

CMS-1392-P-394 Medicare**Submitter :** Ms. Sally Enevoldson**Date & Time:** 09/07/2007**Organization :** University of Kansas Hospital**Category :** Hospital**Issue Areas/Comments****Packaging Drugs and
Biologicals**

Packaging Drugs and Biologicals

The University of Kansas Hospital (KUH) appreciates the opportunity to comment on CMS's proposed 2008 outpatient PPS rule. We are a 512-bed teaching hospital with over 400 residents.

CMS is proposing to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and instead report it on an uncoded revenue code line on the claim. CMS believes that when this data becomes available for analyses, it will allow for the packaging of pharmacy overhead costs into payment for the procedure associated with administering the drug or biological rather than into the payment for the drug or biological. In the meantime, however, CMS proposes a payment rate of ASP plus five percent to cover the acquisition and handling costs for drugs and biologicals.

First of all, while we do not object to the concept of packaging pharmacy overhead costs into the payment for the procedure, we do not believe that CMS is intent on capturing all overhead costs associated with drugs and biologicals. KUH currently receives only 66% of its outpatient Medicare costs in APC payments, placing Medicare as our second worst outpatient payer, only behind Medicaid. CMS seems to be intent on controlling OPSS costs by making a very unprofitable line of business even less profitable. Five percent of ASP does not begin to cover the pharmacy and overall hospital overhead associated with administering drugs and biologicals. At a minimum, CMS should pay hospitals at six percent of ASP, which is what it pays physicians for overhead on drugs and biologicals.

Secondly, KUH does not base its drug and biological charges on ASP. Separating out the charges for the drugs and the overhead would be nearly impossible, requiring us to simply apply a random formula to the drug charge to determine an overhead charge. This would not produce meaningful data for CMS to base an overhead charge on.

The University of Kansas Hospital requests that CMS withdraw its proposal requiring hospitals to remove the pharmacy overhead charge from the charge for the drug or biological. In addition, KUH requests that CMS pay hospitals a minimum of six percent of ASP for overhead on drugs and biologicals. We also ask that CMS consider the hardships that it is placing on hospitals when it reduces already inadequate payments for services to Medicare beneficiaries. Thank you for your consideration.

CMS-1392-P-395 Medicare

Submitter : Mr. Larry Parsons

Date & Time: 09/07/2007

Organization : Rice Medical Center

Category : Hospital

Issue Areas/Comments

Hospital CoPs

Hospital CoPs

September 7, 2007

Docket ID CMS-1392-P
Necessary Provider CAHs

Dear Sirs,

Thank you for allowing us the opportunity to provide a formal written response to the proposed regulations that CMS has developed. We appreciate you taking these comments into account before issuing a final rule. Texas currently has 75 critical access hospitals and the program has been instrumental in maintaining the viability of these vitally important safety net providers.

Specifically, we are writing in response to the Proposed Changes Affecting Critical Access Hospitals and Hospital Conditions of Participation (CMS-1392-P), which states:

In the event that a CAH with a necessary provider designation enters into a co-location arrangement after January 1, 2008, or acquires or creates an off-campus facility after January 1, 2008, that does not satisfy the CAH distance requirements in ?485.610(c), we are proposing to terminate that CAH's provider agreement, in accordance with the provisions of ?489.53(a)(3).

A relatively small number of CAH facilities have psych or rehab distinct part units in the state of Texas. However, according to CMS over a third of all CAHs own or operate health clinics and still more have outpatient departments such as physical therapy and cardiac rehab that are located outside the hospital. It is that aspect of the proposed rule that concerns us so greatly. Texas rural hospitals are particularly well invested in the rural

health clinic program and many of those are provider-based RHCs.

Apparently, CMS has misgivings about CAHs creating or acquiring off-campus locations, but it doesn't seem very logical to extend the hospitals boundaries to include a clinic when there are no inpatient services being provided at that location. There are still a high number of Health Professional Shortage Areas in rural Texas. Placing a critical access hospital's necessary provider status in jeopardy when it seeks to improve access to care for a nearby community also seems counter-intuitive.

Therefore, we would ask that CMS back off its requirement that a critical access hospital satisfy the current statutory CAH distance requirements when it acquires or creates an off-campus facility when that facility happens to be a rural health clinic. We feel this regulation would place an undue burden on critical access hospitals and would put a halt to what is a very cost-effective way to expand access to primary health care services in many rural and frontier areas.

Sincerely your,

Larry F. Parsons
Administrator

CMS-1392-P-396 Medicare

Submitter : Mrs. PHYLLIS RUST

Date & Time: 09/07/2007

Organization : none

Category : Individual

Issue Areas/Comments

Specified Covered Outpatient

Drugs

Specified Covered Outpatient Drugs

As a patient of an ophthalmologist who gives me Botox injections every 3 months for benign essential blepharospasm, it is imperative that this remains covered. I still have a large co-pay even after Medicare/BC coverage, and the elimination of this coverage would be devastating for me as I need these injections to drive, etc.

CMS-1392-P-397 Medicare

Submitter : Ms. Alisa Coleman

Date & Time: 09/07/2007

Organization : Trigg County Hospital

Category : Critical Access Hospital

Issue Areas/Comments

Rural SCH Payments

Rural SCH Payments

September 14, 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 such and such hospital in Washington, DC.

In this paragraph explain the situation at your hospital. Please include:

" How you received your CAH designation

" The types of provider based clinics that your hospital already opens

" The types of such off-site clinics that you are considering in the future

" Any evidence you can provide about how the limiting of off-site clinics would impede care in your community

" Any evidence you can provide about how few providers are operating in your community for Medicare beneficiaries

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,

Alisa Coleman
Administrator

CMS-1392-P-398 Medicare

Submitter : Ms. Wendy Fletcher

Date & Time: 09/07/2007

Organization : none

Category : Individual

Issue Areas/Comments

Specified Covered Outpatient

Drugs

Specified Covered Outpatient Drugs

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-399 Medicare

Submitter : Mr. Robert Fisher

Date & Time: 09/07/2007

Organization : Brookville Hospital

Category : Critical Access Hospital

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

Mr. Herb Kuhn
Acting Deputy Administrator
Centers of Medicare and Medicaid Services

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals affecting the CAH program. I am CEO of Brookville Hospital in Brookville, PA.

We are a necessary provider CAH and have had an outpatient primary service clinic in our community about a mile away from our campus treating many Medicare patients. Due to campus space and patient accessibility considerations, we have also been planning on relocating our outpatient rehabilitation services to an off-site leased location about two miles from our campus. Construction has begun on the facility, but it will not be open until spring, 2008. We are greatly concerned that your proposed rule limiting off-site clinics would impede our ability to provide such appropriate health care services to our service area in the future if implemented. Many of our patients are Medicare age and we have been working to make our services more convenient to patients as our present hospital building is not very accessible for the elderly.

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.

I do understand the reasoning behind the rule and propose an alternative restriction. I suggest that you place a restrictive radius of something like 5 miles from the CAH location, rather than the current proposal. This would achieve the intended purpose of keeping a necessary provider CAH from encroaching on another hospital's service area without such severe limits to the flexibility of the CAH's operations.

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

Sincerely,

Robert E. Fisher, President and CEO
Brookville Hospital
100 Hospital Road

Brookville, PA 15825
rfisher@brookvillehospital.org
814-849-1461

CMS-1392-P-400 Medicare

Submitter : Dr. Alex Morss

Date & Time: 09/07/2007

Organization : Beth Israel Deaconess Medical Center

Category : Physician

Issue Areas/Comments

**Packaging Drugs and
Biologicals**

Packaging Drugs and Biologicals

I am a cardiology fellow at the Beth Israel Deaconess Hospital in Boston, MA. I wish to dissuade you from eliminating separate payments for the use of echo contrast agents. The financial disincentive that this will create will likely cause more expensive testing to be performed more frequently in patients who could likely be adequately assessed by the use of echocardiography with contrast agents.

CMS-1392-P-401 Medicare

Submitter : Mrs. Theresa Parker

Date & Time: 09/07/2007

Organization : Transylvania Community Hospital

Category : Critical Access Hospital

Issue Areas/Comments

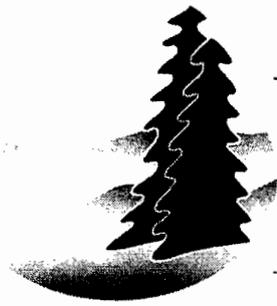
Necessary Provider CAHs

Necessary Provider CAHs

See attachment

CMS-1392-P-401-Attach-1.DOC

#401



TRANSYLVANIA
COMMUNITY
HOSPITAL

September 14, 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 Chief Financial Officer at Transylvania Community Hospital in Brevard, NC.

Transylvania Community Hospital became a CAH in September 2004 after our community experienced 3 large manufacturing plant closings with a loss of 1,500 well insured jobs in 2002. Our community has transformed into a retirement community; currently our hospital payor mix is 54.3% Medicare, 12.1% Medicaid, 8.9% Self-pay & charity care and the remaining 24.3% managed care type payors.

We achieved CAH designation as a “necessary provider”. Currently we operate 2 provider based clinics in geographically remote, hard to access mountainous sites.

Currently, we are planning a significant physician integration strategy that will involve at least 2 other provider based clinics. This involves working with our physicians who have been private based and converting them to employment based. The major reason for this change is PHYSICIAN RECRUITMENT and RETENTION.

Limiting our ability to convert physician practices to provider based would have a significant impact on our hospital's ability to recruit primary care physician's who provide access to care and our ability to support a specialty physician base in a rural mountainous retirement community.

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,

Theresa Parker
Vice President of Finance/Chief Financial Officer
Transylvania Community Hospital

CMS-1392-P-402 Medicare

Submitter : Mr. Laurence Berry, Jr.

Date & Time: 09/07/2007

Organization : University of Virginia Health System

Category : Other Technician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am very concerned about the impact of eliminating separate payment for contrast agents used in echos. 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. 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.

Thank you,

CMS-1392-P-403 Medicare

Submitter : Mr. Mark Zemanek

Date & Time: 09/07/2007

Organization : Leelanau Diagnostic Ultrasound

Category : Health Care Professional or Association

Issue Areas/Comments

**Payment for Diagnostic
Radiopharmaceuticals**

Payment for Diagnostic Radiopharmaceuticals

Strongly suggest NO CUT for contrast agents used in cardiac ultrasound procedures, as this technique is highly useful in diagnosing and managing certain patients with heart disease. Visualizing the heart is sometimes not possible without contrast agents. Baring visualization, much more expensive tests would be required such as transesophageal echocardiogram or cardiac catherization. Thank-you.

CMS-1392-P-404 Medicare

Submitter : Mr. Alan Alexander

Date & Time: 09/07/2007

Organization : Caverna Memorial Hospital

Category : Critical Access Hospital

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

I am writing in response to the proposed rule referenced above, specifically in regard to proposals made affecting the Critical Access Hospital (CAH) program. I am the CEO of Caverna Memorial Hospital in Horse Cave, KY.

We have been a CAH since October 1, 2002. Since conversion to a CAH, we have generated net income margins averaging 1.6% over the past five years. Obviously, even with our conversion to a CAH, we have been able to generate only razor-thin margins. We desperately need the ability to establish or convert current physician clinics in our service area into Rural Health Clinics. If this option is taken away from us, we will most likely lose physicians and be unable to recruit adequate levels of new physicians to service our community. We are located in a HPSA and MUA having only two Family Practitioners and two Internists in Hart County, KY - a county of about 18,000.

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 our rural community. This would be contrary to the original purpose of the CAH program, which was established to provide financial stability for small, rural hospitals and enable us to better serve our communities. The above provisions put forth by CMS would severely curtail our capacity to provide essential care to rural citizens.

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

Alan Alexander
Chief Executive Officer

CMS-1392-P-405 Medicare

Submitter : Ms. Andrea Lewis

Date & Time: 09/07/2007

Organization : University of Colorado Hospital

Category : Other Health Care Professional

Issue Areas/Comments

**Packaging Drugs and
Biologicals**

Packaging Drugs and Biologicals

Please rethink bundling the cost of contrast with the echo because the cost really does pay what is extra compared to an echo without contrast. As a cardiac sonographer, I do not have the license to inject contrast for echo. If I cannot bill for it, I will not be able to afford a registered nurse and all the supplies to start IV's and give Definity. This means my hospital will not be able to give echo contrast agent. This is horrible because for some patients the last imaging option they have is ultrasound with contrast, due to their weight. It is becoming an increasing problem that patients weigh too much for the tables for CT, MRI, or cardiac cath. We can often give diagnostic information that no other imaging can, but we will only be able to see if we can use contrast. Please help us give the best care and quality exams for our patients by reimbursing us for a RN's skill and time.

CMS-1392-P-406 Medicare

Submitter : Dr. Warren Manning

Date & Time: 09/07/2007

Organization : Beth Israel Deaconess Medical Center

Category : Physician

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

The proposal to eliminate separate payment for contrast agents in echoes performed in hospital outpatients is detrimental to care. The cost for the contrast agent is substantial. Reimbursement currently does NOT cover the full cost of the agent (nor any \$\$ for the effort/cost of placement of the intravenous catheter and saline solution). The removal of some reimbursement will be a severe disincentive to use echo contrast in the large minority of patients who would greatly benefit from the use of the endocardial edge detection enhancing agents. The result would be reduced accuracy of stress echo and potentially additional non-invasive and/or invasive/expensive procedures to care for our patients. This neither best serves the patient nor Medicare.

CMS-1392-P-407 Medicare

Submitter : Dr. Melvin SchwartzHeart Care G

Date & Time: 09/07/2007

Organization : Dr. Melvin SchwartzHeart Care G

Category : Physician

Issue Areas/Comments

Conversion Factor

Conversion Factor

Do not bundle echo contrast payment into general echo payments. This will ultimately discourage their use and lead to a tendency to not obtain the best quality information with a study.

CMS-1392-P-408 Medicare

Submitter : Mrs. Kathie Sloan

Date & Time: 09/07/2007

Organization : Baptist Hospital East

Category : Health Care Professional or Association

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am a cardiac sonographer at Baptist Hospital East in Louisville KY. We use contrast agents for echo, if needed, to evaluate wall motion which is of the utmost importance in treating heart disease. We are dealing with a population of obese patients and contrast is needed to completely evaluate these patients. I am urging you to continue to provide separate reimbursement for echo contrast agents. If this is taken away it could result in the use of much more invasive and much more costly procedures to get the same information we could get with the use of contrast agents.

CMS-1392-P-409 Medicare

Submitter : Dr. Susan Simandl

Date & Time: 09/07/2007

Organization : Dr. Susan Simandl

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

Echocardiography may require the use of contrast agents. If the contrast agent is not reimbursed, it is likely that alternative and more costly testing modalities will be advised. Therefore, eliminating payment for contrast may paradoxically increase costs.

CMS-1392-P-410 Medicare

Submitter : Dr. Gilead Lancaster

Date & Time: 09/07/2007

Organization : Bridgeport Hospital / Yale New Haven Health

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am a practicing cardiologist and the director of the Echocardiography department at Bridgeport Hospital, a teaching hospital in the Yale New Haven Health System. We perform over 4,000 echo procedures annually, including a large number of stress echo studies. A large number of our patients have COPD or are obese and echo windows are often less than optimal. In these patients the use of contrast transforms a suboptimal or even useless study to one of diagnostic quality.

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

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.

Finally, 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.

CMS-1392-P-411 Medicare

Submitter : Mr. Keith Fox

Date & Time: 09/07/2007

Organization : University Hospital Cleveland

Category : Other Health Care Professional

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am cardiac sonographer and use contrast agents to assist in imaging difficult patients. Proposed changes to bundle the cost of these products into the already low reimbursement for these studies would be a mistake. Ultrasound contrast is already highly underused and this would cause it to be used even less. If the goal is to treat patients in a cost effective manner then using contrast agents to identify heart function should be welcomed as opposed to ordering much more expensive imaging tests to get the same information. If the goal is to lower the expense of echocardiography then mandating competency standards for performing and reading may prevent poor quality studies being done. Quite honestly the goals should be providing the best care and striving for the best outcomes for the citizens of this country.

CMS-1392-P-412 Medicare

Submitter : Ms. Karen Traynor

Date & Time: 09/07/2007

Organization : Baldwin Area Medical Center, Inc.

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-412-Attach-1.PDF

#412

Baldwin
Area
Medical Center

730 10th Avenue / PO Box 300
Baldwin, Wisconsin 54002

September 06, 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 the Chief Financial Officer at Baldwin Area Medical Center, Inc. (BAMC) in Baldwin, Wisconsin.

BAMC received certification as a CAH facility effective October 1, 2004 under the "necessary provider" designation. BAMC currently operates a general medical / surgical acute care critical access hospital, a provider-based rural health clinic and two provider-based specialty care clinics. As a means to better assure that we are positioned to meet the needs of our patient service area, including the significant level of Medicare eligible residents, BAMC has initiated the research and development of an additional provider-based clinic in a satellite location. The proposed rule as referenced above puts this at risk and will result in unmet primary care medical needs for the senior populations we serve.

Of note, BAMC provides primary care medicine to over 18,800 people (source: Claritus). Applying CDC published standards from the *Ambulatory Medical Care Survey, 2004 Summary* to measure primary care office visits based upon age and sex projections, the total service area requires the presence of primary care medical providers to support nearly 59,400 office visits per year; 25.9% of these visits are Medicare eligible residents.

Under the proposed ruling, any new CAH location (e.g., clinic site) that meets the requirements of provider-based would be subject to 42 C.F.R. § 413.65 and considered part of the CAH for Medicare purposes. As such, the new CAH location would be subject to the proposed language under 42 C.F.R. § 485.610(e) stating that all CAH provider-based locations created or acquired after January 1, 2008 must be more than 35 miles from any other hospital or CAH. Failure to meet this 35 mile rule at the satellite

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clinic location would result in the entire CAH being deemed non-compliant and CAH status would be terminated. Given this scenario, BAMC can no longer consider satellite clinic alternatives regardless of the ability to demonstrate medical need within the community. The facility can not afford to place CAH designation at risk. The resulting loss of CAH status would be catastrophic to BAMC likely triggering a significant reduction to services offered and / or potential closure of the CAH facility as a whole.

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,

Karen Traynor
Chief Financial Officer
Baldwin Area Medical Center, Inc.
Baldwin, Wisconsin

cc: Tim Fry; Manager, Government Affairs
National Rural Health Association

CMS-1392-P-413 Medicare

Submitter : Dr. Steven Smart

Date & Time: 09/07/2007

Organization : Gundersen Lutheran/ACC/ASE

Category : Physician

Issue Areas/Comments

**Packaging Drugs and
Biologicals**

Packaging Drugs and Biologicals

Please continue to provide separate reimbursement for ECHO contrast agents. These agents are not part of routine echocardiography. These contrast agents significantly enhance the studies and are only used when clinically needed for rest and stress echocardiograms. These agents improve study quality so the studies are more often diagnostic in quality. Thereby, other imaging studies are avoided. The proposal to not reimburse these agents will cause a disincentive to the use of contrast agents. More studies will become nondiagnostic. Thereby, costs will increase as other imaging techniques will be needed.

Furthermore, billing will become more complicated. 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 do not package contrast agents with routine echocardiography so patient's can receive the highest quality echocardiograms and ensure that these studies are of diagnostic quality. Please contact me for any questions, phone # 608-788-6274 or email me at smart5@charter.net. Thanks for your consideration.

CMS-1392-P-414 Medicare

Submitter : Todd Winder

Date & Time: 09/07/2007

Organization : Oneida County Hospital

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

I am not sure why this is an issue. CAH's should be allowed to provide services in underserved areas that will enhance health care access.

It sounds to me like this is an attempt to thwart competition. I somewhat agree that one CAH should not necessarily be allowed to infringe upon another CAH service area, at least in the capacity of cost based reimbursement.

However, if this rule is going to be enforced with CAHs it should be the same with all other federally supported providers such as RHCs and FQHCs. Let make sure we keep the playing field even for everyone and not just limit one type of provider.

CMS-1392-P-415 Medicare

Submitter : Mr. Dan Carlile

Date & Time: 09/07/2007

Organization : Mr. Dan Carlile

Category : Other Health Care Provider

Issue Areas/Comments

**Packaging Drugs and
Biologicals**

Packaging Drugs and Biologicals

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.

CMS-1392-P-416 Medicare

Submitter : Dr. Paul Daluga

Date & Time: 09/07/2007

Organization : Union Hospital FMR/Lugar Center for Rural Health

Category : Physician

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

September 7, 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 Family Medicine Residency director with a rural training track in Terre Haute, Indiana

There are many CAH's in our surrounding area all of which have a variety of off-site clinics and facilities. These facilities range from infusion centers to rural health centers all of which provide services to the increasing population of rural elderly in our communities. Due to lack of public transportation and the increasing average age of these elderly folk the demise of these facilities would make access to the above services impossible.

Our residency program has been sending family physicians to these rural areas in our community for the last thirty years. As the population ages and the medical needs of these elderly folk increase it will difficult to convince the needed young physicians to go to rural areas where facilities are non-existent or inadequate because of lack of fair reimbursement on the part of CMS.

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,

Paul Daluga, MD

CMS-1392-P-417 Medicare

Submitter : Ms. Ann FaganCook

Date & Time: 09/07/2007

Organization : Parkview Hospital

Category : Hospital

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

Thank you for allowing us the opportunity to provide a formal written response to the proposed regulations that CMS has developed. We appreciate you taking these comments into account before issuing a final rule. Texas currently has 75 critical access hospitals and the program has been instrumental in maintaining the viability of these vitally important safety net providers.

Specifically, we are writing in response to the proposed changes in CMS-1392-P. A relatively small number of CAH facilities have psych or rehab distinct part units in the state of Texas. However, according to CMS over a third of all CAHs own or operate health clinics and still more have outpatient departments such as physical therapy and cardiac rehab that are located outside the hospital. It is that aspect of the proposed rule that concerns us so greatly. Texas rural hospitals are particularly well invested in the rural health clinic program and many of those are provider-based RHCs.

Apparently CMS has misgivings about CAHs creating or acquiring off-campus locations, but it doesn't seem very logical to extend the hospitals boundaries to include a clinic when there are no inpatient services being provided at that location. There are still a high number of Health Professional Shortage Areas in rural Texas. Placing a critical access hospital's necessary provider status in jeopardy when it seems to improve access to care for a nearby community also seems counter-intuitive.

Therefore, we would ask that CMS back off its requirement that a critical access hospital satisfy the current statutory CAH distance requirements when it acquires or creates an off-campus facility when that facility happens to be a rural health clinic. We feel this regulation would place an undue burden on critical access hospitals and would put a halt to what is a very cost-effective way to expand access to primary health care services in many rural and frontier areas.

CMS-1392-P-418 Medicare

Submitter : Barbie Collns

Date & Time: 09/07/2007

Organization : Bamberg County Hospital

Category : Hospital

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I feel that the reduced reimbursement for guidance services in CMS-1392-P will have a negative impact on the care received by many ESRD patients.

CMS-1392-P-419 Medicare

Submitter : Mr. Edward Pitchford

Date & Time: 09/07/2007

Organization : Charles Cole Memorial Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-419-Attach-1.DOC

CMS-1392-P-419-Attach-2.DOC

#419

September 7, 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 regard to proposals made affecting the Critical Access Hospital (CAH) program. I am a hospital administrator at Charles Cole Memorial Hospital in Coudersport, Pennsylvania.

Charles Cole Memorial Hospital is located in a mountainous area of north central Pennsylvania which is served only by secondary roads. We have built and sustained a vibrant primary care healthcare system that includes satellite provider based rural health clinics and in some cases outreach radiology and PT/OT services. To my knowledge, none of our locations are within 15 miles of another hospital. Due to a significant and very unique situation in our region with a large employer becoming bankrupt and going out of existence, we have adapted and began operations as a CAH effective August 1, 2007.

These proposed regulations, which appear on the surface to not effect our organization, remain troubling as they indicate an interest on behalf of CMS to constrain CAHs. These organizations are already constrained by a number of internal and external factors and they need to have as much flexibility to operate as possible. Another example of an unwarranted constraint is the regulation that does not extend the benefits of CAH reimbursement for lab work performed at our hospital on specimens that were drawn for the convenience of Medicare recipients in our RHCs.

I would encourage CMS to adopt a philosophy that enables CAH to serve Medicare recipients as best as possible by limiting what appear to be unnecessary constraints that don't save the program significant funds. CAHs already have significant challenges and CMS needs to remain supportive and enabling to preserve these organizations which are vital to the regions that they serve.

If there are abusive situations that are precipitating the perceived need for these proposed regulations, I would suggest that the proposed regulations be written very tightly to deal with such arrangements. I believe that my organization is fulfilling the basic needs of the region and should be receiving support from CMS as opposed to being concerned about broad regulation that could impact us now or in the future.

Due to these concerns, I respectfully ask that you withdraw the provisions in this rule pertaining to off-site services owned by CAHs.

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

Sincerely,

Ed Pitchford
President and CEO

CMS-1392-P-420 Medicare

Submitter : Dr. Randolph Whipps

Date & Time: 09/07/2007

Organization : Maryland General Hospital

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I would request that separate reimbursement be continued/ instituted for the use of contrast agents during some echocardiographic procedures. Echo has proven to be a versatile and relatively low cost imaging technique. However some images that are suboptimal can be made adequate with the use of contrast. The otherwise suboptimal studies are then sent for MRI, CT or other expensive imaging procedures. The use of and separate reimbursement for echo contrast is a no brainer. The reimbursement for contrast should not be lumped into the cost of the echo study. Contrast does not need to be used on most studies. A global reimbursement will discourage the use of contrast and lead to more expensive imaging methods.

Respectfully submitted,

Randolph Whipps MD

CMS-1392-P-421 Medicare

Submitter : Mrs. Peggy Foster

Date & Time: 09/07/2007

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 Blepharospasm and Meige Syndrom, 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, Mrs. Peggy Foster

CMS-1392-P-422 Medicare

Submitter : Sylvia Bulhon

Date & Time: 09/07/2007

Organization : none

Category : Individual

Issue Areas/Comments
Specified Covered Outpatient
Drugs

Specified Covered Outpatient Drugs

September 7 2007

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

Sylvia Bulhon
sbulhon@austin.rr.com

CMS-1392-P-423 Medicare

Submitter : Ms. Mary Ann Evanoski

Date & Time: 09/07/2007

Organization : FocusUS

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The code change is necessary, to allow women to have an option for the Treatment of Fibroid Tumors.

CMS-1392-P-424 Medicare

Submitter : Ms. Margaret Hobza

Date & Time: 09/07/2007

Organization : The Nebraska Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

OPPS Impact

OPPS Impact

Our facility and Cardiology groups have determined that the use of Contrast agents for imaging during Echocardiography has an enormous impact on the quality of the service and interpretation. Due to the increasing age and BMI of the general patient population, high quality imaging with ultrasound has become more challenging. Sonocated contrast products have proven to be a very cost effective solution. To reduce the utilization of these agents through financial disincentive, will significantly diminish the ability of the physician to provide the most complete diagnosis and will ultimately result in additional and more expensive procedures and inconvenience to the patient. At the Nebraska Medical Center, we recommend that you do not implement a policy that eliminates separate payment for contrast agents. As a practicing sonographer and Manager of the Echo Lab, I believe this policy would result in an increase in more expensive invasive follow-up procedures and more risk to the patient over the long term.

CMS-1392-P-425 Medicare

Submitter : Mr. Jon Smiley

Date & Time: 09/07/2007

Organization : Sunnyside Community Hospital

Category : Hospital

Issue Areas/Comments

Rural SCH Payments

Rural SCH Payments

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 the Chief Executive Officer of Sunnyside Community Hospital, a CAH in Central Washington (State).

In the past three years our hospital has been able to continue providing services to the place bound individuals of our community only because of the CAH and Rural Health Clinic opportunities we have been able to open.

" We became a Critical Access Hospital in 2004 at a time when our only other option was closure or draconian cuts in service.

" Our hospital currently operates three desperately needed Rural Health Clinics in Sunnyside and Grandview these clinics provide family practice care (including low risk obstetrical care.)

" We wish to convert a pediatrics clinic and an internal medicine clinic to Rural Health Clinic status. These clinics are losing money at present, and we cannot attract and support the additional providers needed to keep them vibrant and functioning without the RHC designation.

" Sunnyside is one of the poorest communities in our state. The per capita household income was estimated at \$27,000 in 2000, while the national average was \$42,000 , (U.S. census bureau 2000 data.) The majority of individuals either cannot afford to travel outside the immediate area for service, or have no car, and very limited public transit to take them there.

" Most providers have severe limitations on accepting new patients in our communities. Our rural health clinics turn no one away, and we provide services on a sliding fee scale. Those who have no ability to pay are provided with charity care.

" Our hospital and clinics serve a primarily Hispanic population, including Migrant Farm Workers who have no other access to care. The payer base for hospital and clinics is 70% Medicare and Medicaid. Our combined charity care to the community was in excess of \$1 million dollars in

2006.
" The only way we can recruit and retain qualified physicians and ancillary primary care providers is to hire these providers into our rural health clinic system. (Since 2004 only one physician has been recruited into the community that did not join our clinic system or become an employed hospital-based physician.)

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,

Jon Smiley
Chief Executive Officer

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

425

September 14, 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 the Chief Executive Officer of Sunnyside Community Hospital, a CAH in Central Washington (State).

In the past three years our hospital has been able to continue providing services to the place bound individuals of our community only because of the CAH and Rural Health Clinic opportunities we have been able to open.

- We became a Critical Access Hospital in 2004 at a time when our only other option was closure or draconian cuts in service.
- Our hospital currently operates three desperately needed Rural Health Clinics in Sunnyside and Grandview – these clinics provide family practice care (including low risk obstetrical care.)
- We wish to convert a pediatrics clinic and an internal medicine clinic to Rural Health Clinic status. These clinics are losing money at present, and we cannot attract and support the additional providers needed to keep them vibrant and functioning without the RHC designation.
- Sunnyside is one of the poorest communities in our state. The per capita household income was estimated at \$27,000 in 2000, while the national average was \$42,000, (U.S. census bureau 2000 data.) The majority of individuals either cannot afford to travel outside the immediate area for service, or have no car, and very limited public transit to take them there.
- Most providers have severe limitations on accepting new patients in our communities. Our rural health clinics turn no one away, and we provide services on a sliding fee scale. Those who have no ability to pay are provided with charity care.
- Our hospital and clinics serve a primarily Hispanic population, including Migrant Farm Workers who have no other access to care. The payer base for hospital and

clinics is 70% Medicare and Medicaid. Our combined charity care to the community was in excess of \$1 million dollars in 2006.

- The only way we can recruit and retain qualified physicians and ancillary primary care providers is to hire these providers into our rural health clinic system. (Since 2004 only one physician has been recruited into the community that did not join our clinic system or become an employed hospital-based physician.)

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,

Jon Smiley
Chief Executive Officer

CMS-1392-P-426 Medicare

Submitter : Ms. Amy Bradfield

Date & Time: 09/07/2007

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 blepharospasm and generalized dystonia, both of which are 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 somewhat 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,

Amy P. Bradfield
Austin TX 78735

CMS-1392-P-427 Medicare

Submitter : Mrs. Anita Croce

Date & Time: 09/07/2007

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 blepharospasm/Meige's Syndrome that are forms 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-428 Medicare

Submitter : Bonnie Hinchman

Date & Time: 09/07/2007

Organization : None

Category : Individual

Issue Areas/Comments

**Specified Covered Outpatient
Drugs**

Specified Covered Outpatient Drugs

I respectfully request that the CMS not change the payment formula for physician-injectable drugs for 2008 and instead maintain the current payment formula.

Thank you.

Sincerely,

Bonnie Hinchman

CMS-1392-P-429 Medicare

Submitter : Mrs. Bonnie Brabec

Date & Time: 09/07/2007

Organization : Nebraska Methodist Hospital

Category : Hospital

Issue Areas/Comments

**Packaging Drugs and
Biologicals**

Packaging Drugs and Biologicals

It is my understanding that CMS is proposing to eliminate separate payment for contrast agents used in stress echocardiogram or transthoracic echocardiograms performed in hospital outpatient settings. Some patient do not have the the right physical make up to visualize the four chambers of the heart much less the left ventricular part of the heart to determine heart disease. Contrast agents 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 will result in the performance of more invasive and costly tests. Contrast agents are relatively costly in comparison with the echocardiogram procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echocardiogram procedures. If CMS 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 ask yourself, if you or one of your loved ones needed to have an echocardiogram done, wouldn't you want to know that they received the very best possible diagnosis when they leave the outpatient department at the most reasonable cost for your money? Don't bundle the charges and increase the financial disincentive to do the right thing for the patients.

CMS-1392-P-430 Medicare

Submitter : Dr. James Ceaser

Date & Time: 09/07/2007

Organization : CoxHealth

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am a practicing cardiologist, and medical director of cardiology at CoxHealth in Springfield, MO. We utilize echocardiographic contrast agents in our lab as needed to ensure a diagnostic study. If separated payment for these agents is discontinued it will significantly effect our ability to use them when needed. This will result in a higher percentage of non-diagnostic studies, and increase the need for more invasive, and expensive tests to obtain the information. This change would be detrimental to our medicare patients, and it is unlikely it would save money. Thank You.

CMS-1392-P-431 Medicare

Submitter : Ms. Jane Welch

Date & Time: 09/07/2007

Organization : Ball Memorial Hospital

Category : Hospital

Issue Areas/Comments

**Implantation of Spinal
Neurostimulators**

Implantation of Spinal Neurostimulators

If the payment for the re-chargeable Neurostimulator (to also include payment for the procedure) is reduced to \$12,314.00, our hospital will no longer be able to afford to provide this service.

The cost of the neurostimulator is over \$20,000 and this does not include the cost of providing the procedure. We will lose money on each case. We believe the neurostimulator saves the Medicare Program substantial money in the fact these chronic pain patients no longer require multiple hospital clinic visits in addition to expensive pain injections. I also believe this device could also save the Government money because it could eliminate the need for patients to pursue disability funding.

Also, I question the validity of the CMS claims data. How many hospitals actually billed the re-chargeable neurostimulator using their cost to charge? I'm certain we did not take this opportunity until 2007. Please reconsider the payment and at least pay us what it costs to provide the service.

Thank you

CMS-1392-P-432 Medicare

Submitter : Ms. Judith Kline

Date & Time: 09/07/2007

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 Benign Essential Blepharospasm, Meige's Syndrome and

Tardive Dyskinesia, all of which are types of dystonias (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 somewhat normally. I respectfully request that the 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,
Judith Kline

CMS-1392-P-433 Medicare

Submitter : Mr. Jacob Chandler

Date & Time: 09/07/2007

Organization : Overlake Hospital Medical Center

Category : Hospital

Issue Areas/Comments

**Implantation of Spinal
Neurostimulators**

Implantation of Spinal Neurostimulators

Given the difference in Median cost between the rechargeable and non-rechargeable neurostimulator I recommend that these procedures be assigned to different APCs. If these were grouped to the same APC, it would be an incentive for facilities to provide only the lower cost, non-rechargeable neurostimulator. The rechargeable neurostimulator is recommended for individuals with a higher level of battery usage. By providing this model it keeps these Medicare patients from having to undergo repeat surgery when their neurostimulator battery runs out. This in turn reduces the cost to Medicare. Combining these services together could have the adverse affect of rewarding using the non-rechargeable stimulator, and repeating the surgery when the battery needs to be replaced, instead of the long term cost efficient use of the rechargeable device.

CMS-1392-P-434 Medicare

Submitter : Mr. Rick Mattioli

Date & Time: 09/07/2007

Organization : University of Chicago Labrotory of Echocardiograph

Category : Other Technician

Issue Areas/Comments

OPPS Impact

OPPS Impact

To whom it may concern,

I am a junior sonographer at a university Hospital. I strongly believe that a injectable suspension contrast agent is a neccesity to acquire the critical information needed to make a clear diagnosis. In the cases of cardiac clot contrast is absoultey invaluable. One echo procedure is cheaper and faster then any other modality for cardiac imaging. Also in cases of obesity where it's not possible for the patient to enter in a MRI of CT machine, a echocardiogram can be viable when searching for signs of ischemia or thrombus and the contrast agent is what makes this possible. It is a much more patient freindly procedure and also much faster. Also cases of difficult acoustic windows a contrast agent if very much a necessity. I think that in the long run having contrast not be billed seperatly can acutally save money for insurance companies. They patient will not have to undergo mutiple tests and therefore not bill as many tests to insurance companies. I recomend that this decision be reconsidered carefully before any more measures are taken.

Yours Truly,

Rick Mattioli

CMS-1392-P-435 Medicare

Submitter : Mr. Bryon Medley

Date & Time: 09/07/2007

Organization : Cox Health Systems

Category : Health Care Professional or Association

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Please consider this submission regarding the proposal to eliminate the separate payment for contrast agents used in echo: Contrast agents are costly in comparison to the echo procedures they are packaged with. Eliminating separate payment will be a financial disincentive to use contrast agents. Contrast agents are already underutilized and this proposal will result in further underutilization. Contrast useage is in the best interest of medicare patients because it allows for a diagnosis that would not be obtained if contrast wasn't used. If CMS nonetheless decides to package contrast, it is required by statute to create a new HCPC code to identify contrast enhanced procedures.

CMS-1392-P-436 Medicare

Submitter : Dr. Sanjay Doddamani

Date & Time: 09/07/2007

Organization : North Shore University Hospital

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

Sir/Madam,

The proposed change on the use of microbubble contrast agents will increase the financial disincentive to use contrast. This will be a very costly mistake . Here is why:

1) Contrast improves endocardial definition (makes the image more readable), especially in obese, long-smoking, chest disease patients, all of whom have a higher morbidity. If the heart cannot be seen well, it will delay or miss (or falsely interpret) the diagnosis of heart disease. Such effects will a) decrease quality b) prolong hospital length of stay and c) cause a delay in recognizing heart MI/heart attack/heart failure/low-EF which will prove more costly since the patients condition may deteriorate and present at only a late stage of the illness.

2) By not reimbursing for contrast, physicians will not want to use it, even when its use is medically appropriate.

3) 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.

4) 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.

5) 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.

I urge you to reconsider any change as it will decrease the quality of health care in a critical area of cardiology where there are dramatic increases in heart failure, MI, embolic stroke and atrial fibrillation. By not heeding to this, there is a risk of actually increasing the overall cost of health care as 1) missed diagnosis 2) wrong diagnosis (calling a pts EF low when contrast may show it is normal, 3) extent of disease can all be shown by contrast.

Sincerely,

Sanjay Doddamani, MD, FASE
Associate Director
Echocardiography
North Shore University Hospital
300 Community Drive
Manhasset, NY 11030
Tel: 516 562 1470

CMS-1392-P-437 Medicare

Submitter : Mr. Cody Kuhnline

Date & Time: 09/07/2007

Organization : Mr. Cody Kuhnline

Category : Other Health Care Professional

Issue Areas/Comments

OPPS Impact

OPPS Impact

My name is Cody Kuhnline & I'm enrolled in Spokane Community College to become a cardiac sonographer. While I am performing clinical observations & assisting in exams the sonographer often uses contrast agent to get a better diagnosis of the wall motion of the heart. My main 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.

CMS-1392-P-438 Medicare

Submitter : Dr. Roberto Lang

Date & Time: 09/07/2007

Organization : University of Chicago

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

The proposal to eliminate separate payments for contrast agents in the outpatient setting will worsen medical practice. Contrast, useful to detect the endocardial borders will simply not be used. I urge not to pass this proposal. This would also create a financial disincentive to use contrast in the stress echo setting. This will lead to more costly testing

CMS-1392-P-439 Medicare

Submitter : Mr. Robert Scieszinski

Date & Time: 09/07/2007

Organization : Door County Memorial Hospital

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

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

 **Door County Memorial Hospital**
MINISTRY HEALTH CARE

Sponsored by Sisters of the Sorrowful Mother

September 14, 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 Chief Financial Officer at Door County Memorial Hospital (DCMH) in Sturgeon Bay, WI.

DCMH is located in a rural area of northeast Wisconsin, 45 miles from Green Bay, WI. We are located on a peninsula that extends into Lake Michigan and therefore are challenged by having water on 3 sides of our county. We obtained our designation in 2006 which has been very instrumental in providing access to medical care for our full time and part time residents.

The hospital is located in Sturgeon Bay, which is the county seat. We have satellite locations which are physician offices on Washington Island (which is very geographically isolated and a Rural Health Clinic) and two other communities on the peninsula.

We are considering the establishment of a fourth clinic in the southern part of the county. This clinic would more than likely be within 35 miles of a Green Bay Hospital. The population that would be served would be primarily farming families and rural residents. The proposed change would take away our organizations opportunity to be cost reimbursed from Medicare and Medicaid. This would represent a significant road block to this attempt to increase access since there a large number of low income and elderly in our county that would qualify for Medicare and Medicaid coverage.

Where caring makes the connection. SM

Due to this concern, I respectfully ask that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAH's. 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,

Robert C. Scieszinski
Vice President and CFO

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