Submitter : **Denise Williams** **Date: 09/05/2007**

Organization : **Provider Roundtable**

Category : **Hospital**

Issue Areas/Comments

Implantation of Cardioverter-Defibrillators

Implantation of Cardioverter-Defibrillators

see attached document concerning implantaiton of cardioverter defibrillators

CMS-1392-P-356-Attach-1.DOC

#356

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

The Provider Roundtable (PRT) is a group of providers representing 20 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

Implantation of Cardioverter Defibrillators

The Provider Roundtable supports CMS' proposal to recognize CPT codes 33240 and 33249 for the implantation of cardioverter defibrillators and discontinue the HCPCS codes G0297, G0298, G0299, and G0300.

If CMS staff have questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

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

Submitter : **Denise Williams** **Date: 09/05/2007**

Organization : **Provider Roundtable**

Category : **Hospital**

Issue Areas/Comments

Nonpass-Through Coded

Nonpass-Through Coded

See attached document concerning nonpass-through coded items

CMS-1392-P-357-Attach-1.DOC

#357

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

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Reporting of All HCPCS codes for drugs

The Provider Roundtable supports CMS' proposal to recognize all HCPCS codes for drugs as an option but not a mandatory requirement. The option will allow greater flexibility and less operational burden on hospital processes.

If CMS staff have questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

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

CMS-1392-P-358

Submitter : **Ms. Joyce Norman** **Date: 09/05/2007**

Organization : **Pacific Surgical Institute of Pain Management**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Dear Sirs,
I am an administrator for a small, physician owned Ambulatory Surgery Center. We are located in San Diego and provide a large volume of pain management and orthopedic services. I have been trying to decipher the changes that are on the horizon, and must say I have had great difficulty in doing so.

I have worked for this center for 8 years and have seen the difficulty first hand, in providing device intensive procedures to our medi-care patients. Historically we have lost money on any procedure which requires the use of specialty equipment (ie: laser, and such), orthopedic implants (ie: anchors, screws, etc.), and implantable devices such as intrathecal pumps and spinal cord stimulators. For the devices which were paid separately, the re-imbursement either barely covered the device, or came short of covering its cost. This has already required careful selection of the procedures which we can provide to our patients, frequently requiring that we inform the physician that they must take their patient to the hospital.

While I understand that a free-standing facility does not have all of the same overhead as a hospital, we do pay the same prices from vendors for our surgical supplies and implants. By bundling the price of an implanted device into the payment rate, and cutting it by 35% you will be preventing our medi-care patients from receiving this care in an ASC.

The proposed plan, which fails to recognize the re-chargeable implantable generator (IPG) for a spinal cord stimulator will force the facilities to implant non-rechargeable generators, which in the long run will increase medi-care costs. We have found that the non-rechargeable generators usually require replacement less than 3 years after implantation. A re-chargeable generator (IPG)
will last 10-12 years, and prevent the need for 3-4 surgeries, which the non-rechargeable generator would require.

Cost efficient care is a necessity, and I am supportive of keeping the costs regulated. However, I must emphatically state that the proposed system will move a large volume of medi-care procedures back into the high cost hospital in-patient system. The ASCs must be re-imbursed, at least at cost, for implanted devices of any kind, so that the remainder of the re-imbursement fees can cover the cost of nursing staff, medications, sterile supplies, anesthesia supplies, fluoroscopic supplies, and the multitude of other items routinely used (which the 65% is also inadequate to cover).

Further, as the patient is responsible for 20% of the allowed amount, performing these procedures in the hospital will increase their out-of-pocket expense further limiting their options for treatment.

I implore that you reconsider your plan before a great deal of hardship and failure occurs.
Sincerely,
Joyce Norman RN

Submitter : Ms. Glynda Lucas **Date:** 09/05/2007

Organization : Ms. Glynda Lucas

Category : Individual

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Please do not lower the reimbursement for outpatient treatment of blepharospasm patients with botulinum toxin. We are having trouble finding qualified doctors who know how to inject for blepharospasm. If you lower the reimbursement, more doctors will join the ranks of those who no longer treat Medicare patients because of unfair reimbursement issues. Please do not create a situation where we cannot have access to care because of low reimbursement rates.

CMS-1392-P-360

Submitter : Mr. Garner Linder **Date:** 09/06/2007

Organization : Bamberg County Hospital and Nursing Center

Category : Nurse

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Please reconsider CMS-1392-P as it will cost our hospital $900,000 next year. 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. This will result in many patients lack of care due to the cost of having to travel to other counties for their care.
Sincerely,
G Linder RN

Submitter : **Mr. Tim Size** **Date: 09/06/2007**

Organization : **Rural Wisconsin Health Cooperative**

Category : **Critical Access Hospital**

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

We are a cooperative of 32 rural, non-profit hospitals in Wisconsin; most of these are CAHs under the 'necessary provider' rule. The proposed limiation on off-site services is an extreme over reaction to what we assume is an observed abuse--a classic case of using a baseball bat to kill a gnat. It is reasonable that CAHs not create new services in the shadow of a competing organization, many miles from their main campus. But to limit all off-campus services to those in place by the end of the year is to freeze the CAH into an increasingly out of date delivery modality. CMS needs to withdraw this rule and enter into a dialogue with CAHs about a reasonable approach that avoids observed abuses but allows for the level of community based access and collaboration being called for by the Institute of Medicine, the National Advisory Committee on Rural Health & Human Services and other national bodies.

Submitter : **Dr. Andrew Chiu** **Date: 09/06/2007**

Organization : **SMDC Health System**

Category : **Physician**

Issue Areas/Comments

OPPS Impact

OPPS Impact

The proposed changes will have a deleterious effect on our facility's ability to provide high quality standard of care advanced cardiac imaging. The use of echo contrast has resulted in lower utilization of other forms of cardiac imaging at a savings to payers. The result of this proposal will be additional cardiac imaging due to disincentives to incur the cost of using echo contrast. In Minnesota we are already practicing at a very high quality and efficiency level in a region of the country which does not enjoy the rate of reimbursement for services other states have. Please take this into consideration.

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

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

Thank you for taking the time to read my comments and for considering the larger impact of the proposed changes that may be missed when looking at the balance sheet from a narrow line-item perspective.

Andrew C. Chiu, MD, FACC
Duluth, MN

Submitter : **Mr. Vincent Studer** **Date: 09/06/2007**

Organization : **Sahwano Medical Center**

Category : **Critical Access Hospital**

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

September 6, 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 Shawano Medical Center in Shawano, Wisconsin.

I am very concerned about CMS proposed rule to limit the ability of Critical Access Hospitals to operate off-site provider based facilities. I am also very troubled that rural health clinics may be considered to fall under the definition of provider-based facilities. Please consider how this will have a negative impact on the health care that are organization provides in this rural area of Wisconsin.
? We received our CAH designation in September 2004 because we provide health care in rural areas with a high percentage of people living in poverty and elderly. This area is also designated as a medically underserved population and health professional shortage area. Unemployment in the area is also higher than the Wisconsin average.
? We opened a provider-based clinic in January 2006 to provide healthcare to the medically underserved population in our service area.
? We have been considering the establishment of rural health clinics in several of the surrounding communities, which do not have healthcare providers in their community and have to travel more than 15 miles to obtain healthcare.
? Limiting of off-site clinics would impede the providing of healthcare in our surrounding communities because it could not be provided without cost based reimbursement.
? Physicians could not be paid competitively without cost based reimbursement and thus would further compound the difficulties in recruiting healthcare providers to work in these areas.

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 our rural communities. 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,

Vince Studer
Chief Financial Officer
Shawano Medical Center

Submitter : **Mrs. Penelope Lindeman** **Date: 09/06/2007**

Organization : **Howard Young Health Care, Inc.**

Category : **Other Health Care Professional**

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

To Whom it May Concern:
I have many concerns regarding the OPPS proposed rule. I am concerned that certain designated dependent procedures may or may not always be performed and coded as presented and assumed in the proposed rules. I understand that not every provider has reported the data elements accurately for these procedures, radiopharmaceuticals and contrast agents.
In our practice, there are times where a proposed bundling would not be appropriate, for example fluoroscopic guidance for a surgical procedure, sometimes the surgeon will not utilize imaging, operative cholecystectomy, sometimes are done without imaging. Pacemakers this is true for as well.

Basically, I am concerned, that by bundling contrast, isotopes, etc. that we will bill for something that did not occur, was not used. Patients have enough trouble with understanding what and why they are billed they way they are. We audit all exams daily to make certain billing is correct, patients are billed for what was performed accurately. Keeping the charges separate allows for us to bill appropriately and accurately.
I appreciate the opportunity to voice these concerns and I hope you consider them,
Sincerely,

Penny Lindeman RT (R) M QM
Director Medical Imaging
Howard Young Health Care, Inc.
Ministry Health Care, Inc.

Submitter : **Mr. Philip Stuart** **Date: 09/06/2007**

Organization : **Tomah Memorial Hospital**

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-365-Attach-1.RTF

#365

September 6, 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 at Tomah Memorial Hospital in Tomah, WI.

Tomah Memorial Hospital is located in Western Wisconsin and is subject to harsh winters. This was one of the reasons for us receiving our designation as a necessary provider. We have been experiencing a decrease in availability of health care providers willing to support outreach services. We have set up a provider based clinic with in the hospital to provide orthopedic and general surgery services. Our primary care clinics are part of two health care systems. These "systems" are not interested in maintaining clinics in many of our small communities. The "systems" would prefer that the people come to them. This makes it very difficult for many of the senior citizens who can not drive to get needed health care. We have identified a need for primary care in two communities, in our service area, that are located approximately ten miles from Tomah. We would like to set up provider based clinics but the proposed rule will prevent us from moving forward. The end result will be many of our rural frail elderly will go with out basic primary care.

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,

Philip J. Stuart
Chief Executive Officer

Submitter : Mr. Tony Hines **Date:** 09/06/2007

Organization : Mr. Tony Hines

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

In May of 2007, I was diagnosed with Indolent Follicular Non-Hodgkins Lymphoma, and in conjunction with my medical team, have been examining several treatment options ranging from chemotherapy to several clinical trials to watchful waiting. After researching and discussing these options, I believe the best choice for my situation is radioimmunotherapy, specifically Zevalin (Ibritumomab tiuxetan) or Bexxar (Tositumomab & Iodine I 131 Tosibumomab).

I 'm worried, however, that some of the proposed changes in Docket 1392-P will take away that option for many other people. As proposed, the changes outlined would drastically reduce Medicare reimbursement for these radiopharmaceuticals, and would ultimately lead to the failure of these two drugs--as well as other promising cancer treatment options under development.

My main concerns are:

' Proposed changes fail to recognize the unique natures of Bexxar and Zevalin.

Page 42669 of the docket states: 'We estimate that, roughly, 15 diagnostic radiopharmaceuticals have a half-life longer than one day such that they could support diagnostic nuclear medicine scans on different days. ' Zevalin and Bexxar happen to be two of those 15 radiopharmaceuticals; they have longer half-lives than one day, and an essential part of the treatment includes diagnostic doses and imaging scans given over several days to help calulate the correct radioactive dose (in the case of Bexxar, given on about day 8). It 's difficult, then, to propose reimbursements for these unique drugs by categorizing them with others. Naturally, a radiopharmaceutical that requires several separate imaging scans is going to cost more than those radiopharmaceuticals allowing only one scan. Certainly, medical professionals and manufacturers can address these inconsistencies better than I; however, Zevalin and Bexxar seem to be square pegs that don' t fit into the round holes proposed in this docket.

' Proposed changes will drastically cut reimbursement for both Bexxar and Zevalin.

Such a drastic cut in reimbursement for these treatments will mean hospitals have to subsidize about 50% of the cost for all Medicare patients. Certainly, hospitals won 't be willing to do this, and Medicare patients will have one less option to treat a disease that' s currently incurable. More importantly, this will create a domino effect; because Bexxar and Zevalin won' t be offered to Medicare patients, they won 't be options for people covered under private insurance, either.

' Proposed changes will exacerbate a difficult marketplace for Bexxar and Zevalin, and stop future research in this promising field of cancer treatment.

The marketplace difficulties faced by both Bexxar and Zevalin have both been well documented in national press (including a recent feature in the NY Times). To date, neither treatment has made money for their manufacturers. If the proposed changes are adopted, there' s little doubt these drugs will cease to exist. What company will want to keep manufacturing a drug it will now lose even more money producing? Far more dire, this will stall several similar drugs currently in development; many other radiopharmaceutical drugs aimed at the treatment of cancer are currently undergoing testing in clinical trials, but will certainly be abandoned because of the failure of Bexxar and Zevalin.

In short, I believe the proposed changes will cripple and kill one of the most promising therapies yet developed for follicular lymphoma. This will set research and treatment back several years. We want to encourage innovation and breakthroughs in all treatments, cancer treatments included, and the proposed changes will have the opposite effect. I respectfully ask you to keep reimbursement for both of these drugs intact.

Thank you for your diligent work, and thank you for the opportunity to provide comment as a concerned patient.

CMS-1392-P-366-Attach-1.PDF

CMS-1392-P-366-Attach-2.PDF

#366

Tony L. Hines
1801 Darlene, Billings, MT 59102
406-698-7485 | tlhines@tlhines.com | www.tlhines.com

Comment On Docket 1392-P, specifically regarding Section II.A.4. - "OPPS: Payment for Therapeutic Radiopharmaceuticals"

Ladies and Gentlemen -

Thank you for the opportunity to comment on this docket, as it impacts an area of great concern to me.

In May of 2007, I was diagnosed with Indolent Follicular Non-Hodgkins Lymphoma, and in conjunction with my medical team, have been examining several treatment options ranging from chemotherapy to several clinical trials to watchful waiting.

After researching and discussing these options, I believe the best choice for my situation is radioimmunotherapy, specifically Zevalin (Ibritumomab tiuxetan) or Bexxar (Tositumomab & Iodine I 131 Tosibumomab). While both of these agents are currently approved for relapsed indolent lymphoma, there's considerable evidence they are incredibly effective for first-line treatment as well--at least as effective as current standard-of-care chemotherapy, with a shorter treatment period (approximately 10 days vs. several months) and fewer overall complications and toxicities.

My medical team and private insurance company have been very helpful, and I've been approved for radioimmunotherapy as my initial treatment. That's good news for me, of course, and I'm thankful to have that option.

I'm worried, however, that some of the proposed changes in Docket 1392-P will take away that option for many other people. As proposed, the changes outlined would drastically reduce Medicare reimbursement for these radiopharmaceuticals, and would ultimately lead to the failure of these two drugs--as well as other promising cancer treatment options under development.

• *Proposed changes fail to recognize the unique natures of Bexxar and Zevalin.*

Page 42669 of the docket states: "We estimate that, roughly, 15 diagnostic radiopharmaceuticals have a half-life longer than one day such that they could support diagnostic nuclear medicine scans on different days." Zevalin and Bexxar happen to be two of those 15 radiopharmaceuticals; they have longer half-lives than one day, and an essential part of the treatment includes diagnostic doses and imaging scans given over several days to help calulate the correct radioactive dose (in the case of Bexxar, given on about day 8). It's difficult, then, to propose reimbursements for these unique drugs by categorizing them with others. Naturally, a radiopharmaceutical that requires several separate imaging scans is going to cost more than those radiopharmaceuticals allowing only one scan. Certainly, medical professionals and manufacturers can address these inconsistencies better than I; however, Zevalin and Bexxar seem to be square pegs that don't fit into the round holes proposed in this docket.

• *Proposed changes will drastically cut reimbursement for both Bexxar and Zevalin.*

Such a drastic cut in reimbursement for these treatments will mean hospitals have to subsidize about 50% of the cost for all Medicare patients. Certainly, hospitals won't be willing to do this, and Medicare patients will have one less option to treat a disease that's currently incurable. More importantly, this will create a domino effect; because Bexxar and Zevalin won't be offered to Medicare patients, they won't be options for people covered under private insurance, either.

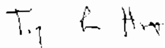
• *Proposed changes will exacerbate a difficult marketplace for Bexxar and Zevalin, and stop future research in this promising field of cancer treatment.*

The marketplace difficulties faced by both Bexxar and Zevalin have both been well documented in national press (including a recent feature in the NY Times). To date, neither treatment has made money for their manufacturers. If the proposed changes are adopted, there's little doubt these drugs will cease to exist. What company will want to keep manufacturing a drug it will now lose even more money producing? Far more dire, this will stall several similar drugs currently in development; many other radiopharmaceutical drugs aimed at the treatment of cancer are currently undergoing testing in clinical trials, but will certainly be abandoned because of the failure of Bexxar and Zevalin.

In short, I believe the proposed changes will cripple and kill one of the most promising therapies yet developed for follicular lymphoma. This will set research and treatment back several years. We want to encourage innovation and breakthroughs in all treatments, cancer treatments included, and the proposed changes will have the opposite effect. I respectfully ask you to keep reimbursement for both of these drugs intact.

Again, thank you for your diligent work, and thank you for the opportunity to provide comment as a concerned patient. I welcome the chance to discuss any of these items further.

Sincerely,



Tony L. Hines

cc:
The Honorable Herb B. Kuhn, Deputy Administrator, CMS
The Honorable Max Baucus, United States Senate
The Honorable Jon Tester, United States Senate
The Honorable Dennis R. Rehberg, United States House of Representatives

Submitter : **Mr. Maurice Kaiser** **Date: 09/06/2007**

Organization : **Bamberg County Hospital**

Category : **Hospital**

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Please reconsider the CMS-1392-P act as it will cost our hospital $900,000 next year. Our hospital specializes in ESRD and Vascular Access within the ESRD community, saving thousands of lives each year. We already serve a poor population of patient's who are not able to pay for services rendered. The CMS-1392-P act could be enough to shut our facility down leaving thousands of individuals without appropriat care.

Submitter : **Mrs. Sandra Daughtry** **Date: 09/06/2007**

Organization : **North Florida Regional Medical Center**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

Submitter : Mr. Gerard Tango **Date:** 09/06/2007

Organization : Mr. Gerard Tango

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As regards Medicare and Medicaid proposed budgetary cuts based on the concept of nonoverlapping services, this is a vague concept and inadequate to serve as a basis for making critical financial and service providing decisions.

Submitter : Mr. RICHARD SALOMONE **Date:** 09/06/2007

Organization : Mr. RICHARD SALOMONE

Category : Individual

Issue Areas/Comments

Packaged Services

Packaged Services

1. Often rural facilities are forced to care for a higher percentage ESRD patients because these patients are often low income patients without the option to travel to larger facilities. The lossed reimbursement from the bundling of guidance services in CMS-1392-P will have a higher impact on these usually small facilities.

2. Please reconsider CMS-1392-P as it has a negative impact on facilities specializing in Vascular Surgery.

Submitter : **Sandy Elliott** **Date: 09/06/2007**

Organization : **Bamberg County Hospital and Nursing Center**

Category : **Nurse**

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Often rural facilities are forced to care for a higher percentage ESRD patients because these patients are often low income patients without the option to travel to larger facilities. The lossed reimbursement from the bundling of guidance services in CMS-1392-P will have a higher impact on these usually small facilities.

Submitter : **Mr. Glen Grady** **Date: 09/06/2007**

Organization : **Memorial Hospital, Inc**

Category : **Critical Access Hospital**

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

See Attached

CMS-1392-P-372-Attach-1.DOC

#372

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 Memorial Hospital Inc. in Neillsville, Wisconsin.

We have been in operation since 1954 and in 1991, long before the Critical Access Hospital program became available to us as a necessary provider (we are 31 miles from the next nearest hospital) we opened three Rural Health Clinics- one on site, and two others at locations in small towns 15 and 20 miles north and east of Neillsville. We added a physical therapy service at one of the clinics about five years ago. These Rural Health Clinics have been an invaluable asset to, not only the frail elderly and poor who do not have transportation available to them to travel to our on site clinic, but also to the large and ever growing Amish population that we serve. Based on my interpretation of this proposed legislation, we would be able to continue to operate these clinics, but we would not be able to open new clinics in other rural areas where transportation, especially in winter, is not available to a large segment of the rural population.

Neillsville is the county seat for Clark County, Wisconsin. Our county has a population of 32,000 and as evidenced by the fact that no political subdivision- even the City of Neillsville, contains as much as 10% of the County's population, we have a very rural population base. We need flexibility in our ability to place outpatient services where our public can get to them. This proposed rule would tie our hands in the future and would be a real disservice to the people of rural America. I really do not understand the reasoning behind it. It does demonstrate a real bias against and insensitivity toward health care providers in rural America and the health care needs of the elderly and poor that try to continue to live a life far simpler than that of the policy makers in the Washington DC beltline. I do believe that this policy is not reflective of Congressional intent and that is a sad commentary on the policy wars that seem to go on between the branches of national government where policy direction is given and that of where policy is interpreted, written into code, and enforced. Rural American health care seems too often to be a pawn in this chess game between Congress and CMS.

I have been around a long time. I have seen and heard it first hand in the Halls of Congress and CMS Headquarters Building in Baltimore- and I am just a small, inarticulate, low budget hospital administrator with no portfolio.

Sad. Nonproductive. It really makes me wonder why this bias exists against the rural America of the elderly, the very small time farm operators, and the non Wal-Mart towns who are trying to support and sustain there friends and neighbors.

Due to these concerns, I 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,

Glen Grady
Administrator

Submitter : **Mr. R.D. Williams** **Date: 09/06/2007**

Organization : **Ashe Memorial Hosptial**

Category : **Critical Access Hospital**

Issue Areas/Comments

Hospital CoPs

Hospital CoPs

RE: CAH COP changes

To Whom It May Concern:

This letter is to comment on the notice of proposed rulemaking for Hospital Outpatient Prospective Payment System (OPPS) that includes proposals specific to Critical Access Hospitals (CAH). This proposed rulemaking was published on July 16, 2007 and will be effective January 1, 2008 if implemented.

Ashe Memorial Hospital recently converted to Critical Access Hospital status effective September 1, 2007. It is hoped that this conversion will allow our hospital to remain a viable entity providing much needed Healthcare services to this community. Our current payor mix is 46% Medicare, 18% Medicaid, 25% commercial and managed care, 10% self-pay and charity care, and other 1%. Conversion to Critical Access status given our care mix in a rural retirement community will allow our hospital to stabilize and continue to provide needed acute care services to the residents of Ashe County, North Carolina.

I express serious concern about the provisions in the proposed rule which will eliminate the potential of any CAH, to establish a provider based location including a department or a remote location or an off campus distinct part psychiatric or rehabilitation unit on or after January 1, 2008 that does not meet the distance criteria for CAH from another hospital or CAH. The penalty for establishing such a unit can be the loss of CAH certification. CMS proposes &any off campus location must satisfy the distance requirements, without exception and regardless of whether the main provider CAH is a necessary provider CAH. This proposal has significant potential to create a negative situation for Ashe Memorial Hospital. It will impact access to care for Medicare beneficiaries in our rural community.

We believe that potential access will be diminished in our rural community because we are experiencing a growing inability to recruit and retain physicians in private practice, non-provider based practices. Over the past 5 years we have lost eight primary care providers, five family medicine, two family medicine physician extenders and one internist from our community due to the inability of the physicians to make competitive salaries even though they are productive. As we recruit new physicians, we are finding the hospital needs to offer an employment arrangement, which compensates physicians at a higher base, in order to be competitive with other communities. The only way that we can afford to create that level of access is through the provider based arrangements. Currently, we are operating one provider based clinic in the most remote area of our county and on our campus we are converting a second clinic to a provider based status. We have another eight primary care physicians in our community located in two different practice locations. In order to maintain their presence and their service in this community, we must maintain the ability to consider conversion to provider based status.

As you are aware, a strong primary care base in a community is needed to support other specialties such as general surgery, orthopedics, gynecology, ophthalmology, urology, gastroenterology, etc. Without that primary care base, significant erosion of access for our population would occur. Currently over 65% of our county s population is over the age of 45. This lack of access would create an inability of many of our elderly adults to receive needed appropriate services provided by AMH as critical access hospital in our local area.

We therefore recommend that you alter this provision and encourage you to stay with the existing provisions that include that 75% of the patient population must be from within the primary service area of the critical access hospital. Thank you for your consideration of this matter

Sincerely;

R.D. Williams, CEO
Ashe Memorial Hospital

Submitter : **Luis Cordova** **Date: 09/06/2007**

Organization : **Luis Cordova**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:

Thank you for seeking to improve patient access to care and trying to keep down related costs. As the daughter of a patient with Blepharospasms (sustained involuntary muscle spasms around my father's eyes and mouth), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. My father receives injections of botulinum toxin to alleviate the debilitating symptoms. These injections are critically important to his ability to function normally. As it is, we cannot get the botox shots as often as needed because medicare only covers every three months and dad actually needs them at about 2 months and one week. We are working to find a physician that will work with us on the injection schedules and payment out of pocket, but pricing is not uniform and difficult to pin down.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula or improve it by allowing patients to get shots on an as-needed basis. Reductions in reimbursement could lead to fewer qualified physicians. My father already must travel from Silver City, NM to Tuscon, AZ to get the shots. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve his 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.

Sincerely,

Maria Schneider on behalf of Luis Cordova

CMS-1392-P-375

Submitter : Ms. Debbie Miller **Date:** 09/06/2007

Organization : IQH

Category : Other Health Care Professional

Issue Areas/Comments

OPPS Impact

OPPS Impact

Is the OPPS measure reporting mandatory for critical access hospitals?

What definition is used for "clinic" in the measures? If a hospital owns an outside clinic are these cases included or are only the clinics within the hospital included?

Submitter : **Mr. David Pearson** **Date: 09/06/2007**

Organization : **TX Organization of Rural**

Category : **Health Care Professional or Association**

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 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.

CMS-1392-P-376-Attach-1.DOC

#376

Docket ID CMS-1392-P
Necessary Provider CAHs

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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.

Submitter : **Rosemary Nichols** **Date: 09/06/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

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 blephrospasm, 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 debilitating blinking and involuntary eye closure. 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.

Submitter : **Mrs. Margaret Almond** **Date: 09/06/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Kerry Weems, CMS Director

Dear Mr. Weems:

I would like to commend CMS on 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 both blepharospams and oramandibular dystonia, I have been receiving botox injections for more than 15 years. Without these injections, I would be unable to see as my eyelids drop shut. This is not a cosmetic procedure. The dystonias are caused by movement disorders 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 wish I did not have to get these injections approximately every three months; however at sixty-seven years of age, the debilitating dystonic symptoms and movements require the injections to function normally. While research is continuing to be done on these dystonias, currently there no known cause nor is there a known cure. Botox helps alleviate the spasms.

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. I was sent from doctor to doctor with diagnosis of 'it's all in your head'. After more than four years, I was able to find a professional who knows how to inject botox into the correct muscle. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no econimic rewards or penalties to providers, depending on where the injection are given.

Thank you for allowing me to provide these comments.

Sincerely,

Margaret H. Almond
5624 Birchhill Rd.
Charlotte, NC 28227
704-537-6523
maggiealmond@carolina.rr.com

Submitter : **Mrs. Mary Wilmarth** **Date: 09/06/2007**

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 Blepharospasm, I have serious concerns about CMS's proposal to reduce payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the spasms and to keep my eye lids open. Without it I would not be able to see nor stand the nerve racking experience of the spasms that occur with blepharospasm. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physicians-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. I have personally had experience with someone who did not do it properly and I could see for two weeks. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there-are no rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

Mary Wilmarth
3618 E. Peach Ho;;ow Circle.
Pearland, Texas 77584

Submitter : **Mr. Terrence Brenny** **Date: 09/06/2007**

Organization : **Stoughton Hospital Association**

Category : **Critical Access Hospital**

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

See Attached Letter

CMS-1392-P-380-Attach-1.DOC

#380

August 30, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1392-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

Stoughton Hospital located within Stoughton, WI, a City of 13,000 residents has served the communities of Stoughton, Oregon, Evansville, and McFarland for 103 years. Our combined service area is comprised of approximately 55,000 residents. We are a sole community Hospital; there are no other hospitals located within the other service area communities. In October, 2004, Stoughton Hospital became a necessary provider Critical Access Hospital with a distinct geri psych unit.

Since 2001, Stoughton Hospital has operated a rehabilitation/sports medicine satellite outpatient clinic within the neighboring service area community of Oregon, WI. As a lessee tenant, we have moved the program two times due to phenomenal growth and demand for these services in that community.

In April, 2007, the Hospital Governing Board approved the Hospital leasing life/safety improved expanded new Rehabilitation facilities within the community of Oregon, a relocation of approximately two (2) miles from the present clinic site. An urgent care service will be added within the facility due to lack of this service in the community and strong community demand for the same. Formal lease contract documents were signed May 14, 2007. The construction plans were reviewed and approved by Mr. Lynn Wallace, State of Wisconsin, Bureau of Health Services, Division of Quality Assurance (State and Federal life safety engineer). Construction is currently underway with completion anticipated April, 2008 per contract.

In view of above developments, Stoughton Hospital is seriously concerned about the recently proposed CMS rule 42 CFR 485.610 (e) that appears to restrict Critical Access Hospitals from creating, acquiring or relocating outpatient satellite centers within our service area after January 1, 2008. Obviously, Stoughton Hospital must insist and has demonstrated the Hospital has "created and acquired" the Oregon satellite operation by virtue of its ongoing six (6) years operations there and signed lease contract obligation for an improved replacement facility currently under construction that precedes the date of proposed rule posting.

We request clarification and exemption for our Oregon rehabilitation/urgent care project from the proposed rule January 1, 2008 restriction based on facts and merits of our request.

Sincerely,

Terrence Brenny
President/CEO
Stoughton Hospital

Submitter : **Dr. Christopher Abadi** **Date: 09/06/2007**

Organization : **Cardiovascular Associates and Newport Hospital**

Category : **Physician**

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am writing in regard to the use of ultrasound contrast with cardiac echo. Eliminating separate pay for its use will result in underutilization which will lead to additional, more costly, diagnostic testing. Its that simple. Contrast is important in a lot of cases to be able to get a diagnostic study. Non-diagnostic studies lead to additional tests. The cost of the contrast agents without appropriate reimbursement will preclude their use. If this proposal goes through, medical expense will increase.

Sincerely, Christopher Abadi MD FACC, Cardiovascular Associates of Rhode Island, Medical Director Newport Hospital Echocardiography Laboratory.

Submitter : **Ms. Pat Miller** **Date: 09/06/2007**

Organization : **Ms. Pat Miller**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Wccms:

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 serviccs. Howcver, 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 allcviate 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 rclieve 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 providc these comments.
Sincercly,

Pat Miller

Submitter : **Mrs. Kitrena Foster** **Date: 09/06/2007**

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,(a movement disorder resulting from sustained involuntry 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 botulunum 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,

Submitter : **Mr. Larry Roe** **Date: 09/06/2007**

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 (BEB, a movement disorder resulting in sustained involuntary muscle spasms of the eye lids), 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 and 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,

Larry J. Roe
lacaroe@sbcglobal.net

Submitter : **Mr. Lynn Yarbrough** **Date: 09/06/2007**

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, I am a man who lives daily with the condition called Benign Essential Blepharospasm (BEB), a dystonia that causes my eyes to blink violently and spastically. I have been under the care of at least eight different Neurologists and Opthalmologists, each of whom has prescribed injections of Botulinum Toxin (Botox) around my eyes as the treatment of choice. I have received these injections at Mass. Eye & Ear Hospital, The University of San Francisco Med Center, the University of Southern California Med Center, and other hospitals, as well as several outpatient clinics.

Without these treatments I would become effectively blind. I would be unable to drive a car or play tennis or participate in any number of activities that contribute to my general health and well-being. The injections, applied every 3-6 months, completely relieve the symptoms and allow me to conduct a normal life. I can no longer do without them.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, but 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 already. 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 that depend on the venue where the injections are given.

I am aware that many people use Botox for purely cosmetic treatment of skin wrinkles, etc. I am also aware that Alergan Corp. currently has a monopoly on the production and sale of Botox, at least in this country. These facts, and the high toxicity of the product, make the price excessively high. These are issues that need to be addressed without depriving people like myself, whose sight is threatened, of access to Botox at a reasonable cost.

Thank you for allowing me to provide these comments.

Sincerely,

Lynn D. Yarbrough

CMS-1392-P-386 Medicare

Submitter : **Mrs. Karen Phelps** **Date & Time:** **09/06/2007**

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 blepharospasms (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 physcian-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 ecomomic rewards or penlties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments.
Sincerely,
Karen Phelps

CMS-1392-P-387 Medicare

Submitter : **Mr. Brian Duong** **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 a mild form of Apraxia of eyelid opening , 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,

Brian Duong

CMS-1392-P-388 Medicare

Submitter : Bruce Nourjian **Date & Time:** 09/07/2007

Organization : Bruce Nourjian

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 Blepharospasms(which cause my eyelids to spasm shut), 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,

Bruce S. Nourjian

CMS-1392-P-389 Medicare

Submitter : **Mr. Bruce Roesler** **Date & Time:** **09/07/2007**

Organization : **Mercy Medical Center - New Hampton**

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

GENERAL

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 hospital administrator at Mercy Medical Center, New Hampton, Iowa.

Our 18-bed critical access hospital sponsors the only primary care clinic in our community. An adjoining community, 10 miles away, is attemting to recruit a family practice physician to replace two others who would like to retire. If this rule is enacted, our CAH would not be able to assist that community by making that clinic part of our CAH's provider-based clinic. Effectively, the proposed rule may diminish any hope of that clinic eventually securing a doctor, and thereby diminish access to Medicare beneficiaries and others who today depend on that clinic.

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 county. 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,

Bruce Roesler
Administrator

CMS-1392-P-390 Medicare

Submitter : **Mrs. Pauline Barnes** **Date & Time:** **09/07/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

As a patient with a form of dystonia called blepharospasm,(a movement disorder of the eyes 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.

CMS-1392-P-391 Medicare

Submitter : **Jamie Berardi** **Date & Time:** **09/07/2007**

Organization : **Center for Hyperbarics and Wound Care Candler Hosp**

Category : **Hospital**

Issue Areas/Comments

Wound Care Services

Wound Care Services

See attachment.

CMS-1392-P-391-Attach-1.PDF

CMS-1392-P-391-Attach-2.PDF

#391

September 7, 2007

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

ATTN: CMS-1392-P

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

Dear Administrator Weems:

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

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf®. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 application amount for Apligraf from $323.28 to $132.82 — a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.

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

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

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

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

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

Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact **Jamie Berardi, Program Director at (912) 819-8187.**

Sincerely,

Jamie Berardi

CMS-1392-P-392 Medicare

Submitter : **Mrs. Donna Surrency** **Date & Time:** **09/07/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments
Specified Covered Outpatient Drugs

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 Benign Essential Blepharospasms, 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 this debilitating disorder. These injections are critically important to my ability to function normally. As a new Medicare recipient,I respectfully request that CMS not change the payment fomula 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 successfully to relieve these spasms in the eye area. Also, this change policy would destroy the uniformity of payments across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are give. Thanks for allowing me to provide these comments.

CMS-1392-P-393 Medicare

Submitter : **Mr. Donald Collins** **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 (BEB), 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,

Donald Collins