CMS-1392-P-580 **Medicare**

Submitter : Dr. p owen **09/10/2007**

Organization : LRMC
Physician

Category :

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

INTRAVASCULAR ULTRASOUND FOR CORONARY INTERVENTION IS AN INVALUABLE AID TO PROCEDURES BUT TIME CONSUMING AND AT TIMES A STAND ALONE PROCEDURE. HOW WOULD WE DEAL WITH A SITUATION WHERE WE ARE SUMMONED AT NIGHT BY A COLLEAGUE TO ASSESS A LESION AND CONSIDER INTERVENTION AND THE ivus SUGGESTS "NO INTERVENTION"? SIMILARLY WITH THE PRESSURE WIRE. HAVING A CODE COMPLETELY TIED TO THE INTERVENTION SEEMS IMPRACTICAL AND DENIES APPROPRIATE MANAGEMENT STRATEGIES.

CMS-1392-P-581 **Medicare**

Submitter : Miss. Bonnie Hawkins **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

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 cervical dystonia, (Dystonia is a movement disorder resulting from sustained involuntary muscle spasms.)I have serious concerns about CMS's proposal to bundle the payment rate to hospitals for physician-injected drugs. I have received injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I have received were critically important for my ability to function normally and have relief of the pain associated with dystonia.

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

2. Thank you for allowing me to provide these comments.

CMS-1392-P-582 **Medicare**

Submitter : Dr. Gordon Goldman **09/10/2007**

Organization : ExAblate of St. Louis
Physician

Category :

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

September 10, 2007

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

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

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

Dear Deputy Kuhn:

I have been in the clinical practice of gynecology in St. Louis County for over thirty years. As such, I have been witness to a parade of novel treatment methods during those three decades that has proven to decrease the danger to patients, decrease the costs of services and increase the access of patients to superior medical care. It is with this in mind, that I find it so gratifying to have the opportunity to comment upon the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for the calendar year 2008.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it

today, much the same as the hysteroscope, laparoscope, laser, ultrasonic instumentation and robotic surgery have done over the past three decades. I am proud to be among the most forward thinking physicians in this country, being able to offer this new technology to the women of Missouri and surrounding states. It is my strong belief this new technology has the potential to significantly improve health outcomes in several fields, with the uterine fibroid application being the □Plymouth Rock□ upon which other specialties will base future therapies. As a gynecologist, I liken this to the introduction of laparoscopy initially for minor gynecologic procedures, but advancing to the point where most major surgical procedures can be done by this minimally invasive technology. I also have witnessed the spread of that technology to general surgery, orthopedics, cardiovascular and many other specialties. I expect the same will occur with MRgFUS.

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

1) Treatment objective is non-invasive tumor destruction.
2) The □surgery□ is conducted using and external energy source which penetrates into the body to reach the tumor.
3) Imaging technology is basic to the procedure.
4) Extensive treatment planning is required with continuous intra-procedural monitoring.
5) Capital expenditures are enormous to provide dedicated specialized treatment rooms.
6) Procedure times are lengthy, ranging from two to five hours, not including post-procedure review and documentation.

However, the reimbursement rate for this procedure continues to be far below the costs incurred to provide this service and does not adequately reflect the treatment planning components required to perform MRgFUS.

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

MRgFUS procedures provide excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals and outpatient centers to offer this less invasive procedure option to patients with uterine fibroids.

I appreciate the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Gordon M. Goldman, M.D., FACOG

Medical Director, ExAblate of St. Louis

CMS-1392-P-582-Attach-1.DOC

#582

September 10, 2007

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

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

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

Dear Deputy Kuhn:

I have been in the clinical practice of gynecology in St. Louis County for over thirty years. As such, I have been witness to a parade of novel treatment methods during those three decades that has proven to decrease the danger to patients, decrease the costs of services and increase the access of patients to superior medical care. It is with this in mind, that I find it so gratifying to have the opportunity to comment upon the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for the calendar year 2008.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it today, much the same as the hysteroscope, laparoscope, laser, ultrasonic instumentation and robotic surgery have done over the past three decades. I am proud to be among the most forward thinking physicians in this country, being able to offer this new technology to the women of Missouri and surrounding states. It is my strong belief this new technology has the potential to significantly improve health outcomes in several fields, with the uterine fibroid application being the 'Plymouth Rock' upon which other specialties will base future therapies. As a gynecologist, I liken this to the introduction of laparoscopy initially for minor gynecologic procedures, but advancing to the point where most major surgical procedures can be done by this minimally invasive technology. I also have witnessed the spread of that technology to general surgery, orthopedics, cardiovascular and many other specialties. I expect the same will occur with MRgFUS.

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

1) Treatment objective is non-invasive tumor destruction.
2) The 'surgery' is conducted using and external energy source which penetrates into the body to reach the tumor.
3) Imaging technology is basic to the procedure.
4) Extensive treatment planning is required with continuous intra-procedural monitoring.
5) Capital expenditures are enormous to provide dedicated specialized treatment rooms.
6) Procedure times are lengthy, ranging from two to five hours, not including post-procedure review and documentation.

However, the reimbursement rate for this procedure continues to be far below the costs incurred to provide this service and does not adequately reflect the treatment planning components required to perform MRgFUS.

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

MRgFUS procedures provide excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals and outpatient centers to offer this less invasive procedure option to patients with uterine fibroids.

I appreciate the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Gordon M. Goldman, M.D., FACOG
Medical Director, ExAblate of St. Louis

CMS-1392-P-583 **Medicare**

Submitter : Jean Pison **09/11/2007**

Organization : none
Individual

Category :

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 blepharospam, 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,
Jean Pison

CMS-1392-P-584 **Medicare**

Submitter : Mrs. Brenda Dashkin **09/11/2007**

Organization : Mrs. Brenda Dashkin
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P,Specified Covered Outpatient Drugs
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Cervical Dystonia(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. Anyonc 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 ecsonomic rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Kindest regards.

CMS-1392-P-585 **Medicare**

Submitter : Mrs. Gloria Esham **09/11/2007**

Organization : none
Individual

Category :

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 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,

Gloria Esham

CMS-1392-P-586 **Medicare**

Submitter : Mrs. Sandra Blackwell **09/11/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

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

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

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

Sincerely,
Sandra Blackwell, 3992 Furr Court, Bloomington, IN 47404

CMS-1392-P-587 **Medicare**

Submitter : Ms. Anne Marie Bicha **09/11/2007**

Organization : American Gastroenterological Association
Health Care Provider/Association

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-587-Attach-1.PDF

#587

4720 Montgomery Lane
Suite 430
Bethesda, MD 20814-5320

PH 240.482.3221 MAIN
FX 301.652.9405

www.gastro.org

September 11, 2007

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System

Dear Mr. Weems:

The American Gastroenterological Association (AGA) is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 16,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system.

The AGA appreciates the opportunity to provide comments on the 2008 proposed rule affecting hospital outpatient departments and ambulatory surgical centers (CMS-1392-P). We support the changes proposed for the hospital outpatient departments (HOPD), and we also support CMS' efforts to make payment policies and procedures consistent between the hospital outpatient and ambulatory surgical center (ASC) settings.

Our comments that follow are limited to changes proposed for ambulatory surgical centers.

ASC Rates at 65% of Hospital Outpatient Department Rates
Using 2006 Medicare volume data, GI procedures were the volume leader at 34%, accounting for the second largest expenditure of dollars at 27%. Clearly, with our members as leading providers of ASC services, the AGA remains extremely concerned about CMS' decision to set the ASC facility fee payments at 65% of the hospital outpatient department (HOPD) rates, effective January 1, 2008.

Paying for procedures performed in ASCs at 65% of HOPD rates will jeopardize beneficiary access to many gastrointestinal endoscopic services in the more efficient and cost-effective ASC setting. GI procedures are currently paid at approximately 79-84% of HOPD rates, a rate supported by the GAO in report GAO-07-86. Paying ASCs at 65% of HOPD rates will be a substantial and unsustainable reduction for many ASCs that provide endoscopy services. We believe this action by CMS may lead to the closing of many single specialty ASC facilities that focus on Gastroenterology, or restricting their services to non-Medicare patients.

We are extremely concerned that this low rate of 65% of HOPD rates will have a negative impact on Medicare's efforts to increase colorectal cancer screening. The precipitous drop in ASC reimbursement for screening colonoscopy (codes G0105, G0121) will mean that ASCs providing GI endoscopy services will be unable to meet their expenses and overhead. Contrary to CMS' projections, we believe this reduction in reimbursement will lead to Medicare beneficiaries being referred to the HOPD setting for colorectal cancer screening services.

We are concerned that CMS has not considered in their analysis the potential impact of shifting services to the more expensive HOPD setting. The HOPD is the costliest and least efficient setting for endoscopy services, and is less convenient for Medicare beneficiaries. In many areas of the country, hospitals may not have the capacity to accommodate all beneficiaries requiring colorectal cancer screening and other GI procedures, resulting in substantial delays in care. The unintended consequence of shifting endoscopic procedures back to the more costly HOPD setting will result in higher costs to the Medicare program and higher coinsurance for beneficiaries.

In states with Certificate of Need (CON) regulations, ASCs may be specifically licensed to solely provide endoscopy services. As a result, these facilities do not have the ability to change their case and procedure mix to offset the devastating cuts in ASC reimbursement. ASCs tend to be small businesses; approximately 73% would be considered small businesses according to the Small Business Administration size standards, and 72% have 20 or fewer full time employees. A drop in reimbursement to 65% of HOPD rates is too drastic a reduction for any small business to absorb. No business can operate with this amount of loss while also dealing with increased business expenses such as overhead and staff salaries. We urge CMS to reconsider the potential impact of this payment decision.

There is currently no consensus on what is the appropriate rate of ASC to HOPD payments. CMS has determined a rate of approximately 65% through their calculations. GAO report GAO-07-86, released in November 2006, resulted in a weighted figure of 84%, with a final amount of approximately 82% due to adjustments. H.R. 1823, the "The Ambulatory Surgical Center Payment Modernization Act," sets ASC rates at 75% of HOPD rates.

We continue to be concerned about CMS setting a uniform rate for all specialties regardless of whether the costs of each specialty bear a comparable relationship to the relative payment structure for each specialty/procedure in the HOPD payment system. Changing all ASC payments to a uniform rate based on the HOPD payment results in a substantial decrease for gastroenterology and several other specialties. At the same time, this methodology substantially increases ASC payments for other specialties which have a much lower volume of procedures

performed in the ASC setting. In our comments to CMS in November 2006, the AGA recommended that CMS obtain data to determine the legitimate cost differences between the hospital and the ASC setting and validate its assumption that a uniform proportion of HOPD payment is appropriate for all services.

CMS proposes to pay ASCs 35% less than what they pay a hospital for the exact same surgical procedure. This price differential is unrelated to the costs that ASCs actually incur in delivering services. It is driven entirely by the CMS' narrow interpretation of budget neutrality requirements and will jeopardize the ability of many ASCs to continue to provide high quality surgical care to Medicare beneficiaries. The direct costs related to clinical labor, equipment, and supplies, as well as the costs of the facility suite, should be similar in both settings and in our judgment, the cost differential between these setting is substantially less than 35% of the HOPD rate.

In the final rule, while CMS performed a more expansive analysis of case migration and chose to estimate budget neutrality using case migration, CMS concentrated on migration analysis for the 793 new procedures added to the ASC list, assuming that any shift in site traceable to the wide shift in payment rates for endoscopic and other procedures already on the ASC list would be negligible. CMS also concluded, and factored into its budget neutrality compilation, that it would incur costs when eventually 15% of cases now done in physician offices move over to the ASC, even though the new ASC facility fee for cases now performed 50% in the office would never exceed the practice expense component under the Medicare physician fee schedule.

CMS has determined that the positive and negative migration factored together resulted in a net effect of zero. The AGA disagrees and believes migration of underrepresented services already on the ASC list is very likely. We encourage CMS to assess actual migration and publicly release the data once it becomes available. Negative migration will likely occur for many high volume GI endoscopy procedures if significant numbers of procedures shift from the ASC to HOPD setting due to inadequate ASC reimbursement, increasing costs to the Medicare program which is not intended by CMS.

The AGA is pleased that CMS decided to phase-in the final rule over a four-year time frame, mitigating the even more devastating impact if this rule had been implemented over a two-year time frame as originally proposed. However, a four-year phase-in results in the inability of the ASC to cover their costs for medical devices such as endoluminal stents for gastrointestinal neoplasms. Given CMS' proposal to link ASC reimbursement to the HOPD system, it needs to make uniform policy decisions between these two payment systems. ASC payment rates should have an explicit mechanism to take into account the cost of technology. For services that involve costly disposables such as endoluminal stents, the ASC rate should be set in 2008 to assure full payment for the device since any differential between the costs in an ASC and HOPD would be in overhead and not in direct costs or the cost of devices. These devices cost the same regardless of whether they are used or implanted in the ASC or HOPD setting; therefore, CMS needs to ensure appropriate device payments in both settings.

Quality Data
In this proposed rule, CMS announces its intention to require quality reporting in the future by ASCs in order for ASCs to receive their full update. We are pleased that ASCs will have the opportunity to share standardized quality indicators with CMS and the public, as this is consistent with hospital required quality reporting. A data reporting infrastructure should allow comparison of quality when a service can be performed in multiple ambulatory settings.

Unlike hospital outpatient settings, which require abstraction of clinical data based on chart review, followed by compilation and submission in specified XML format to an approved data submission vendor, most ASCs are small businesses with a mean of 2 and median of 2.5 operating rooms per facility, according to CMS data. It is unusual for an ASC to have a medical records department staffed by multiple individuals. The AGA supports an administrative claims approach to quality measure reporting to be the most feasible, practical and economic approach for ASCs. We encourage CMS to work together with the ASC community to develop level II HCPCS codes that would allow ASC facility level quality measures to be reported using a claims based approach that can be accommodated using both the CMS-1500 and UB-04 forms. In addition, the AGA recommends that CMS provide a testing period for ASCs to collect and submit quality data.

Budget Neutrality
The AGA recommends that CMS re-evaluate their narrow definition of budget neutrality and instead calculate budget neutrality across the entire Part B system for outpatient services. There is no explicit evidence that Congress intended for CMS to add 793 additional services to the ASC list and still pay for all of those additional services with the same amount of dollars that had originally excluded these services. A broader application of the mandated budget neutrality adjustment that also includes savings effects resulting from case migration out of the higher cost hospital setting and into the lower cost ASC is essential to determine an appropriate payment rate for ASCs. This change would enable ASC payments for GI endoscopy procedures to be at a higher percentage of HOPD rates.

ASC Payment Updates
CMS has the option to update ASC rates using either the Consumer Price Index for Urban consumers (CPI-U) or the hospital market basket beginning in 2010. Unfortunately, CMS has chosen to use the lower CPI-U update. As we indicated last year, inflationary costs for nursing services and medical device costs affect ASCs no differently than they affect hospitals. Using different updates for ASCs vs. hospital outpatient departments will continue to create greater disparity in the relativity of these two payments systems and negatively impact the percent of ASC to HOPD payments. There is no evidence that hospital costs increase at rates in excess of those of ASCs. AGA recommends again that CMS utilize the hospital market basket methodology for updating the ASC conversion factor for inflation starting in 2010.

We note that the HOPD setting has enjoyed 3% or higher annual updates since the implementation of the Medicare Modernization Act of 2003, while ASC rates have been frozen during the same period. It makes little sense to artificially and arbitrarily widen the gap between ASC and HOPD payment rates by an inflation factor update that is unrelated to the relative costs incurred by each setting in providing surgical services.

Thank you for the opportunity to provide these comments. If we may provide any additional information, please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 240-482-3223, or abicha@gastro2.org.

Sincerely,

Mark Donowitz, MD

Mark Donowitz, MD, AGAF
Chair, American Gastroenterological Association

CMS-1392-P-588 **Medicare**

Submitter : Mrs. Kathryn McCreary **09/11/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.
1. I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
2. Thank you for allowing me to provide these comments.
Sincerely,
Kathryn McCreary

CMS-1392-P-589 **Medicare**

Submitter : Mrs. Kathryn McCreary **09/11/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (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.
1. 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.
2. Thank you for allowing me to provide these comments.

Sincerely,
Kathryn McCreary

CMS-1392-P-590 **Medicare**

Submitter : Ms. Mary Ellis **09/11/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:

Regarding: CMS-1392-P, OPPS: Packaged Services

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

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

Thank you for allowing me to provide these comments.

Sincerely,

Mary Ellis

CMS-1392-P-591 **Medicare**

Submitter : Mrs. Sandra Meaux **09/11/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Spasmodic Torticollus, (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.
1. I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
2. Thank you for allowing me to provide these comments.

CMS-1392-P-592 **Medicare**

Submitter : Mrs. Betty Dillingham **09/11/2007**

Organization : Gibson General Hospital
Social Worker

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

September 11, 2007

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule (CMS-1392-P) and how it will impact the programs of the Critical Access Hospitals. Our hospital is located in a small rural town in Indiana in a county highly populated with people over the age of 65. Many services are not easily accessible to this age group.

We opened a new service one year ago to address the mental health needs of the older population. I am the director of the Intensive Outpatient Senior Enrichment Program. We work with people who are coping with depression, anxiety, grief, and loss to name a few. Our physical location is across the street from the hospital because there is no space available in the main building.

I understand if this measure passed we would be grandfathered in. I am very concerned about future off-site programs that our hospital and other rural hospitals throughout the United States might want to establish. Unless you live in an area that has limited services including transportation to larger cities you do not understand the negative impact this proposal would have on people. This is why the staff members at our hospital work so hard every day to keep our doors open.

I ask that you reconsider and withdraw the provisions in this rule pertaining to off-site clinics owned by Critical Access Hospitals. Thank you for your consideration.

Sincerely,

Betty Dillingham, ACSW,LCSW
Director, Senior Enrichment Program
Gibson General Hospital
Princeton, Indiana 47670

CMS-1392-P-593 **Medicare**

Submitter : Mrs. Sandra Meaux **09/11/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Spasmodic Torticollis, 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.
1. 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.
2. Thank you for allowing me to provide these comments.

CMS-1392-P-594 **Medicare**

Submitter : Dr. Ravin Davidoff **09/11/2007**

Organization : Boston Medical Center
Individual

Category :

Issue Areas/Comments

OPPS Impact

OPPS Impact

For years we performed our exercise stress tests and dobutamine echos without contrast and our interobserver and intraobserver reproducibility data were very poor. We frequently were unable to make a clinical diagnosis because of limited endocardial resolution and forced to proceed to an additional more expensive nuclear stress test or invasive cardiac catheterization. We then made a decision to utilize contrast agents more liberally and our quality has markedly improved. In regular transthoracic echos in select patients, contrast adds greatly to our level of certainty about LV function upon which decisions about pharmacologic treatment as well as device decisions eg ICD's and biV ICD's, are made. In our experience in a fiscally prudent academic institution, we perform fewer confirmatory studies after echo than previously and fewer "unnecessary" invasive cardiac catheterizations for equivocal stress tests. I believe that "packaging" of contrast with echo would result in significantly less use of these contrast agents and would negatively impact quality with a likely increase in use of nuclear stress tests (as the primary or second test) and perhaps more invasive catheterizations

CMS-1392-P-595 **Medicare**

Submitter : Wanda Wilson CRNA PhD MSN **09/11/2007**

Organization : American Assoc. of Nurse Anesthetists
Health Care Professional or Association

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1392-P-595-Attach-1.PDF

#595

September 14, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Bldg
200 Independence Ave., SW
Washington, DC 20201

ATTN: CMS-1392-P

Re: Comments on Medicare Program: Proposed Changes for Hospital Outpatient Prospective Payment System and CY2008 Payment Rates; (72 Fed. Reg. 42628, August 2, 2007).

I. INTERRUPTED PROCEDURES
II. NECESSARY PROVIDER CAHs
III. HOSPITAL CoPs

Dear Sir/Madam:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the proposed rule for the Medicare Program; Proposed Changes for Hospital Outpatient Prospective Payment System and CY2008 Payment Rates; *(72 Fed. Reg. 42628, August 2, 2007).* The AANA is submitting comments in the areas of Interrupted Procedures, Necessary Provider CAHs, and Hospital CoPs.

The AANA is the professional association for more than 36,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice nurses who administer about 27 million anesthetics given to patients each year in the United States, according to the 2005 AANA Member Survey. Nurse anesthetists have provided anesthesia in the U.S. for over 125 years, and high quality, cost effective CRNA services continue to be in high demand. CRNAs are Medicare Part B providers and since 1986, have billed Medicare directly for 100 percent of the physician fee schedule amount for their services.

CRNA services include administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery. CRNAs also provide assessment and evaluation for acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost two-thirds of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Forces. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists, and all varieties of specialty surgeons.

I. INTERRUPTED PROCEDURES

We appreciate CMS efforts to amend 42 CFR §419.44 to more accurately reflect the current OPPS payment policy for interrupted procedures. We understand that CMS proposes to first make a technical and conforming change to the title of §419.44 by removing the word "surgical" in order to encompass all the procedures performed in hospital outpatient departments (HOPDs). The proposed title for §419.44 would read "Payment reductions for procedures." We agree with this change. Our members provide anesthesia and analgesic services for surgical, diagnostic and other procedures and this change clarifies that §419.44 and its payment modifiers, specifically modifiers 74, 73 and 52, which apply to all procedures performed in HOPDs.

CMS' second proposal in this section includes changing the heading of §419.44(b) from "Terminated procedures" to "Interrupted procedures." We agree that this title change more accurately characterizes the various reasons why a procedure may be disrupted or discontinued. We also agree with the proposed conforming changes to §419.44(b)(1) and (b)(2) by removing the word "surgical" to encompass all procedures performed at HOPDs.

Lastly, we agree with CMS' proposal to add a new paragraph (b)(3) to reflect the current policy of the application of a 50 percent to the Outpatient Prospective Payment System (OPPS) payment when a hospital reports modified 52 for interrupted or discontinued services that do not require anesthesia.

II. NECESSARY PROVIDER CAHs

We appreciate CMS' efforts to maintain hospital-level services in rural communities to ensure patients' access to care in these communities. CRNAs are proud to be the sole anesthesia providers in almost two-thirds of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. Our members would primarily provide these services in the CAH hospital facility.

Current law allows a Critical Access Hospital (CAH) to create or acquire an off-campus location so long as the off-campus location satisfies the location criteria for a CAH and operates under the CAH's provider agreement under 42 CFR §413.65. Our understanding is that CMS proposes to clarify that if a necessary provider CAH, or a CAH that does not have a necessary provider designation operates a provider-based facility as defined in §413.65(a)(2), or a psychiatric or rehabilitation distinct part unit that was created or acquired on or after January 1, 2008, that the CAH and its off-campus units must comply with the distance requirement. The distance requirement under 42 CFR §485.610(c) states that the CAH must be at least a 35-mile drive to the nearest hospital or CAH or 15 miles in the case of mountainous terrain or in areas with only secondary roads. If a necessary provider CAH enters into a co-location arrangement or acquires or creates an off-campus facility after January 1, 2008, the CAH must correct the situation that led to noncompliance with the distance requirement or it will lose its CAH provider agreement with CMS. A noncompliant necessary provider CAH would have to convert to a hospital that is paid under the Inpatient Provider Payment System (IPPS). CAHs that were certified as a necessary provider by the state before January 1, 2006, do not have to meet the distance requirements to other hospitals or CAHs according to 1820(c)(2)(B)(i)(II) of the Social Security Act.

This proposal raises a number of questions for our members who work in CAHs.

- For a CAH designated as a necessary provider after January 1, 2006, or a CAH that is not designated as a necessary provider, that operates an off-campus or distinct part unit after January 1, 2006, how does population encroachment on the off-campus or distinct part unit affect the CAH? For instance, in the case of a CAH operated off-campus or distinct part unit that is located between the CAH facility and an urban area. Both the CAH

facility and the off-campus or distinct part unit are in compliance with the distance requirement. However, over time the population in the nearest urban area grows such that the off-campus or distinct part unit is no longer compliant with the distance requirement, but the CAH facility remains compliant with the distance requirement. What are the consequences for the CAH facility that remains compliant with the distance requirement?

Our concern with this proposal is that linking distance requirement compliance of the off-campus or distinct part unit to the continued designation of a hospital as a CAH could result in decreasing patients' access to surgical and other procedures that are provided in the CAH facility which remains compliant with the distance requirement. An otherwise compliant CAH facility would have to convert to a hospital under the IPPS thereby losing the funding necessary to provide services to its surrounding rural community. We request that in clarifying this proposed rule that CMS in its final rule take into consideration these possible unintended consequences. We welcome the opportunity to work with CMS to develop a final rule that ensures access to surgical and other services provided at the primary CAH facility.

Our other related questions include:

- If a CAH that is *not* a necessary provider operates a provider-based facility as defined in §413.65(a)(2), or a psychiatric or rehabilitation distinct part unit that was created or acquired on or after January 1, 2008, does not comply with the distance requirement, what are the consequences of non-compliance for this CAH?

- Is it correct to state that if a CAH that was certified as a necessary provider by the state before January 1, 2006, and its off-campus or distinct part units were in existence at the time of the original certification, that neither the CAH nor the off-campus units must comply with the distance requirement?

- Is it correct to state that if a necessary provider CAH that was designated as a necessary provider after January 1, 2006, or a CAH that does not have a necessary provider designation, operates an off-campus or distinct part unit that was created or acquired on

or after January 1, 2008, that the CAH and its off-campus units must comply with the distance requirement?

- If a necessary provider CAH was certified as a necessary provider by the state before January 1, 2006, but created or acquired on or after January 1, 2006 an off-campus or distinct part unit that does not comply with the distance requirement, does the necessary provider CAH risk losing its CAH provider agreement?

- If a necessary provider CAH was certified as a necessary provider by the state before January 1, 2006, but created or acquired on or after January 1, 2008, an off-campus or distinct part unit that does not comply with the distance requirement, does the necessary provider CAH risk losing its CAH provider agreement?

- If a necessary provider CAH in existence after January 1, 2006, or CAH that is not a necessary provider in existence after January 1, 2006, creates or attains an off-campus or distinct part unit between January 1, 2006 and January 1, 2008 that is not in compliance with the distance requirements, what are the consequences for the CAH?

III. HOSPITAL COPs

We appreciate CMS' efforts to update the Medicare Part A Hospital Conditions of Participation (CoP) at 42 CFR §482.52(b) so that this section of the CoP better reflect current anesthesia practice. In our comments to CMS' proposed rule (70 FR 15266, 03/25/05), we agreed with CMS' proposal to change the CoP at §482.52 so that any qualified anesthesia provider could complete the postanesthesia evaluation such that the provider who completed the postanesthesia evaluation did not have to be the same qualified anesthesia provider who provided the anesthesia services. We thank you for the changes you made to the CoP in this area as it reflects current safe and effective anesthesia practice and allows hospitals needed flexibility in staff scheduling.

A. Proposed Revisions to Preanesthesia and Postanesthesia Evaluations

We understand that CMS would like to revise §482.52 in a number of areas. First, CMS would like to revise §482.52(b)(1) and (b)(3) so that these sections of the CoP apply to all surgical and

other procedures provided in inpatient and outpatient settings that would require anesthesia services. We agree that it is appropriate to clarify that the completion of preanesthesia and postanesthesia evaluations applies to surgical and other procedures that require anesthesia services.

Second, CMS in its proposal argues that the distinctions between inpatient and outpatient procedures are blurring and should therefore be treated similarly when it comes to completing the preanesthesia and postanesthesia evaluations. CMS also argues that the 48-hour requirement for the postanesthesia evaluation to be completed for either inpatient or outpatient procedures is dated and should be revised. According to CMS, the current language regarding the completion and documentation of the postanesthesia evaluation "within 48 hours after surgery" assumes that all patients receiving anesthesia services have undergone surgery and have not been discharged from the hospital prior to the end of the 48-hours timeframe so that the patient is still available for evaluation. CMS notes that currently patients who receive anesthesia services (either general anesthesia or monitored anesthesia care) and have undergone diagnostic or therapeutic procedures as well as patients who have undergone inpatient surgical procedures, are often discharged before 48 hours after their procedure or surgery. CMS has therefore proposed to change §482.52(b)(3) so that it states that for inpatient and outpatient procedures a "postanesthesia evaluation [must be] completed and documented by an individual qualified to administer anesthesia...after surgery or a procedure requiring anesthesia services, but before discharge or transfer from the postanesthesia recovery area."

We believe that requiring the anesthesia provider to complete and document the postanesthesia evaluation before the patient is transferred or discharged would create a number of unintended consequences to the detriment of patients' health and their continued access to surgical and other services requiring anesthesia. Typically, after a surgery or other procedure, a patient whether inpatient or outpatient is transferred to the recovery area of the hospital. While the patient is in recovery the qualified anesthesia provider moves on to provide anesthesia services to the next patient. In the recovery area a nurse at the direction of the surgeon or lead physician begins to monitor and document many of the attributes required in a postanesthesia evaluation such as the patient's cardiopulmonary status, level of consciousness. Such a nurse provides additional follow-up care and further observes the patient. The monitoring and documenting of these items is also important to the surgeon or lead physician who is determining whether a patient is ready

to be transferred from the recovery area or discharged from the hospital. The surgeon or lead physician, or medical staff delegated by the physician, determines when it is appropriate to discharge a patient. The patient is then transferred or discharged. Within the same day or the next the qualified anesthesia provider follows-up with the patient in person or by phone as to any complications that may have occurred during postanesthesia recovery. The effects of anesthesia can last beyond the point at which a patient is transferred or discharged. However, though there may be residual effects from the anesthesia, this does not mean that it is not appropriate to transfer or discharge the patient. Though a patient who has undergone anesthesia but before being discharged is advised not to drive, sign important legal papers, etc. until the following day, a patient can safely be transferred or discharged so they may return home and rest according to the post procedure instructions specific to that patient.

The CoP for §482.52(b)(3) as proposed would create a situation in which a patients who could be safely transferred or discharged are needlessly held for hours in the recovery area. Such prolonged time in the recovery area is not necessarily best for the patient's full recovery. Alternatively, if the qualified anesthesia provider must complete the postanesthesia evaluation before the patient is transferred or discharged, this could cause qualified anesthesia providers to complete the postanesthesia evaluation without capturing or addressing the patient's full postanesthesia experience or anesthesia related complications. Currently, anesthesia providers who complete the postanesthesia evaluation by making follow-up visits or calls to patients that day or the next are able to capture and address any complications due to anesthesia that may arise after transfer or discharge.

In addition, if the qualified anesthesia provider must complete the postanesthesia evaluation before the patient is transferred or discharged, this could cause a decrease in patients' access to surgical and other procedures that require anesthesia. Current, safe anesthesia practice allows for the qualified anesthesia provider to move to the next anesthesia case while the prior patient is in the recovery area. Anesthesia providers are required, and in fact it is crucial for a patient's safety that an anesthesia provider remains with a patient throughout a surgery or procedure. If the anesthesia provider must complete the postanesthesia evaluation before the first patient is transferred or discharged this means the anesthesia provider would have to remain with the first patient and therefore, cannot simultaneously provide anesthesia services for the second patient. Subsequent surgeries or procedures cannot occur without the anesthesia provider, thereby

slowing the number of surgical or other cases the hospital can schedule each day. A reduced number of cases per day results in a decrease in patients' access to timely surgical and other services that require anesthesia. Additionally, many hospitals may only have one or a very limited number of anesthesia providers. CMS' proposed change under the above scenario could mean that the hospital would unnecessarily have to hire an additional anesthesia provider to comply with the CoP at an increased cost to the hospital and to the patient, without yielding benefits such as increased patient safety or access to care.

We agree that each patient should have a postanesthesia evaluation conducted by a qualified anesthesia provider. However, the timing for completing of the evaluation should coincide with current safe anesthesia practice that is best for the patients and their continued access to surgical and other services that require anesthesia.

We appreciate CMS' objective in harmonizing the CoP for postanesthesia exams for inpatients and outpatients. We want to stress, however, that harmonizing these conditions in the way CMS has proposed yields unintended practical consequences, some of which are detrimental to patients, their access to healthcare, and optimal safe delivery of healthcare services. We welcome the opportunity to work with CMS to revise the CoP to best reflect continued access to safe and effective provision of anesthesia services.

B. Request that Online Interpretive Guidelines Manual be Updated

We appreciate CMS' efforts to post online its various manuals including the Medicare State Operations Manual, Appendix A, Survey Protocol Regulations and Interpretive Guidelines for Hospitals. In April 2005, changes were made to the Interpretive Guidelines for §482.52(a), organization and staffing of anesthesia services. Additionally, in November 2006, as noted in this proposed rule, CMS made changes to the CoP at: (1) §482.52(b)(3), completing of the postanesthesia evaluation by any qualified anesthesia provider; (2) §482.24(c)(i) and §482.24(c)(1)(ii), authentication of verbal orders; and (3) §482.25(b)(2)(i), securing controlled and non-controlled substances and medications. Unfortunately, none of these changes are reflected in the online Interpretive Guidelines Manual. Last, though the Interpretive Guidelines Manual at Tag #A-0417 provides the regulation authorizing states to opt-out from the Medicare hospital CoP requirement for operating practitioner supervision of nurse anesthetists (42 CFR §482.52(c), "Standard, State Exemption"), the guidelines themselves do not reflect the

regulation, so that surveyors in the 14 states that have opted-out from this requirement may erroneously conclude that the requirements of §482.52(a) apply to hospitals in opt-out states via the guidelines at Tag #A-0417. While CMS may have issued separate transmittals on some of these changes, such transmittals are difficult to locate on the CMS website. When healthcare professionals (including our members), hospital administrators or others are searching for guidance on how to comply with Medicare's rules and regulations they should be able to access the most current information. We agree that the online manual system is an excellent way to create this access. However, if the manuals are continually out-of-date, they are of little use which creates great frustration to those who in good faith are doing their best to understand and comply with Medicare's complex rules and regulations. We respectfully request, that the Interpretive Guidelines Manual be updated regularly to reflect changes in the CoP and in the Interpretive Guidelines so that our members and their employers can readily monitor and comply with Medicare's rules and regulations. We also request that Medicare notify healthcare professionals and their professional associations on a timely basis when the Interpretive Guidelines Manual and other manuals have been updated, and when updates have been proposed for review and consideration.

We thank you for the opportunity to comment on the proposed rule. Should you have any questions regarding these matters, please feel free to contact the AANA Senior Director of Federal Government Affairs, Frank Purcell, at 202.484.8400.

Sincerely,

Wanda Wilson, CRNA, PhD, MSN
AANA President

cc: Jeffery M. Beutler, CRNA, MS, AANA Executive Director
Frank Purcell, AANA Senior Director of Federal Government Affairs
Pamela Kirby, JD - AANA Associate Director, Federal Regulatory & Payment Policy

CMS-1392-P-596 **Medicare**

Submitter : **09/11/2007**

Organization :
Nurse

Category :

Issue Areas/Comments

GENERAL

GENERAL

CPT code of 28890 should not be considered as office procedure thus the rate applied to this code should not be lowered.
The Ossatron is performed in ASC/OPHD setting with appropriate anesthesia given to these patients.

CMS-1392-P-597 **Medicare**

Submitter : Lynn Bergren **09/11/2007**

Organization : Woodland Centers
Other Association

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

I am writing in support of the Association for Ambulatory Behavioral Healthcare and their recent meetings with you. We are very concerned about the effect the proposed cut and the continued cuts to the Partial Hospital Program benefit. This is a benefit that assists many of our clients in rural Minnesota be able to remain in the community, stay out of inpatient care and have successful and productive lives. We hear comments on a regular basis from clients who benefit from this service. Our client satisfactions surveys continue to rate the program very high. I am asking that you act on the following: remove PHP from APC codes and have independent status using Home Helath as an example, Allow the current rate to stand for 2008, Establish the current rate of 234.73 as the base annually and adjust the base according to the CPI or other inflation adjusting mechinism. Thank you for your attention to this matter. Lynn Bergren Woodland Center 320-235-4613, 1125 SE 6th St Willmar, MN 56201

CMS-1392-P-598 **Medicare**

Submitter : Mrs. **09/11/2007**

Organization : Mrs.
Individual

Category :

Issue Areas/Comments

ASC Impact

ASC Impact

Not allowing for reimbursement of many implantables causes many of the procedures to not be able to be performed in an ASC. Higher dollar implantables should start being reimbursed separately.

Conversion Factor

Conversion Factor

Our providers are reviewing their expenses routinely trying to find ways to save and bring costs down. You have to do this cautiously to ensure that you are not bringing down the quality of care and service given to the patient. With Medicare reducing the amount of payments, this becomes harder and harder. It not only effects the Medicare population but other payers follow suit and reduce their reimbursement as well. It then becomes the payers that are the only ones with profits and they do not use these profits to improve the health of the patients. The provides would use it to purchase improved and more efficient equipment and retain staff that can provide services to the patient.

CMS-1392-P-599 **Medicare**

Submitter : Mrs. Kelly Edwards **09/11/2007**

Organization : Rex Healthcare
Other Health Care Professional

Category :

Issue Areas/Comments

OPPS Impact

OPPS Impact

As a Diagnostic Medical Sonographer and Diagnostic Services Manager of a Heart Station Department, I am urging you to continue to provide separate reimbursement for echo contrast agents. We currently use contrast agents during echos here at Rex Healthcare. My concern is that if separate payment for contrast is elimated for hospital outpatients, patient access to these studies will be severely limited and Medicare expenditures for more invasive follow-up procedure may increase. Please consider this when making your decision. Thank you.

CMS-1392-P-600 **Medicare**

Submitter : Ms. Joan Murray **09/11/2007**

Organization : St. James Parish Hospital
Health Care Professional or Association

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

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

I am writing in repsonse 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 St. James Parish Hospital in Lutcher, La.

We were designated a Critical Access Hospital in August of 2001. With this desingation we were ble to assure healthcare for our seniours and uninsured of our community. We were designated as a "necessary provider" by the state of Louisiana. Because of the changes in regulation by CMS we have been "grandfathered" as a necessary provider.

Because the CAH program helped us to improve our financial situation we were able to plan and build a new replacment hospital for our community. Our building was dunded by the USDA and will be complete in December of 2007. We plan to move into the new building in January of 2008.

We are currently leasing beds to a psychiatric hospital, under the hospital within a hospital rules. The psychiatric hospital is interesed in continuing to lease those beds in our current building, after we move to the new hospital. The impact of Katrian on psychiatric care has been devastating to Louisiana and we cannot risk lossing any more psych beds.

We also plan to continue to operate our out-patient wound care clinic, which services our Medicare population. For the future, we do anticipate a need for more clinis and have also considered a RHC. Many of our seniors rely on us to bring specialty care to our community because of the problem that they face with tranportation.

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 opposit of the intention of the CAH program, which is to provide the financial stability for small, rural hospital to serve their communities. Such provisions would eliminate our flexibility to provide the care needed to rural senious.

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

Sincerely,

Joan Murray
jmurray@stjamesparishhospital.com

CMS-1392-P-601 **Medicare**

Submitter : Mrs. Willa Waters **09/11/2007**

Organization : none
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

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

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

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