agent because use of the agents does positively affect the sensitivity and specificity of echoardiography and does definitely reduce the utilization of subsequent procedures in the event of supoptimal/nondiagnositic studies when contrast agents are not used.

Thank you,

Kevin Mikielski, D.O.

CMS-1392-P-498 Medicare

Submitter : Mrs. Monica Archer **Date & Time:** 09/09/2007

Organization : None

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Cervical Dystonia, both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments.

CMS-1392-P-499 Medicare

Submitter : **Mrs. Monica Archer** **Date & Time:** **09/09/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Cervical Dystonia, (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.

Thank you for allowing me to provide these comments.

CMS-1392-P-500 Medicare

Submitter : **Mr. Robert Collins** **Date & Time:** **09/09/2007**

Organization : **Bamberg County Hospital**

Category : **Hospital**

Issue Areas/Comments

Packaged Services

Packaged Services

As a Trustee at the Bamberg County Hospital and Nursing Center, I respectfully request reconsideration of CMS-1392-P. Vascular procedures contribute a significant amount to our revenues in this small rural hospital in one of the poorest counties in the country. This change will result in a loss of $900,000 to our hospital which would jeopardize the operation of the entire hospital and thus dramatically affect the lives of 15,000 of the country's poorest citizens.

CMS-1392-P-501 Medicare

Submitter : **Mr. Marvin Sharp** **Date & Time:** **09/09/2007**

Organization : **Mr. Marvin Sharp**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

I would like to request that CMS not change the payment formula for physican injectable drugs for 2008, and instead maintain the current payment formulas. For those of us who have blepharospasms of the eyes these injections that we receive kep us functioning as a member of society. With out these injections we are functionally blind. We need to be able to see knowledgeable doctors who know how to inject botox in the right places so that we might continue to see. Any doctor can inject botox but most do not have the experience to put it in the right place or the know how to inject the right amount. Many doctors inject botox but most can not inject it sucessfully. I know from experience, because I had to fight to get a doctor who knew what he was doing. Acute Beign Blepharospasms of the eyes is a neurological condition that leaves you functionally blind and without the botox injections (the only treatment now available) to relieve the spasms, we would be blind. Please consider this in your decesion. Thank you very much.

CMS-1392-P-502 Medicare

Submitter : **Mrs. Kay Haun** **Date & Time:** **09/09/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with cervical dystonia , (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.
I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective. Thank you for allowing me to provide these comments.

CMS-1392-P-503 Medicare

Submitter : **Lori Gerlach** **Date & Time:** **09/09/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with cervical dystonia and/or spasamadic torticolis, both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS s proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments.

CMS-1392-P-504 Medicare

Submitter : **Dr. Charles Peterson** **Date & Time:** **09/09/2007**

Organization : **Arizona Sports Medicine Center**

Category : **Physician**

Issue Areas/Comments

Physician Paymen Services Provided in ASCs

Physician Paymen Services Provided in ASCs

To Whom It May Concern:
I write this letter in response to Medicare's ASC 2008 proposed rate calculations as it affects orthotripsy. I am a sports medicine physician in Arizona and orthotripsy has been a part of my practice for the last five years. With your current proposals, I will no longer be able to perform this valuable service.
The core of the matter seems to be confusion between the roles of office based orthotripsy versus ambulatory surgery centers. In office procedures give patients quite a bit of discomfort. Despite this, they choose to go through it rather than continue to suffer with chronic tendonitis, which often limits their ADLs.
Ideally, patients are able to have the procedure in a more controlled setting with proper anesthesia and postoperative care, especially as pertaining to Medicare patients, who may have other medical comorbidities. I have performed the procedure both ways, and the experience is always better for physician and patient when performed with anesthesia in a surgical center rather than with local or regional alone.
My most recent orthotripsy patient was a United States Olympic athlete. Surprisingly, his insurance did not cover the procedure. He's preparing to compete in the Beijing Olympics and was unable to continue with his training due to his severe plantar fasciitis. We were obliged to perform the procedure in the office. He is a very strong and dedicated athlete, used to enduring physical pain. He tolerated the procedure, but at follow-up commented that it was painful enough that he would find a way financially to have the procedure with anesthesia if he had to ever have it again. If this Olympic athlete felt this way, imagine how an elderly patient with Medicare would feel. Efficacy rates are often higher in a surgical center than in the office, as patients are able to tolerate the procedure better, alleviating the need for repeat procedures, a cost savings.
Many private insurance companies follow the lead of Medicare reimbursement. If Medicare were to drop the reimbursement as proposed, based on physician office reimbursement rates, I can only imagine that private insurances will follow suit. The end result would be taking the tool of orthotripsy from my and other physicians hands, leaving us with limited tools or more aggressive and more dangerous open surgery.
Unfortunately, the proposed payment is so low, that even with office-based procedures, it would destroy my ability to perform orthotripsy. They might then proceed to invasive surgery, with cure rates no better than orthotripsy combined with a risk for infection and a prolonged recovery and missed time from work and other activities. By basing reimbursement on the in-office rate, CMS ignores the fact that $175 will never buy a half hour of OR time. This effectively destroys my and other physicians ability to perform the procedure the patients need in the way that they need it.
If the choice were mine alone, every orthotripsy procedure that I performed would be in the OR setting. Safety would be better, compliance would be better, the results would be better, and patients would suffer less. With my Medicare patients, I believe this even more strongly. With many Medicare patients,I would refuse to perform the procedure in-office, as safety would be inadequate, and the unfortunate results are that these patients would have to continue to suffer or choose an even more risky invasive procedure. The code 28890 is ideally an OR code, needed only once to achieve proper results. Forcing the procedure out of the OR would drive up the need for repeat treatments and thus costs. The logic and consequences are so clear in my mind, but I can only hope that you will see through this issue and make the right decision so that I can continue to provide excellent and safe care for my patients.

Sincerely,

Charles S. Peterson, M.D.
Arizona Sports Medicine Center
Instructor in Family Medicine, Mayo College of Medicine

CMS-1392-P-504-Attach-1.DOC

#504

September 9, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Resources
Attention CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS 1392-P

To Whom It May Concern:

I write this letter in response to Medicare's ASC 2008 proposed rate calculations as it affects orthotripsy. I am a sports medicine physician in Arizona and orthotripsy has been a part of my practice for the last four to five years. I am concerned that with your current proposals, I will no longer be able to perform this valuable service.

The core of the matter seems to be confusion between the roles of office based orthotripsy versus ambulatory surgery center or outpatient surgical center procedures. Unfortunately, some insurance companies have been slow in covering treatment for orthotripsy, despite its proven efficacy. Because of this, the only alternative for these patients is a cash rate procedure. Using a surgical center makes the procedure prohibitively expensive for many cash pay patients and they elect to have office based orthotripsy. In my experience, this gives patients quite a bit of discomfort. Despite the discomfort, they choose to go through this rather than continue to suffer with their chronic tendonitis, which often limits their activities of daily life.

Ideally, patients are able to have the procedure in a more controlled setting with proper anesthesia and postoperative care, especially as pertaining to Medicare patients, who may have other medical comorbidities. I have performed the procedure both ways, and the experience is always better for physician and patient when performed with anesthesia in a surgical center rather than with local or regional alone.

My most recent orthotripsy patient was actually a United States Olympic athlete. Surprisingly, his insurance did not cover the procedure. He's preparing to compete in the

Beijing Olympics and was unable to continue with his training due to his severe plantar fasciitis. We were obliged to perform the procedure in the office. He is a very strong and dedicated athlete, used to enduring physical pain. He tolerated the procedure, but at follow-up commented that it was painful enough that he would find a way financially to have the procedure with anesthesia if he had to ever have it again. This told me very clearly that anesthesia is preferable to local. If this Olympic athlete felt this way, imagine how an elderly patient with Medicare would feel. Efficacy rates are often higher in a surgical center than in the office, as patients are able to tolerate the procedure better, alleviating the need for repeat procedures, a cost savings.

In addition, many private insurance companies follow the lead of Medicare reimbursement. If Medicare were to drop the reimbursement as proposed, based on physician office reimbursement rates, I can only imagine that private insurances will follow suit. The end result would be taking the tool of orthotripsy from my and other physicians' hands, leaving us with limited tools or more aggressive and more dangerous open surgery, or having to put our patients through office procedures with local only.

Unfortunately, the proposed payment is so low, that even with office-based procedures, it would destroy my ability to perform orthotripsy, and my patients would be left with the painful choice of either enduring with medical treatments that have failed or proceeding with invasive surgery, with cure rates no better than orthotripsy combined with a risk for infection and a prolonged recovery and missed time from work and other activities. By basing reimbursement on the in-office rate, CMS ignores the fact that $175 will never buy a half hour of OR time. This effectively destroys my and other physicians' ability to perform the procedure the patients need in the way that they need it.

If the choice were mine alone, every orthotripsy procedure that I performed would be in the OR setting. Safety would be better, compliance would be better, the results would be better, and patients would suffer less. With my Medicare patients, I believe this even more strongly. With many Medicare patients, I would refuse to perform the procedure in-office, as safety would be inadequate, and the unfortunate results are that these patients would have to continue to suffer or choose an even more risky invasive procedure. The code 28890 is ideally an OR code, needed only once to achieve proper results. Forcing the procedure out of the OR would drive up the need for repeat treatments and thus costs. The logic and consequences are so clear in my mind, but I can only hope that you will see through this issue and make the right decision so that I can continue to provide excellent and safe care for my patients.

Sincerely,

Charles S. Peterson, M.D.
Arizona Sports Medicine Center
Instructor in Family Medicine, Mayo College of Medicine

CMS-1392-P-505 Medicare

Submitter : ena wilmot **Date & Time:** 09/09/2007

Organization : none

Category : Individual

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (or the form dystonia you have), both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician- injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

Ena Wilmot

CMS-1392-P-506 Medicare

Submitter : **Dr. Kenneth Ford** **Date & Time:** **09/09/2007**

Organization : **The Heart Group**

Category : **Physician**

Issue Areas/Comments

OPPS Impact

OPPS Impact

Bundling echo contrast reimbursement with 2d-echo reimbursement is a critical mistake. Doing so would not decrease the cost of delivering medical care. It would result in an enormous increase in the cost to treat the same patients. Contrast agents already are underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate. Anytime contrast is not used, an additional (and more expensive) test will be required to get the necessay information. For suboptimal echo studies, the next test ordered will be either a transesophageal echo, nuclear test, CT, MRI or cath. My group does approximately 5000 stress echos each year. If contrast were not available (because the hospital can not afford for me to use it), I estimate that over 4000 additional stress nuclear tests will become necessary each year. These tests are reimbursed at 2 to 3 times the cost of a stress echo. In addition, approximately 1/4 to 1/3 of the 5000 2D echos my group does each year will be nondiagnostic and require further testing. The costs to medicare will be staggering. In addition, if CMS nonetheless decides to bundle echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures. Please use some common sense! Save the tax payers money and avoid driving up the cost of treating medicare patients. (If physician payment is decreased any further to help cover these new costs, most physicians will no longer be able to afford to participate in medicare. This will lead to collapse of the entire medical system in the United States.) If anyone wishes to discuss this further they can call me at my office number:

270-575-2652
J. Kenneth Ford MD, FACC
Director of Cardiac Imaging and Cardiac Cath Lab
Western Baptist Hospital
Paducah, KY

CMS-1392-P-507 Medicare

Submitter : **Ms. lynn potter** **Date & Time:** **09/10/2007**

Organization : **Ms. lynn potter**

Category : **Drug Industry**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Please consider no changes ot the medicare reimbursement program for treatment drugs of Bexxar and Zevalin for cancer. I know personally of lives these drugs have changed. Please keep the price down and within reason so more lives in our great country may be saved.

CMS-1392-P-508 Medicare

Submitter : **Dr. Eddy Luh** **Date & Time:** **09/10/2007**

Organization : **Nevada Vascular Institute**

Category : **Physician**

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

We commend CMS for its work to establish a comprehensive process for APC and ASC payment.

I have reviewed RVUs as well as the facility cost to provide services for CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser, first vein treated). I am concerned with the element of equipment expense. New technologies frequently require the purchase of capital equipment. This cost of capital, to be absorbed into the cost of doing business, must be compensated in a manner that is affordable to the provider (in all practice settings) and reasonable to the payor.

Based on the CMS utilization formula for equipment cost per minute, I am finding a discrepancy in the equipment expense.

The Federal Register, Volume 72, July 12, 2007 identifies equipment expense for all physicians at 4.08. Based on the CMS equation:

(1/(minutes/yr * usage)) * price * ((interest rate/(1-(1/(1 + interest rate) * life of equipment)))) + Maintenance)

The allowed equipment expense is 4.08. When calculated using the ASP for the equipment used, the calculation is 4.75.

Payment for CPT code 36478, in the hospital outpatient department is in APC 0092 with an unadjusted national average payment of $1,684.02. Other procedures in that category include:
a. 37650: Ligation femoral vein
b. 37760: Ligation of perforator veins
c. 37765: Stab phlebectomy of varicose veins
We are requesting that 36478 be moved to APC 0091 with an unadjusted national average payment of is $2,780.84.Other procedures in this category include:
d. 37700: Ligation and division of long Saphenous vein at SFJ or distal interruptions
e. 37718: Ligation, division and stripping, short Saphenous vein
f. 37722: Ligation, division and stripping GSV from SFJ to knee or below
g. 37735: Ligation, division and complete stripping of GSV or LSV with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
h. 36478: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated

We believe CPT code 36478 is more clinically related to procedures in APC 0092 than to APC 0091.

In previous years, low cost laser fibers (not matched to the laser for compatibility) were available from various companies. March 28, 2007, a successfully litigated patent infringement suit resulted in these fibers being removed from the market. Although there has been no increase in fiber cost, the potential to reduce cost through the use unmatched fibers has been removed. Ensured compatibility between laser and fiber enhances patient safety. We believe resource consumption for CPT code 36478 is more closely related to APC 0091.

We are requesting that you move CPT code 36478 from APC 0092 to APC 0091.

CPT code 36478 has been moved form ASC group 9 to ASC group 8. We are requesting that CPT code 36478 be placed back into group 9.

GENERAL

GENERAL

We commend CMS for its work to establish a comprehensive process for APC and ASC payment.

I have reviewed RVUs as well as the facility cost to provide services for CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging
guidance and monitoring, percutaneous, laser, first vein treated). I am concerned with the element of equipment expense. New technologies frequently require the purchase of capital equipment. This cost of capital, to be absorbed into the cost of doing business, must be compensated in a manner that is affordable to the provider (in all practice settings) and reasonable to the payor.

Based on the CMS utilization formula for equipment cost per minute, I am finding a discrepancy in the equipment expense.

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f. 37722: Ligation, division and stripping GSV from SFJ to knee or below
g. 37735: Ligation, division and complete stripping of GSV or LSV with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
h. 36478: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated

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We are requesting that you move CPT code 36478 from APC 0092 to APC 0091.

CPT code 36478 has been moved form ASC group 9 to ASC group 8. We are requesting that CPT code 36478 be placed back into group 9.

CMS-1392-P-509 Medicare

Submitter : Michael Carda **09/10/2007**

Organization : Alegent Lakeside Hospital
Other Technician

Category :

Issue Areas/Comments

OPPS Impact

OPPS Impact

' Contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate. .
' Underutilization of contrast agents is not in the best interest of Medicare patients or Medicare itself, as inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.
' Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.
' IF CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.
-Finally, as a cardiac sonographer, if contrast agents are bundled into an echo, with no way to reimburse the costs, I will use these agents far less frequently. This will have an impact on care given to medicare/medicaid patients. Why should medicare patients get inferior care?

CMS-1392-P-510 Medicare

Submitter : Dr. Timothy Fenske **09/10/2007**

Organization : Medical College of Wisconsin
Physician

Category :

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I am writing to express my concern regarding the proposed changes by CMS for reimbursement for therapeutic radiopharmaceuticals. I am a lymphoma specialist and have already seen the market forces and reimbursement issues at work, making obtaining Zevalin and Bexxar difficult for patients. As recently reported in the NY Times (see http://www.nytimes.com/2007/07/14/health/14lymphoma.html?ex=1189483200&en=162b285db9fc7004&ei=5070), while costly, these are extremely effective and well tolerated agents. In general one treatment with Zevalin or Bexxar costs about the same as a several-month course of chemotherapy, but the radioimmunotherapy is tolerated much better. In many cases Zevalin or Bexxar is more effective than prescribing yet another course of conventional chemotherapy.

The new proposed reimbursement for these agents will essentially mean that hospitals will lose money everytime a patient is treated with Bexxar or Zevalin. As a result there will be even less incentive to prescribe, and less impetus for the research and development community to develop more such agents. Eventually the pharmaceutical companies will simply stop making Zevalin and Bexxar. As evidence of this, Biogen/Idec has already sold off Zevalin recently.

I ask you to seriously re-consider to CMS proposal so that this important option will remain available to patients.

CMS-1392-P-511 Medicare

Submitter : **09/10/2007**

Organization : Prothrombin-time Self Testing Coalition
Device Industry

Category :

Issue Areas/Comments

2 Times Rule

2 Times Rule

See Attachment

CMS-1392-P-511-Attach-1.PDF

September 10, 2007

Via Electronic Submission to: http://www.cms.hhs.gov/eRulemaking
Kerry Weems
Acting Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1392-P
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule

CMS-1392-P

Comments on: 2 Times Rule—APC Assignment for Codes G0248 and G0249 for Home PT/INR Monitoring

Dear Mr. Weems:

On behalf of the Prothrombin-time Self Testing (PST) Coalition comprising HemoSense, Inc., International Technidyne Corporation and Roche Diagnostics Corporation, we are pleased to submit comments on the above-captioned Proposed Rule[1] regarding Prothrombin Time (PT)/International Normalized Ratio (INR) home monitoring for anticoagulation management. We are deeply concerned that the proposed reassignment of the home PT/INR monitoring services codes (G0248 and G0249) from APC 0421 to APC 0097, which will reduce payments for these services by 34-percent in 2008 on top of a 33-percent reduction in 2007, will make it financially impossible for hospitals to offer these services and will reduce patient access to home PT/INR monitoring, which has been shown to improve outcomes of patients on chronic warfarin anticoagulation. We urge CMS to maintain current APC 0421. Alternatively, we would recommend that CMS create a new APC to include codes G0248 and G0249 and two other higher cost procedures from proposed APC 0097 (codes 93271 and 95250). Our rationale to support these recommendations is presented below.

I. Background on Home PT/INR Monitoring and Coding and Payment Under OPPS Through 2007

Home PT/INR monitoring is performed by patients receiving chronic anticoagulation therapy with warfarin to facilitate maintenance of anticoagulation within desired ranges. Home PT/INR monitoring has been shown in published clinical studies to reduce the incidence of serious adverse events (strokes, bleeding and death) among patients requiring anticoagulation with warfarin.[2] Home PT/INR monitoring is covered by Medicare for patients with mechanical heart valves meeting specific coverage criteria.[3]

Medicare coverage is provided as a diagnostic service and reported under three "G" codes for (1) training (G0248), (2) furnishing of the equipment and supplies (technical component service under G0249), and

[1] 72 Fed Reg. 42,628 (Aug. 2, 2007).

[2] Heneghan C, Alonso-Coello P, Garcia-Alamino JM, *et al.* Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. *Lancet*. 2006; 367: 404–411.

[3] Medicare National Coverage Determinations Manual (Pub 100-3), Ch. 1., § 190.11. Home Prothrombin Time INR Monitoring for Anticoagulation Management.

(3) physician review and interpretation of test results (professional component service under G0250—this latter component is not billable by hospitals nor paid under OPPS). The descriptors for the codes relevant for OPPS are:

Code	Descriptor
G0248	Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing
G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per 4 tests

Home PT/INR monitoring is an unusual service under the OPPS because it involves the furnishing of equipment and supplies by hospitals, physicians or IDTFs for use by patients in their homes. Code G0248 involves use of home monitoring equipment and supplies together with clinical staff time required for education about anticoagulation and training on use of the devices. Code G0249 involves the dedicated use of a home monitor by a single patient for a minimum 28-day period, supplies to perform four (4) PT/INR tests in the home and clinical staff, equipment and supplies to monitor the home testing.[4]

Medicare coverage for home PT/INR monitoring began July 2002. The "G" codes were assigned to APC 0708 "New Technology—Level III ($100-$200)," which was renumbered as APC 1503 "New Technology—Level III ($100-$200) in 2004. G0248 and G0249 remained assigned to APC 1503 through 2006. Very few claims were reported under these codes, and no single claims were identified in the files supporting the Outpatient PPS payments for 2003, 2004, 2005 or 2006.

For 2007, CMS proposed a reassignment of codes G0248 and G0249 from APC 1503 to APC 0604 "Level 1 Clinic Visits" with a proposed payment rate of $49.75—a 67-percent reduction in the payment rate. In response to comments submitted by the PST Coalition[5] and a recommendation made by the Advisory Panel on Ambulatory Payment Classification Groups (APC Advisory Panel), in the Final Rule for the 2007 OPPS, CMS reassigned codes G0248 and G0249 to APC 0421 "Prolonged Physiologic Monitoring" with a payment rate of $100.01. Although this represented a 33-percent reduction in payment for home PT/INR monitoring, we concluded that the three (3) codes under APC 0421 were reasonably homogeneous clinically, and it appeared reasonable to monitor whether the reduced payment amount would have a negative impact on patient access to this procedure.

[4] The National Coverage Determination limits coverage to testing no more than once per-week. The 4-test payment units under code G0249 reflects testing over a minimum 28-day period. Medicare instructions to hospitals permit hospitals to report code G0249 as three (3) units—i.e., 12 tests. CMS allows hospitals to report this way because patients must be physically present at the hospital at the time these services are billed and it was assumed that patients would otherwise attend the hospital approximately every three (3) months for evaluation and management of their anticoagulation and/or underlying condition.

[5] Letter to Mark McClellan, M.D., Ph.D. from L. Cohen (ITC), D. Phillips (HemoSense), and J. Ridge (Roche Diagnostics), dated September 29, 2006.

II. Concern about the Proposed Reassignment of Home PT/INR Monitoring to APC 0097

In the 2008 Proposed Rule, CMS is proposing to discontinue APC 0421, to which codes G0248 and G0249 were first assigned in 2007 (joining code 95250 ["Glucose monitoring, cont"]), and to reassign these codes to APC 0097 "Prolonged Physiologic and Ambulatory Monitoring." This reconfigured APC 0097 includes 17 codes, which range in median cost from $33.92 to $119.84—a 3.5-fold range of costs.[6] The proposed payment amount for reconfigured APC 0097 is $66.21, which represents a 34-percent reduction in payment for codes G0248 and G0249 from 2007. The 2007 payment rate already represented a 33-percent reduction in payment for these services from the 2006 rate. If finalized as proposed, the 2008 payment for these procedures would be 56-percent lower than the 2006 payment rate. This would result in an APC that underpays certain higher cost, low volume services, like home PT/INR monitoring, while overpaying certain lower cost, high volume procedures—driving utilization of those procedures at the expense of home PT/INR monitoring.

The median costs for home PT/INR monitoring are at the upper end of costs in APC 0097. In particular, the median cost for code G0249 ($119.84)[7], which involves the dedicated use of a home monitoring device by an individual patient, is the highest within the APC—nearly twice the median cost and proposed payment rate for the overall APC ($66.22).

Among the prolonged and ambulatory monitoring procedures included under APC 0097, code G0249 is unusual clinically in covering an extended period of monitoring. Code G0249 and code 93271 ("ECG/monitoring and analysis") both cover extended periods of monitoring and have median costs at the upper range of costs for this APC ($119.84 and $95.85, respectively).[8]

We also note that codes G0248 and G0249 were just reassigned in 2007 to APC 0421 from APC 1503 so the 2008 proposal does not reflect any experience with these procedures under this APC assignment.

III. Recommendation

We would urge CMS to proceed cautiously in reassigning these procedures to new APCs two years in a row when the result is a drastic 56-percent reduction in payment for a procedure that offers significant improvement in patient outcomes but has had limited adoption and use, in part due to concerns about reimbursement. Therefore, we would urge CMS to consider one of the following options:

1. Retain APC 0421. We recommend that CMS retain APC 0421 comprising codes G0248, G0249 and 95250. These procedures are reasonably homogeneous clinically, and the median costs—especially those for codes G0249 and 95250—are economically coherent. Retaining this APC would allow CMS

[6] It would appear that the reconfigured APC 0097 does not violate the 2-times rule because the lowest median cost service (0154T) and the highest two median cost services (95250 and G0249) have low frequencies, and the next lowest median cost service (93799) is an unlisted procedure code, which is assigned to the lowest paying APC in a group by CMS policy. No median costs were available for codes 94775 and 94776, which were introduced in 2007.

[7] Our reference in these comments to claims-based median costs is not intended to suggest that these costs reflect actual purchase prices of any specific product sold or offered for sale by any of the companies comprising the PST Coalition.

[8] As noted above, code G0249 involves a minimum 28-day period. Code 93271 involves a 30-day period of monitoring. Although code 93270 ("ECG recording") also involves a 30-day period of recording, the median costs for this code are much lower than codes G0249 and 93271. However, code 93270 represents a split of the technical component service for prolonged ECG recording, monitoring and analysis with code 93271. The combined costs for the two codes 93270 and 93271 would be substantially higher than those of other procedures in APC 0097.

time to collect data on the median costs for these procedures as adoption and use of these procedures expands to allow a more robust assignment of the APC. Discontinuing this APC only one year after assigning codes G0248 and G0249 to this APC does not allow for any experience with this APC assignment to inform appropriate APC assignment in 2008 or beyond. The APC Advisory Panel also recommended retaining APC 0421 at its recent meeting; we appreciated the Panel's recognition of the appropriateness of retaining this APC assignment.

2. Create a new APC comprising codes G0248, G0249, 95250 and 93271. This would involve creation of a new APC carved out of the proposed reconfigured APC 0097 comprising the three highest cost procedures in the APC as well as code G0248. These four (4) codes are reasonably homogeneous clinically and would create an APC that is more economically coherent than the proposed APC 0097. Although we believe code G0248 should be assigned to this APC, we would support assignment of G0248 to a different APC from that to which code G0249 is assigned based upon differences in the claims-based median costs for these codes ($67.83 for code G0248 and $119.84 for code G0249).

We believe option 1 would be the most appropriate alternative for CMS to adopt in the Final Rule as it would retain codes G0248 and G0249 in the same APC and would allow more time for CMS to collect meaningful claims-based cost data for these procedures. At the same time, we would support CMS's adoption of option 2 to maintain the [already reduced] payment rate for home PT/INR monitoring under OPPS and to limit negative impact on access to this procedure.

* * * *

Anticoagulation therapy with warfarin sodium can reduce the risk of serious thromboembolic events in patients who are at risk for such events due to mechanical heart valves, atrial fibrillation, deep venous thrombosis or other thrombophilic disorders. At the same time, therapy with warfarin puts patients at-risk for significant bleeding if therapy is excessive or thromboembolism if therapy is insufficient. Studies have shown that careful monitoring of anticoagulation therapy with home PT/INR testing can reduce thromboembolic events, hemorrhagic adverse events and deaths.

Despite the benefits, adoption of the home PT/INR monitoring under Medicare has occurred at a very slow pace since coverage was first approved in 2002. Reimbursement has been a key factor inhibiting access to this technology. Until this year, the principal restraint on adoption has been the limited scope of Medicare coverage; coverage is limited to patients with mechanical heart valves, a relatively small subset of the overall population undergoing anticoagulation therapy. We are addressing the coverage issue with the Coverage and Analysis Group through a reconsideration request we submitted in June, and we hope to have a decision about expanded coverage by the end of March 2008.

Appropriate adoption and use will not occur, however, if the payment rate is inadequate to cover the cost of the service. The proposed payment rate represents a 56-percent reduction from 2006. We urge CMS to adopt one of the alternatives recommended above to assure that payment will be adequate to support appropriate use of this technology.

We appreciate the opportunity to comment on this Proposed Rule. Please contact our reimbursement counsel, Paul Radensky, M.D., J.D., at 305.347.6557 or by e-mail at pradensky@mwe.com if you have any questions about our comments or would like to discuss these further. Thank you for your consideration of our comments.

Sincerely,

/s/ Larry Cohen

Larry Cohen
President
International Technidyne Corporation

/s/ David Phillips

David Phillips
Vice President, Marketing
HemoSense, Inc.

/s/ Anthony Callaway

Anthony Callaway
Director Of Health Policy
Roche Diagnostics Corporation

Cc: Denise Garris, American College of Cardiology
Paul Radensky, M.D., J.D., McDermott, Will & Emery LLP

CMS-1392-P-512 Medicare

Submitter : Laura Cross **09/10/2007**

Organization : St. Mary's Hospital
Health Care Professional or Association

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I am a Cardiac Sonographer who has been performing echocardiograms for over 30 years. I oppose the elimination of separate payment for echo contrast. Not only does it benefit the patient by providing valuable information but it also provides the sonographer with an additional tool to prevent muscular skeletal disorders. In addition:
Contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate.
Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.
Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.
IF CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

Please consider my request

CMS-1392-P-513 Medicare

Submitter : Mr. Kelly McBryde **09/10/2007**

Organization : UltraGroup, LLC
Health Care Industry

Category :

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

The proposed changes for CAH off-campus services are "swinging the pendulum" to the other extreme as a reaction to the over aggressive competitive strategies of a few CAH facilities. A compromised minimum mileage limitation (ie: 10 miles) would certainly be effective without the potential effect of reducing and/or limiting resources for the rural citizens. Please reconsider the proposed rule change and thank you for this opportunity. Kelly McBryde

CMS-1392-P-514 Medicare

Submitter : Ms. Sarah Mettille **09/10/2007**

Organization : PBCC
Individual

Category :

Issue Areas/Comments

GENERAL

GENERAL

Bexxar is an essential drug that has kept my mother around longer and could potentially help others as well.

CMS-1392-P-515 Medicare

Submitter : Miss. sharon gibson **09/10/2007**

Organization : bebrf,inc.
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

please maintain current drug coverage.I DEPEND ON MY INJECTIONS TO BE ABLE TO WORK AND FUNCTION NORMALLY.

CMS-1392-P-516 Medicare

Submitter : Mr. William Watkins **09/10/2007**

Organization : Bluffton Hospital
Critical Access Hospital

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-516-Attach-1.DOC

Bluffton Hospital
BLANCHARD VALLEY HEALTH SYSTEM

139 Garau Street #516
Bluffton, Ohio 45817

419-369-2302
Fax 419-369-4431
www.bvhealthsystem.org

September 10, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Delivered Via On-Line Form: *http://www.cms.hhs.gov/eRulemaking*

Subject: CMS-1392-P – Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals made affecting the Critical Access Hospital (CAH) program. I am a hospital administrator at Bluffton Hospital in Bluffton, Ohio.

Bluffton Hospital received its CAH status in 2004 as a necessary provider for this geographic area and about 35% of the patients are Medicare beneficiaries. Included in our service base we operate a diagnostic clinic in Ottawa, Ohio in Putnam County where there is no hospital. Bluffton has operated the diagnostic clinic since 1996 with more than 5,000 patients having laboratory specimens collected, EKG's, mammograms, and diagnostic radiology on an annual basis. We were able to help recruit a group of family practice physicians to the Ottawa community with these services, and over the years have also placed OBGYN services and orthopedics at this same location. During a recent flood in Ottawa we were able to remain open and continue to provide access to healthcare for many of those in need.

This area is lacking in available public or assisted transportation for many of its residents and by taking this clinic to Ottawa, Bluffton has been able to provide easy and ready access for those peoples where getting to and maneuvering in a more metropolitan area may be a hardship or limiting. While we have no plans at this time to replicate this service in another community, should there be a need we would want to extend our service to that community and the CAH designation makes that outreach more feasible.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAHs. As stated above, such provisions would have a devastating impact on the access to quality health care in my rural community. This is the opposite of the intention of the CAH program, which is to provide the financial stability for small, rural hospitals to serve their communities. Such provisions would eliminate our flexibility to provide the care needed to rural seniors.

Thank you for considering these comments. Please contact me if you have any questions.

Sincerely,

William D. Watkins
Chief Administrative Officer

CMS-1392-P-517 Medicare

Submitter : Mrs. Marilyn Hill **09/10/2007**

Organization : Greenville Hospital System
Other Technician

Category :

Issue Areas/Comments

OPPS Impact

OPPS Impact

I have been performing Echocardiograms for over 14 years. I believe underutilization of contrast agents is not in the best interest of Medicare patients or Medicare itself, as inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.