#535

September 10, 2007

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

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

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

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals made affecting the Critical Access Hospital (CAH) program. I am the hospital administrator at Tri-State Memorial Hospital in Clarkston, WA.

Our community is in a crisis situation with regard to access to primary care for Medicare patients. All physicians have closed their practices to new Medicare patients resulting in many seeking care in our Emergency Room which is much more costly than in a clinic setting.

I am attempting to build a Rural Health Clinic and employ appropriate providers to meet this grave need for access. This legislation would make it unfeasible for my hospital to be able to provide care to this group of patients. The ramifications would be extremely negative for Medicare patients in our area and result in greater costs since they will not be getting the preventative care they need until they become so sick they are seen in the ER and possibly admitted. It would be very short sited to reduce this access to care which would result in harm for patients served by Rural Health Clinics, and much greater costs overall for Medicare. If you feel situations exist where this program is being used inappropriately, please address it on that basis and do not "throw the baby out with the bath water".

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,

Christopher W. Noland MHA, FACHE
Chief Executive Officer
Tri-State Memorial Hospital
Clarkston, WA 99403
509-758-4650

CMS-1392-P-536 **Medicare**

Submitter : **Robert Pascasio** **09/10/2007**

Organization : **Bayside Community Hospital**
Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

September 10, 2007

RE: Docket ID CMS-1392-P
Necessary Provider CAHs

To Whom it May Concern:

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).□

While I□m told that only a relatively small number of CAH facilities have psych or rehab distinct part units in the state of Texas, over a third of all CAHs own or operate health clinics, such as us. We have one here in our home community of Anahuac, and another approximately 12 miles away in Mont Belvieu, that until we opened did not have a local medical provider of any kind. 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.

Respectfully,

Robert A. Pascasio, FACHE
Administrator/CEO

CMS-1392-P-537 Medicare

Submitter : Ms. Radi Ann Porter **09/10/2007**

Organization : Southeast Arizona medical Center
Rural Health Clinic

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1392-P-537-Attach-1.DOC

#537

September 10, 2007

Herb Kuhn
Acting Deputy Administrator
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200 Independence Avenue
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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 Board member for Southeastern Arizona Medical Center in Douglas Arizona, a border community.

Our service area includes a higher proportion of Hispanics, a lower median income and one of the highest unemployment rates in the state. The incidence of diabetes with complications is significantly higher in our community. We provide all of our services in a HPSA. Our location on the US Mexico border presents added challenges in providing care, including the provision of significant amounts of uncompensated care to undocumented aliens. We struggle with many issues including recruitment, and retention of professional staff. Our CAH designation allowed this facility, not only to survive but, to migrate from out of state corporate control to a community based not-for-profit environment.

Our facility is located 4 miles outside of the city proper and the transit service only travels to our location four times during the business day. The city of Douglas now has a public transit system with less than 1 year's operational history. We are currently operating a Rural clinic that is on site but have recently acquired an second location in the community which is off campus. Both of these sites are providing internal medicine services and family care through the services of physician extender roles such as nurse practitioners. The impact of limiting these types of clinics is significant because transportation is a major barrier to care in our community. Limiting off site clinics will increase the burden of travel to the clinic location creating an added barrier to health care in a community with a significant need to improve access to health 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,

Radi Ann Porter, RN
Director Home Health
SAMC Board Member

CMS-1392-P-538 Medicare

Submitter : Ms. Linda Fitzgerald-Mays **09/10/2007**

Organization : Botsford Hospital
Nurse

Category :

Issue Areas/Comments

Quality Data

Quality Data

The proposed hospital outpatient quality measures will be labor intensive as there is not an automated system to capture/ meausure if scripts are written in the outpatient setting for cardiac or pneumonia diagnoses without hands on review. Claims for drug coverage is a possibility but not all utilize the drug coverage product. When all of healthcare delivery is computerized then the reporting will be manageable.

CMS-1392-P-539 Medicare

Submitter : Mr. Norman Ringel **09/10/2007**

Organization : none

Other Health Care Professional

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 Benign Essential Blepharospasm, I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

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

Thank you for allowing me to provide these comments

CMS-1392-P-540 Medicare

Submitter : Mr. Ross Matlack **09/10/2007**

Organization : Holzer Medical Center - Jackson Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

Please see attached.

CMS-1392-P-540-Attach-1.PDF

#540

HOLZER
MEDICAL CENTER
—— JACKSON ——

ROSS A. MATLACK, FACHE
PRESIDENT

500 BURLINGTON ROAD, JACKSON, OHIO 45640 (740) 395-8500

September 10, 2007

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

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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 with regard to proposals made affecting the Critical Access Hospital (CAH) program. I am the President of Holzer Medical Center – Jackson, located in rural Southeastern Ohio.

The following briefly highlights our organization and our concerns about this proposed rule:

- Holzer Medical Center – Jackson entered the CAH program on July 1, 2004 as a *necessary provider*
- Jackson County is a designated Health Professions Shortage Area
- Holzer Medical Center – Jackson provides essential hospital and physician office services to the people in need in Appalachian Ohio
- The hospital currently operates the following off-site locations: a safety-net dental clinic, a pediatric office, and a large two-physician primary care clinic (in addition to numerous on-campus services)
- An essential function of our institutional mission is the creation of effective primary care linkage for underserved and in many cases completely unserved patient populations. One of the tools at our disposal to accomplish this goal is to create primary care physician offices in areas of greater access for patients.
- Rural America is not served by robust public transportation systems. In fact, Jackson County, Ohio does not have *any* mass transit capabilities. Denying CAHs the opportunity to invest in physician offices in communities where physicians are desperately needed grossly disadvantages the patients living in these arease. Again, this is not like urban or suburban locations.

- We remain committed to a strategy of community outreach and education, fully supported by efforts to align patients in long-term relationships with primary care physicians. We believe this proposed rule grossly inhibits these much needed services.

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, children, and everyone in-between.

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

Sincerely,

Ross A. Matlack, FACHE
President

CMS-1392-P-541 Medicare

Submitter : Mr. Mark Kime **09/10/2007**

Organization : Porter
Other Technician

Category :

Issue Areas/Comments

Payment for Diagnostic Radiopharmaceuticals

Payment for Diagnostic Radiopharmaceuticals

Underutilization of contrast agents is not in the best interest of Medicare patients or Medicare itself, as inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

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

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

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

CMS-1392-P-542 **Medicare**

Submitter : **Mr. James Ehasz** **09/10/2007**

Organization : **Southwest Health Center**
Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

Southwest Health Center received Critical Access Hospital status on November 1, 2005 under the necessary provider provision of the rule. Southwest Health Center includes a nursing home and provider based inpatient psychiatric unit. Southwest Health Center was allowed to request CAH status only after the beginning of our fiscal year that began after October 1, 2004 according to the Medicare Modernization Act. Southwest Health Center□s fiscal year begins each July 1st. I am particularly bothered by the provision of the rule that prevents creating any new providers after January 1, 2008. It is also unclear whether the rule would prevent existing provider based units from relocating to another site. These provisions extremely handicap rural providers seeking to offer essential services to Medicare recipients. Our provider based inpatient psychiatric unit is for elderly patients. This unit serves a large area as there are no other providers. The surrounding area nursing homes, not just Platteville, use our service to treat acute mental illness and erratic behavior of many nursing home residents. Without our psychiatric unit, many nursing homes in this area would not have an option for treatment of their residents. Now this proposed rule threatens to restrict even further the availability of essential services to rural residents.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to off-site 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,

James Ehasz
Chief Financial Officer
Southwest Health Center
1400 east Side Road
Platteville, WI 53818-9800
(608) 348-2331
Ehasz@southwesthealth.org

CMS-1392-P-543 Medicare

Submitter : Mr. Henry Lipman **09/10/2007**

Organization : Franklin Regional Hospital
Hospital

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

Dear Deputy Administrator Kuhn:

My comments are 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 Franklin Regional Hospital in Franklin, New Hampshire.

Our hospital is situated in one of the more economically distressed communities in NH. It also is designated as Medically Underserved and shares a boundry with a county (Belknap) that has a Primary Care Shortage (PSA)designation.

" We received our CAH designation in July,2004 as a Necessary Provider

" We currently offer two primary care provider based Rural Health Clinics

" The types of off-site clinics we are considering in the future would be additional primary care to meet the growing over 65 population, outpatient rehab, outpatient oncology and sleep studies.

" Limiting of off-site clinics would impede care in our community as the needs and population ages. Other providers won't likely make up the difference due to our socio-economic and demographic factors.

" No new providers have established operations in our community for Medicare beneficiaries without Hospital support in at least the last five years.

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 serious adverse 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,

Henry D. Lipman
Administrator
Franklin Regional Hospital
603-527-2802

CMS-1392-P-544 Medicare

Submitter : **09/10/2007**

Organization :
Nurse

Category :

Issue Areas/Comments

2 Times Rule

2 Times Rule

The times two rule was created at the beginning of OPPS to provide flexibility for appropriate prospective payment based on costs more than type service. These exceptions should have been identified in the early years of OPPS, and I question the annual need for exceptions, which should be rare after many years of revisions and exceptions to standard payment. Your lumping all types of fracture treatment in APC 43 exceeds your authority in my opinion. Costs range from $1 to $3000 in this one APC. You propose to pay the same for finger treatments as hip dislocations and spinal fractures. This huge variation in costs should be divided among several APCs. Many are not low volume services and to lump all closed fractures in one APC violates more than a 10 times increase in cost in some cases. These services should be split among several APCs for fair payment, despite their classification as closed fracture treatment. It costs more to treat spinal fractures than toe fractures. I maintain that the times two rule exception may be used as a technical loophole for sweeping changes beyond its intent. The rule should be retired if misused.

CMS-1392-P-545 **Medicare**

Submitter : Mrs. Carol Punches **09/10/2007**

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 Cervical Dystonia, 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 have not been able to afford even my 20% this last year and have suffered horribly. My family is giving me the money so I can go get my injections.

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. My last injections were done by a neurologist without the guidance equipment and I couldn't even lift my head off the bed without using my hand for almost a

month. 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,

Carol J. Punches

846 S. Maple Lane
Chino Valley, AZ 86323

CMS-1392-P-546 Medicare

Submitter : Mr. James Eison **09/10/2007**

Organization : none
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

I am a 69 year old patient who has had blepharospasm of both eyelids since 1995. The only treatment that has proven to be effective has been injections of botulinum toxin (7 injections around each eye) every 3 months. Without this treatment, my eyelids spasm and close. Botulinum has been a Godsend to me. It has enabled me to continue to work and lead a normal, productive life. Therefore I am very concerned about the CMS proposal to reduce the payment rate to hospitals for physician-injected drugs. I am requesting that CMS not change the payment formula for physician-injectable drugs for 2008, and instead leave the current payment formula as is. Thank you.

CMS-1392-P-547 Medicare

Submitter : Dan Rode **09/10/2007**

Organization : American Health Information Management Association
Health Care Professional or Association

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-547-Attach-1.DOC

#547

American Health Information
Management Association

September 10, 2007

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
PO Box 8011
Baltimore, Maryland 21244-1850

Re: File Code CMS-1392-P

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Proposed Rule (72 *Federal Register* 42628)

Dear Mr. Weems:

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Hospital Outpatient Prospective Payment System (OPPS) and calendar year 2008 Rates, as published in the August 2, 2007 *Federal Register*. Our comments focus on those areas of particular interest to our members.

AHIMA is a not-for-profit professional association representing more than 51,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting, and utilizing data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most.

Consistency in medical coding and the use of medical coding standards in the US is a key issue for AHIMA. As part of this effort, AHIMA is one of the Cooperating Parties, along with CMS, the Department of Health and Human Services' (HHS) National Center for Health Statistics (NCHS), and the American Hospital Association (AHA). The Cooperating Parties oversee correct coding rules associated with the *International Classification of Diseases Ninth Revision, Clinical Modification* (ICD-9-CM).

1730 M Street, NW, Suite 502, Washington, IL 20036
phone (202) 659-9440 · *fax* (202) 659-9422 · www.ahima.org

AHIMA participates in a variety of coding usage and standardization activities in the US and internationally, including the American Medical Association's (AMA's) Current Procedural Terminology® (CPT®) Editorial Panel.

AHIMA and its members also participate in a variety of projects with other industry groups and agencies of the Health and Human Services Department related to the use of secondary data for a variety of purposes including quality monitoring, reimbursement, public health, patient safety, biosurveillance, and research.

Because of AHIMA's history of seeking uniformity and integrity in the collection, storage, use, and distribution of health information and data, we have noted through out these comments proposals by CMS that violate the principles of uniformity, consistency, and integrity. AHIMA and it member applaud the current work of the Department of Health and Human Services (HHS), the Agency for Healthcare Research and Quality (AHRQ), various committees, as well as CMS is seeking accurate, consistent, and uniform secondary data, and we urge CMS to maintain these same principles when it comes to the requirements for data under the Medicare program.

II-A-4: OPPS – Packaged Services (72FR42648)

While AHIMA supports CMS' goal to encourage hospitals to provide care as efficiently as possible, we have concerns regarding the implications of a fully-developed encounter-based payment methodology for OPPS services. The proposed rule states (page 42652): "Ideally, we would consider a complete HOPD [hospital outpatient department) service to be the totality of care furnished in a hospital outpatient encounter or in an episode of care." In this context, what would be the definition of "encounter" and "episode of care?" Would an encounter encompass all outpatient services provided in the hospital on a single day? It seems reasonable to package CPT add-on codes with the primary procedure with which they are reported. However, hospital outpatients may be seen in multiple departments or clinics (especially in tertiary care centers and university teaching hospitals), for unrelated services, on a given day. So, for example, it might not be appropriate to package all diagnostic tests performed on the day of a scheduled procedure because these tests might have been performed in a different department or clinic and may not be related to the scheduled procedure.

As CMS expands the packaging concept, AHIMA recommends that CMS strongly encourage and work with the HIM profession and hospitals to report the appropriate HCPCS codes for any packaged services that were performed, consistent with CPT instructions. To ensure complete and accurate data collection, it is important that all services provided be accurately reported, regardless of whether they are paid separately.

III-D-7: Implantation of Cardioverter-Defibrillators (72FR42714)

AHIMA fully support CMS' proposal to delete the Level II HCPCS codes for ICD insertion procedures and require the appropriate CPT codes instead. As noted in the proposed rule, the use

of CPT codes is less administratively burdensome because it ensures that the same code set is used across all payers.

III-8-7: Implantation of Spinal Neurostimulators (72FR42715)

For the reason noted above, AHIMA appreciates CMS' decision to continue to use the CPT codes for neurostimulator implantation rather than create Level II HCPCS codes. If new codes that distinguish between chargeable and nonchargeable neurostimulators are ultimately felt to be necessary, we recommend that CMS pursue the creation of new CPT codes with the AMA rather than create Level II HCPCS codes.

III-D-9: SRS Treatment Delivery Services (72FR42716)

AHIMA recommends that CPT codes for linear accelerator-based SRS treatment delivery services be used under the OPPS instead of HCPCS Level II codes. If the existing CPT codes for linear accelerator-based SRS treatment delivery services do not adequately differentiate facility resource use for these procedures, AHIMA recommends that CMS pursue modification of these CPT codes or creation of new CPT codes rather than continuing to use Level II HCPCS codes.

Use of different code sets for the same service, for different payers, is not consistent with government and industry goals data uniformity and consistency and is administratively burdensome for hospitals. The regulations for electronic transactions and code sets promulgated under the Health Insurance Portability and Accountability Act (HIPAA) indicate that maintainers of the various code set standards should work together in order to attain and maintain coding consistency and avoid duplicate codes.

IX: Proposed Hospital Coding and Payment for Visits (72FR42751)

Need for national guidelines: AHIMA urges CMS to adopt national guidelines for coding emergency department and clinic visits. **The use of hospital-specific internal coding guidelines is contrary to government and industry goals of data uniformity and consistency.** Also, national guidelines are needed in order to provide a standard benchmark for auditing facility visit code levels. CMS is working within the American Health Information Community (the Community) framework and with other uniform efforts for clinical data and other secondary data. National coding guidelines are a key part of the efforts to achieve the goals of the Community and the industry. These goals will not be achieved until uniformity and consistency are maintained in all government and industry processes including those outlined in this CMS proposal.

Regardless of whether the national distribution of levels appears to be normal, data across hospitals are not consistent or comparable as long as visit codes are not assigned in accordance with a set of national guidelines. And reimbursement at the individual hospital level is not necessarily accurate, since there is no national standard for the facility definition of each visit code and hospitals are free to define each visit level however they wish. The expert panel convened by AHIMA and the American Hospital Association coded a sample of medical records

using several different hospitals' internal guidelines and major discrepancies were identified. The same service was often assigned to very different levels, depending on which set of internal guidelines was used. Final visit codes often varied considerably for the same medical record, again depending on which set of internal guidelines was used.

It is unconscionable that CMS has failed to replace the hospital-specific coding guidelines with a set of national guidelines, when the movement throughout the healthcare industry is toward data standardization, as demonstrated by ongoing efforts to standardize quality measures, data elements, and data sets. CMS stated in the proposed rule that their goal is to ensure that OPPS national or hospital-specific visit guidelines continue to facilitate consistent and accurate reporting of hospital outpatient visits. However, it is impossible to achieve consistent and accurate reporting of hospital outpatient visits as long as there is no national standard for the definitions of the visit levels. The need for consistent and comparable coding of visits should be particularly important to CMS as it strives to achieve greater bundling of OPPS payments.

The proposed rule indicates that CMS has been actively engaged in evaluating and comparing various guideline models. The AHA/AHIMA expert panel has also recently reviewed nationally-available guideline models. Based on this review, AHIMA believes that there are existing guideline models that could be successfully implemented under the OPPS, after a reasonable amount of expansion or modification. **AHIMA recommends that CMS work with the expert panel on selection and implementation of one of these models.**

Need for different visit codes: Regardless of whether national or hospital-specific guidelines are used, either new CPT codes or Level II HCPCS codes must be created to replace the use of the CPT evaluation and management (E/M) codes. Use of the E/M codes for facility reporting violates the regulations for electronic transactions and code sets promulgated under HIPAA because they are not being used in accordance with CPT definitions. As CMS has acknowledged in this and previous proposed OPPS rules, CPT E/M codes were defined to reflect the activities of physicians and do not necessarily describe well the range and mix of services provided by hospitals during visits of clinic and emergency department patients and critical care encounters.

Distinction between new and established patients: AHIMA recommends that the distinction between new and established patients for clinic visits be eliminated. Due to confusion regarding the definition of "new" and "established," we do not believe these codes are being reported accurately (for example, a patient may be "new" to a particular hospital clinic but have an existing hospital medical record number because the patient has previously been seen in another hospital department). We agree with the APC Panel recommendation that hospitals bill the appropriate level clinic visit code according to the resources expended while treating the beneficiary. In other words, the coding guidelines should reflect any resource cost differences between new and established patients rather than reporting different codes for new and established patients.

Consultation Codes: AHIMA supports CMS' proposal to change the status of the consultation codes so that they are no longer recognized for payment under the OPPS. We agree with the APC Panel's recommendation that consultation services be built into the coding guidelines for

reporting outpatient clinic levels based on the complexity and resources used for these outpatient visits.

Principles for visit coding guidelines: Some of the principles CMS believes should be applied to hospital-specific guidelines are too vague and subject to interpretation. This is the true of both the original set of principles and the new ones being proposed. For example, one principle states: "The coding guidelines should be clear to facilitate accurate payments and be usable for compliance purposes and audits." Whether or not a set of hospital-specific guidelines meets this principle, is subject to interpretation. This is one example of the benefits of national guidelines. CMS could ensure that any set of national guidelines they implement under the OPPS meets their interpretation of this principle. Also, it is impossible to judge whether or not a visit code level is "accurate" when there is no national standard as to the services that should comprise a given level.

One of the current principles indicates that the coding guidelines should meet the HIPAA requirements. However, it is not possible for any set of hospital-specific guidelines to comply with this principle because hospitals are required to use the CPT E/M codes in a way that is contrary to the CPT definitions, which is a violation of HIPAA.

One of the proposed new principles states that "the coding guidelines should not change with great frequency." What does CMS consider to be "great frequency?" We recommend that this principle be revised to define great frequency – perhaps the guidelines shouldn't change more often than annually.

Critical Care: AHIMA recommends that payment for critical care services be provided for less than 30 minutes of critical care. There are times when patients expire without being admitted and a lot of resources are utilized in a very short period of time.

XIII-E: Cardiac Rehabilitation Services (72FR42773)

AHIMA opposes the proposal to discontinue recognizing the CPT codes for cardiac rehabilitation services under the OPPS and to establish two new Level II HCPCS codes for facility reporting instead. As stated elsewhere in this comment letter, it is administratively burdensome to have two different code sets for reporting the same services. Also, the proposed Level II HCPCS codes describe a "per hour" service, which seems contrary to CMS' goals of increased packaging and bundling. The CPT codes describe cardiac rehabilitation services "per session," which is more consistent with an increased packaging strategy. Also, we have heard anecdotally from hospitals that a session is typically an hour.

XVII: Quality Data (72FR42799)

XVII-B: Proposed Hospital Outpatient Measures (72FR42800)

According to the proposed rule, the quality measures CMS is proposing address care provided in a large number of adult patients in hospital outpatient settings, across a diverse set of conditions,

and were selected for the initial set of Hospital Outpatient Quality Data Reporting Program (HOP QDRP) measures based on their relevance as a set to all hospitals. However, CMS does not indicate in the proposed rule whether or not they have assessed these measures for data collection and reporting feasibility, especially in a future electronic environment.

The measures that CMS is proposing had not received National Quality Forum (NQF) endorsement at the time the proposed rule was written. AHIMA understands CMS' appreciation and support for NQF endorsement of measures not only for inpatient measures but outpatient measures as well. We would caution CMS about finalizing the 10 measures prior to NQF endorsement. It is unclear if CMS expects to receive endorsement by NQF for these measures or what the process will be if these measures are not endorsed by NQF. AHIMA recommends that CMS provide further detail on the process of these measures and their expected endorsement by NQF.

XVII-C: Other Proposed Hospital Outpatient Measures (72FR42801)

CMS has identified an additional 30 measures that it anticipates implementing for the hospital outpatient setting. AHIMA applauds CMS' effort to utilize measures that are currently in place and have received endorsement by NQF or expect to receive endorsement shortly. It is unclear what the implementation process will be for the hospital to implement the potential 30 additional measures. There is no discussion regarding a phased approach or whether CMS anticipates implementing the measures all at once. We recommend that CMS identify the expectation for implementation of these measures to allow hospitals enough time for preparation of resources, staff training, and support of this additional requirement.

After a review of the NQF endorsement column of the chart that highlights the potential additional quality measures CMS anticipates implementing, we have identified over 50 percent of those measures that expect to retire their endorsement by the middle of 2009. It is unclear if CMS expects to receive continued endorsement by NQF on these measures, or will retire these measures before they have been implemented for the CY 2010. AHMA recommends that CMS possibly reconsider these measures or select those measures that will have a longer shelf life by NQF endorsement.

XVII-E-1: Proposed Requirements for HOP Quality Data Reporting for CY 2009 and Subsequent Calendar Years – Administrative Requirements (72FR42803)

CMS anticipates utilizing the same administrative steps necessary for the HOP QDRP program as it currently utilizes for the IPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program for participation in the program. AHIMA applauds CMS for using current processes that have been established and are familiar to hospitals. This is consistent with the desire by the Secretary to use standard processes and not implement new processes and procedures that are unnecessary, inefficient and wasteful. This method will also allow the hospitals to have a shorter learning curve on the methods necessary to submit measures in order to participate in the HOP QDRP program.

Although the administrative steps are consistent with those currently used for IPPS reporting, CMS should consider developing an electronic method for completing and reviewing the current status of required forms (e.g., Notice of Participation Form, Nonparticipation Form, Withdrawal Form, etc.).

XVII-E-2: Proposed Requirements for HOP Quality Data Reporting for CY 2009 and Subsequent Calendar Years – Data Collection and Submission Requirements (72FR42804)

As noted above, AHIMA applauds CMS for using current processes that have been established and are familiar to hospitals, but CMS should clarify if CART-OPD will be a module within the current CART application or a standalone application. Some hospitals may utilize the same staff to collect and report RHQDAPU and HOP QDRP data and these individuals should not be required to install, maintain and operate two separate applications. AHIMA recommends that CMS consider a version of CART-OPD that will operate as a module of the current CART application to reduce administrative burden for hospitals.

XVII-E-3: Proposed Requirements for HOP Quality Data Reporting for CY 2009 and Subsequent Calendar Years – HOP QDRP Validation Requirements (72FR42804)

CMS anticipates utilizing the same validation requirements necessary for the HOP QDRP program as it currently utilizes for the IPPS RHQDAPU program for participation in the program. AHIMA applauds CMS for using current processes that have been established and are familiar with the hospitals. This is consistent with the desire by the Secretary to use standard processes and not implement new processes and procedures that are unnecessary, inefficient and wasteful. This method will also allow the hospitals to have a shorter learning curve on the methods necessary to submit measures in order to participate in the HOP QDRP program.

CMS anticipates implementing a Value Based Purchasing (VBP) program that will replace the RHQDAPU program. AHIMA requests that CMS provide further clarification on what the expectation and impacts will be for the HOP QDRP program with OPPS data validation requirements and other elements of the program that are expected to change with the VBP program.

XVII-F: Publication of HOP QDRP Data Collected (72FR42805)

AHIMA applauds CMS' efforts to allow participating hospitals the opportunity to preview the reported quality measures that CMS receives prior to being posted to the website. AHIMA is concerned that there is no process or procedure identified for hospitals to appeal the information that is being posted should there be a discrepancy.

XVII-H: HOP QDRP Reconsiderations (72FR42805)

CMS anticipates implementing a reconsideration process for the HOP QDRP, which was found to be a successful addition to the IPPS RHQDAPU program. AHIMA applauds CMS for planning to use current processes as described in the proposed rule, which have been established

and are familiar with the hospitals. This is consistent with the desire by the Secretary to use standard processes and not implement new processes and procedures that are unnecessary, inefficient and wasteful. This method will also allow the hospitals to have a shorter learning curve on the methods necessary to submit measures in order to participate in the HOP QDRP program.

XVII-I: Reporting of ASC Quality Data (72FR42805)

AHIMA applauds CMS' effort to consider not introducing the HOP QDRP program for ASC in the CY 2008. The burden of transitioning to the revised payment system will certainly require a significant amount of resources and some time to adjust to the new system. Hospitals gaining experience under the HOP QDRP will enable them in the future to share best practices and lessons learned with the ASCs which will enable the ASCs to have a reduced learning curve and leverage the experience that hospitals will gain during this program implementation.

Conclusion

AHIMA appreciates the opportunity to comment on the proposed modifications to the Hospital OPPS. If AHIMA can provide any further information, or if there are any questions or concerns with regard to this letter and its recommendations, please contact Sue Bowman, RHIA, CCS, AHIMA's director of coding policy and compliance at (312) 233-1115 or sue.bowman@ahima.org, or myself at (202) 659-9440 or dan.rode@ahima.org.

Sincerely,

Dan Rode, MBA, FHFMA
Vice President, Policy and Government Relations

cc. Sue Bowman, RHIA, CCS

CMS-1392-P-548 Medicare

Submitter : Mr. Andrew Craigie **09/10/2007**

Organization : Garfield County Hospital Critical Access Hospital

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

September 10, 2007

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

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

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

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to

proposals made affecting the Critical Access Hospital (CAH) program. I am the hospital administrator at Garfield County Hospital in Pomeroy, WA.

We operate a provider based rural health clinic in our community and are located approximately 40 miles from Tri-state Memorial Hospital, a CAH, in Clarkston, Washington. Our hospital staffs one physician and three mid level providers providing services in our hospital, long-term care and clinic. We have noticed a trend over the past six years that an increasing number of Medicare and Medicaid patients are traveling from Clarkston to utilize services at our rural health clinic. This

pattern exists because few providers in Clarkston are willing to accept new Medicare and Medicaid patients. This situation places a burden on both the patient and our practice and does not promote optimum care. We believe that this pattern also adversely impacts utilization of emergency services at Tri-state Hospital.

Tri-state Hospital is considering the development of a provider based clinic to alleviate the access issue for Medicare and Medicaid participants in their community. We believe that this is a valuable and necessary solution to a growing problem. The proposed changes effecting necessary provider designation would jeopardize the ability of the hospital to respond to this critical need. Therefore I ask that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAHs.

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

Sincerely,

Andrew Craigie, CEO
Garfield County Public Hospital District
509-843-1591

CMS-1392-P-549 Medicare

Submitter : Angela Kramer **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

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

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Spasmodic Torticollis and Writer's Cramp (Dystonia), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMSys proposal to bundle the payment rate to hospitals for physician-injected drugs.y I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms.y 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.y

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.y The guidance service is critically important for this treatment to be effective.y

Thank you for allowing me to provide these comments.

CMS-1392-P-550 Medicare

Submitter : Mr. J. Keener Lynn **09/10/2007**

Organization : Southern Surgery Center
Ambulatory Surgical Center

Category :

Issue Areas/Comments

ASC Impact

ASC Impact

The proposed APC rate for GI at 65% HOPD for Surgery Centers is not a reasonable rate and should be re-evaluated. A more acceptable rate, which is a reduced rate from current, is 75% of the HOPD rate. The proposed rate of 65% HOPD may cause some GI procedures to be performed in the HOPD setting at higher cost to Medicare and to patients. Thank you for your consideration.

J. Keener Lynn, FACMPE

CMS-1392-P-551 Medicare

Submitter : Angela Kramer **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered
Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding:y 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 and Writer's Cramp, both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMSys proposal to reduce the payment rate to hospitals for physician-injected drugs.y I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms.y These injections are critically important to my ability to function normally.

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

Thank you for allowing me to provide these comments.

CMS-1392-P-552 Medicare

Submitter : Mrs. Carol Punches **09/10/2007**

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, 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 have not been able to get my injections this past year (I need them every 3 months)because I can't pay my 20% copay. My family is giving me the money because my neck is twisting so bad that my spine is turning and I am having side aches and digestive problems caused from this. The pain is almost unbearable without the injections. Without the guidance equipment the injections are very dangerous. I have only had this done twice without guidance and will never do it again. Once I couldn't even lift my head up off the bed without my hands and the other time besides being difficult to swallow my head dropped forward for over a month.

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.

Carol J. Punches
846 S. Maple Lane
Chino Valley, AZ 86323

CMS-1392-P-553 Medicare

Submitter : Jason Chandler **09/10/2007**

Organization : BrainLAB
Device Industry

Category :

Issue Areas/Comments

Packaged Services

Packaged Services

See attached.

Quality Data

Quality Data

See attached.

CMS-1392-P-553-Attach-1.PDF

CMS-1392-P-553-Attach-1.PDF

#553

BrainLAB

king possibilities

September 10, 2007

VIA Electronic Submission to http://www.cms.hhs.gov/eRulemaking and E-Mail

Herb B. Kuhn, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1392-P
Proposed 2008 Changes to the Hospital Outpatient Prospective Payment System: Packaged Services & Quality Data

Dear Mr. Kuhn:

BrainLAB appreciates this opportunity to submit comments on the proposed rule updating the Medicare hospital outpatient prospective payment system ("HOPPS") as set forth in the Proposed Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2008, 72 Fed. Reg. 42628 (Aug. 2, 2007).

BrainLAB develops, manufactures, and markets software-driven medical equipment to provide advanced radiotherapy, radiosurgery, and neurosurgery services, among other things. Accordingly, the company is keenly interested in the impact CMS's proposed changes to HOPPS payments for 2008 would have on its products and on patient access to the medical services performed using its technologies.

Specifically, BrainLAB wishes to comment on CMS's proposal to package payment for the following CPT Codes:

- 77421 (Stereoscopic x-ray guidance) which describes our ExacTrac x-ray guidance system;
- 61795 (Stereotactic computer-assisted volumetric (navigational) procedure, intracranial, extracranial, or spinal (List separately in addition to code for primary procedure)); and
- 0054T, 0055T, and 0056T which describe computer-assisted navigation for orthopedic surgery.

For the reasons discussed herein, BrainLAB believes that CMS should reconsider its proposal to package payment for these codes into the payment rates for the associated APCs and continue to pay separately for these procedures in CY 2008. In addition, while BrainLAB supports quality data reporting measures, it recommends that CMS adopt a more transparent process (including panels with industry representation) for developing and implementing quality measures.

First, BrainLAB disagrees with the CMS proposal to package payment for the above-referenced CPT codes because, as CMS concedes (72 Fed. Reg. at 42654), guidance services are generally optional and are not always reported when the independent procedure is performed. BrainLAB believes that packaging payment for such services will encourage hospitals and physicians to inappropriately base decisions on whether to use guidance on financial rather than clinical considerations. Although CMS does not intend to create "payment incentives [or disincentives] to use guidance for independent procedures, or to perform one form of guidance instead of another" (72 Fed. Reg. at 42655), packaging payment for all guidance services, would place cost above clinical appropriateness as the overriding consideration. BrainLAB agrees that packaging for procedures that have 1:1 relationship with the independent procedure is reasonable and appropriate; however, such is not the case with the above-referenced CPT codes.

Further, with respect to ExacTrac, as many of the CMS medical officers may recall, BrainLAB and a distinguished group of neurosurgeons from across the country worked with the Division of Outpatient Care, Dr. Bill Rogers (Director, PRIT Team), and various staff in the Administrator's office to obtain a new code for stereoscopic Kv x-ray (C9722 Stereoscopic Kv X-ray) which became effective January 1, 2006. Given that this code is relatively new, the data that CMS used to establish payment rates for APCs associated with this technology may not accurately reflect costs and/or utilization. Therefore, CMS should at least defer packaging payment for this code until more reliable data can be established.

Finally, with respect to CMS's proposed quality data reporting measures, BrainLAB believes that CMS should establish a more transparent process for developing and implementing quality measures so that regulated parties can better understand the rationale behind them. Specifically, panels that develop such quality measures should include industry representation.

* * * *

We appreciate your attention to this important matter. Please contact me at 440.213.3951 or Gail Daubert at 202.414.9241 for any further information you may need.

Sincerely,

Jason Chandler

Jason Chandler
Director of Business Development,
BrainLAB

cc: American College of Radiology, Pam Kassing, Director
Carol Bazell, Director, Division of Outpatient Care, CMS
Ken Simon, M.D., Medical Officer, CMS